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[Reference:]

Dear Sir:

This submission contains additional findings and supporting evidence for submission [

]. In our earlier submission of adverse findings in juvenile female rats, we identified the following adverse effects after treatment:

- an acceleration of vaginal perforation
- a decrease in uterine blotted and/or wet weights
- decreased ovary weight
- increased adrenal weight
- increased liver weight

It was concluded that materials containing [

], were having estrogenic effects at a dose as low as 30 mg/kg/day.

Data from subsequent female pubertal assay studies being submitted (see Attachment 1) support these findings and, to better understand the mechanism of action, examines additional endpoints associated with reproductive and endocrine health. Endpoints examined in these new studies, not measured in the originally submitted studies, include age at first estrus, ovarian histology (corpus lutea, granulosa cell morphology, oocyte morphology), uterine histology, and thyroid histology. Hormone level analyses (estradiol, lutenizing hormone, T4, and TSH) and thymus, thyroid gland, and pituitary weights were also measured.

To better understand the toxicological significance of organ weight changes observed in earlier studies, the histology of the ovary and uterus were examined. The following histological changes occurred at doses as low as 60 mg/kg/day with mixtures containing [ ]:

- absence of corpus lutea

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307491

- oocyte degeneration
- granulosa cell necrosis
- uterine atrophy
- uterine hypotrophy

Onset of first estrus occurred earlier and corresponded with earlier onset of puberty. Changes in Estradiol, T4, and TSH occurred, but were variable throughout studies and were not a requirement for an earlier onset of puberty. Changes in weight and histology of the thyroid gland, changes in the weight of the pituitary, thymus gland, and the spleen also occurred, but did so inconsistently among studies.

The new studies being submitted have [ ]. In general, increasing [ ] still caused estrogenic effects but at higher doses compared to [ ]. A dose with no adverse pubertal effects for [ ] was determined using data from the new studies. Doses of 10 mg/kg/day in two studies and 20 mg/kg/day in another did not elicit estrogenic effects.

The implications from [ ] estrogenic action resulting in premature sexual maturation on reproductive health are still uncertain. A one-generation reproductive study in rats with [ ], did not result in any changes to rat fertility. This study is in the draft report stage and will be submitted upon request. [ ] was previously determined to cause an early onset of sexual maturation in a rat female pubertal assay, the results of which were communicated to the EPA in submission [ ] on April 19, 2004. This indicates that there may be no consequences to reproductive health from the estrogenic action of [ ]. Additional one-generation studies in the rat with [ ] to determine whether this is a valid conclusion are currently in progress.

If you have any questions, please contact me at [ ]

Sincerely,

[ ]
[ ]
[ ]

Attachments

WIL-187041
WIL-187042
WIL-187043
WIL-187044
WIL-187051
WIL-187054
WIL-187055
WIL-187056
WIL-187060
WIL-187061

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FINAL REPORT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187041

STUDY DIRECTOR

[redacted] B.S.

STUDY INITIATION DATE

September 2, 2004

STUDY COMPLETION DATE

December 9, 2005

PERFORMING LABORATORY

WIL Research Laboratories, LLC*
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

04-023

SPONSOR

[redacted]

* = Formerly WIL Research Laboratories, Inc.
**Formerly [redacted]

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] or [ ], in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to three groups each of 15 Crl:CD®(SD)[1] immature female rats. Dosage levels for [ ] were 60, 250 and 1000 mg/kg/day and dosage levels for [ ] were 5, 20 and 60 mg/kg/day. The dose volume for all groups was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director.

Dosing procedures were performed from November 16 through December 7, 2004, when the animals were 22 to 41 days of age; the study start was staggered, based on age. At the initiation of dose administration, individual body weights ranged from 44.8 g to 61.1 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[ ]	60	12	5	15
3	[ ]	250	50	5	15
4	[ ]	1000	200	5	15
5	[ ]	5	1	5	15
6	[ ]	20	4	5	15
7	[ ]	60	12	5	15

[1] Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

Due to spacing constraints, the dose group names are presented on the tables and figures as corn oil, [ ]/60, [ ]/250, [ ]/1000, [ ]/5, [ ]/20 and [ ]/60 for the vehicle control, 60, 250 and 1000 mg/kg/day [ ] and 5, 20 and 60 mg/kg/day [ ] groups, respectively.

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (100% pure corn oil, exp. dates 2/2/05 and 3/19/06) was dispensed into a storage container and stirred throughout use. The [ ] and [ ] dosing formulations were prepared by weighing an appropriate amount of test article for each group into a tared, calibrated storage container. A stir bar and approximately 80% of the vehicle were added to the storage container, and the mixture was stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The [ ] and [ ] dosing formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature. Three samples from the control group and three sets of samples from the test article formulations were collected prior to the initiation of dose administration. Two sets of samples for concentration verification were collected on the first day of each preparation and two sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and six sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC, for possible future analysis.

Thirteen dams with 10 female pups each (130 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on November 2, 2004. The pups were 6 to 8 days old upon receipt. Pups were identified by tail tattoo and initially housed in plastic maternity cages (by litter with their own or a fostering dam) during the acclimation period (14 to 16 days) until randomization of the pups on postnatal day

(PND) 21. Following randomization, the female pups were weaned, identified by metal eartag and housed three per cage in plastic maternity cages. Environmental controls were set to maintain an average daily temperature of 71±5°F and an average daily relative humidity of 50±20%. Actual mean daily temperatures ranged from 70.4°F to 70.8°F (21.3°C to 21.6°C), and mean daily relative humidity ranged from 35.3% to 46.6%. Light timers were calibrated to provide a 12-hour light (6 a.m. to 6 p.m.)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse-osmosis-purified water were offered *ad libitum*.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for attainment of vaginal patency beginning on PND 25 (Adams, *et al.*, 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles *(i.e.*, the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia), beginning on the day vaginal patency was observed. Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A gross necropsy was performed only on animals that were found dead. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum thyroxine (T_4)

and thyroid stimulating hormone (TSH). The uterus (wet and blotted), ovaries/oviducts, liver, kidney, pituitary gland, adrenal glands and thyroid glands were weighed. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The blotted uterus weight was greater than the wet uterus weight for female no. 69173-06 (60 mg/kg/day [ ] group). Therefore, the uterine weights for this female were not included in calculation of the means, and luminal fluid weight could not be calculated. The ovaries, uterus (horns and body), cervix, vagina, pituitary gland, thyroid glands and gross lesions were retained from all females, including those found dead. After fixation, the ovaries, cervix, uterus (body and horns) and thyroid glands were trimmed according to standard operating procedures and the protocol. At the time of trimming, the cassettes containing the uterus, ovaries, vagina and pituitary for female nos. 69168-05, 69169-04 and 69173-05 (5 mg/kg/day [ ] group) were open and it could not be determined which organs belonged to the appropriate animal. The tissues being processed for microscopic evaluation for these females were arbitrarily assigned to each female. This event had no impact on the outcome of the study because all of these females were in the same test article-treated group.

Trimmed tissues were processed into paraffin blocks, sectioned at 4 to 8 microns, mounted on glass microscope slides and stained with hematoxylin and eosin. Microscopic examination was performed by [ ], Assistant Director, Anatomic Pathology, WIL Research Laboratories, LLC. The tissues available for microscopic examination were of satisfactory quality and quantity to adequately evaluate this study. There was no evidence of infectious disease in any of the organs or tissues examined that would have affected the validity of the study.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. Mean body weights, body weight changes, days of acquisition of

vaginal patency, estrous cycle length, age at the first occurrence of estrus, serum hormone levels, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
November 2, 2004	Experimental starting date (animal receipt)
November 16, 2004	Experimental start date (first day of dose administration)
November 16 - December 7, 2004	Test article administration
December 8, 2004	Last day of euthanasia
January 28, 2005	Experimental termination/completion date (last microscopic evaluation)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS – [ ]

One female in the 250 mg/kg/day [ ] group was found dead at 33 days of age, approximately 45 minutes after being administered the 12th dose. This animal had no clinical findings and no test article-related effects on body weight prior to death. At necropsy, this female had dark red areas on the lungs and the lungs were not fully

collapsed. Because there was no evidence of toxicity in this animal prior to death, the death occurred after dose administration, necropsy findings indicated changes in the lungs and no mortality was observed in animals in the 1000 mg/kg/day [ ] group, the death in the 250 mg/kg/day [ ] group was attributed to possible intubation error and not to the test article. One animal in the control group was found dead at 25 days of age, after three doses. On the day prior to death this animal had an unkempt appearance at the daily observations and labored respiration at the daily observations and 1 hour following dose administration. At necropsy, this animal had a mass in the lung, involving the pericardium and heart, with of two lobes of the lung adhered to the diaphragm and pericardium. This death was also attributed to possible intubation error. All other animals in the control and [ ]-treated groups survived to the scheduled euthanasia.

Wiping the mouth on the cage walls and/or floor, salivation, salivation prior to dose administration and clear material around the mouth were observed at the time of dose administration and/or 1 hour following dose administration in the 250 and 1000 mg/kg/day [ ] groups. The increased incidences of these findings occurred in a dose-related manner; the findings were attributed to the test article but were not considered adverse.

No test article-related effects on body weights or body weight gains were observed in the 60, 250 and 1000 mg/kg/day [ ] groups. The only statistically significant ($p<0.05$ or $p<0.01$) differences from the control group were increased mean body weight gain during PND 24-25 and decreased mean body weight gain during PND 27-28 in the 1000 mg/kg/day [ ] group. No test article-related trends were evident.

Vaginal patency was achieved at an earlier age in the 60, 250 and 1000 mg/kg/day [ ] groups than in the control group; the differences were statistically significant ($p<0.01$). Mean days of acquisition were 33.2, 29.6, 26.5 and 27.9 in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. The values in all [ ]-treated groups

were below the minimum mean value in the WIL historical control data (31.7 days). Since the females were younger on the day that vaginal patency was observed, mean body weights on the day of acquisition in these groups were also lower than the control group value; the differences in these groups were statistically significant ($p<0.01$). The changes in these parameters were consistent with an interpretation of estrogenic effects resulting from the test article.

Mean estrous cycle length in the 1000 mg/kg/day [ ] group (3.2 days) was statistically significantly ($p<0.01$) reduced compared to the control group value (4.9 days). The mean ages at the first occurrence of estrus (32.7, 27.4 and 28.1 days of age) in the 60, 250 and 1000 mg/kg/day [ ] groups, respectively, were earlier than in the control group (34.4 days of age). The differences were statistically significant ($p<0.01$) in the 250 and 1000 mg/kg/day [ ] groups. While vaginal patency and the onset of estrus occurred earlier in all [ ]-treated groups, notable disruption of the estrous cycle (extended estrus) was evident only in the 250 and 1000 mg/kg/day groups. In the 250 mg/kg/day [ ] group, 10 females were in persistent estrus for at least one cycle (3 or more consecutive days of estrus). In the 1000 mg/kg/day [ ] group, 13 females were in persistent estrus for at least one cycle. The differences in all [ ]-treated groups were observed in a dose-related manner and were consistent with estrogenic activity induced by the test article.

A statistically significant ($p<0.05$) increase in the mean T_4 level was observed in the 1000 mg/kg/day [ ] group. No other statistically significant differences in T_4 or TSH levels were observed. Mean TSH level was slightly increased in the 1000 mg/kg/day [ ] group. However, the value was equal to that in the 60 mg/kg/day [ ] group; no dose-related trend was evident.

Test article-related reductions in mean absolute and relative (to final body weight) ovary weights were observed in the 1000 mg/kg/day [ ] group; the differences from the control group were statistically significant ($p<0.01$). Mean absolute and relative uterus

weights (wet and blotted) in the 250 and 1000 mg/kg/day [ ] groups were lower than the control group values; the differences in the 1000 mg/kg/day [ ] group were statistically significant ($p<0.05$ or $p<0.01$). Luminal fluid data were highly variable; however, mean luminal fluid weights in the 250 and 1000 mg/kg/day [ ] groups were lower (not statistically significant) than in the control group. Mean absolute and relative liver, thyroid gland and adrenal gland weights in the 1000 mg/kg/day [ ] group were increased. The differences were statistically significant ($p<0.05$ or $p<0.01$) compared to the control group values. Mean absolute and relative adrenal gland weights were also increased in the 250 mg/kg/day [ ] group; the difference in relative weight was statistically significant ($p<0.05$) compared to the control group value. These increases were considered test article-related. No other [ ]-related or statistically significant differences in organ weights were observed in the test article-treated groups.

In the control, 60, 250 and 1000 mg/kg/day groups, decreased numbers of corpora lutea and/or absent corpora lutea were observed microscopically in 2/15 (including the female that died on PND 25), 3/15, 12/15 (including the female that died on PND 33) and 15/15 females, respectively. The findings in the 1000 mg/kg/day [ ] group correlated to reduced mean ovary weights.

Uterine hypoplasia was observed in 2/15, 1/15, 9/15 (including the female that died on PND 33) and 13/15 females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. This finding was characterized by poor delineation between the endometrium and the myometrium of the uterine horns. The uterine horns tended to be small, with a uniformly eosinophilic and homogeneous appearance of the endometrium and myometrium without a clear demarcation between the endometrial stroma and the inner circular layer of the myometrium. There was little or no differentiation of the endometrial stromal cells, and the endometrial mucosa had fewer diverticula and glands. Hypoplastic uterus in the 250 and 1000 mg/kg/day [ ] groups correlated with reduced mean uterus weights.

Thyroid gland follicular cell hypertrophy was noted in 1/15, 1/15, 7/15 (including the female that died on PND 33) and 15/15 females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. This finding was characterized by the presence of enlarged follicular epithelial cells, with an increased amount of finely vacuolated, often slightly basophilic cytoplasm. Cell nuclei in affected thyroid glands tended to be rounder than in unaffected glands (which were generally oval in shape) and had a more open chromatin pattern, compared to a uniformly distributed chromatin pattern in unaffected glands. There was no clear effect on the quantity of colloid in affected thyroid glands, but the colloid in affected glands tended to be paler-staining, and often had a vacuolated or foamy appearance. There was no appreciable subjective difference in the degree of hypertrophy in affected thyroid glands, and all were graded as minimal in severity. Thyroid gland follicular cell hypertrophy correlated to increased mean thyroid gland weights and mean T_4 level in the 1000 mg/kg/day [ ] group.

1.6. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in estrogenic effects in the 60, 250 and 1000 mg/kg/day groups, as evidenced by early attainment of vaginal patency and occurrence of the first estrus (all [ ] groups). Other indications of estrogenic activity were observed in the 250 and 1000 mg/kg/day [ ] groups following vaginal opening. These observations consisted of persistent estrus and uterine (hypoplasia) and ovarian (decreased/absent corpora lutea) microscopic lesions (250 and 1000 mg/kg/day [ ] groups) and by decreased estrous cycle length and decreased mean ovary weights (1000 mg/kg/day [ ] group). These changes were accompanied by decreased mean uterus weights and thyroid gland follicular cell hyperplasia (250 and 1000 mg/kg/day [ ] groups) and increased T_4 level (1000 mg/kg/day [ ] group).

1.7. RESULTS – [ ]

All animals survived to the scheduled euthanasia. Wiping the mouth on the cage walls and/or floor was observed in all [ ]-treated groups at the time of dose administration. Salivation, salivation prior to dosing and clear material around the mouth were observed at the time of dose administration in the 60 mg/kg/day [ ] group. These findings were attributed to the test article. A single occurrence of salivation was also observed in the 5 mg/kg/day [ ] group at the time of dose administration. None of the findings persisted to 1 hour following dose administration; therefore, these findings were not considered adverse.

No test article-related changes in mean body weights or body weight gains were observed in the 5, 20 and 60 mg/kg/day [ ] groups. Differences from the control group were slight and not statistically significant.

Vaginal patency was achieved earlier in the 60 mg/kg/day [ ] group than in the control group. The difference was statistically significant ($p<0.01$). Mean days of acquisition were 33.2, 33.3, 32.7 and 29.1 in the control, 5, 20 and 60 mg/kg/day [ ] groups, respectively. The value in the 60 mg/kg/day [ ] group was below the minimum mean value in the WIL historical control data (31.7 days). Since the females were younger on the day that vaginal patency was observed, mean body weight on the day of acquisition in the 60 mg/kg/day [ ] group was also statistically significantly ($p<0.01$) lower than the control group value. These differences were consistent with an interpretation of estrogenic effects resulting from the test article.

No differences in mean estrous cycle length were observed when comparing the [ ]-treated groups to the control group. Estrous cycle lengths in females of this age are highly variable, and combined with the limited number of animals and days of data collection, evaluation for a test article-related effect was inconclusive. There was no persistent estrus in any [ ]-treated group. The mean age at first occurrence of estrus in the 60 mg/kg/day [ ] group was earlier than in the control group; the

difference was not statistically significant. This change was consistent with an interpretation of estrogenic effects resulting from the test article.

Mean T_4 and TSH levels in the 5, 20 and 60 mg/kg/day [ ] groups were similar to those in the control group; no statistically significant differences were noted.

No test article-related changes in mean absolute or relative organ weights were observed in the 5, 20 and 60 mg/kg/day [ ] groups.

Decreased corpora lutea were observed microscopically in 3/15 and 4/15 females in the 20 and 60 mg/kg/day [ ] groups, respectively. This finding was potentially test article-related; however, there were no organ weight correlates to this finding. Uterine hypoplasia, as previously described, was noted in 7/15 females in the 60 mg/kg/day [ ] group compared to 2/15 in the control group.

Thyroid gland follicular cell hypertrophy, as previously described, was observed in 1/15, 1/15, 3/15 and 10/15 females in the control, 5, 20 and 60 mg/kg/day [ ] groups, respectively. The increase in the 60 mg/kg/day [ ] group was considered test article-related. There were no changes in mean thyroid gland weights or T_4 and TSH levels correlating to follicular cell hypertrophy. No other test article-related microscopic findings were observed in the [ ]-treated groups.

1.8. CONCLUSIONS – [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats exhibited slight estrogenic effects in the 60 mg/kg/day group, as evidenced by early achievement of vaginal patency and occurrence of the first estrus. Microscopic findings of uterine hypoplasia and decreased corpora lutea in the 60 mg/kg/day [ ] group also indicated estrogenic activity following vaginal opening. In addition, thyroid follicular cell hypertrophy was also observed at this dose level.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

[ ] Date
Staff Toxicologist, Developmental and
Reproductive Neurotoxicology
Study Director

Pathologist of Record:

[ ] Date
Assistant Director, Anatomic Pathology

Report Prepared By:

[ ] Date
Senior Study Analyst

Report Reviewed By:

[ ] Date
Director, Developmental and
Reproductive Toxicology

[ ] Date
Group Supervisor, Study Analysis and Reports

[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

[ ] Date
Group Supervisor, Study Analysis and Reports

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

[ ]	Manager, Clinical Pathology
[ ]	Senior Operations Manager, Vivarium
[ ]	Manager, Gross Pathology and Developmental Toxicology Laboratory
[ ]	Group Supervisor, Formulations Laboratory
[ ]	Manager, Histology
[ ]	Director, Metabolism and Analytical Chemistry
[ ]	Operations Manager, Developmental, Reproductive and Neurotoxicology

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
11/15/04	Test Article Preparation	11/15/04	12/20/04	[ ]
11/16/04	Test Article Administration	11/16/04	12/20/04	[ ]
11/19/04	Vaginal Perforation	11/19/04	12/20/04	[ ]
11/30/04	Animal Care	11/30/04	12/20/04	[ ]
11/30/04	Equipment	11/30/04	12/20/04	[ ]
12/6/04	Blood Collection	12/6/04	1/27/05	[ ]
12/6/04	Necropsy	12/6/04	1/27/05	[ ]
1/6/05	Trimming of Tissues	1/6/05	02/16/05	[ ]
2/1/05	Study Records (Rx-1)	2/1/05	03/25/05	[ ]
2/1-2/05	Study Records (I-1)	2/2/05	03/25/05	[ ]
2/2/05	Study Records (I-2)	2/2/05	03/25/05	[ ]
2/3/05	Study Records (C-1)	2/3/05	03/25/05	[ ]
2/3/05	Study Records (C-2)	2/3/05	03/25/05	[ ]
2/7/05	Study Records (N-1)	2/7/05	03/25/05	[ ]
2/8-9/05	Draft Report	2/9/05	03/25/05.	[ ]

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Parts 160 and 792), the OECD Principles of Good Laboratory Practice, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendments with the following exceptions. The data located in Appendices A (Certificates of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), if applicable, and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____
[ ] Date
Compliance Specialist

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

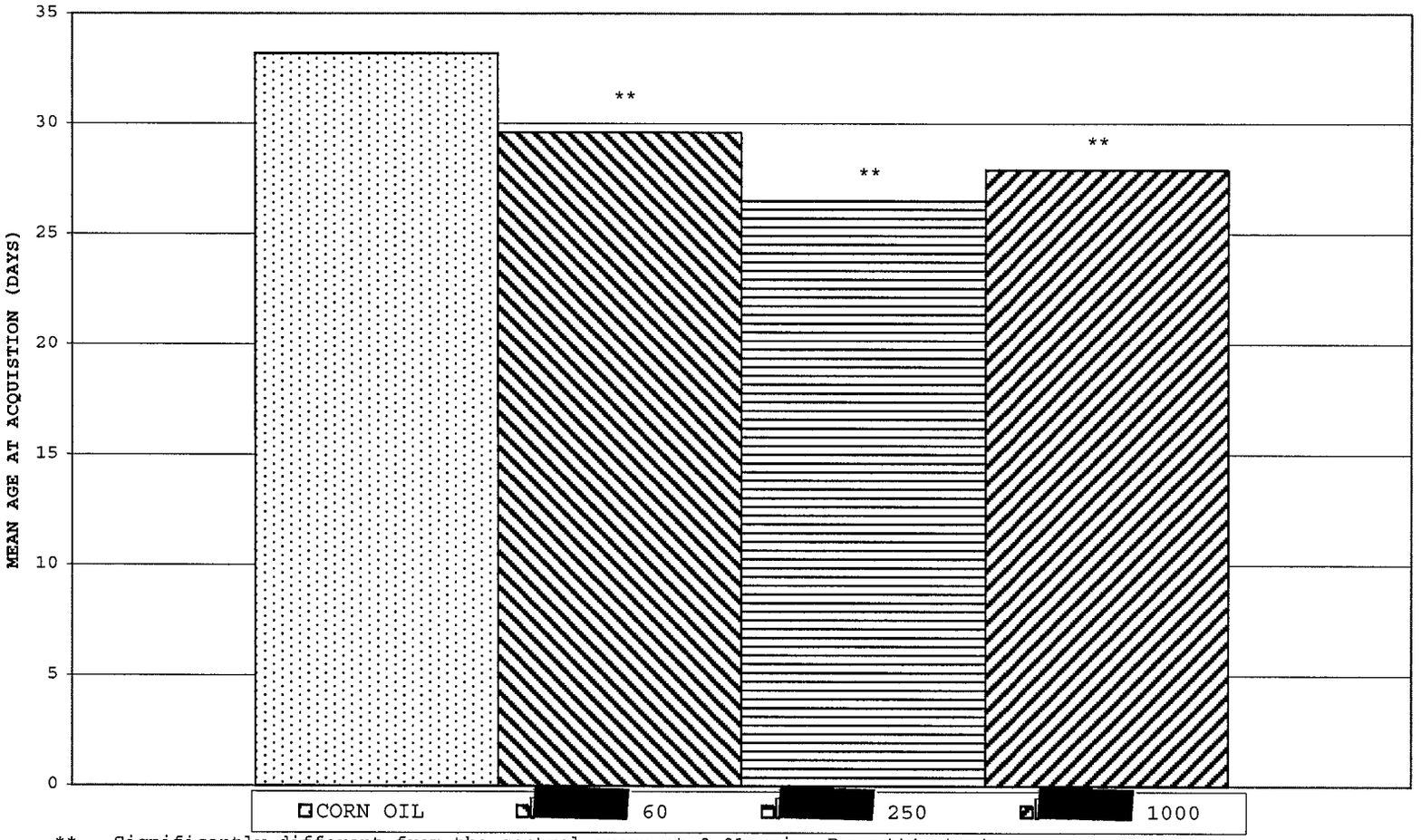
- **Protocol Section 4.1.5 (as revised, Amendment II)** states that the test article was to be stored at ambient conditions under nitrogen. On November 15, 2004, the test article was not purged with nitrogen after use.
- **Protocol Section 5.3** states that animals were to be supplied by Charles River Laboratories, Inc., Portage, Michigan. However, animals were received from the Raleigh, North Carolina facility of Charles River Laboratories.
- **Protocol Section 5.4** states that the immature female pups were to be 8-10 days old upon receipt. However, the pups were 6-8 days old at the time of receipt.
- **Protocol Section 5.5** states that at randomization, the female body weight range would be 30 g to 50 g and all animals assigned to the study would be approximately ±5 g of the mean. However, the body weight range used for randomization was 41 g to 58 g, and actual weights were -8 g to +9 g of the mean.
- **Protocol Section 7.5.3** states that samples of the dosing mixtures were to be collected on the first and last day of each weekly preparation, intending that the sample from the first day would be collected prior to the bulk formulation being divided into aliquots for daily dispensation and the sample from the last day would be collected from the aliquot used for the last day of dosing. However, both samples were collected from aliquots on the appropriate days. Therefore, no samples were collected from the bulk formulation (prior to dividing into aliquots) on the day of preparation.
- **Protocol Section 7.5.4** states that [ ]was to be notified prior to shipping the formulations samples, and that the notification was to include test article and study identification, carrier and estimated time/date of arrival. However, on November 16, 23 and 30 and December 7, 2004, [ ]was notified by e-mail prior to shipping samples, and the notification did not include the test article identifications.
- **Protocol Section 7.5.4** states that each vial plus the sample weight was to be recorded with an accuracy of ± 0.0005 g. However, samples that were collected on October 25 and November 16, 22 and 23, 2004 only reflected the net weight of the sample, not the weight of the vial.

- **Protocol Section 8.1** states that blood was to be collected from all animals following euthanasia. However, blood was not collected from animal nos. 69165-03 (250 mg/kg/day [ ] group) and 69166-08 (5 mg/kg/day [ ] group).
- **Protocol Section 9.2.1** states that the harvesting of uteri was to be performed in the same sequence as the animals were dosed. Due to the normal diurnal fluctuation in circulating concentrations of thyroid hormone levels, the necropsy order was randomized to minimize the potential effect, across all groups, that the time of day of sample collection may have had on thyroid hormone levels.
- **Protocol Section 11** does not require statistical analyses of serum hormone levels. However, statistical analyses were conducted on these data to aid in interpretation.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

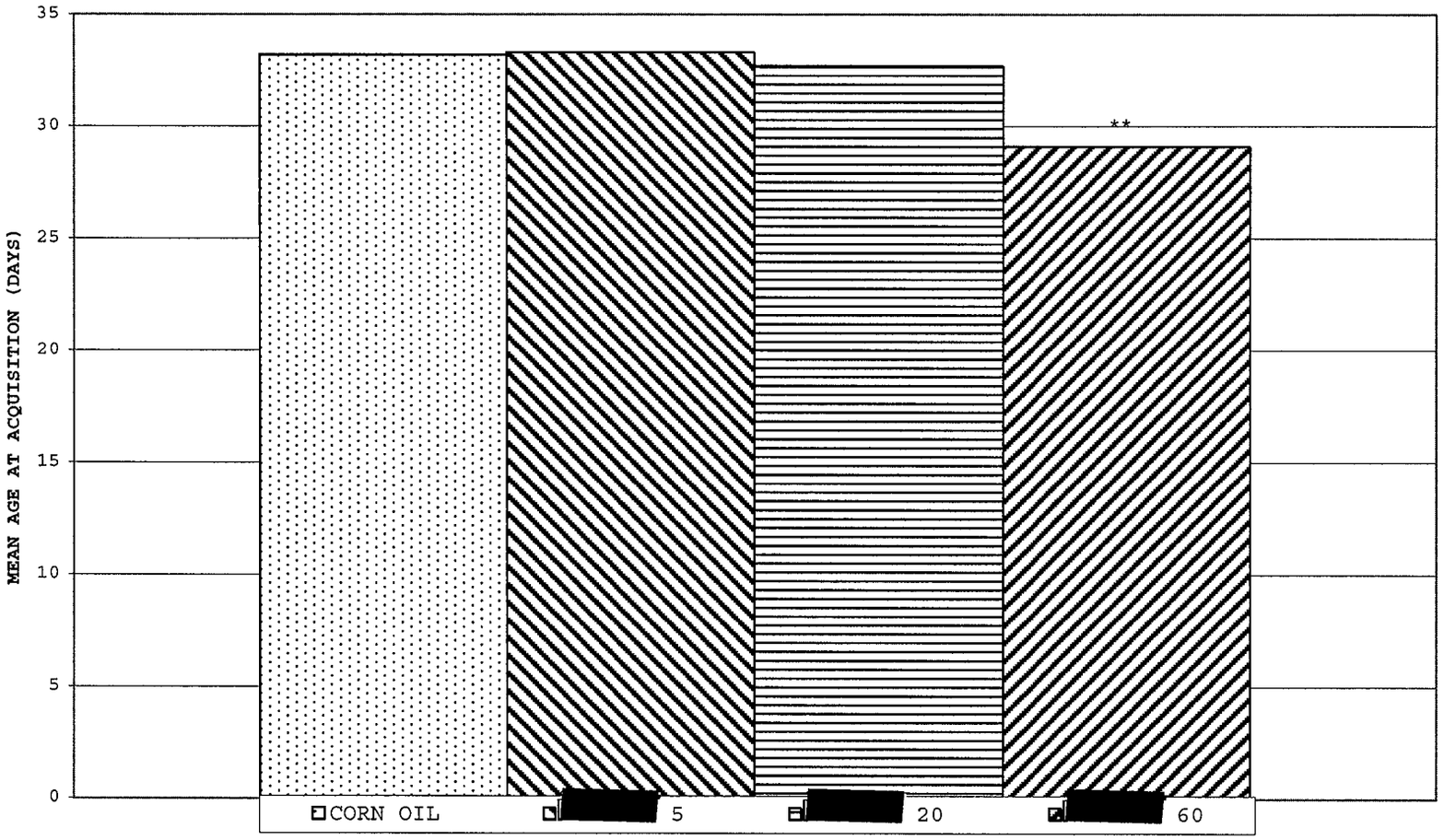
FIGURES 1-12

PROJECT NO.:WIL-187041
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted]GURE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



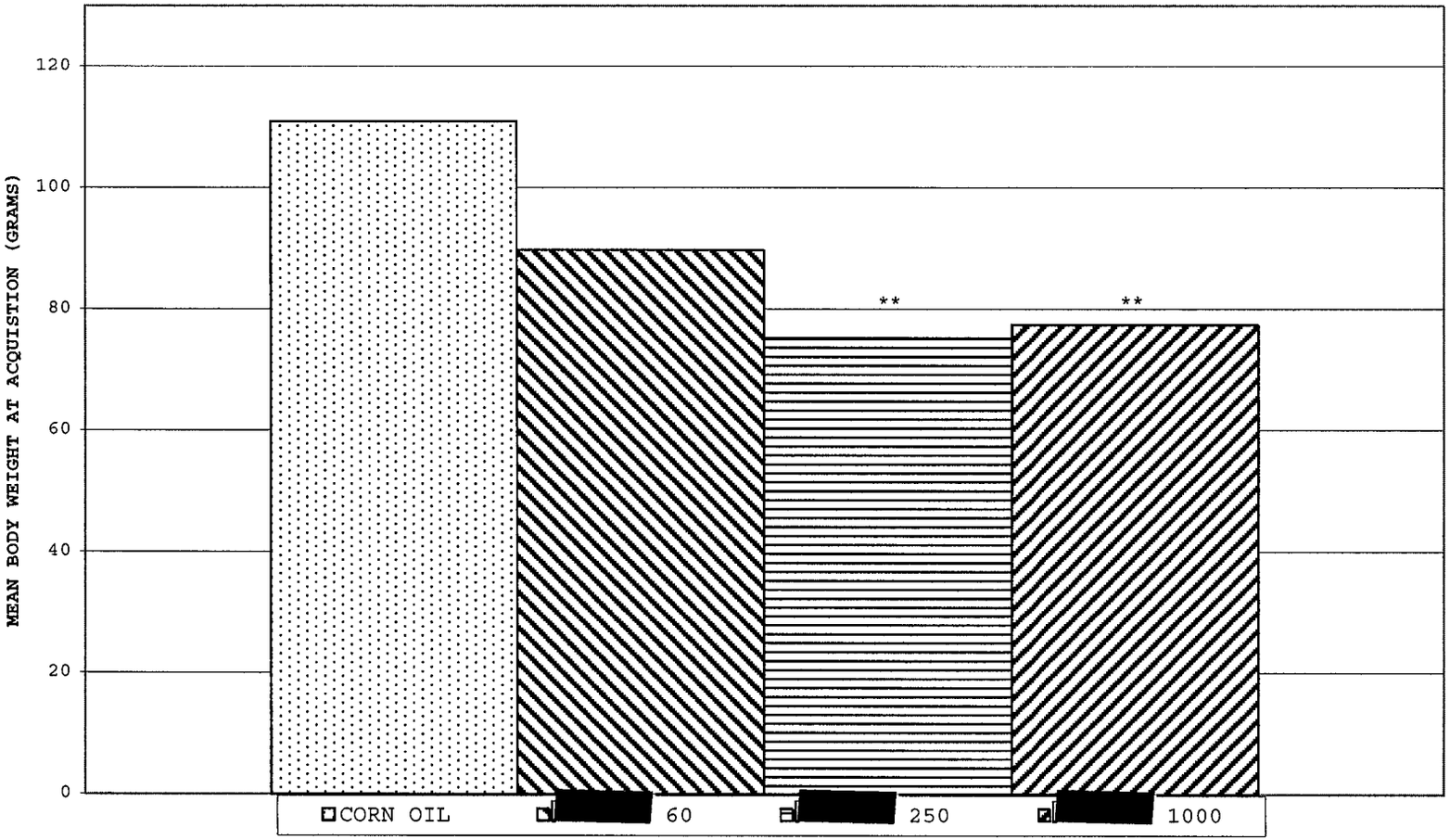
** = Significantly different from the control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187041 GURE [redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



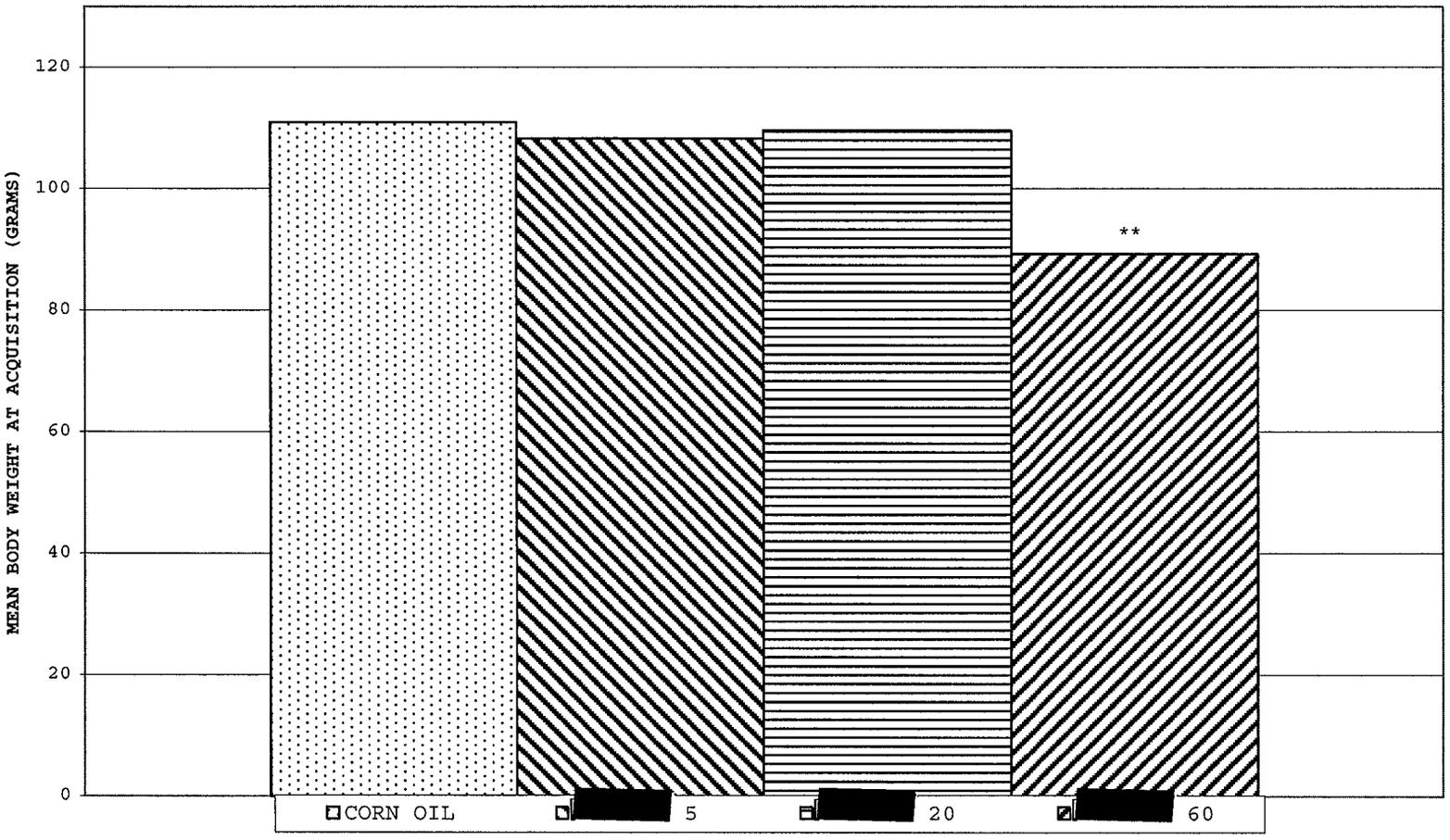
** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187041
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted]GURE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN BODY WEIGHT(GRAMS)AT ACQUISITION OF VAGINAL PATENCY



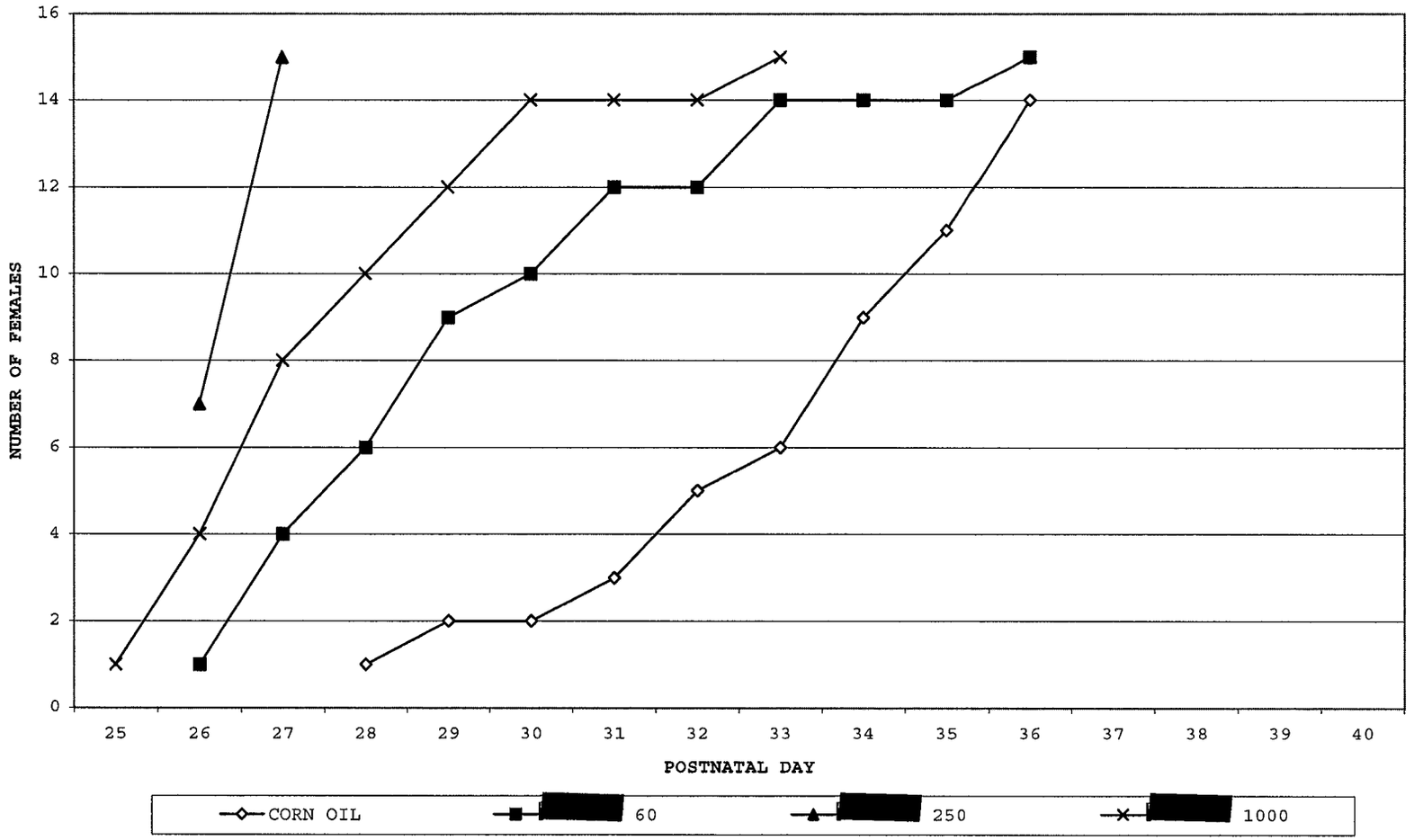
** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187041 GURE [redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN BODY WEIGHT (GRAMS) AT ACQUISITION OF VAGINAL PATENCY

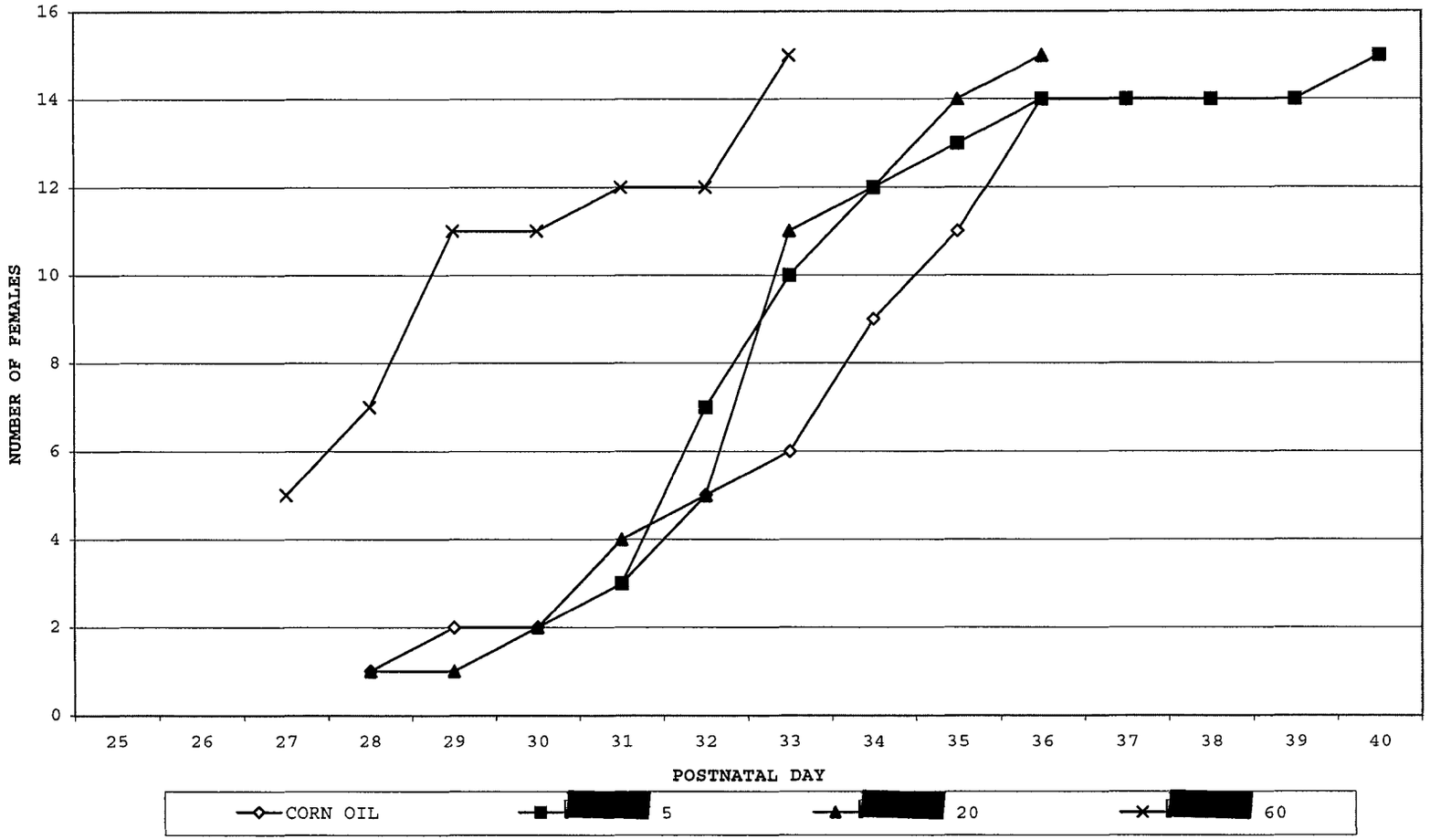


** = Significantly different from control group at 0.01 using Dunnett's

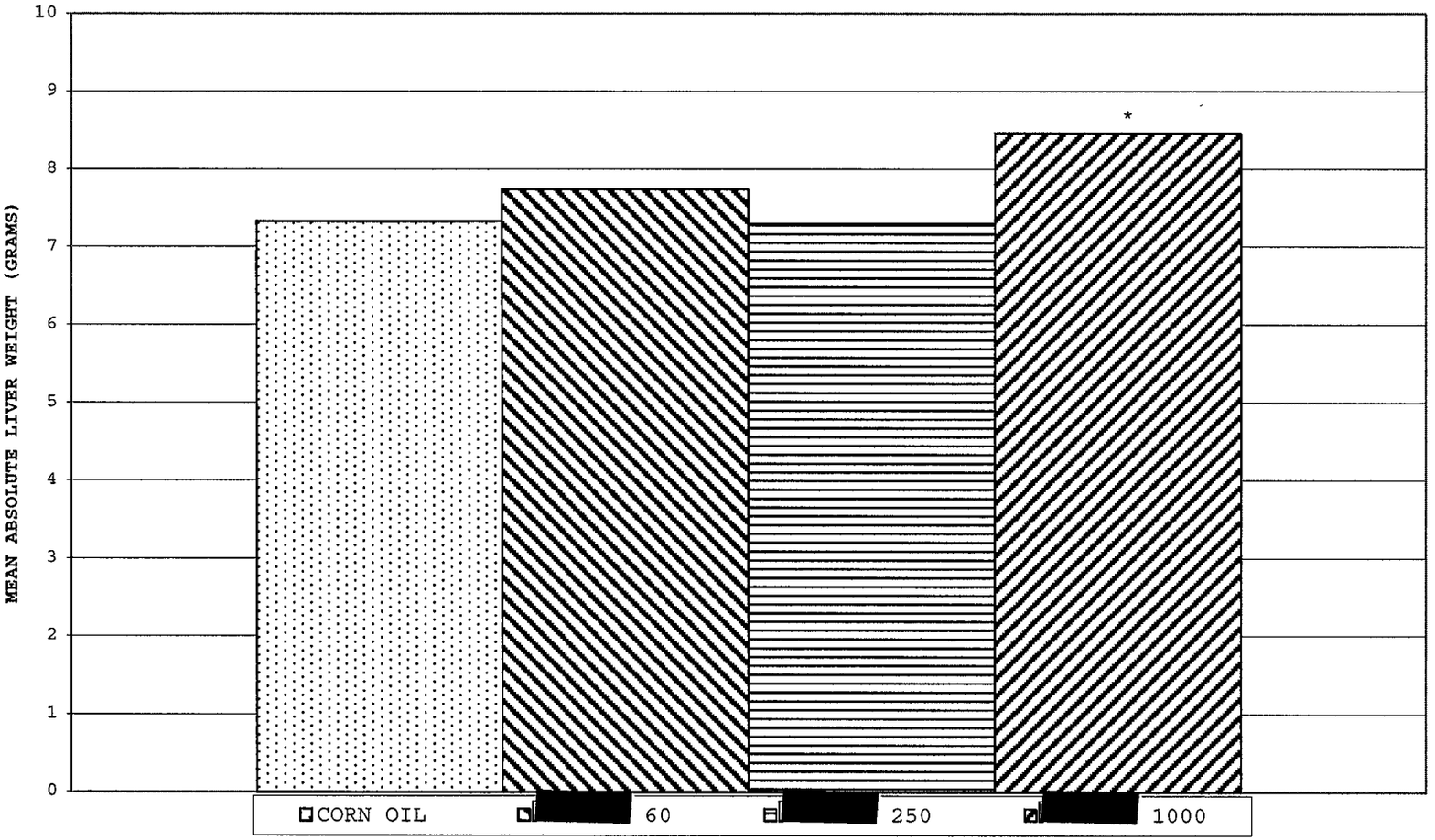
SPONSOR NO.:WIL-187041
SPONSOR: [redacted] PUBERTAL ASSAY OF [redacted] GURE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY



PROJECT NO.:WIL-187041
SPONSOR: [redacted] PUBERTAL ASSAY OF [redacted] GURE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY

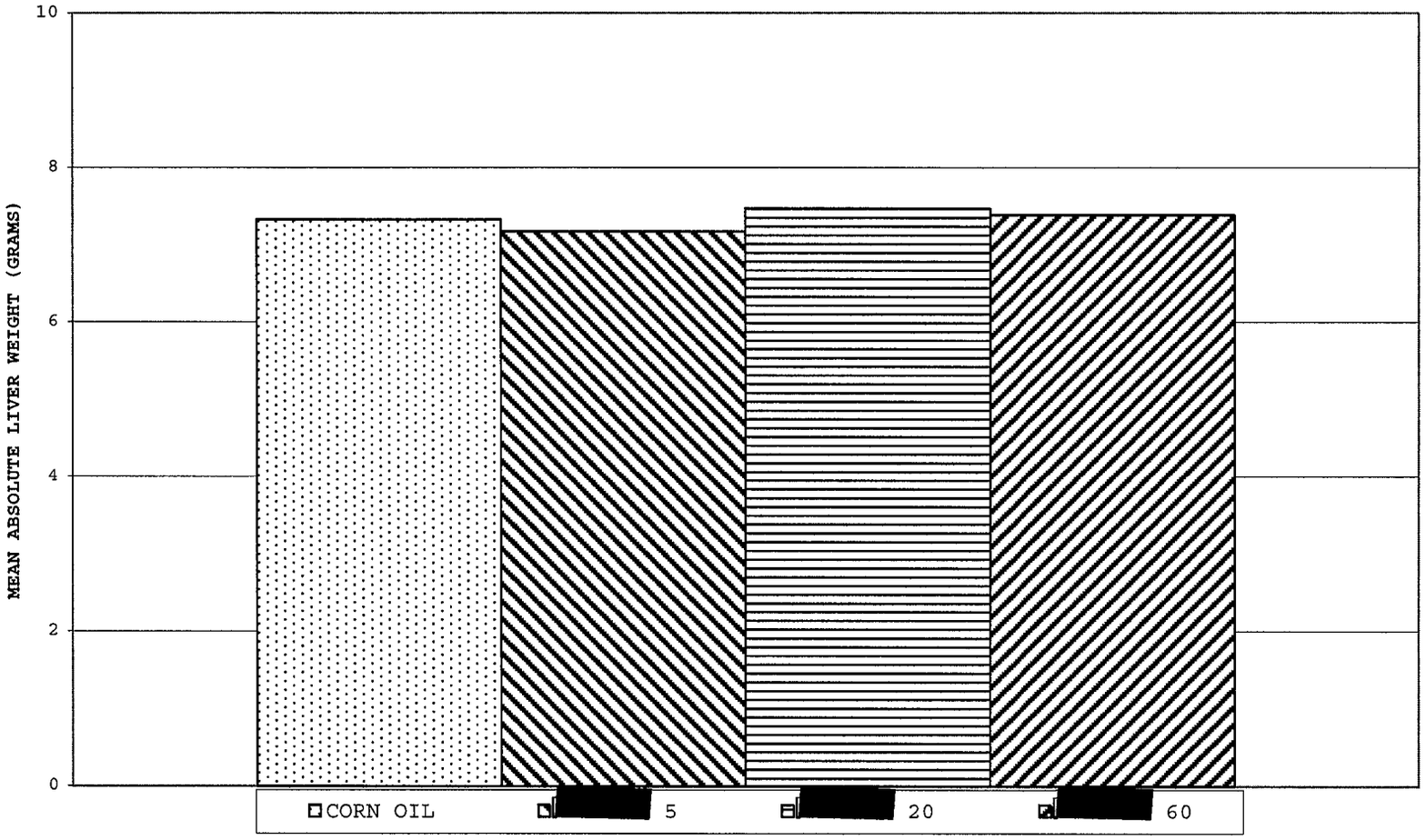


PROJECT NO.:WIL-187041
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN ABSOLUTE LIVER WEIGHT (GRAMS)

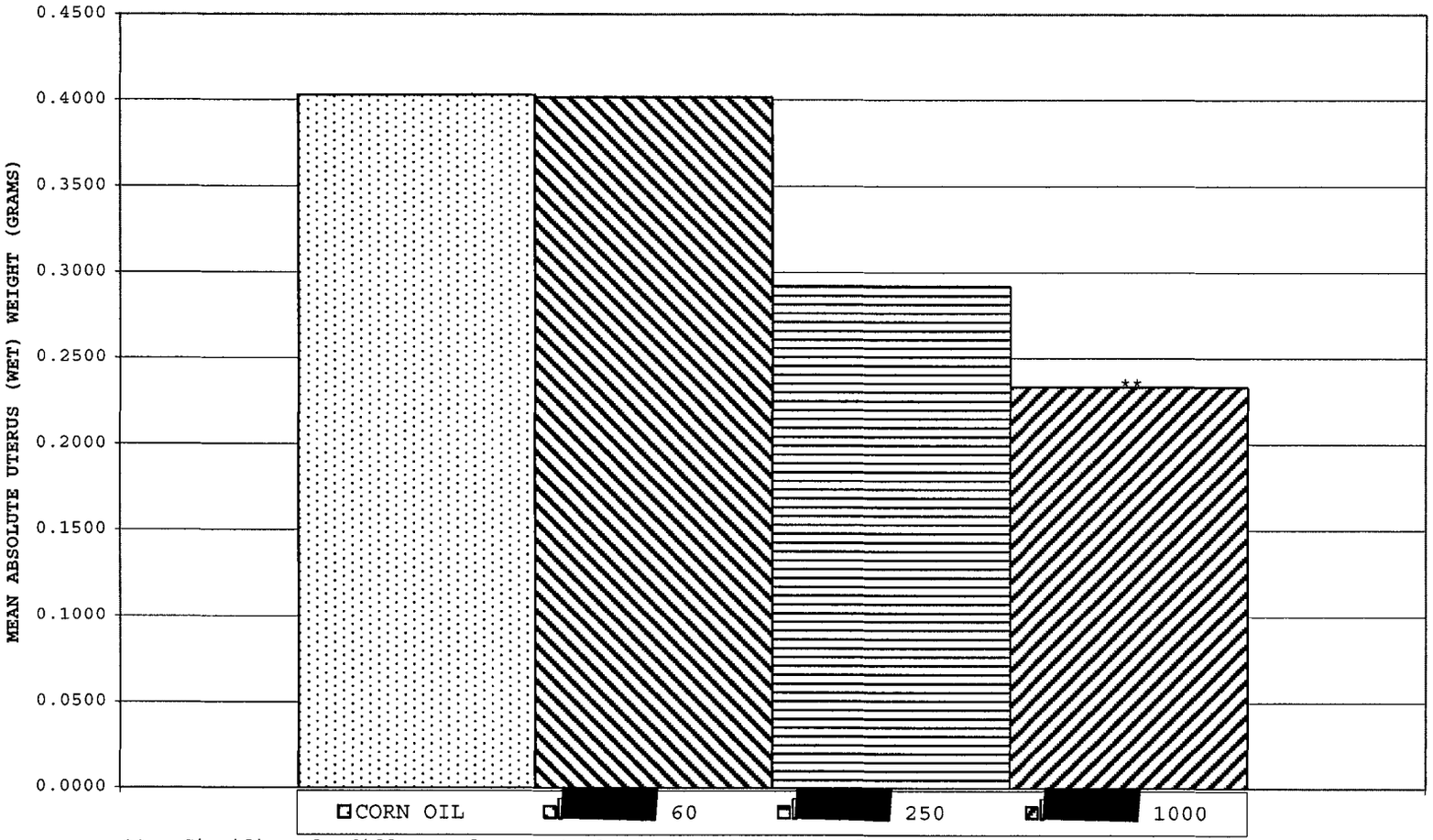


* = Significantly different from control group at 0.05 using Dunnett's test

PROJECT NO.:WIL-187041
SPONSOR: [redacted] PUBERTAL ASSAY OF [redacted]GURE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN ABSOLUTE LIVER WEIGHT (GRAMS)

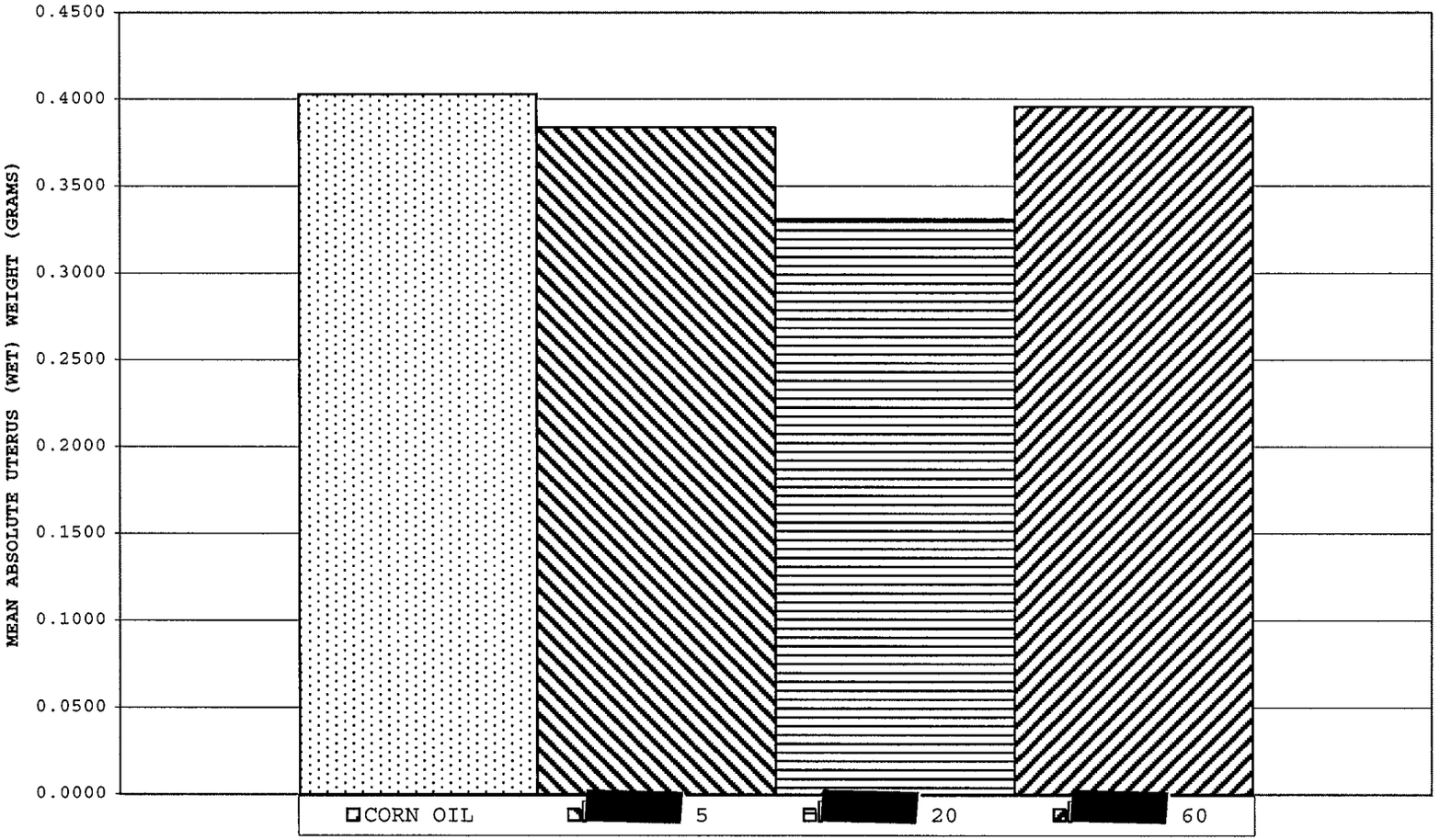


PROJECT NO.:WIL-187041
SPONSOR: [redacted] PUBERTAL ASSAY OF [redacted] GURE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN ABSOLUTE UTERUS (WET) WEIGHT (GRAMS)

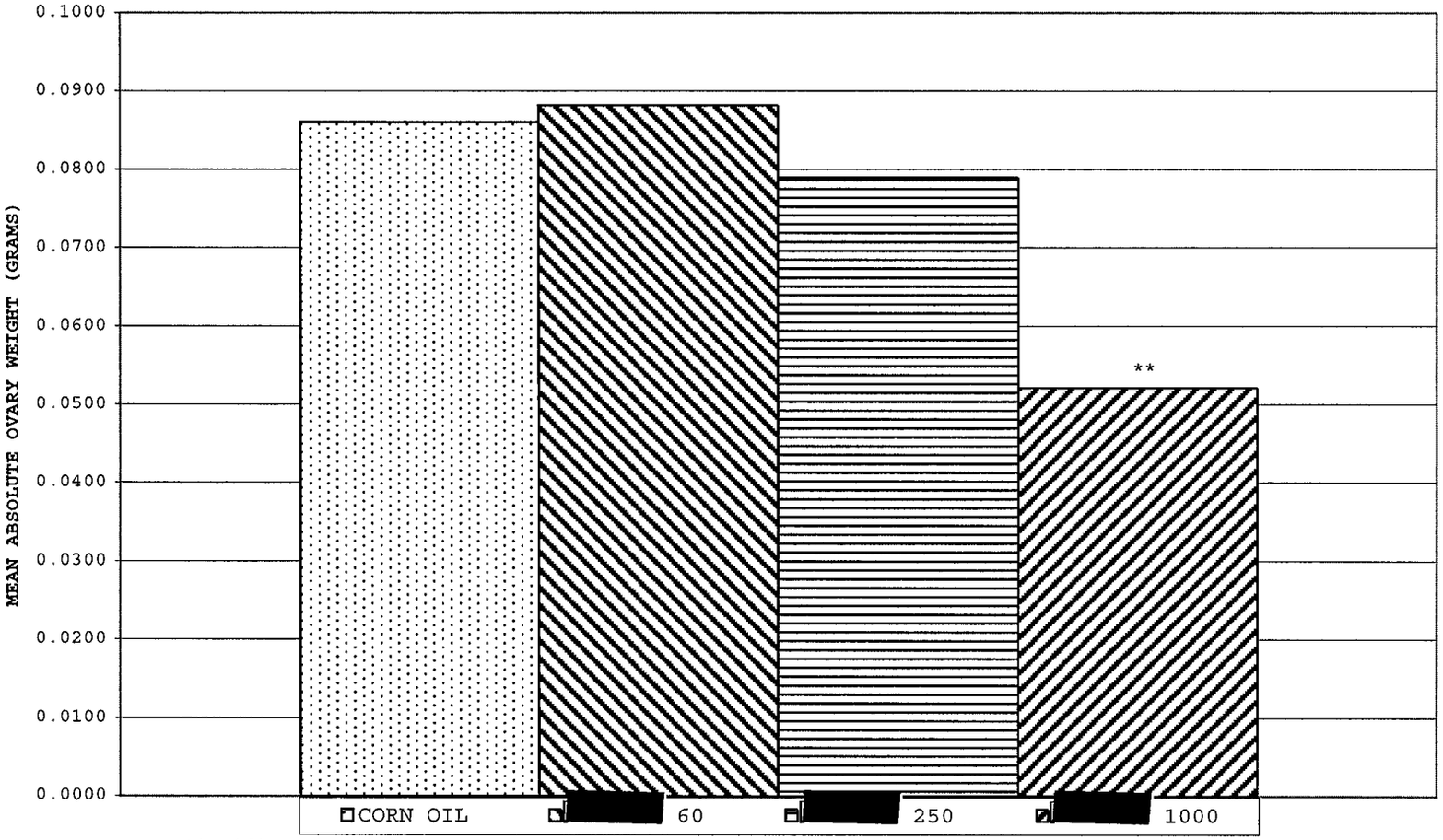


** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187041
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted]URE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN ABSOLUTE UTERUS (WET) WEIGHT (GRAMS)

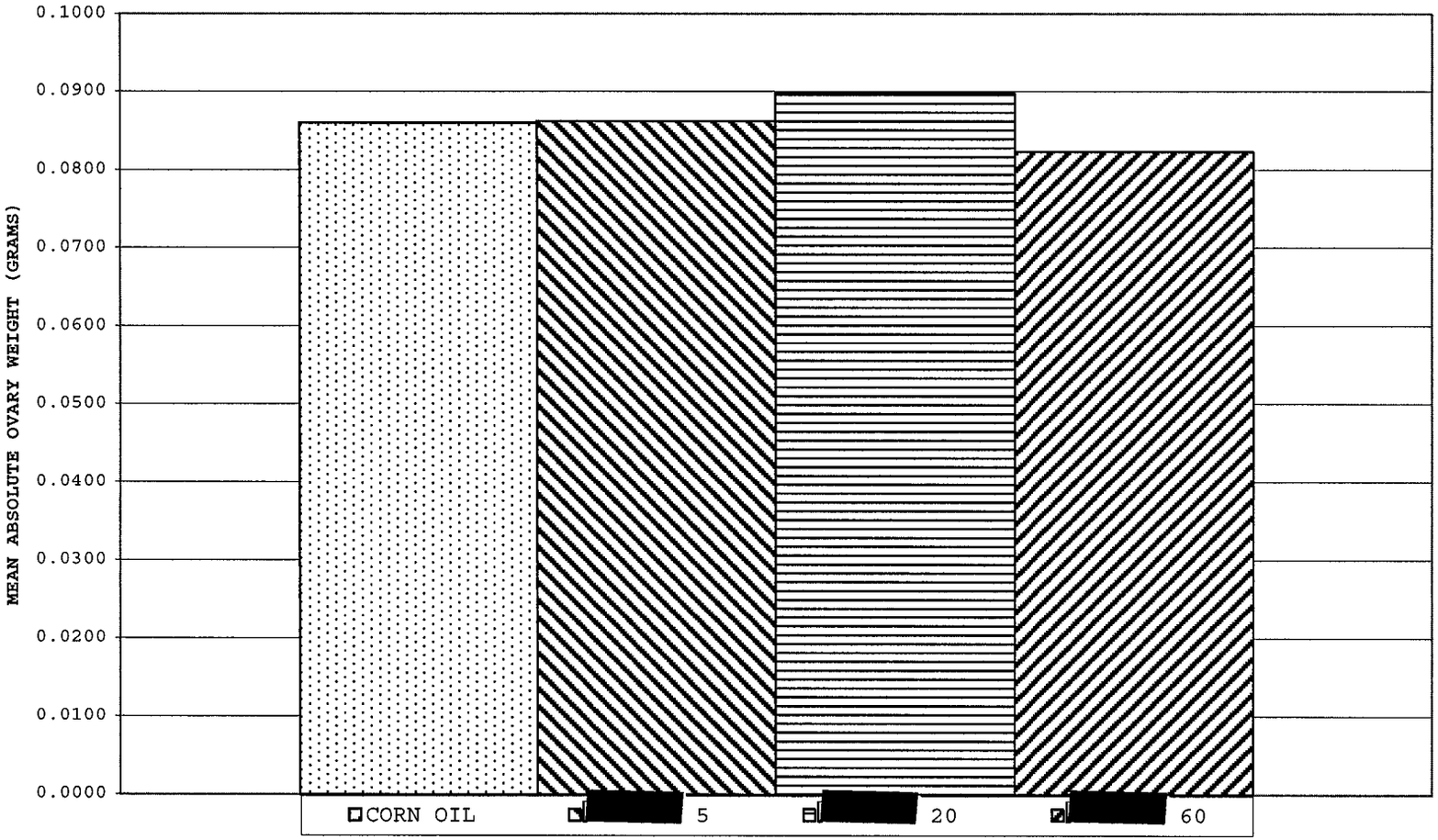


PROJECT NO.:WIL-187041
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted]URE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



** = Significantly different from control group at 0.01 uaing Dunnett's test

PROJECT NO.:WIL-187041
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted]URE [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-023 MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



TABLES 1-25

TABLE 1

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	1				2				3				4			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
25	14	1	0	0	15	0	0	0	15	0	0	0	15	0	0	0
26	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
27	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
28	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
29	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
30	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
31	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
32	14	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
33	14	0	0	0	15	0	0	0	14	1	0	0	15	0	0	0
34	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
35	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
36	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
37	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
38	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
39	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
40	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
41	14	0	0	0	15	0	0	0	14	0	0	0	15	0	0	0
42	0	0	0	14	0	0	0	15	0	0	0	14	0	0	0	15

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000

TABLE 1

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF SURVIVAL AND DISPOSITION
SPONSOR NO.:04-023

FEMALES

GROUP :	5				6				7			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0
30	15	0	0	0	15	0	0	0	15	0	0	0
31	15	0	0	0	15	0	0	0	15	0	0	0
32	15	0	0	0	15	0	0	0	15	0	0	0
33	15	0	0	0	15	0	0	0	15	0	0	0
34	15	0	0	0	15	0	0	0	15	0	0	0
35	15	0	0	0	15	0	0	0	15	0	0	0
36	15	0	0	0	15	0	0	0	15	0	0	0
37	15	0	0	0	15	0	0	0	15	0	0	0
38	15	0	0	0	15	0	0	0	15	0	0	0
39	15	0	0	0	15	0	0	0	15	0	0	0
40	15	0	0	0	15	0	0	0	15	0	0	0
41	15	0	0	0	15	0	0	0	15	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	15

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

5- [redacted] 5 6- [redacted] 20 7- [redacted] 60

PSURVv4.08
01/22/2005

TABLE 2 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-023
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	11-16-04 TO 12-08-04						
GROUP:	1	2	3	4	5	6	7
NORMAL							
-NO SIGNIFICANT CLINICAL OBSERVATIONS	291/15	310/15	303/15	300/15	306/15	314/15	312/15
DISPOSITION							
-FOUND DEAD	1/ 1	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
-SCHEDULED EUTHANASIA	14/14	15/15	14/14	15/15	15/15	15/15	15/15
BODY/INTEGUMENT							
-HAIR LOSS RIGHT FORELIMB	5/ 1	5/ 2	3/ 1	9/ 4	9/ 3	1/ 1	2/ 1
-HAIR LOSS LEFT FORELIMB	5/ 1	5/ 2	3/ 1	14/ 4	9/ 3	1/ 1	3/ 1
-UNKEMPT APPEARANCE	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0
-ABDOMEN APPEARS SWOLLEN	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
CARDIO-PULMONARY							
-LABORED RESPIRATION	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000 5- [redacted] 5 6- [redacted] 20
7- [redacted] 60

PCSUv4.05
02/16/2005

TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	11-16-04 TO 12-07-04						
GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING	0/ 0	0/ 0	7/ 6	42/14	5/ 4	4/ 4	15/10
ORAL/DENTAL							
-SALIVATION	0/ 0	0/ 0	11/ 6	21/12	1/ 1	0/ 0	0/ 0
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	5/ 3	20/11	0/ 0	0/ 0	3/ 3
-SALIVATION PRIOR TO DOSING	0/ 0	0/ 0	14/ 8	33/ 8	0/ 0	0/ 0	2/ 2
-WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING	0/ 0	1/ 1	6/ 5	13/ 8	0/ 0	0/ 0	2/ 2

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000 5- [redacted] 5 6- [redacted] 20
7- [redacted] 60

PCSUv4.05
02/16/2005
R:02/16/2005

TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-023
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	11-16-04 TO 12-07-04						
GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-WIPES MOUTH ON CAGE FLOOR AND/OR WALLS	0/ 0	0/ 0	2/ 2	11/ 7	0/ 0	0/ 0	0/ 0
BODY/INTEGUMENT							
-WET CLEAR MATERIAL VENTRAL NECK	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
CARDIO-PULMONARY							
-LABORED RESPIRATION	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0
ORAL/DENTAL							
-SALIVATION	0/ 0	0/ 0	3/ 2	14/ 5	0/ 0	0/ 0	0/ 0
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	28/ 8	97/12	0/ 0	0/ 0	0/ 0
-WET RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	3/ 3	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000 5- [redacted] 5 6- [redacted] 20
7- [redacted] 60

PCSUv4.05
01/28/2005
R:01/28/2005

TABLE 5

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 22							
MEAN	52.8	52.0	53.0	51.3	52.2	52.3	52.5
S.D.	4.31	4.10	4.49	4.27	4.43	3.72	3.66
N	15	15	15	15	15	15	15
PND 23							
MEAN	56.0	56.6	57.5	53.3	56.6	57.2	57.3
S.D.	3.71	4.11	4.80	5.69	4.33	3.87	3.37
N	15	15	15	15	15	15	15
PND 24							
MEAN	60.1	61.6	62.6	57.6	61.8	62.5	62.6
S.D.	5.57	4.29	4.82	7.14	4.73	4.06	4.05
N	15	15	15	15	15	15	15
PND 25							
MEAN	65.6	66.5	67.9	64.2	65.8	67.8	67.9
S.D.	5.49	4.00	5.06	6.93	5.19	4.37	3.69
N	14	15	15	15	15	15	15
PND 26							
MEAN	70.3	71.1	72.4	69.2	70.1	72.9	72.9
S.D.	5.98	4.46	5.43	6.96	5.65	4.65	3.92
N	14	15	15	15	15	15	15
PND 27							
MEAN	75.5	75.8	77.6	73.5	75.0	77.9	77.7
S.D.	6.01	4.57	5.47	6.42	6.17	4.89	4.00
N	14	15	15	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

TABLE 5

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF BODY WEIGHTS [G]

FEMALES

	GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 28								
	MEAN	81.1	81.2	82.4	77.7	80.1	83.1	83.3
	S.D.	6.44	4.46	5.48	7.48	6.12	5.01	4.52
	N	14	15	15	15	15	15	15
PND 29								
	MEAN	86.8	86.3	88.2	83.4	84.7	88.2	88.3
	S.D.	7.05	4.66	6.18	8.23	6.60	6.03	4.76
	N	14	15	15	15	15	15	15
PND 30								
	MEAN	92.0	91.5	93.4	88.3	90.3	93.5	93.6
	S.D.	7.75	4.92	5.94	8.14	6.47	5.57	5.34
	N	14	15	15	15	15	15	15
PND 31								
	MEAN	97.8	96.8	98.6	93.0	96.4	99.6	99.1
	S.D.	8.56	6.14	6.38	9.38	7.48	6.35	6.31
	N	14	15	15	15	15	15	15
PND 32								
	MEAN	104.0	102.5	105.4	99.0	101.1	105.5	105.3
	S.D.	8.90	6.16	6.87	8.71	7.72	6.54	6.84
	N	14	15	15	15	15	15	15
PND 33								
	MEAN	110.0	108.6	111.3	104.2	106.9	111.5	111.7
	S.D.	8.49	6.34	7.37	9.42	7.72	6.78	6.56
	N	14	15	15	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

TABLE 5

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:		CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 34								
	MEAN	115.3	114.4	114.6	110.7	113.1	117.6	117.3
	S.D.	9.21	6.89	5.74	9.62	8.60	7.14	6.93
	N	14	15	14	15	15	15	15
PND 35								
	MEAN	121.5	120.5	119.8	116.2	117.8	123.1	123.1
	S.D.	10.18	7.01	6.51	9.37	8.54	7.28	7.24
	N	14	15	14	15	15	15	15
PND 36								
	MEAN	126.9	126.7	125.3	121.1	122.3	129.5	127.8
	S.D.	10.44	8.07	6.66	8.79	9.23	8.32	8.19
	N	14	15	14	15	15	15	15
PND 37								
	MEAN	132.8	130.9	130.0	126.4	128.1	133.8	132.0
	S.D.	11.15	9.37	7.15	10.55	9.40	8.17	8.83
	N	14	15	14	15	15	15	15
PND 38								
	MEAN	138.0	135.5	134.3	131.7	133.5	138.5	137.4
	S.D.	11.28	9.77	6.81	10.20	8.61	9.79	8.11
	N	14	15	14	15	15	15	15
PND 39								
	MEAN	142.0	140.3	138.4	135.6	137.6	142.9	142.7
	S.D.	10.52	11.54	8.30	10.76	9.44	7.89	7.57
	N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 40							
MEAN	147.3	144.6	141.1	140.0	142.0	148.9	146.6
S.D.	11.35	11.33	7.47	10.40	9.36	8.89	7.79
N	14	15	14	15	15	15	15
PND 41							
MEAN	150.4	148.6	144.5	144.6	146.1	152.1	150.4
S.D.	12.31	12.05	8.30	11.55	10.44	10.71	8.86
N	14	15	14	15	15	15	15
PND 42							
MEAN	153.1	152.3	147.5	148.5	149.4	154.4	152.9
S.D.	11.69	11.84	8.74	10.88	10.30	11.41	8.65
N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PJTBWSUv5.11
01/22/2005

TABLE 6

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-023
SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 22- 23							
MEAN	3.2	4.6	4.6	1.9	4.4	4.8	4.8
S.D.	3.36	0.76	0.76	1.95	1.20	0.69	1.06
N	15	15	15	15	15	15	15
PND 23- 24							
MEAN	4.1	5.0	5.0	4.4	5.3	5.3	5.2
S.D.	3.32	0.73	1.03	2.17	1.16	1.01	1.01
N	15	15	15	15	15	15	15
PND 24- 25							
MEAN	4.9	4.9	5.3	6.6b	3.9	5.3	5.3
S.D.	0.95	0.80	0.91	1.47	1.58	1.00	0.63
N	14	15	15	15	15	15	15
PND 25- 26							
MEAN	4.6	4.6	4.5	5.0	4.3	5.1	5.0
S.D.	0.88	1.15	0.86	1.36	1.92	0.76	1.04
N	14	15	15	15	15	15	15
PND 26- 27							
MEAN	5.2	4.7	5.2	4.3	4.8	5.0	4.8
S.D.	0.89	1.30	0.60	1.34	1.65	1.09	1.08
N	14	15	15	15	15	15	15
PND 27- 28							
MEAN	5.7	5.4	4.9	4.2a	5.1	5.2	5.6
S.D.	1.16	0.84	1.21	1.85	0.79	0.95	1.48
N	14	15	15	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

TABLE 6

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:		CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 28- 29								
	MEAN	5.7	5.1	5.8	5.6	4.6	5.1	5.0
	S.D.	1.20	0.81	2.10	1.60	1.22	1.69	1.41
	N	14	15	15	15	15	15	15
PND 29- 30								
	MEAN	5.2	5.2	5.2	5.0	5.6	5.3	5.2
	S.D.	1.08	1.04	2.10	0.97	1.50	1.33	1.53
	N	14	15	15	15	15	15	15
PND 30- 31								
	MEAN	5.7	5.3	5.2	4.7	6.0	6.1	5.5
	S.D.	1.30	1.74	1.45	2.18	2.55	1.65	1.63
	N	14	15	15	15	15	15	15
PND 31- 32								
	MEAN	6.3	5.7	6.7	6.0	4.8	5.9	6.2
	S.D.	1.49	0.66	1.32	2.67	2.98	1.76	1.04
	N	14	15	15	15	15	15	15
PND 32- 33								
	MEAN	5.9	6.1	5.9	5.1	5.8	5.9	6.5
	S.D.	1.46	1.86	1.75	3.08	1.56	1.76	1.90
	N	14	15	15	15	15	15	15
PND 33- 34								
	MEAN	5.3	5.8	4.5	6.6	6.1	6.1	5.5
	S.D.	2.34	1.96	1.59	2.80	1.68	2.13	2.31
	N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

TABLE 6

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:		CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 34- 35								
	MEAN	6.2	6.1	5.2	5.5	4.7	5.5	5.9
	S.D.	1.82	2.45	2.32	3.43	3.11	1.57	2.01
	N	14	15	14	15	15	15	15
PND 35- 36								
	MEAN	5.4	6.2	5.5	4.8	4.5	6.4	4.7
	S.D.	1.38	2.80	2.08	1.86	3.31	2.65	2.79
	N	14	15	14	15	15	15	15
PND 36- 37								
	MEAN	5.9	4.2	4.8	5.4	5.8	4.3	4.1
	S.D.	1.87	3.50	2.29	2.60	2.95	2.87	3.14
	N	14	15	14	15	15	15	15
PND 37- 38								
	MEAN	5.2	4.5	4.3	5.3	5.4	4.7	5.5
	S.D.	2.14	3.17	2.77	3.21	2.98	6.75	3.12
	N	14	15	14	15	15	15	15
PND 38- 39								
	MEAN	4.0	4.8	4.1	3.9	4.1	4.5	5.2
	S.D.	3.39	3.53	5.21	3.38	2.65	4.95	3.68
	N	14	15	14	15	15	15	15
PND 39- 40								
	MEAN	5.3	4.3	2.7	4.3	4.4	6.0	3.9
	S.D.	2.96	2.77	4.02	5.46	2.11	3.32	2.35
	N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
PND 40- 41							
MEAN	3.1	4.1	3.4	4.6	4.1	3.1	3.8
S.D.	3.10	2.08	3.01	4.28	3.36	3.88	2.72
N	14	15	14	15	15	15	15
PND 41- 42							
MEAN	2.7	3.7	2.9	3.9	3.4	2.3	2.5
S.D.	3.93	3.64	3.46	2.44	3.04	4.75	3.12
N	14	15	14	15	15	15	15
PND 22- 42							
MEAN	100.9	100.2	95.0	97.2	97.2	102.0	100.4
S.D.	10.60	11.25	8.45	10.18	9.45	10.00	5.96
N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.11
01/22/2005

TABLE 7

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
VAGINAL PATENCY (PND)							
MEAN	33.2	29.6b	26.5b	27.9b	33.3	32.7	29.1d
S.D.	2.55	2.77	0.52	2.07	2.37	2.06	2.29
N	14	15	15	15	15	15	15
BODY WEIGHT (GRAMS)							
MEAN	110.9	89.7b	75.2b	77.4b	108.2	109.5	89.2d
S.D.	14.71	14.65	6.64	10.34	13.80	12.67	12.74
N	14	15	15	15	15	15	15

PND= POSTNATAL DAY

b = Significantly different from control group 1 at 0.01 using Dunnett's test

d = Significantly different from control group 1 at 0.01 using Dunnett's test

PJTBBv1.11
01/22/2005
R:02/16/2005

TABLE 8

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF ESTROUS CYCLE DATA

SPONSOR NO.:04-023

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
ESTROUS CYCLE LENGTH (DAYS)							
MEAN	4.9	5.4	5.5	3.2b	5.2	5.2	5.4
S.D.	0.53	0.79	1.06	1.17	0.66	0.68	0.64
N	9	14	14	11	12	6	13
MEAN AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)							
MEAN	34.4	32.7	27.4b	28.1b	34.5	34.8	32.6
S.D.	3.20	2.74	1.06	2.49	2.45	2.51	2.32
N	14	15	15	15	15	15	15

MODIFIED STATISTICS USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

b = Significantly different from control group 1 at 0.01 using Dunnett's test

PCYCv5.22
01/22/2005
R:02/16/2005

TABLE 9

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF SPECIAL CHEMISTRY VALUES

SPONSOR NO.:04-023

FEMALES

ANALYSIS	GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
TOTAL T4 (uG/dL)								
DAY 42	MEAN	4.53	4.63	4.67	5.52a	4.61	4.71	4.75
	S.D.	1.079	0.754	0.992	1.264	0.925	1.095	1.189
	N	14	15	13	15	14	15	15
TSH (ng/ml)								
DAY 42	MEAN	11.3	13.7	11.3	13.7	10.7	12.4	12.5
	S.D.	3.96	6.51	3.83	5.40	2.48	2.89	5.10
	N	14	15	13	15	14	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

MODIFIED STATISTICS USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

a = Significantly different from control group 1 at 0.05 using Dunnett's test

PCPSv5.2
01/27/2005
R:01/27/2005

TABLE 10 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:04-023

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	1	0	1	0	0	0	0
LUNGS							
-MASS	1	0	0	0	0	0	0
-ADHESIONS	1	0	0	0	0	0	0
-AREA(S), DARK RED	0	0	1	0	0	0	0
-NOT FULLY COLLAPSED	0	0	1	0	0	0	0

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000 5- [redacted] 5 6- [redacted] 20
7- [redacted] 60

PGRSI2v4.05
01/22/2005

TABLE 11

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS [G]

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
UTERUS- WET (G)							
MEAN	0.4029	0.4016	0.2920	0.2332b	0.3839	0.3309	0.3955
S.D.	0.17372	0.20783	0.07038	0.02545	0.14889	0.07722	0.20622
N	14	15	14	15	15	15	14
UTERUS- BLOTTED (G)							
MEAN	0.3105	0.3156	0.2598	0.2153b	0.3152	0.3034	0.2906
S.D.	0.08009	0.08471	0.04435	0.02735	0.07116	0.05824	0.07245
N	14	15	14	15	15	15	14
LUMINAL FLUID (G)							
MEAN	0.0924	0.0859	0.0322	0.0179	0.0687	0.0276	0.1050
S.D.	0.11073	0.14269	0.03541	0.00522	0.09337	0.02367	0.14608
N	14	15	14	15	15	15	14
LIVER (G)							
MEAN	7.3235	7.7381	7.2926	8.4595a	7.1679	7.4738	7.3849
S.D.	0.90891	1.41640	0.76014	0.94833	0.61105	0.92198	0.49966
N	14	15	14	15	15	15	15
KIDNEYS (G)							
MEAN	1.5704	1.5632	1.4971	1.4784	1.5172	1.5936	1.5448
S.D.	0.17658	0.15247	0.10466	0.10282	0.12097	0.15119	0.12617
N	14	15	14	15	15	15	15
ADRENAL GLANDS (G)							
MEAN	0.0395	0.0403	0.0441	0.0448a	0.0395	0.0434	0.0432
S.D.	0.00480	0.00578	0.00636	0.00567	0.00436	0.00562	0.00530
N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

a = Significantly different from control group 1 at 0.05 using Dunnett's test

b = Significantly different from control group 1 at 0.01 using Dunnett's test

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
			FEMALES				
OVARIES/OVIDUCTS (G)							
MEAN	0.0860	0.0881	0.0789	0.0521b	0.0862	0.0898	0.0823
S.D.	0.00753	0.01205	0.00916	0.01241	0.01682	0.01319	0.01719
N	14	15	14	15	15	15	15
PITUITARY (G)							
MEAN	0.0087	0.0087	0.0090	0.0078	0.0085	0.0094	0.0091
S.D.	0.00238	0.00125	0.00095	0.00127	0.00098	0.00120	0.00108
N	14	15	14	15	15	15	15
THYROID GLANDS (G)							
MEAN	0.0177	0.0182	0.0192	0.0234a	0.0205	0.0204	0.0193
S.D.	0.00336	0.00331	0.00732	0.00740	0.00515	0.00478	0.00416
N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

POFBSTv5.05
01/27/2005
R:02/16/2005

TABLE 12

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
FINAL BODY WT (G)							
MEAN	153.	152.	148.	149.	149.	154.	153.
S.D.	11.6	11.8	8.7	10.9	10.3	11.4	8.8
N	14	15	14	15	15	15	15
UTERUS- WET							
MEAN	0.261	0.266	0.197	0.158a	0.259	0.214	0.251
S.D.	0.1051	0.1407	0.0410	0.0206	0.1056	0.0446	0.1341
N	14	15	14	15	15	15	15
UTERUS- BLOTTED							
MEAN	0.202	0.208	0.176	0.145b	0.213	0.197	0.189
S.D.	0.0451	0.0587	0.0252	0.0202	0.0532	0.0352	0.0414
N	14	15	14	15	15	15	15
LIVER							
MEAN	4.773	5.051	4.942	5.691b	4.796	4.830	4.838
S.D.	0.3697	0.6850	0.3949	0.4326	0.2553	0.4010	0.2892
N	14	15	14	15	15	15	15
KIDNEYS							
MEAN	1.026	1.027	1.015	0.997	1.016	1.032	1.011
S.D.	0.0852	0.0790	0.0453	0.0512	0.0654	0.0597	0.0649
N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

FEMALES

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 5	[redacted] 20	[redacted] 60
ADRENAL GLANDS							
MEAN	0.026	0.027	0.030a	0.030a	0.026	0.028	0.028
S.D.	0.0029	0.0050	0.0038	0.0043	0.0033	0.0033	0.0026
N	14	15	14	15	15	15	15
OVARIES/OVIDUCTS							
MEAN	0.056	0.058	0.054	0.035b	0.058	0.058	0.054
S.D.	0.0059	0.0087	0.0079	0.0084	0.0105	0.0089	0.0102
N	14	15	14	15	15	15	15
PITUITARY							
MEAN	0.006	0.006	0.006	0.005	0.006	0.006	0.006
S.D.	0.0016	0.0008	0.0007	0.0007	0.0009	0.0007	0.0005
N	14	15	14	15	15	15	15
THYROID GLANDS							
MEAN	0.012	0.012	0.013	0.016a	0.014	0.013	0.013
S.D.	0.0027	0.0028	0.0046	0.0049	0.0033	0.0035	0.0031
N	14	15	14	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

POFBSTv5.05
01/27/2005
R:02/16/2005

TABLE 13

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	15
NUMBER OF ANIMALS (ALL TYPES OF DEATH COMBINED)	15	15	15	15	15	15	15
OVARIES							
TOTAL NUMBER EXAMINED	15	15	15	15	15	15	15
EXAMINED, UNREMARKABLE	11	12	3	0	14	11	11
-CORPORA LUTEA ABSENT	1-A	0	0	9	0	0	0
PRESENT	1-A	NONE	NONE	9	NONE	NONE	NONE
-JUVENILE OVARY	1-A	0	0	0	0	0	0
PRESENT	1-A	NONE	NONE	NONE	NONE	NONE	NONE
-CYST, CORPORA LUTEA	2	0	0	1	0	1	0
PRESENT	2	NONE	NONE	1	NONE	1	NONE
-DECREASED CORPORA LUTEA	1	3	12-B	6	1	3	4
PRESENT	1	3	12-B	6	1	3	4
THYROID GLANDS							
TOTAL NUMBER EXAMINED	15	15	15	15	15	15	15
EXAMINED, UNREMARKABLE	13	14	8	0	14	12	5
-DECREASED COLLOID	1-A	0	0	0	0	0	0
SEVERE	1-A	NONE	NONE	NONE	NONE	NONE	NONE
-HYPERTROPHY, FOLLICULAR CELL	1	1	7-B	15	1	3	10
MINIMAL	1	1	7-B	15	1	3	10
UTERUS							
TOTAL NUMBER EXAMINED	15	15	15	15	15	15	15
EXAMINED, UNREMARKABLE	11	14	6	2	15	15	8
-HEMORRHAGE	1	0	0	0	0	0	0
MINIMAL	1	NONE	NONE	NONE	NONE	NONE	NONE

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000 5- [redacted] 5 6- [redacted] 20
7- [redacted] 60

A = FE[redacted]. 69169-01 (FOUND DEAD ON PND 25)

B = INCLUDES FEMALE NO. 69169-07 (FOUND DEAD ON PND 33)

----- FEMALE -----

GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	15
NUMBER OF ANIMALS (ALL TYPES OF DEATH COMBINED)	15	15	15	15	15	15	15
UTERUS - CONTINUED							
-JUVENILE UTERUS	1-A	0	0	0	0	0	0
PRESENT	1-A	NONE	NONE	NONE	NONE	NONE	NONE
-HYPOPLASIA	2	1	9-B	13	0	0	7
MINIMAL	2	1	9-B	13	NONE	NONE	7
CERVIX							
TOTAL NUMBER EXAMINED	15	15	15	15	15	15	15
EXAMINED, UNREMARKABLE	14	15	15	15	15	15	15
-JUVENILE CERVIX	1-A	0	0	0	0	0	0
PRESENT	1-A	NONE	NONE	NONE	NONE	NONE	NONE

1- CORN OIL 2- [redacted] 60 3- [redacted] 250 4- [redacted] 1000 5- [redacted] 5 6- [redacted] 20
7- [redacted] 60
A = FE[redacted]. 69169-01 (FOUND DEAD ON PND 25)
B = INCLUDES FEMALE NO. 69169-07 (FOUND DEAD ON PND 33)

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:04-023

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69165-01	F	CORN OIL	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69166-06	F	CORN OIL	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69167-07	F	CORN OIL	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69175-02	F	CORN OIL	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69168-04	F	CORN OIL	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69169-01	F	CORN OIL	DISPOSITION	11-20-04	6:15	P	FOUND DEAD
69169-01	F	CORN OIL	BODY/INTEGUMENT	11-19-04	7:02	P	UNKEMPT APPEARANCE
69169-01	F	CORN OIL	CARDIO-PULMONARY	11-19-04	7:02	P	LABORED RESPIRATION
69169-08	F	CORN OIL	DISPOSITION	12-07-04	6:56	P	SCHEDULED EUTHANASIA
69170-05	F	CORN OIL	DISPOSITION	12-07-04	6:56	P	SCHEDULED EUTHANASIA
69171-03	F	CORN OIL	DISPOSITION	12-07-04	6:56	P	SCHEDULED EUTHANASIA
69171-09	F	CORN OIL	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69171-09	F	CORN OIL	BODY/INTEGUMENT	11-18-04	7:24	1	HAIR LOSS RIGHT FORELIMB
				11-18-04	7:24	1	HAIR LOSS LEFT FORELIMB
				11-19-04	7:04	1	HAIR LOSS RIGHT FORELIMB
				11-19-04	7:04	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:15	1	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:15	1	HAIR LOSS LEFT FORELIMB
				11-29-04	6:54	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	6:54	1	HAIR LOSS LEFT FORELIMB
				11-30-04	6:47	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	6:47	1	HAIR LOSS LEFT FORELIMB
69173-07	F	CORN OIL	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69174-01	F	CORN OIL	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69175-01	F	CORN OIL	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69175-04	F	CORN OIL	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69176-09	F	CORN OIL	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69165-06	F	[redacted] 60	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69165-10	F	[redacted] 60	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69166-07	F	60	DISPOSITION	12-06-04	8:59	P	SCHEDULED EUTHANASIA
69168-08	F	60	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69168-10	F	60	DISPOSITION	12-06-04	8:59	P	SCHEDULED EUTHANASIA
69170-02	F	60	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69170-10	F	60	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69171-05	F	60	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69171-05	F	60	BODY/INTEGUMENT	11-18-04	7:29	1	HAIR LOSS RIGHT FORELIMB
				11-18-04	7:29	1	HAIR LOSS LEFT FORELIMB
				11-19-04	7:07	1	HAIR LOSS RIGHT FORELIMB
				11-19-04	7:07	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:19	2	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:19	2	HAIR LOSS LEFT FORELIMB
				11-29-04	6:57	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	6:57	1	HAIR LOSS LEFT FORELIMB
69172-04	F	60	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69172-07	F	60	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69173-03	F	60	DISPOSITION	12-08-04	6:21	P	SCHEDULED EUTHANASIA
69174-05	F	60	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69174-06	F	60	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69176-08	F	60	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69177-06	F	60	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69177-06	F	60	BODY/INTEGUMENT	11-29-04	6:58	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	6:58	1	HAIR LOSS LEFT FORELIMB
69165-03	F	250	DISPOSITION	12-06-04	8:55	P	SCHEDULED EUTHANASIA
69166-05	F	250	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69166-09	F	250	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69167-01	F	250	DISPOSITION	12-06-04	8:59	P	SCHEDULED EUTHANASIA
69168-06	F	250	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69169-07	F	250	DISPOSITION	11-28-04	12:39	P	FOUND DEAD

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:04-023

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69176-10	F	250	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69171-04	F	250	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69171-08	F	250	DISPOSITION	12-07-04	6:57	P	SCHEDULED EUTHANASIA
69171-08	F	250	BODY/INTEGUMENT	11-25-04	7:22	1	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:22	1	HAIR LOSS LEFT FORELIMB
				11-29-04	7:00	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:00	1	HAIR LOSS LEFT FORELIMB
				11-30-04	6:55	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	6:55	1	HAIR LOSS LEFT FORELIMB
69172-02	F	250	DISPOSITION	12-07-04	6:58	P	SCHEDULED EUTHANASIA
69173-10	F	250	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69175-03	F	250	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69175-05	F	250	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69175-06	F	250	DISPOSITION	12-08-04	6:22	P	SCHEDULED EUTHANASIA
69176-04	F	250	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69165-09	F	1000	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69167-03	F	1000	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69167-06	F	1000	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69167-09	F	1000	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69168-02	F	1000	DISPOSITION	12-06-04	8:59	P	SCHEDULED EUTHANASIA
69169-06	F	1000	DISPOSITION	12-07-04	6:58	P	SCHEDULED EUTHANASIA
69170-04	F	1000	DISPOSITION	12-07-04	6:58	P	SCHEDULED EUTHANASIA
69170-07	F	1000	DISPOSITION	12-07-04	6:58	P	SCHEDULED EUTHANASIA
69171-01	F	1000	DISPOSITION	12-07-04	6:58	P	SCHEDULED EUTHANASIA
69171-01	F	1000	BODY/INTEGUMENT	11-29-04	7:04	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:04	1	HAIR LOSS LEFT FORELIMB
				11-30-04	6:59	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	6:59	1	HAIR LOSS LEFT FORELIMB
				12-07-04	6:56	P	ABDOMEN APPEARS SWOLLEN

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:04-023

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69172-03	F	1000	DISPOSITION	12-07-04	6:58	P	SCHEDULED EUTHANASIA
69173-09	F	1000	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69176-07	F	1000	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69177-03	F	1000	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69177-03	F	1000	BODY/INTEGUMENT	11-18-04	7:49	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:28	1	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:28	3	HAIR LOSS LEFT FORELIMB
				11-29-04	7:05	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:05	2	HAIR LOSS LEFT FORELIMB
				11-30-04	7:01	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	7:01	1	HAIR LOSS LEFT FORELIMB
69177-08	F	1000	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69177-08	F	1000	BODY/INTEGUMENT	11-18-04	7:49	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:28	1	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:28	1	HAIR LOSS LEFT FORELIMB
				11-29-04	7:05	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:05	1	HAIR LOSS LEFT FORELIMB
				11-30-04	7:01	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	7:01	1	HAIR LOSS LEFT FORELIMB
69177-09	F	1000	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69177-09	F	1000	BODY/INTEGUMENT	11-18-04	7:49	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:29	2	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:29	3	HAIR LOSS LEFT FORELIMB
				11-29-04	7:05	1	HAIR LOSS LEFT FORELIMB
				11-30-04	7:01	1	HAIR LOSS LEFT FORELIMB
69165-04	F	5	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69173-05	F	5	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69166-08	F	5	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69168-05	F	5	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:04-023

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69168-09	F	[redacted] 5	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69169-04	F	[redacted] 5	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69170-06	F	[redacted] 5	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69170-08	F	[redacted] 5	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69171-06	F	[redacted] 5	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69171-06	F	[redacted] 5	BODY/INTEGUMENT	11-18-04	7:59	1	HAIR LOSS RIGHT FORELIMB
				11-18-04	7:59	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:31	2	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:31	2	HAIR LOSS LEFT FORELIMB
				11-29-04	7:07	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:07	1	HAIR LOSS LEFT FORELIMB
				11-30-04	7:05	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	7:05	1	HAIR LOSS LEFT FORELIMB
69171-10	F	[redacted] 5	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69171-10	F	[redacted] 5	BODY/INTEGUMENT	11-18-04	7:59	1	HAIR LOSS RIGHT FORELIMB
				11-18-04	7:59	1	HAIR LOSS LEFT FORELIMB
				11-19-04	7:23	1	HAIR LOSS RIGHT FORELIMB
				11-19-04	7:23	1	HAIR LOSS LEFT FORELIMB
				11-25-04	7:31	2	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:31	2	HAIR LOSS LEFT FORELIMB
69174-03	F	[redacted] 5	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69174-07	F	[redacted] 5	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69175-08	F	[redacted] 5	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69175-10	F	[redacted] 5	DISPOSITION	12-08-04	6:23	P	SCHEDULED EUTHANASIA
69177-05	F	[redacted] 5	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69177-05	F	[redacted] 5	BODY/INTEGUMENT	11-25-04	7:33	1	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:33	1	HAIR LOSS LEFT FORELIMB
				11-29-04	7:09	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:09	1	HAIR LOSS LEFT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69165-05	F	[redacted] 20	DISPOSITION	12-06-04	8:59	P	SCHEDULED EUTHANASIA
69166-03	F	20	DISPOSITION	12-06-04	8:59	P	SCHEDULED EUTHANASIA
69167-02	F	20	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69167-08	F	20	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69168-01	F	20	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69169-02	F	20	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69169-03	F	20	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69169-10	F	20	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69172-05	F	20	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69172-09	F	20	DISPOSITION	12-07-04	6:59	P	SCHEDULED EUTHANASIA
69173-01	F	20	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69173-04	F	20	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69175-07	F	20	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69176-05	F	20	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69177-10	F	20	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69177-10	F	20	BODY/INTEGUMENT	11-25-04	7:36	1	HAIR LOSS RIGHT FORELIMB
				11-25-04	7:36	2	HAIR LOSS LEFT FORELIMB
69165-07	F	[redacted] 60	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69166-10	F	60	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69167-04	F	60	DISPOSITION	12-06-04	8:56	P	SCHEDULED EUTHANASIA
69167-05	F	60	DISPOSITION	12-06-04	8:57	P	SCHEDULED EUTHANASIA
69168-07	F	60	DISPOSITION	12-06-04	8:58	P	SCHEDULED EUTHANASIA
69169-05	F	60	DISPOSITION	12-07-04	7:00	P	SCHEDULED EUTHANASIA
69169-09	F	60	DISPOSITION	12-07-04	7:00	P	SCHEDULED EUTHANASIA
69170-01	F	60	DISPOSITION	12-07-04	7:00	P	SCHEDULED EUTHANASIA
69171-02	F	60	DISPOSITION	12-07-04	7:00	P	SCHEDULED EUTHANASIA
69172-01	F	60	DISPOSITION	12-07-04	7:00	P	SCHEDULED EUTHANASIA
69173-06	F	60	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA
69174-02	F	60	DISPOSITION	12-08-04	6:24	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 11-16-04 TO 12-08-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69174-08	F	[redacted] 60	DISPOSITION	12-08-04	6:25	P	SCHEDULED EUTHANASIA
69174-09	F	[redacted] 60	DISPOSITION	12-08-04	6:25	P	SCHEDULED EUTHANASIA
69177-07	F	[redacted] 60	DISPOSITION	12-08-04	6:25	P	SCHEDULED EUTHANASIA
69177-07	F	[redacted] 60	BODY/INTEGUMENT	11-25-04	7:41	1	HAIR LOSS LEFT FORELIMB
				11-29-04	7:15	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:15	1	HAIR LOSS LEFT FORELIMB
				11-30-04	7:14	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	7:14	1	HAIR LOSS LEFT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69176-08	F	[redacted] 60	ORAL/DENTAL	12-04-04	11:36	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69165-03	F	[redacted] 250	BEHAVIOR/CNS	11-29-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69166-05	F	[redacted] 250	ORAL/DENTAL	11-29-04	11:58	1	SALIVATION PRIOR TO DOSING
				12-04-04	11:39	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69166-09	F	[redacted] 250	ORAL/DENTAL	11-28-04	11:45	1	SALIVATION PRIOR TO DOSING
				11-29-04	11:59	1	SALIVATION PRIOR TO DOSING
				12-01-04	11:48	1	SALIVATION PRIOR TO DOSING
				12-04-04	11:40	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69167-01	F	[redacted] 250	ORAL/DENTAL	12-01-04	11:49	1	SALIVATION PRIOR TO DOSING
69168-06	F	[redacted] 250	BEHAVIOR/CNS	11-29-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69168-06	F	[redacted] 250	ORAL/DENTAL	12-02-04	12:02	2	SALIVATION PRIOR TO DOSING
69176-10	F	[redacted] 250	BEHAVIOR/CNS	11-29-04	12:06	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69176-10	F	[redacted] 250	ORAL/DENTAL	11-29-04	12:06	2	SALIVATION
				12-01-04	11:50	2	SALIVATION PRIOR TO DOSING
				12-04-04	11:41	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	11:56	1	SALIVATION
				12-06-04	11:56	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	11:46	1	SALIVATION
				12-07-04	11:46	1	WET CLEAR MATERIAL AROUND MOUTH
69171-04	F	[redacted] 250	BEHAVIOR/CNS	11-29-04	12:06	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69171-04	F	[redacted] 250	ORAL/DENTAL	11-30-04	12:07	1	SALIVATION
69171-08	F	[redacted] 250	ORAL/DENTAL	11-29-04	12:01	1	SALIVATION PRIOR TO DOSING
				11-29-04	12:07	3	SALIVATION
				12-01-04	11:51	2	SALIVATION PRIOR TO DOSING
69172-02	F	[redacted] 250	BEHAVIOR/CNS	11-29-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69172-02	F	[redacted] 250	BEHAVIOR/CNS	12-02-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69173-10	F	[redacted] 250	ORAL/DENTAL	11-29-04	12:02	1	SALIVATION PRIOR TO DOSING
				12-01-04	11:52	2	SALIVATION PRIOR TO DOSING
				12-02-04	12:04	1	SALIVATION PRIOR TO DOSING
				12-04-04	11:44	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-05-04	11:47	1	SALIVATION PRIOR TO DOSING
				12-07-04	11:46	2	SALIVATION
				12-07-04	11:46	2	WET CLEAR MATERIAL AROUND MOUTH
69175-03	F	[redacted] 250	ORAL/DENTAL	11-30-04	12:08	1	SALIVATION
				12-06-04	11:59	1	SALIVATION
				12-07-04	11:47	1	SALIVATION
69176-04	F	[redacted] 250	BEHAVIOR/CNS	12-06-04	11:59	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69176-04	F	[redacted] 250	ORAL/DENTAL	12-02-04	12:06	3	SALIVATION PRIOR TO DOSING
				12-03-04	12:23	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-04-04	11:46	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	11:59	2	SALIVATION
				12-06-04	11:59	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	11:47	2	SALIVATION
				12-07-04	11:47	2	WET CLEAR MATERIAL AROUND MOUTH
69165-09	F	[redacted] 1000	BEHAVIOR/CNS	11-28-04	11:55	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-29-04	12:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69165-09	F	[redacted] 1000	ORAL/DENTAL	11-24-04	12:16	1	SALIVATION

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP		CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69165-09	F	[redacted]	1000	ORAL/DENTAL	11-30-04	12:15	1	WET CLEAR MATERIAL AROUND MOUTH
69167-03	F	[redacted]	1000	BEHAVIOR/CNS	11-27-04	11:30	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					11-28-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-01-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69167-03	F	[redacted]	1000	ORAL/DENTAL	11-28-04	11:54	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
					12-04-04	11:50	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69167-06	F	[redacted]	1000	BEHAVIOR/CNS	11-28-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					11-29-04	12:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-01-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-02-04	12:08	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69167-06	F	[redacted]	1000	ORAL/DENTAL	11-29-04	12:16	2	WET CLEAR MATERIAL AROUND MOUTH
					12-01-04	11:56	1	SALIVATION PRIOR TO DOSING
69167-09	F	[redacted]	1000	BEHAVIOR/CNS	11-28-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					11-30-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69167-09	F	[redacted]	1000	ORAL/DENTAL	11-30-04	12:15	1	SALIVATION
69168-02	F	[redacted]	1000	BEHAVIOR/CNS	11-27-04	11:35	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-02-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69168-02	F	[redacted]	1000	ORAL/DENTAL	11-23-04	12:23	2	SALIVATION

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69168-02	F	[redacted] 1000	ORAL/DENTAL	11-27-04	11:28	1	SALIVATION PRIOR TO DOSING
				11-28-04	11:57	2	SALIVATION PRIOR TO DOSING
				11-29-04	12:10	1	SALIVATION PRIOR TO DOSING
				12-02-04	12:09	3	SALIVATION PRIOR TO DOSING
				12-04-04	11:51	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69169-06	F	[redacted] 1000	BEHAVIOR/CNS	11-27-04	11:31	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-30-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69169-06	F	[redacted] 1000	ORAL/DENTAL	11-25-04	12:21	1	SALIVATION PRIOR TO DOSING
				11-26-04	11:27	1	SALIVATION
				11-27-04	11:28	1	SALIVATION PRIOR TO DOSING
				11-28-04	11:57	1	SALIVATION PRIOR TO DOSING
				11-29-04	12:11	1	SALIVATION PRIOR TO DOSING
				11-30-04	12:15	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	11:57	1	SALIVATION PRIOR TO DOSING
				12-02-04	12:09	3	SALIVATION PRIOR TO DOSING
				12-03-04	12:29	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-04-04	11:52	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	12:03	1	SALIVATION
				12-06-04	12:03	1	WET CLEAR MATERIAL AROUND MOUTH
69170-04	F	[redacted] 1000	BEHAVIOR/CNS	11-28-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-30-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69170-04	F	[redacted] 1000	ORAL/DENTAL	11-27-04	11:29	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP		CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69170-04	F	[redacted]	1000	ORAL/DENTAL	12-06-04	12:03	2	SALIVATION
					12-06-04	12:03	1	WET CLEAR MATERIAL AROUND MOUTH
69170-07	F	[redacted]	1000	BEHAVIOR/CNS	11-27-04	11:35	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					11-30-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-01-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69170-07	F	[redacted]	1000	ORAL/DENTAL	11-26-04	11:29	1	SALIVATION
					11-29-04	12:12	1	SALIVATION PRIOR TO DOSING
					12-01-04	11:59	3	SALIVATION PRIOR TO DOSING
					12-02-04	12:10	2	SALIVATION PRIOR TO DOSING
					12-05-04	11:54	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
					12-06-04	12:03	1	WET CLEAR MATERIAL AROUND MOUTH
69172-03	F	[redacted]	1000	BEHAVIOR/CNS	11-27-04	11:36	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					11-28-04	12:07	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					11-29-04	12:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69172-03	F	[redacted]	1000	ORAL/DENTAL	11-28-04	12:07	2	SALIVATION
					11-29-04	12:16	2	WET CLEAR MATERIAL AROUND MOUTH
					11-30-04	12:22	1	WET CLEAR MATERIAL AROUND MOUTH
					12-06-04	12:04	1	WET CLEAR MATERIAL AROUND MOUTH
69173-09	F	[redacted]	1000	BEHAVIOR/CNS	12-01-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-06-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
					12-07-04	11:52	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69173-09	F	[redacted] 1000	ORAL/DENTAL	11-24-04	12:21	1	SALIVATION
				11-27-04	11:34	1	SALIVATION PRIOR TO DOSING
				11-28-04	12:01	3	SALIVATION PRIOR TO DOSING
				11-29-04	12:13	1	SALIVATION PRIOR TO DOSING
				11-30-04	12:22	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:00	2	SALIVATION PRIOR TO DOSING
				12-02-04	12:12	3	SALIVATION PRIOR TO DOSING
				12-03-04	12:33	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-04-04	11:55	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-05-04	11:58	2	SALIVATION PRIOR TO DOSING
				12-06-04	12:02	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:04	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	11:52	2	SALIVATION
				12-07-04	11:52	2	WET CLEAR MATERIAL AROUND MOUTH
69176-07	F	[redacted] 1000	BEHAVIOR/CNS	11-29-04	12:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-30-04	12:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	11:51	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69176-07	F	[redacted] 1000	ORAL/DENTAL	11-23-04	12:28	3	SALIVATION
				11-24-04	12:22	2	SALIVATION
				11-25-04	12:24	1	SALIVATION PRIOR TO DOSING
				11-26-04	11:31	1	SALIVATION
				11-27-04	11:34	1	SALIVATION PRIOR TO DOSING
				11-28-04	12:02	1	SALIVATION PRIOR TO DOSING
				11-29-04	12:14	2	SALIVATION PRIOR TO DOSING
				11-29-04	12:18	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69176-07	F	[redacted] 1000	ORAL/DENTAL	12-01-04	12:00	1	SALIVATION PRIOR TO DOSING
				12-02-04	12:12	3	SALIVATION PRIOR TO DOSING
				12-03-04	12:34	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-05-04	11:59	2	SALIVATION PRIOR TO DOSING
				12-06-04	12:05	2	SALIVATION
				12-06-04	12:05	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	11:51	2	SALIVATION
				12-07-04	11:51	1	WET CLEAR MATERIAL AROUND MOUTH
69177-03	F	[redacted] 1000	BEHAVIOR/CNS	12-01-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	11:52	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69177-03	F	[redacted] 1000	ORAL/DENTAL	12-04-04	11:57	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-07-04	11:52	1	SALIVATION
				12-07-04	11:52	1	WET CLEAR MATERIAL AROUND MOUTH
69177-08	F	[redacted] 1000	BEHAVIOR/CNS	11-28-04	12:06	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	11:53	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69177-08	F	[redacted] 1000	ORAL/DENTAL	11-26-04	11:32	1	SALIVATION
				11-27-04	11:37	1	SALIVATION PRIOR TO DOSING
				11-28-04	12:06	3	SALIVATION
				11-29-04	12:15	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69177-08	F	[redacted] 1000	ORAL/DENTAL	12-01-04	12:01	1	SALIVATION PRIOR TO DOSING
				12-02-04	12:13	3	SALIVATION PRIOR TO DOSING
				12-03-04	12:36	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-04-04	11:58	2	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-05-04	12:00	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	12:08	1	SALIVATION
				12-06-04	12:08	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	11:53	2	SALIVATION
				12-07-04	11:53	2	WET CLEAR MATERIAL AROUND MOUTH
69177-09	F	[redacted] 1000	BEHAVIOR/CNS	11-27-04	11:40	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-30-04	12:23	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:08	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69177-09	F	[redacted] 1000	ORAL/DENTAL	12-06-04	12:08	1	SALIVATION
				12-06-04	12:08	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	11:52	1	WET CLEAR MATERIAL AROUND MOUTH
69165-04	F	[redacted] 5	ORAL/DENTAL	11-23-04	12:34	2	SALIVATION
69166-08	F	[redacted] 5	BEHAVIOR/CNS	11-29-04	12:26	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69171-10	F	[redacted] 5	BEHAVIOR/CNS	12-02-04	12:24	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69174-07	F	[redacted] 5	BEHAVIOR/CNS	11-29-04	12:27	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69177-05	F	[redacted] 5	BEHAVIOR/CNS	11-29-04	12:27	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:24	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69167-02	F	[redacted] 20	BEHAVIOR/CNS	11-29-04	12:35	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69169-03	F	[redacted] 20	BEHAVIOR/CNS	12-02-04	12:31	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69173-04	F	[redacted] 20	BEHAVIOR/CNS	12-01-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69176-05	F	[redacted] 20	BEHAVIOR/CNS	12-01-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69166-10	F	[redacted] 60	BEHAVIOR/CNS	11-28-04	12:30	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69167-04	F	[redacted] 60	ORAL/DENTAL	12-02-04	12:34	1	SALIVATION PRIOR TO DOSING
				12-04-04	12:22	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69167-05	F	[redacted] 60	BEHAVIOR/CNS	11-28-04	12:29	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-29-04	12:43	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:25	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:39	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69167-05	F	[redacted] 60	ORAL/DENTAL	11-29-04	12:43	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:34	1	SALIVATION PRIOR TO DOSING
				12-04-04	12:23	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69169-05	F	[redacted] 60	BEHAVIOR/CNS	11-29-04	12:44	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69169-09	F	[redacted] 60	BEHAVIOR/CNS	12-02-04	12:39	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69170-01	F	[redacted] 60	BEHAVIOR/CNS	11-28-04	12:29	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69170-01	F	[redacted] 60	ORAL/DENTAL	11-25-04	12:55	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69171-02	F	[redacted] 60	BEHAVIOR/CNS	11-27-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69172-01	F	[redacted] 60	BEHAVIOR/CNS	11-29-04	12:43	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69172-01	F	[redacted] 60	ORAL/DENTAL	11-29-04	12:43	2	WET CLEAR MATERIAL AROUND MOUTH
69173-06	F	[redacted] 60	BEHAVIOR/CNS	11-27-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69174-02	F	[redacted] 60	BEHAVIOR/CNS	11-27-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:26	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:40	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69177-07	F	[redacted] 60	BEHAVIOR/CNS	12-07-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69169-01	F	CORN OIL	CARDIO-PULMONARY	11-19-04	13:11	P	LABORED RESPIRATION
69166-05	F	[redacted] 250	ORAL/DENTAL	12-01-04	12:42	1	WET CLEAR MATERIAL AROUND MOUTH
69166-09	F	[redacted] 250	BEHAVIOR/CNS	11-30-04	12:53	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69166-09	F	[redacted] 250	ORAL/DENTAL	11-26-04	12:13	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	12:49	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:43	2	WET CLEAR MATERIAL AROUND MOUTH
69168-06	F	[redacted] 250	ORAL/DENTAL	11-25-04	13:00	2	WET CLEAR MATERIAL AROUND MOUTH
				11-26-04	12:12	2	WET CLEAR MATERIAL AROUND MOUTH
				11-26-04	12:12	1	SALIVATION
				11-27-04	12:11	2	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	12:38	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	12:49	3	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:54	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:43	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:51	3	WET CLEAR MATERIAL AROUND MOUTH
69176-10	F	[redacted] 250	ORAL/DENTAL	12-01-04	12:44	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:52	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:35	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:38	1	WET CLEAR MATERIAL AROUND MOUTH
69171-08	F	[redacted] 250	ORAL/DENTAL	11-27-04	12:12	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	12:50	3	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:43	3	WET CLEAR MATERIAL AROUND MOUTH
69173-10	F	[redacted] 250	BEHAVIOR/CNS	11-27-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69173-10	F	[redacted] 250	ORAL/DENTAL	11-23-04	13:03	1	SALIVATION
				11-27-04	12:13	1	SALIVATION
				12-01-04	12:44	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:52	2	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:32	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:36	1	WET RED MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69173-10	F	250	ORAL/DENTAL	12-07-04	12:38	3	WET CLEAR MATERIAL AROUND MOUTH
69175-03	F	250	ORAL/DENTAL	12-05-04	12:36	1	WET CLEAR MATERIAL AROUND MOUTH
69176-04	F	250	ORAL/DENTAL	11-27-04	12:14	1	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	12:41	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:52	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:39	2	WET CLEAR MATERIAL AROUND MOUTH
69165-09	F	1000	BEHAVIOR/CNS	12-02-04	13:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69167-03	F	1000	ORAL/DENTAL	11-27-04	12:31	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:58	3	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:46	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:55	1	WET CLEAR MATERIAL AROUND MOUTH
69167-09	F	1000	BEHAVIOR/CNS	12-02-04	13:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69167-09	F	1000	ORAL/DENTAL	11-26-04	12:28	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	13:13	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:59	1	WET CLEAR MATERIAL AROUND MOUTH
69168-02	F	1000	BEHAVIOR/CNS	11-29-04	13:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69168-02	F	1000	ORAL/DENTAL	11-25-04	13:24	2	WET CLEAR MATERIAL AROUND MOUTH
				11-27-04	12:32	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:58	3	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:47	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:56	2	WET CLEAR MATERIAL AROUND MOUTH
69169-06	F	1000	ORAL/DENTAL	11-26-04	12:28	1	WET CLEAR MATERIAL AROUND MOUTH
				11-27-04	12:32	2	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	12:58	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:59	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69169-06	F	[redacted] 1000	ORAL/DENTAL	12-02-04	13:08	2	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:47	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	13:07	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:56	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:52	2	WET CLEAR MATERIAL AROUND MOUTH
69170-04	F	[redacted] 1000	ORAL/DENTAL	11-23-04	13:40	2	SALIVATION
				11-24-04	13:08	2	WET CLEAR MATERIAL AROUND MOUTH
				11-25-04	13:25	3	WET CLEAR MATERIAL AROUND MOUTH
				11-26-04	12:29	1	SALIVATION
				11-26-04	12:29	2	WET CLEAR MATERIAL AROUND MOUTH
				11-27-04	12:32	3	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	12:59	3	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	13:14	3	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:21	1	SALIVATION
				11-30-04	13:21	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:59	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:09	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:09	3	SALIVATION
				12-03-04	13:47	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	13:08	1	WET RED MATERIAL AROUND MOUTH
				12-05-04	12:56	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:52	1	WET CLEAR MATERIAL AROUND MOUTH
69170-07	F	[redacted] 1000	BEHAVIOR/CNS	11-29-04	13:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69170-07	F	[redacted] 1000	ORAL/DENTAL	11-29-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:59	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:09	2	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:48	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:57	2	WET RED MATERIAL AROUND MOUTH
69172-03	F	[redacted] 1000	ORAL/DENTAL	12-03-04	13:48	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69173-09	F	[redacted] 1000	BEHAVIOR/CNS	11-27-04	12:33	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-02-04	13:11	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-07-04	12:40	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69173-09	F	[redacted] 1000	ORAL/DENTAL	11-23-04	13:40	3	SALIVATION
				11-25-04	13:25	1	WET CLEAR MATERIAL AROUND MOUTH
				11-26-04	12:29	3	WET CLEAR MATERIAL AROUND MOUTH
				11-26-04	12:29	1	SALIVATION
				11-27-04	12:33	1	SALIVATION
				11-27-04	12:33	2	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	12:59	3	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	13:14	3	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:21	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:00	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:10	3	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:48	2	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	13:09	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:57	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:52	1	SALIVATION
				12-06-04	12:53	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:40	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:40	1	SALIVATION
69176-07	F	[redacted] 1000	BEHAVIOR/CNS	11-27-04	12:33	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				11-29-04	13:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-07-04	12:39	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69176-07	F	[redacted] 1000	ORAL/DENTAL	11-25-04	13:26	1	WET CLEAR MATERIAL AROUND MOUTH
				11-27-04	12:33	1	SALIVATION
				11-27-04	12:33	2	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	13:15	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:22	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69176-07	F	[redacted] 1000	ORAL/DENTAL	12-01-04	13:00	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:49	2	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:57	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:53	1	SALIVATION
				12-06-04	12:53	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:39	1	SALIVATION
				12-07-04	12:39	3	WET CLEAR MATERIAL AROUND MOUTH
69177-03	F	[redacted] 1000	ORAL/DENTAL	11-30-04	13:22	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:00	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:10	2	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	13:09	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:58	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:53	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:42	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:42	1	SALIVATION
69177-08	F	[redacted] 1000	BODY/INTEGUMENT	12-07-04	12:41	2	WET CLEAR MATERIAL VENTRAL NECK
69177-08	F	[redacted] 1000	ORAL/DENTAL	11-27-04	12:34	2	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	13:00	3	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	13:15	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:22	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:00	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:10	2	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	13:09	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:58	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:54	1	SALIVATION
				12-06-04	12:54	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-16-04 TO 12-07-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69177-08	F	[redacted] 1000	ORAL/DENTAL	12-07-04	12:40	3	WET CLEAR MATERIAL AROUND MOUTH
69177-09	F	[redacted] 1000	BEHAVIOR/CNS	11-27-04	12:34	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69177-09	F	[redacted] 1000	ORAL/DENTAL	11-24-04	13:09	2	WET CLEAR MATERIAL AROUND MOUTH
				11-25-04	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
				11-26-04	12:30	2	WET CLEAR MATERIAL AROUND MOUTH
				11-27-04	12:34	2	WET CLEAR MATERIAL AROUND MOUTH
				11-28-04	13:00	2	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	13:15	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:22	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:01	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	13:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	12:58	2	WET RED MATERIAL AROUND MOUTH
				12-06-04	12:54	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:40	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.08
01/28/2005

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: CORN OIL												
69165-01	48.2	53.4	55.5	60.8	66.0	71.3	77.5	82.8	87.9	93.3	100.5	108.3
69166-06	49.3	55.0	58.9	63.9	67.9	74.3	79.6	86.0	91.3	96.5	102.8	110.2
69167-07	58.0	61.5	66.3	71.4	75.4	80.5	86.9	92.1	97.7	102.2	109.3	115.6
69175-02	48.6	53.3	59.1	63.3	68.3	72.6	78.0	82.5	85.8	92.0	97.0	102.1
69168-04	46.2	49.2	47.0	50.6	52.9	58.1	63.7	68.6	73.2	76.9	83.0	89.5
69169-01	61.1	55.4	51.1									
69169-08	50.6	56.4	61.5	67.5	73.1	79.1	86.1	92.8	99.8	107.9	116.4	118.8
69170-05	55.8	53.3	59.6	65.7	71.4	76.3	82.9	90.7	95.8	103.6	110.7	116.7
69171-03	56.2	60.4	63.2	68.4	73.1	77.8	83.8	89.3	93.9	100.6	106.7	114.5
69171-09	54.2	54.8	61.7	67.7	71.7	75.9	80.7	87.4	91.8	98.0	105.0	110.5
69173-07	55.0	58.7	64.0	67.4	72.3	76.5	80.0	83.4	87.3	92.0	97.2	102.4
69174-01	51.5	55.5	61.2	65.3	69.8	74.5	77.9	83.1	88.0	91.9	95.8	102.1
69175-01	48.9	52.7	60.2	63.9	69.1	75.5	80.8	85.3	91.4	97.3	105.2	111.2
69175-04	51.0	56.9	62.8	68.7	74.0	81.0	87.5	94.2	100.1	106.0	113.0	119.7
69176-09	56.9	63.3	69.1	74.0	78.6	83.4	90.6	97.4	104.5	110.5	113.7	117.8
MEAN	52.8	56.0	60.1	65.6	70.3	75.5	81.1	86.8	92.0	97.8	104.0	110.0
S.D.	4.31	3.71	5.57	5.49	5.98	6.01	6.44	7.05	7.75	8.56	8.90	8.49
N	15	15	15	14	14	14	14	14	14	14	14	14

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: CORN OIL									
69165-01	110.3	116.5	121.4	128.3	132.3	134.3	142.5	145.8	151.5
69166-06	114.8	120.8	126.0	133.7	135.0	140.4	147.0	145.0	149.6
69167-07	116.2	126.5	130.2	136.9	139.0	144.8	154.5	154.8	158.8
69175-02	108.0	112.9	117.0	121.2	126.8	130.1	132.6	140.5	142.5
69168-04	94.7	98.9	105.0	111.1	116.4	122.6	127.8	130.8	131.8
69169-08	129.0	137.6	143.0	148.7	151.5	158.9	162.6	165.3	159.4
69170-05	120.6	128.8	133.8	142.6	149.6	146.4	155.4	161.3	164.0
69171-03	119.8	127.1	133.9	140.9	146.3	150.2	153.9	159.5	166.7
69171-09	115.6	120.9	128.5	134.5	142.0	147.0	149.5	150.3	159.4
69173-07	107.5	112.4	114.8	117.4	122.9	130.9	130.9	131.5	133.1
69174-01	108.0	112.4	118.9	122.3	128.1	131.2	136.2	135.1	141.4
69175-01	116.9	122.8	129.5	136.9	145.4	151.9	156.5	162.0	161.4
69175-04	127.5	131.8	137.7	144.5	152.1	149.4	159.1	162.9	164.9
69176-09	125.2	131.2	137.1	140.2	144.2	149.8	153.6	161.0	159.0
MEAN	115.3	121.5	126.9	132.8	138.0	142.0	147.3	150.4	153.1
S.D.	9.21	10.18	10.44	11.15	11.28	10.52	11.35	12.31	11.69
N	14	14	14	14	14	14	14	14	14

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: [redacted] 60												
69165-06	51.7	56.7	62.0	67.9	73.9	78.2	84.5	90.2	93.4	99.0	104.1	111.2
69165-10	47.3	52.4	56.2	62.3	68.4	75.4	79.9	85.9	90.0	97.1	103.2	111.6
69166-07	47.6	52.2	56.8	61.2	65.1	69.4	74.5	78.8	82.5	82.5	88.2	92.3
69168-08	54.8	57.8	62.3	65.5	70.4	74.1	79.1	84.8	91.2	97.4	101.5	106.8
69168-10	49.1	54.2	58.3	63.9	67.9	73.0	77.8	83.3	89.2	95.3	100.8	106.8
69170-02	52.8	58.5	64.2	69.8	73.4	78.2	84.2	90.3	95.6	102.3	108.3	115.7
69170-10	58.2	62.3	67.0	71.0	75.8	79.5	84.9	89.8	94.8	99.4	105.7	110.8
69171-05	57.5	61.2	67.5	71.7	76.6	82.0	87.2	90.8	96.7	103.5	109.3	110.8
69172-04	52.6	57.2	62.4	67.8	72.9	79.7	83.2	89.2	95.8	102.1	107.8	116.1
69172-07	47.2	51.2	56.8	61.9	67.9	70.3	75.5	80.6	85.6	90.7	95.8	103.6
69173-03	53.0	57.8	61.9	66.6	70.6	76.2	82.5	87.3	91.8	97.8	104.4	111.7
69174-05	56.2	61.4	66.4	71.3	76.3	81.2	86.4	92.3	97.3	103.3	109.5	115.3
69174-06	49.4	54.8	59.5	64.5	68.0	73.2	80.0	83.7	90.3	94.5	100.4	106.1
69176-08	57.1	62.2	67.7	71.7	77.0	79.6	84.8	90.0	95.8	100.6	105.8	110.1
69177-06	46.2	49.8	55.7	60.7	62.5	66.8	73.0	77.7	82.3	86.5	93.1	100.2
MEAN	52.0	56.6	61.6	66.5	71.1	75.8	81.2	86.3	91.5	96.8	102.5	108.6
S.D.	4.10	4.11	4.29	4.00	4.46	4.57	4.46	4.66	4.92	6.14	6.16	6.34
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: [redacted] 60									
69165-06	112.7	119.1	126.0	129.2	135.5	136.3	143.8	149.1	154.9
69165-10	116.2	123.3	131.5	137.1	144.5	148.6	149.4	157.1	161.2
69166-07	98.4	99.7	106.1	105.7	110.8	109.6	111.4	114.1	119.8
69168-08	111.7	120.7	126.2	129.9	135.5	139.0	145.7	148.8	148.8
69168-10	113.2	121.2	124.8	131.4	133.0	140.7	144.6	149.0	151.0
69170-02	123.6	129.5	140.4	144.2	150.8	159.8	159.1	164.9	171.5
69170-10	118.3	122.3	128.4	135.6	139.5	143.8	147.8	151.9	157.5
69171-05	118.6	125.8	127.6	132.7	130.2	142.1	143.6	149.7	145.9
69172-04	122.7	127.7	132.8	141.2	147.7	152.0	159.8	163.4	165.9
69172-07	112.4	119.7	128.2	125.5	133.9	141.0	144.3	145.4	144.5
69173-03	118.4	124.2	129.7	132.5	138.2	140.5	146.8	148.7	150.4
69174-05	120.7	122.1	132.4	139.7	144.3	150.4	154.6	158.3	162.1
69174-06	110.6	118.7	124.6	132.4	131.9	138.1	143.2	148.3	152.3
69176-08	116.0	121.3	128.6	126.9	128.3	134.7	138.0	144.2	151.0
69177-06	103.0	112.7	113.3	120.1	127.8	127.5	136.4	136.4	147.6
MEAN	114.4	120.5	126.7	130.9	135.5	140.3	144.6	148.6	152.3
S.D.	6.89	7.01	8.07	9.37	9.77	11.54	11.33	12.05	11.84
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: [redacted] 250												
69165-03	45.5	49.6	54.5	59.5	64.5	69.1	74.2	80.9	85.4	88.4	94.7	101.1
69166-05	50.0	53.0	56.8	62.2	66.9	71.4	76.3	82.3	89.7	93.3	100.6	108.1
69166-09	52.0	56.6	61.6	68.2	73.1	77.9	81.7	89.5	94.4	100.9	106.6	115.2
69167-01	53.4	57.1	61.7	66.8	70.6	75.4	79.6	84.3	91.7	95.0	100.0	107.8
69168-06	50.6	55.1	58.9	65.5	68.6	74.5	78.1	83.9	88.5	94.4	99.4	103.9
69169-07	60.2	65.7	71.2	76.8	83.3	88.7	94.3	102.1	106.5	113.5	121.0	128.9
69176-10	59.6	63.2	67.0	72.6	76.9	82.8	87.1	90.3	95.0	100.8	106.1	112.2
69171-04	50.7	55.5	59.7	65.3	69.2	75.6	80.6	86.4	90.4	94.7	103.1	107.7
69171-08	55.8	60.8	65.0	70.8	74.3	79.5	85.2	96.5	95.6	101.3	110.3	115.3
69172-02	50.6	55.6	62.8	66.4	71.3	76.4	81.7	87.3	93.2	99.7	105.9	112.7
69173-10	56.0	60.5	65.5	71.5	76.5	80.7	83.3	88.8	95.9	99.3	107.9	110.2
69175-03	46.1	50.1	56.5	60.0	64.0	69.2	75.5	78.9	83.6	91.3	98.0	102.9
69175-05	53.8	58.8	64.7	69.1	73.2	78.8	83.2	86.7	91.9	96.8	102.4	106.0
69175-06	51.2	56.7	62.7	68.2	73.8	78.8	86.5	90.5	97.1	102.7	109.4	115.9
69176-04	58.9	64.5	69.9	75.2	80.0	84.8	89.3	95.0	102.5	107.4	115.3	121.4
MEAN	53.0	57.5	62.6	67.9	72.4	77.6	82.4	88.2	93.4	98.6	105.4	111.3
S.D.	4.49	4.80	4.82	5.06	5.43	5.47	5.48	6.18	5.94	6.38	6.87	7.37
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: [redacted] 250									
69165-03	104.4	112.1	115.3	121.4	125.2	124.0	131.4	134.1	138.8
69166-05	111.6	118.4	123.8	123.6	131.8	134.1	134.5	143.7	147.0
69166-09	119.4	126.2	131.2	137.2	139.0	145.4	148.6	155.0	150.3
69167-01	109.7	112.0	120.9	125.3	129.8	131.0	136.6	140.0	145.3
69168-06	107.9	113.3	118.4	120.0	129.3	129.7	135.7	134.8	134.9
69176-10	116.3	116.9	124.0	131.1	133.7	140.8	139.3	138.6	144.1
69171-04	112.9	118.3	123.6	127.6	132.6	135.2	136.1	141.7	141.7
69171-08	120.6	129.5	136.1	140.6	146.6	157.0	155.8	160.2	167.9
69172-02	118.6	122.2	129.5	136.5	141.0	147.1	151.0	154.0	156.5
69173-10	114.8	120.8	123.4	132.4	130.0	139.1	136.0	140.8	147.0
69175-03	108.6	112.6	120.7	125.4	128.9	138.3	141.4	139.4	146.0
69175-05	114.1	117.4	118.8	123.4	127.0	135.8	134.9	137.9	136.8
69175-06	121.4	126.1	131.4	135.4	140.6	144.6	147.0	150.7	154.2
69176-04	123.7	131.5	136.7	140.7	144.6	135.9	147.5	152.3	153.9
MEAN	114.6	119.8	125.3	130.0	134.3	138.4	141.1	144.5	147.5
S.D.	5.74	6.51	6.66	7.15	6.81	8.30	7.47	8.30	8.74
N	14	14	14	14	14	14	14	14	14

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: [redacted] 1000												
69165-09	46.7	48.3	54.4	60.1	64.2	68.7	73.3	78.8	85.0	89.7	97.5	102.9
69167-03	50.9	52.3	56.6	65.2	71.5	77.4	81.2	86.5	91.2	97.2	101.5	110.4
69167-06	48.1	50.8	55.2	63.0	68.2	70.8	71.4	79.8	84.9	88.7	93.1	99.2
69167-09	54.9	57.4	62.3	68.0	72.6	77.0	82.8	88.6	93.9	97.5	102.9	102.3
69168-02	47.7	47.7	47.7	56.9	60.4	65.8	67.2	71.8	76.5	77.1	84.4	87.3
69169-06	53.2	54.7	59.9	67.3	71.9	75.5	82.0	86.7	90.9	97.5	103.8	112.3
69170-04	54.3	57.6	63.8	68.9	76.3	79.5	84.2	89.3	94.4	100.0	99.6	110.4
69170-07	58.5	61.5	65.3	70.7	76.0	77.3	81.8	87.6	90.6	95.9	99.5	107.5
69171-01	46.4	47.5	50.2	55.6	59.2	64.6	67.0	70.4	74.6	80.5	87.4	90.1
69172-03	55.5	61.5	67.2	74.8	79.8	85.0	91.7	98.9	103.7	110.6	118.1	123.8
69173-09	52.9	54.9	62.0	67.7	71.1	75.1	78.3	83.2	89.8	95.6	101.6	106.3
69176-07	57.7	62.2	69.0	75.4	79.2	82.8	87.7	96.3	100.8	107.1	112.8	113.6
69177-03	50.1	47.7	50.4	55.4	63.1	68.9	74.8	77.8	83.5	83.0	94.3	97.9
69177-08	46.2	47.3	47.5	56.0	62.1	66.1	71.9	76.9	83.2	86.8	95.9	101.2
69177-09	46.7	47.4	52.7	57.7	62.1	68.1	70.9	77.8	81.7	88.1	92.8	97.2
MEAN	51.3	53.3	57.6	64.2	69.2	73.5	77.7	83.4	88.3	93.0	99.0	104.2
S.D.	4.27	5.69	7.14	6.93	6.96	6.42	7.48	8.23	8.14	9.38	8.71	9.42
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: [redacted] 1000									
69165-09	108.8	117.9	120.2	127.9	132.5	140.2	137.1	140.3	144.6
69167-03	113.7	123.8	130.1	137.7	139.5	144.3	149.6	154.9	157.0
69167-06	103.0	107.1	113.4	113.9	119.8	126.5	129.6	131.2	134.8
69167-09	112.2	115.2	122.5	126.7	131.9	132.5	138.7	141.8	147.4
69168-02	93.7	96.7	102.8	103.7	111.5	113.6	119.3	123.2	126.7
69169-06	114.8	124.5	128.3	135.0	144.2	149.8	156.6	161.7	161.9
69170-04	119.4	126.4	129.0	134.1	136.6	144.2	147.4	152.5	159.0
69170-07	111.3	117.1	123.9	127.5	135.1	138.5	144.2	148.6	151.5
69171-01	97.2	104.2	109.2	114.8	122.5	127.0	133.0	136.4	142.1
69172-03	129.7	132.9	136.5	143.4	152.7	152.3	155.8	160.5	161.0
69173-09	110.8	111.4	114.1	118.1	121.4	124.8	130.2	126.7	131.3
69176-07	126.3	124.5	127.0	136.4	134.4	141.8	145.3	151.8	152.9
69177-03	105.3	113.5	117.5	121.4	129.5	128.3	134.1	142.9	146.9
69177-08	109.0	115.1	122.6	128.4	134.4	142.5	133.5	150.0	154.7
69177-09	106.0	113.3	119.0	127.7	129.9	128.2	145.2	146.4	155.9
MEAN	110.7	116.2	121.1	126.4	131.7	135.6	140.0	144.6	148.5
S.D.	9.62	9.37	8.79	10.55	10.20	10.76	10.40	11.55	10.88
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: [redacted] 5												
69165-04	45.1	49.3	53.5	59.7	60.7	67.8	73.0	78.0	84.7	89.3	92.7	100.6
69173-05	48.4	53.7	59.4	63.8	68.7	74.7	81.1	83.5	91.8	97.7	101.9	108.4
69166-08	47.2	50.5	56.1	59.9	65.2	69.9	75.0	78.7	83.7	87.8	93.7	99.1
69168-05	52.7	54.9	59.4	59.7	60.2	65.3	70.3	75.4	81.9	87.9	91.4	97.4
69168-09	55.8	59.5	64.8	68.4	73.1	75.7	80.4	85.7	91.4	94.2	100.9	106.0
69169-04	56.1	59.1	66.2	70.2	75.6	80.3	85.0	91.4	95.3	100.5	105.5	112.1
69170-06	57.2	59.9	64.7	66.6	71.1	74.9	80.1	85.3	89.3	95.2	100.2	106.0
69170-08	51.8	56.8	61.4	65.1	69.3	73.0	77.6	81.2	85.6	91.0	96.6	100.8
69171-06	51.6	56.4	62.5	67.0	70.6	74.5	80.2	84.5	88.5	93.4	100.0	103.2
69171-10	59.7	64.5	72.3	79.1	82.8	90.8	95.9	101.7	108.4	114.7	124.3	129.1
69174-03	52.1	58.2	63.5	66.6	72.5	78.2	83.2	89.4	94.4	99.5	105.0	113.1
69174-07	56.6	61.1	65.3	68.9	72.0	77.4	81.2	87.0	90.7	97.3	100.7	103.6
69175-08	51.9	56.4	60.5	65.4	69.2	74.2	77.9	81.7	88.0	94.9	100.1	107.0
69175-10	52.1	58.5	62.1	67.2	73.7	79.3	85.3	88.5	94.8	109.2	104.8	111.2
69177-05	44.8	49.8	55.8	59.0	67.0	68.4	74.8	78.2	86.3	92.8	98.9	106.2
MEAN	52.2	56.6	61.8	65.8	70.1	75.0	80.1	84.7	90.3	96.4	101.1	106.9
S.D.	4.43	4.33	4.73	5.19	5.65	6.17	6.12	6.60	6.47	7.48	7.72	7.72
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: [redacted] 5									
69165-04	104.7	110.3	116.9	122.2	127.1	131.3	137.1	141.4	145.7
69173-05	114.3	118.8	124.8	123.0	135.8	136.0	144.1	141.3	146.9
69166-08	104.3	109.3	113.7	117.1	123.8	128.3	128.7	130.4	129.0
69168-05	102.4	108.5	111.0	116.6	123.8	131.9	134.1	136.7	140.5
69168-09	110.5	121.4	118.7	124.6	126.4	131.1	134.7	141.2	144.5
69169-04	117.7	124.4	130.3	133.5	139.6	141.4	146.0	156.3	158.3
69170-06	111.3	116.2	120.2	128.8	135.7	144.2	145.4	152.4	158.9
69170-08	107.0	112.6	118.2	123.6	130.4	134.3	138.8	141.1	143.4
69171-06	112.9	117.9	121.2	126.1	134.0	136.5	141.1	146.3	150.2
69171-10	138.3	143.1	150.0	155.7	158.0	165.2	168.6	174.3	170.7
69174-03	120.4	122.5	128.0	136.5	141.7	147.3	151.5	151.3	158.2
69174-07	109.9	117.4	117.0	125.1	128.9	130.1	136.4	141.4	142.4
69175-08	113.7	118.5	125.0	129.5	134.4	139.6	143.7	148.2	151.7
69175-10	115.2	115.3	117.6	127.0	130.2	130.1	136.2	137.4	141.9
69177-05	113.3	110.7	122.0	131.7	132.3	136.4	143.5	151.5	159.3
MEAN	113.1	117.8	122.3	128.1	133.5	137.6	142.0	146.1	149.4
S.D.	8.60	8.54	9.23	9.40	8.61	9.44	9.36	10.44	10.30
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 11

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 6: [redacted] 20												
69165-05	51.7	56.1	61.8	67.8	73.0	78.2	82.0	88.4	93.7	97.1	103.4	108.4
69166-03	55.4	60.4	65.3	68.5	73.3	80.4	85.1	88.4	94.6	98.7	105.5	109.9
69167-02	51.7	57.5	61.3	65.8	72.3	76.5	81.6	86.8	91.5	96.9	99.4	108.2
69167-08	45.6	50.4	54.8	58.9	63.3	67.7	73.1	76.7	84.4	89.0	94.1	100.2
69168-01	49.3	53.9	58.7	63.1	68.4	73.4	77.3	81.7	86.5	93.3	99.8	105.0
69169-02	49.9	55.0	61.4	67.8	73.6	77.9	83.8	90.0	95.4	103.2	111.1	114.5
69169-03	52.2	56.2	63.0	69.0	73.4	78.1	83.9	86.8	93.7	97.7	105.8	110.5
69169-10	56.7	61.8	68.7	74.6	79.3	84.6	89.8	96.9	102.4	108.0	115.5	120.4
69172-05	58.5	64.1	68.4	74.0	80.0	84.0	91.1	96.5	99.9	107.2	113.7	118.8
69172-09	56.5	61.7	68.2	73.5	79.8	84.1	88.6	97.0	99.8	106.9	112.6	120.5
69173-01	47.7	52.2	57.8	63.5	68.5	73.5	79.8	84.0	89.8	96.4	103.5	109.5
69173-04	51.0	55.3	61.2	65.7	69.5	73.3	77.7	83.1	86.6	92.7	99.3	103.3
69175-07	49.2	54.4	59.0	64.8	69.7	74.6	80.3	83.9	89.5	95.4	101.5	108.5
69176-05	56.1	59.4	64.3	69.6	74.1	78.6	84.6	87.7	93.7	100.5	103.0	110.6
69177-10	53.5	59.3	63.6	70.6	75.7	83.4	87.6	94.7	101.0	110.7	114.5	123.6
MEAN	52.3	57.2	62.5	67.8	72.9	77.9	83.1	88.2	93.5	99.6	105.5	111.5
S.D.	3.72	3.87	4.06	4.37	4.65	4.89	5.01	6.03	5.57	6.35	6.54	6.78
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 12

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 6: [redacted] 20									
69165-05	113.9	119.2	126.8	126.8	134.6	139.9	148.3	145.9	142.6
69166-03	113.3	117.4	124.4	127.4	134.1	139.3	137.1	141.5	145.2
69167-02	110.5	119.2	124.3	128.2	134.9	142.1	147.8	142.8	154.3
69167-08	106.4	112.4	118.7	121.9	129.8	133.5	139.7	136.8	133.6
69168-01	111.0	117.2	122.7	126.4	132.5	134.4	139.6	143.1	145.6
69169-02	125.0	127.7	142.1	144.7	142.5	154.1	158.4	163.7	155.1
69169-03	116.9	120.6	125.9	129.2	133.9	136.9	140.5	142.1	148.2
69169-10	127.3	132.3	139.9	147.1	151.9	153.8	158.5	163.2	169.6
69172-05	124.1	131.1	135.3	137.4	146.6	149.0	158.0	164.8	167.9
69172-09	126.9	133.6	141.5	143.2	148.6	154.7	158.5	165.0	167.9
69173-01	119.4	123.9	131.0	136.4	143.9	145.7	152.1	160.2	162.8
69173-04	110.3	114.3	119.6	124.7	126.9	131.2	136.9	141.7	141.2
69175-07	113.3	118.8	121.6	132.1	139.0	144.1	152.6	159.0	163.1
69176-05	117.6	123.7	128.0	137.5	121.0	136.2	144.0	147.9	152.5
69177-10	128.0	135.2	140.6	143.4	156.6	149.3	162.1	163.4	165.8
MEAN	117.6	123.1	129.5	133.8	138.5	142.9	148.9	152.1	154.4
S.D.	7.14	7.28	8.32	8.17	9.79	7.89	8.89	10.71	11.41
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 7: [redacted] 60												
69165-07	48.3	54.0	58.6	64.5	70.9	75.3	82.1	88.1	93.4	98.1	104.7	109.6
69166-10	50.6	56.3	59.7	66.0	70.2	74.1	79.2	84.6	89.4	94.9	101.8	109.3
69167-04	52.5	57.5	61.4	67.5	72.6	78.2	82.2	88.6	95.3	99.2	104.8	111.2
69167-05	50.3	56.3	60.6	65.6	72.8	76.3	81.4	85.9	90.5	92.9	99.4	107.6
69168-07	53.1	57.5	62.3	67.1	71.4	74.4	81.4	84.2	89.3	94.2	99.3	105.0
69169-05	55.2	59.4	65.3	70.7	76.7	79.8	88.0	92.7	95.0	103.5	109.9	117.2
69169-09	55.9	61.7	67.8	73.3	79.3	83.8	89.6	94.3	102.3	109.0	116.1	121.3
69170-01	61.0	63.6	70.2	74.3	79.5	84.9	90.4	96.3	102.1	107.3	114.0	119.3
69171-02	51.1	53.6	59.3	64.2	68.8	73.3	76.3	83.7	86.8	90.7	97.9	100.4
69172-01	51.1	55.9	62.2	67.2	72.5	77.8	82.5	88.1	92.9	98.9	105.6	110.3
69173-06	53.1	58.1	64.3	69.4	72.8	79.3	84.1	88.8	94.8	100.8	106.7	114.1
69174-02	49.2	53.9	58.5	64.4	68.2	74.3	78.0	83.4	86.9	90.9	94.6	105.1
69174-08	53.7	58.7	64.4	69.9	74.6	80.5	86.6	92.0	98.9	106.0	113.6	119.9
69174-09	56.2	61.8	68.0	72.5	76.9	81.9	89.2	94.1	99.2	107.0	112.9	120.0
69177-07	46.2	51.6	55.9	61.8	66.2	71.4	78.5	80.0	86.7	92.7	97.5	105.8
MEAN	52.5	57.3	62.6	67.9	72.9	77.7	83.3	88.3	93.6	99.1	105.3	111.7
S.D.	3.66	3.37	4.05	3.69	3.92	4.00	4.52	4.76	5.34	6.31	6.84	6.56
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO :WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 7: [redacted] 60									
69165-07	114.0	119.6	120.2	127.8	137.4	140.4	147.1	151.1	147.4
69166-10	112.5	119.8	124.9	130.6	134.9	138.8	146.2	150.0	149.4
69167-04	118.8	120.7	125.3	126.3	135.3	138.0	142.9	144.0	144.4
69167-05	112.7	116.8	122.5	124.2	125.6	138.8	140.6	143.1	144.1
69168-07	112.4	119.1	122.8	123.8	132.1	136.2	140.7	144.9	149.8
69169-05	122.3	126.0	129.3	138.7	143.4	147.5	153.5	154.0	160.0
69169-09	122.7	131.5	139.2	145.1	150.8	156.2	160.0	165.3	168.3
69170-01	128.0	134.4	140.8	145.5	148.4	154.6	158.0	162.1	166.8
69171-02	109.0	112.6	115.6	120.3	127.3	134.5	138.0	140.1	146.0
69172-01	117.1	126.5	124.7	131.6	137.2	141.6	145.6	147.6	151.4
69173-06	119.3	126.6	135.6	133.6	143.8	141.4	140.4	148.3	150.1
69174-02	108.5	114.7	122.0	122.0	128.9	137.5	137.5	137.1	145.4
69174-08	125.7	131.2	135.1	140.8	145.1	147.6	152.9	156.8	157.8
69174-09	128.0	132.9	139.8	144.3	143.7	154.2	157.0	166.1	166.5
69177-07	108.0	114.4	119.9	125.3	127.8	132.6	138.6	145.9	146.4
MEAN	117.3	123.1	127.8	132.0	137.4	142.7	146.6	150.4	152.9
S.D.	6.93	7.24	8.19	8.83	8.11	7.57	7.79	8.86	8.65
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: CORN OIL												
69165-01	5.2	2.1	5.3	5.2	5.3	6.2	5.3	5.1	5.4	7.2	7.8	2.0
69166-06	5.7	3.9	5.0	4.0	6.4	5.3	6.4	5.3	5.2	6.3	7.4	4.6
69167-07	3.5	4.8	5.1	4.0	5.1	6.4	5.2	5.6	4.5	7.1	6.3	0.6
69175-02	4.7	5.8	4.2	5.0	4.3	5.4	4.5	3.3	6.2	5.0	5.1	5.9
69168-04	3.0	-2.2	3.6	2.3	5.2	5.6	4.9	4.6	3.7	6.1	6.5	5.2
69169-01	-5.7	-4.3										
69169-08	5.8	5.1	6.0	5.6	6.0	7.0	6.7	7.0	8.1	8.5	2.4	10.2
69170-05	-2.5	6.3	6.1	5.7	4.9	6.6	7.8	5.1	7.8	7.1	6.0	3.9
69171-03	4.2	2.8	5.2	4.7	4.7	6.0	5.5	4.6	6.7	6.1	7.8	5.3
69171-09	0.6	6.9	6.0	4.0	4.2	4.8	6.7	4.4	6.2	7.0	5.5	5.1
69173-07	3.7	5.3	3.4	4.9	4.2	3.5	3.4	3.9	4.7	5.2	5.2	5.1
69174-01	4.0	5.7	4.1	4.5	4.7	3.4	5.2	4.9	3.9	3.9	6.3	5.9
69175-01	3.8	7.5	3.7	5.2	6.4	5.3	4.5	6.1	5.9	7.9	6.0	5.7
69175-04	5.9	5.9	5.9	5.3	7.0	6.5	6.7	5.9	5.9	7.0	6.7	7.8
69176-09	6.4	5.8	4.9	4.6	4.8	7.2	6.8	7.1	6.0	3.2	4.1	7.4
MEAN	3.2	4.1	4.9	4.6	5.2	5.7	5.7	5.2	5.7	6.3	5.9	5.3
S.D.	3.36	3.32	0.95	0.88	0.89	1.16	1.20	1.08	1.30	1.49	1.46	2.34
N	15	15	14	14	14	14	14	14	14	14	14	14

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: CORN OIL									
69165-01	6.2	4.9	6.9	4.0	2.0	8.2	3.3	5.7	103.3
69166-06	6.0	5.2	7.7	1.3	5.4	6.6	-2.0	4.6	100.3
69167-07	10.3	3.7	6.7	2.1	5.8	9.7	0.3	4.0	100.8
69175-02	4.9	4.1	4.2	5.6	3.3	2.5	7.9	2.0	93.9
69168-04	4.2	6.1	6.1	5.3	6.2	5.2	3.0	1.0	85.6
69169-08	8.6	5.4	5.7	2.8	7.4	3.7	2.7	-5.9	108.8
69170-05	8.2	5.0	8.8	7.0	-3.2	9.0	5.9	2.7	108.2
69171-03	7.3	6.8	7.0	5.4	3.9	3.7	5.6	7.2	110.5
69171-09	5.3	7.6	6.0	7.5	5.0	2.5	0.8	9.1	105.2
69173-07	4.9	2.4	2.6	5.5	8.0	0.0	0.6	1.6	78.1
69174-01	4.4	6.5	3.4	5.8	3.1	5.0	-1.1	6.3	89.9
69175-01	5.9	6.7	7.4	8.5	6.5	4.6	5.5	-0.6	112.5
69175-04	4.3	5.9	6.8	7.6	-2.7	9.7	3.8	2.0	113.9
69176-09	6.0	5.9	3.1	4.0	5.6	3.8	7.4	-2.0	102.1
MEAN	6.2	5.4	5.9	5.2	4.0	5.3	3.1	2.7	100.9
S.D.	1.82	1.38	1.87	2.14	3.39	2.96	3.10	3.93	10.60
N	14	14	14	14	14	14	14	14	14

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: [redacted] 60												
69165-06	5.0	5.3	5.9	6.0	4.3	6.3	5.7	3.2	5.6	5.1	7.1	1.5
69165-10	5.1	3.8	6.1	6.1	7.0	4.5	6.0	4.1	7.1	6.1	8.4	4.6
69166-07	4.6	4.6	4.4	3.9	4.3	5.1	4.3	3.7	0.0	5.7	4.1	6.1
69168-08	3.0	4.5	3.2	4.9	3.7	5.0	5.7	6.4	6.2	4.1	5.3	4.9
69168-10	5.1	4.1	5.6	4.0	5.1	4.8	5.5	5.9	6.1	5.5	6.0	6.4
69170-02	5.7	5.7	5.6	3.6	4.8	6.0	6.1	5.3	6.7	6.0	7.4	7.9
69170-10	4.1	4.7	4.0	4.8	3.7	5.4	4.9	5.0	4.6	6.3	5.1	7.5
69171-05	3.7	6.3	4.2	4.9	5.4	5.2	3.6	5.9	6.8	5.8	1.5	7.8
69172-04	4.6	5.2	5.4	5.1	6.8	3.5	6.0	6.6	6.3	5.7	8.3	6.6
69172-07	4.0	5.6	5.1	6.0	2.4	5.2	5.1	5.0	5.1	5.1	7.8	8.8
69173-03	4.8	4.1	4.7	4.0	5.6	6.3	4.8	4.5	6.0	6.6	7.3	6.7
69174-05	5.2	5.0	4.9	5.0	4.9	5.2	5.9	5.0	6.0	6.2	5.8	5.4
69174-06	5.4	4.7	5.0	3.5	5.2	6.8	3.7	6.6	4.2	5.9	5.7	4.5
69176-08	5.1	5.5	4.0	5.3	2.6	5.2	5.2	5.8	4.8	5.2	4.3	5.9
69177-06	3.6	5.9	5.0	1.8	4.3	6.2	4.7	4.6	4.2	6.6	7.1	2.8
MEAN	4.6	5.0	4.9	4.6	4.7	5.4	5.1	5.2	5.3	5.7	6.1	5.8
S.D.	0.76	0.73	0.80	1.15	1.30	0.84	0.81	1.04	1.74	0.66	1.86	1.96
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: [redacted] 60									
69165-06	6.4	6.9	3.2	6.3	0.8	7.5	5.3	5.8	103.2
69165-10	7.1	8.2	5.6	7.4	4.1	0.8	7.7	4.1	113.9
69166-07	1.3	6.4	-0.4	5.1	-1.2	1.8	2.7	5.7	72.2
69168-08	9.0	5.5	3.7	5.6	3.5	6.7	3.1	0.0	94.0
69168-10	8.0	3.6	6.6	1.6	7.7	3.9	4.4	2.0	101.9
69170-02	5.9	10.9	3.8	6.6	9.0	-0.7	5.8	6.6	118.7
69170-10	4.0	6.1	7.2	3.9	4.3	4.0	4.1	5.6	99.3
69171-05	7.2	1.8	5.1	-2.5	11.9	1.5	6.1	-3.8	88.4
69172-04	5.0	5.1	8.4	6.5	4.3	7.8	3.6	2.5	113.3
69172-07	7.3	8.5	-2.7	8.4	7.1	3.3	1.1	-0.9	97.3
69173-03	5.8	5.5	2.8	5.7	2.3	6.3	1.9	1.7	97.4
69174-05	1.4	10.3	7.3	4.6	6.1	4.2	3.7	3.8	105.9
69174-06	8.1	5.9	7.8	-0.5	6.2	5.1	5.1	4.0	102.9
69176-08	5.3	7.3	-1.7	1.4	6.4	3.3	6.2	6.8	93.9
69177-06	9.7	0.6	6.8	7.7	-0.3	8.9	0.0	11.2	101.4
MEAN	6.1	6.2	4.2	4.5	4.8	4.3	4.1	3.7	100.2
S.D.	2.45	2.80	3.50	3.17	3.53	2.77	2.08	3.64	11.25
N	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: [redacted] 250												
69165-03	4.1	4.9	5.0	5.0	4.6	5.1	6.7	4.5	3.0	6.3	6.4	3.3
69166-05	3.0	3.8	5.4	4.7	4.5	4.9	6.0	7.4	3.6	7.3	7.5	3.5
69166-09	4.6	5.0	6.6	4.9	4.8	3.8	7.8	4.9	6.5	5.7	8.6	4.2
69167-01	3.7	4.6	5.1	3.8	4.8	4.2	4.7	7.4	3.3	5.0	7.8	1.9
69168-06	4.5	3.8	6.6	3.1	5.9	3.6	5.8	4.6	5.9	5.0	4.5	4.0
69169-07	5.5	5.5	5.6	6.5	5.4	5.6	7.8	4.4	7.0	7.5	7.9	
69176-10	3.6	3.8	5.6	4.3	5.9	4.3	3.2	4.7	5.8	5.3	6.1	4.1
69171-04	4.8	4.2	5.6	3.9	6.4	5.0	5.8	4.0	4.3	8.4	4.6	5.2
69171-08	5.0	4.2	5.8	3.5	5.2	5.7	11.3	-0.9	5.7	9.0	5.0	5.3
69172-02	5.0	7.2	3.6	4.9	5.1	5.3	5.6	5.9	6.5	6.2	6.8	5.9
69173-10	4.5	5.0	6.0	5.0	4.2	2.6	5.5	7.1	3.4	8.6	2.3	4.6
69175-03	4.0	6.4	3.5	4.0	5.2	6.3	3.4	4.7	7.7	6.7	4.9	5.7
69175-05	5.0	5.9	4.4	4.1	5.6	4.4	3.5	5.2	4.9	5.6	3.6	8.1
69175-06	5.5	6.0	5.5	5.6	5.0	7.7	4.0	6.6	5.6	6.7	6.5	5.5
69176-04	5.6	5.4	5.3	4.8	4.8	4.5	5.7	7.5	4.9	7.9	6.1	2.3
MEAN	4.6	5.0	5.3	4.5	5.2	4.9	5.8	5.2	5.2	6.7	5.9	4.5
S.D.	0.76	1.03	0.91	0.86	0.60	1.21	2.10	2.10	1.45	1.32	1.75	1.59
N	15	15	15	15	15	15	15	15	15	15	15	14

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: [redacted] 250									
69165-03	7.7	3.2	6.1	3.8	-1.2	7.4	2.7	4.7	93.3
69166-05	6.8	5.4	-0.2	8.2	2.3	0.4	9.2	3.3	97.0
69166-09	6.8	5.0	6.0	1.8	6.4	3.2	6.4	-4.7	98.3
69167-01	2.3	8.9	4.4	4.5	1.2	5.6	3.4	5.3	91.9
69168-06	5.4	5.1	1.6	9.3	0.4	6.0	-0.9	0.1	84.3
69176-10	0.6	7.1	7.1	2.6	7.1	-1.5	-0.7	5.5	84.5
69171-04	5.4	5.3	4.0	5.0	2.6	0.9	5.6	0.0	91.0
69171-08	8.9	6.6	4.5	6.0	10.4	-1.2	4.4	7.7	112.1
69172-02	3.6	7.3	7.0	4.5	6.1	3.9	3.0	2.5	105.9
69173-10	6.0	2.6	9.0	-2.4	9.1	-3.1	4.8	6.2	91.0
69175-03	4.0	8.1	4.7	3.5	9.4	3.1	-2.0	6.6	99.9
69175-05	3.3	1.4	4.6	3.6	8.8	-0.9	3.0	-1.1	83.0
69175-06	4.7	5.3	4.0	5.2	4.0	2.4	3.7	3.5	103.0
69176-04	7.8	5.2	4.0	3.9	-8.7	11.6	4.8	1.6	95.0
MEAN	5.2	5.5	4.8	4.3	4.1	2.7	3.4	2.9	95.0
S.D.	2.32	2.08	2.29	2.77	5.21	4.02	3.01	3.46	8.45
N	14	14	14	14	14	14	14	14	14

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: [redacted] 1000												
69165-09	1.6	6.1	5.7	4.1	4.5	4.6	5.5	6.2	4.7	7.8	5.4	5.9
69167-03	1.4	4.3	8.6	6.3	5.9	3.8	5.3	4.7	6.0	4.3	8.9	3.3
69167-06	2.7	4.4	7.8	5.2	2.6	0.6	8.4	5.1	3.8	4.4	6.1	3.8
69167-09	2.5	4.9	5.7	4.6	4.4	5.8	5.8	5.3	3.6	5.4	-0.6	9.9
69168-02	0.0	0.0	9.2	3.5	5.4	1.4	4.6	4.7	0.6	7.3	2.9	6.4
69169-06	1.5	5.2	7.4	4.6	3.6	6.5	4.7	4.2	6.6	6.3	8.5	2.5
69170-04	3.3	6.2	5.1	7.4	3.2	4.7	5.1	5.1	5.6	-0.4	10.8	9.0
69170-07	3.0	3.8	5.4	5.3	1.3	4.5	5.8	3.0	5.3	3.6	8.0	3.8
69171-01	1.1	2.7	5.4	3.6	5.4	2.4	3.4	4.2	5.9	6.9	2.7	7.1
69172-03	6.0	5.7	7.6	5.0	5.2	6.7	7.2	4.8	6.9	7.5	5.7	5.9
69173-09	2.0	7.1	5.7	3.4	4.0	3.2	4.9	6.6	5.8	6.0	4.7	4.5
69176-07	4.5	6.8	6.4	3.8	3.6	4.9	8.6	4.5	6.3	5.7	0.8	12.7
69177-03	-2.4	2.7	5.0	7.7	5.8	5.9	3.0	5.7	-0.5	11.3	3.6	7.4
69177-08	1.1	0.2	8.5	6.1	4.0	5.8	5.0	6.3	3.6	9.1	5.3	7.8
69177-09	0.7	5.3	5.0	4.4	6.0	2.8	6.9	3.9	6.4	4.7	4.4	8.8
MEAN	1.9	4.4	6.6	5.0	4.3	4.2	5.6	5.0	4.7	6.0	5.1	6.6
S.D.	1.95	2.17	1.47	1.36	1.34	1.85	1.60	0.97	2.18	2.67	3.08	2.80
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: [redacted] 1000									
69165-09	9.1	2.3	7.7	4.6	7.7	-3.1	3.2	4.3	97.9
69167-03	10.1	6.3	7.6	1.8	4.8	5.3	5.3	2.1	106.1
69167-06	4.1	6.3	0.5	5.9	6.7	3.1	1.6	3.6	86.7
69167-09	3.0	7.3	4.2	5.2	0.6	6.2	3.1	5.6	92.5
69168-02	3.0	6.1	0.9	7.8	2.1	5.7	3.9	3.5	79.0
69169-06	9.7	3.8	6.7	9.2	5.6	6.8	5.1	0.2	108.7
69170-04	7.0	2.6	5.1	2.5	7.6	3.2	5.1	6.5	104.7
69170-07	5.8	6.8	3.6	7.6	3.4	5.7	4.4	2.9	93.0
69171-01	7.0	5.0	5.6	7.7	4.5	6.0	3.4	5.7	95.7
69172-03	3.2	3.6	6.9	9.3	-0.4	3.5	4.7	0.5	105.5
69173-09	0.6	2.7	4.0	3.3	3.4	5.4	-3.5	4.6	78.4
69176-07	-1.8	2.5	9.4	-2.0	7.4	3.5	6.5	1.1	95.2
69177-03	8.2	4.0	3.9	8.1	-1.2	5.8	8.8	4.0	96.8
69177-08	6.1	7.5	5.8	6.0	8.1	-9.0	16.5	4.7	108.5
69177-09	7.3	5.7	8.7	2.2	-1.7	17.0	1.2	9.5	109.2
MEAN	5.5	4.8	5.4	5.3	3.9	4.3	4.6	3.9	97.2
S.D.	3.43	1.86	2.60	3.21	3.38	5.46	4.28	2.44	10.18
N	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: [redacted] 5												
69165-04	4.2	4.2	6.2	1.0	7.1	5.2	5.0	6.7	4.6	3.4	7.9	4.1
69173-05	5.3	5.7	4.4	4.9	6.0	6.4	2.4	8.3	5.9	4.2	6.5	5.9
69166-08	3.3	5.6	3.8	5.3	4.7	5.1	3.7	5.0	4.1	5.9	5.4	5.2
69168-05	2.2	4.5	0.3	0.5	5.1	5.0	5.1	6.5	6.0	3.5	6.0	5.0
69168-09	3.7	5.3	3.6	4.7	2.6	4.7	5.3	5.7	2.8	6.7	5.1	4.5
69169-04	3.0	7.1	4.0	5.4	4.7	4.7	6.4	3.9	5.2	5.0	6.6	5.6
69170-06	2.7	4.8	1.9	4.5	3.8	5.2	5.2	4.0	5.9	5.0	5.8	5.3
69170-08	5.0	4.6	3.7	4.2	3.7	4.6	3.6	4.4	5.4	5.6	4.2	6.2
69171-06	4.8	6.1	4.5	3.6	3.9	5.7	4.3	4.0	4.9	6.6	3.2	9.7
69171-10	4.8	7.8	6.8	3.7	8.0	5.1	5.8	6.7	6.3	9.6	4.8	9.2
69174-03	6.1	5.3	3.1	5.9	5.7	5.0	6.2	5.0	5.1	5.5	8.1	7.3
69174-07	4.5	4.2	3.6	3.1	5.4	3.8	5.8	3.7	6.6	3.4	2.9	6.3
69175-08	4.5	4.1	4.9	3.8	5.0	3.7	3.8	6.3	6.9	5.2	6.9	6.7
69175-10	6.4	3.6	5.1	6.5	5.6	6.0	3.2	6.3	14.4	-4.4	6.4	4.0
69177-05	5.0	6.0	3.2	8.0	1.4	6.4	3.4	8.1	6.5	6.1	7.3	7.1
MEAN	4.4	5.3	3.9	4.3	4.8	5.1	4.6	5.6	6.0	4.8	5.8	6.1
S.D.	1.20	1.16	1.58	1.92	1.65	0.79	1.22	1.50	2.55	2.98	1.56	1.68
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: [redacted] 5									
69165-04	5.6	6.6	5.3	4.9	4.2	5.8	4.3	4.3	100.6
69173-05	4.5	6.0	-1.8	12.8	0.2	8.1	-2.8	5.6	98.5
69166-08	5.0	4.4	3.4	6.7	4.5	0.4	1.7	-1.4	81.8
69168-05	6.1	2.5	5.6	7.2	8.1	2.2	2.6	3.8	87.8
69168-09	10.9	-2.7	5.9	1.8	4.7	3.6	6.5	3.3	88.7
69169-04	6.7	5.9	3.2	6.1	1.8	4.6	10.3	2.0	102.2
69170-06	4.9	4.0	8.6	6.9	8.5	1.2	7.0	6.5	101.7
69170-08	5.6	5.6	5.4	6.8	3.9	4.5	2.3	2.3	91.6
69171-06	5.0	3.3	4.9	7.9	2.5	4.6	5.2	3.9	98.6
69171-10	4.8	6.9	5.7	2.3	7.2	3.4	5.7	-3.6	111.0
69174-03	2.1	5.5	8.5	5.2	5.6	4.2	-0.2	6.9	106.1
69174-07	7.5	-0.4	8.1	3.8	1.2	6.3	5.0	1.0	85.8
69175-08	4.8	6.5	4.5	4.9	5.2	4.1	4.5	3.5	99.8
69175-10	0.1	2.3	9.4	3.2	-0.1	6.1	1.2	4.5	89.8
69177-05	-2.6	11.3	9.7	0.6	4.1	7.1	8.0	7.8	114.5
MEAN	4.7	4.5	5.8	5.4	4.1	4.4	4.1	3.4	97.2
S.D.	3.11	3.31	2.95	2.98	2.65	2.11	3.36	3.04	9.45
N	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 6: [redacted] 20												
69165-05	4.4	5.7	6.0	5.2	5.2	3.8	6.4	5.3	3.4	6.3	5.0	5.5
69166-03	5.0	4.9	3.2	4.8	7.1	4.7	3.3	6.2	4.1	6.8	4.4	3.4
69167-02	5.8	3.8	4.5	6.5	4.2	5.1	5.2	4.7	5.4	2.5	8.8	2.3
69167-08	4.8	4.4	4.1	4.4	4.4	5.4	3.6	7.7	4.6	5.1	6.1	6.2
69168-01	4.6	4.8	4.4	5.3	5.0	3.9	4.4	4.8	6.8	6.5	5.2	6.0
69169-02	5.1	6.4	6.4	5.8	4.3	5.9	6.2	5.4	7.8	7.9	3.4	10.5
69169-03	4.0	6.8	6.0	4.4	4.7	5.8	2.9	6.9	4.0	8.1	4.7	6.4
69169-10	5.1	6.9	5.9	4.7	5.3	5.2	7.1	5.5	5.6	7.5	4.9	6.9
69172-05	5.6	4.3	5.6	6.0	4.0	7.1	5.4	3.4	7.3	6.5	5.1	5.3
69172-09	5.2	6.5	5.3	6.3	4.3	4.5	8.4	2.8	7.1	5.7	7.9	6.4
69173-01	4.5	5.6	5.7	5.0	5.0	6.3	4.2	5.8	6.6	7.1	6.0	9.9
69173-04	4.3	5.9	4.5	3.8	3.8	4.4	5.4	3.5	6.1	6.6	4.0	7.0
69175-07	5.2	4.6	5.8	4.9	4.9	5.7	3.6	5.6	5.9	6.1	7.0	4.8
69176-05	3.3	4.9	5.3	4.5	4.5	6.0	3.1	6.0	6.8	2.5	7.6	7.0
69177-10	5.8	4.3	7.0	5.1	7.7	4.2	7.1	6.3	9.7	3.8	9.1	4.4
MEAN	4.8	5.3	5.3	5.1	5.0	5.2	5.1	5.3	6.1	5.9	5.9	6.1
S.D.	0.69	1.01	1.00	0.76	1.09	0.95	1.69	1.33	1.65	1.76	1.76	2.13
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 12

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 6: [redacted] 20									
69165-05	5.3	7.6	0.0	7.8	5.3	8.4	-2.4	-3.3	90.9
69166-03	4.1	7.0	3.0	6.7	5.2	-2.2	4.4	3.7	89.8
69167-02	8.7	5.1	3.9	6.7	7.2	5.7	-5.0	11.5	102.6
69167-08	6.0	6.3	3.2	7.9	3.7	6.2	-2.9	-3.2	88.0
69168-01	6.2	5.5	3.7	6.1	1.9	5.2	3.5	2.5	96.3
69169-02	2.7	14.4	2.6	-2.2	11.6	4.3	5.3	-8.6	105.2
69169-03	3.7	5.3	3.3	4.7	3.0	3.6	1.6	6.1	96.0
69169-10	5.0	7.6	7.2	4.8	1.9	4.7	4.7	6.4	112.9
69172-05	7.0	4.2	2.1	9.2	2.4	9.0	6.8	3.1	109.4
69172-09	6.7	7.9	1.7	5.4	6.1	3.8	6.5	2.9	111.4
69173-01	4.5	7.1	5.4	7.5	1.8	6.4	8.1	2.6	115.1
69173-04	4.0	5.3	5.1	2.2	4.3	5.7	4.8	-0.5	90.2
69175-07	5.5	2.8	10.5	6.9	5.1	8.5	6.4	4.1	113.9
69176-05	6.1	4.3	9.5	-16.5	15.2	7.8	3.9	4.6	96.4
69177-10	7.2	5.4	2.8	13.2	-7.3	12.8	1.3	2.4	112.3
MEAN	5.5	6.4	4.3	4.7	4.5	6.0	3.1	2.3	102.0
S.D.	1.57	2.65	2.87	6.75	4.95	3.32	3.88	4.75	10.00
N	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 7: [redacted] 60												
69165-07	5.7	4.6	5.9	6.4	4.4	6.8	6.0	5.3	4.7	6.6	4.9	4.4
69166-10	5.7	3.4	6.3	4.2	3.9	5.1	5.4	4.8	5.5	6.9	7.5	3.2
69167-04	5.0	3.9	6.1	5.1	5.6	4.0	6.4	6.7	3.9	5.6	6.4	7.6
69167-05	6.0	4.3	5.0	7.2	3.5	5.1	4.5	4.6	2.4	6.5	8.2	5.1
69168-07	4.4	4.8	4.8	4.3	3.0	7.0	2.8	5.1	4.9	5.1	5.7	7.4
69169-05	4.2	5.9	5.4	6.0	3.1	8.2	4.7	2.3	8.5	6.4	7.3	5.1
69169-09	5.8	6.1	5.5	6.0	4.5	5.8	4.7	8.0	6.7	7.1	5.2	1.4
69170-01	2.6	6.6	4.1	5.2	5.4	5.5	5.9	5.8	5.2	6.7	5.3	8.7
69171-02	2.5	5.7	4.9	4.6	4.5	3.0	7.4	3.1	3.9	7.2	2.5	8.6
69172-01	4.8	6.3	5.0	5.3	5.3	4.7	5.6	4.8	6.0	6.7	4.7	6.8
69173-06	5.0	6.2	5.1	3.4	6.5	4.8	4.7	6.0	6.0	5.9	7.4	5.2
69174-02	4.7	4.6	5.9	3.8	6.1	3.7	5.4	3.5	4.0	3.7	10.5	3.4
69174-08	5.0	5.7	5.5	4.7	5.9	6.1	5.4	6.9	7.1	7.6	6.3	5.8
69174-09	5.6	6.2	4.5	4.4	5.0	7.3	4.9	5.1	7.8	5.9	7.1	8.0
69177-07	5.4	4.3	5.9	4.4	5.2	7.1	1.5	6.7	6.0	4.8	8.3	2.2
MEAN	4.8	5.2	5.3	5.0	4.8	5.6	5.0	5.2	5.5	6.2	6.5	5.5
S.D.	1.06	1.01	0.63	1.04	1.08	1.48	1.41	1.53	1.63	1.04	1.90	2.31
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 18

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 7: [redacted] 60									
69165-07	5.6	0.6	7.6	9.6	3.0	6.7	4.0	-3.7	99.1
69166-10	7.3	5.1	5.7	4.3	3.9	7.4	3.8	-0.6	98.8
69167-04	1.9	4.6	1.0	9.0	2.7	4.9	1.1	0.4	91.9
69167-05	4.1	5.7	1.7	1.4	13.2	1.8	2.5	1.0	93.8
69168-07	6.7	3.7	1.0	8.3	4.1	4.5	4.2	4.9	96.7
69169-05	3.7	3.3	9.4	4.7	4.1	6.0	0.5	6.0	104.8
69169-09	8.8	7.7	5.9	5.7	5.4	3.8	5.3	3.0	112.4
69170-01	6.4	6.4	4.7	2.9	6.2	3.4	4.1	4.7	105.8
69171-02	3.6	3.0	4.7	7.0	7.2	3.5	2.1	5.9	94.9
69172-01	9.4	-1.8	6.9	5.6	4.4	4.0	2.0	3.8	100.3
69173-06	7.3	9.0	-2.0	10.2	-2.4	-1.0	7.9	1.8	97.0
69174-02	6.2	7.3	0.0	6.9	8.6	0.0	-0.4	8.3	96.2
69174-08	5.5	3.9	5.7	4.3	2.5	5.3	3.9	1.0	104.1
69174-09	4.9	6.9	4.5	-0.6	10.5	2.8	9.1	0.4	110.3
69177-07	6.4	5.5	5.4	2.5	4.8	6.0	7.3	0.5	100.2
MEAN	5.9	4.7	4.1	5.5	5.2	3.9	3.8	2.5	100.4
S.D.	2.01	2.79	3.14	3.12	3.68	2.35	2.72	3.12	5.96
N	15	15	15	15	15	15	15	15	15

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TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:04-023

GROUP: CORN OIL SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-01	36	121.2	N	N	N	N	N	N	N	N	N	N	N	Y				
69166-06	36	124.6	N	N	N	N	N	N	N	N	N	N	N	Y				
69167-07	35	123.5	N	N	N	N	N	N	N	N	N	N	Y					
69175-02	33	101.8	N	N	N	N	N	N	N	N	Y							
69168-04	36	106.5	N	N	N	N	N	N	N	N	N	N	N	Y				
69169-08	34	128.9	N	N	N	N	N	N	N	N	N	Y						
69170-05	34	120.2	N	N	N	N	N	N	N	N	N	Y						
69171-03	34	120.8	N	N	N	N	N	N	N	N	N	Y						
69171-09	35	123.4	N	N	N	N	N	N	N	N	N	N	Y					
69173-07	29	82.9	N	N	N	N	Y											
69174-01	32	97.4	N	N	N	N	N	N	N	Y								
69175-01	31	97.3	N	N	N	N	N	N	Y									
69175-04	32	113.6	N	N	N	N	N	N	N	Y								
69176-09	28	90.0	N	N	N	Y												
MEAN	33.2	110.9																
S.D.	2.55	14.71																
N	14	14																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

SPONSOR NO.:04-023

GROUP: [redacted] 60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-06	27	78.3	N	N	Y													
69165-10	27	75.1	N	N	Y													
69166-07	31	82.4	N	N	N	N	N	N	Y									
69168-08	31	96.6	N	N	N	N	N	N	Y									
69168-10	36	124.1	N	N	N	N	N	N	N	N	N	N	N	Y				
69170-02	33	114.6	N	N	N	N	N	N	N	N	Y							
69170-10	30	95.3	N	N	N	N	N	Y										
69171-05	28	87.6	N	N	N	Y												
69172-04	29	88.5	N	N	N	N	Y											
69172-07	27	70.1	N	N	Y													
69173-03	28	82.5	N	N	N	Y												
69174-05	29	91.7	N	N	N	N	Y											
69174-06	29	83.2	N	N	N	N	Y											
69176-08	26	77.0	N	Y														
69177-06	33	98.5	N	N	N	N	N	N	N	N	Y							
MEAN	29.6	89.7																
S.D.	2.77	14.65																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

PND= POSTNATAL DAY

TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:04-023

GROUP: [redacted] 250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-03	26	64.2	N	Y														
69166-05	26	66.8	N	Y														
69166-09	27	77.5	N	N	Y													
69167-01	27	75.2	N	N	Y													
69168-06	27	74.3	N	N	Y													
69169-07	27	89.6	N	N	Y													
69176-10	27	82.2	N	N	Y													
69171-04	27	75.3	N	N	Y													
69171-08	27	79.0	N	N	Y													
69172-02	27	77.0	N	N	Y													
69173-10	26	75.7	N	Y														
69175-03	26	64.7	N	Y														
69175-05	26	72.7	N	Y														
69175-06	26	73.1	N	Y														
69176-04	26	80.1	N	Y														
MEAN	26.5	75.2																
S.D.	0.52	6.64																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

GROUP: [redacted] 1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-09	30	84.8	N	N	N	N	N	Y										
69167-03	27	76.8	N	N	Y													
69167-06	29	78.8	N	N	N	N	Y											
69167-09	27	76.9	N	N	Y													
69168-02	28	67.8	N	N	N	Y												
69169-06	30	91.7	N	N	N	N	N	Y										
69170-04	26	75.8	N	Y														
69170-07	27	77.8	N	N	Y													
69171-01	26	58.8	N	Y														
69172-03	27	85.1	N	N	Y													
69173-09	25	67.5	Y															
69176-07	26	71.1	N	Y														
69177-03	29	76.6	N	N	N	N	Y											
69177-08	33	100.9	N	N	N	N	N	N	N	N	Y							
69177-09	28	70.8	N	N	N	Y												
MEAN	27.9	77.4																
S.D.	2.07	10.34																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

SPONSOR NO.:04-023

GROUP: [redacted] 5 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-04	33	100.4	N	N	N	N	N	N	N	N	Y							
69173-05	33	110.4	N	N	N	N	N	N	N	N	Y							
69166-08	31	88.0	N	N	N	N	N	N	Y									
69168-05	36	110.0	N	N	N	N	N	N	N	N	N	N	N	Y				
69168-09	32	100.8	N	N	N	N	N	N	N	Y								
69169-04	34	119.0	N	N	N	N	N	N	N	N	N	Y						
69170-06	40	144.8	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
69170-08	34	106.2	N	N	N	N	N	N	N	N	N	Y						
69171-06	32	99.5	N	N	N	N	N	N	N	Y								
69171-10	32	123.6	N	N	N	N	N	N	N	Y								
69174-03	31	99.9	N	N	N	N	N	N	Y									
69174-07	32	99.5	N	N	N	N	N	N	N	Y								
69175-08	35	118.4	N	N	N	N	N	N	N	N	N	N	Y					
69175-10	31	98.6	N	N	N	N	N	N	Y									
69177-05	33	103.7	N	N	N	N	N	N	N	N	Y							
MEAN	33.3	108.2																
S.D.	2.37	13.80																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

PND= POSTNATAL DAY

TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:04-023

GROUP: [redacted] 20 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-05	35	119.6	N	N	N	N	N	N	N	N	N	N	Y					
69166-03	31	98.3	N	N	N	N	N	N	Y									
69167-02	32	99.5	N	N	N	N	N	N	N	Y								
69167-08	35	113.5	N	N	N	N	N	N	N	N	N	N	Y					
69168-01	33	105.1	N	N	N	N	N	N	N	N	Y							
69169-02	34	125.7	N	N	N	N	N	N	N	N	N	Y						
69169-03	33	110.1	N	N	N	N	N	N	N	N	Y							
69169-10	30	101.5	N	N	N	N	N	Y										
69172-05	33	119.5	N	N	N	N	N	N	N	N	Y							
69172-09	31	106.7	N	N	N	N	N	N	Y									
69173-01	33	108.5	N	N	N	N	N	N	N	N	Y							
69173-04	33	103.2	N	N	N	N	N	N	N	N	Y							
69175-07	28	80.1	N	N	N	Y												
69176-05	36	128.1	N	N	N	N	N	N	N	N	N	N	N	Y				
69177-10	33	123.6	N	N	N	N	N	N	N	N	Y							
MEAN	32.7	109.5																
S.D.	2.06	12.67																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 19

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

GROUP: [redacted] 60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
69165-07	27	74.4	N	N	Y													
69166-10	29	84.8	N	N	N	N	Y											
69167-04	29	88.8	N	N	N	N	Y											
69167-05	27	75.3	N	N	Y													
69168-07	31	93.9	N	N	N	N	N	N	Y									
69169-05	27	81.8	N	N	Y													
69169-09	29	95.2	N	N	N	N	Y											
69170-01	27	86.7	N	N	Y													
69171-02	27	72.6	N	N	Y													
69172-01	28	81.9	N	N	N	Y												
69173-06	29	88.6	N	N	N	N	Y											
69174-02	33	104.4	N	N	N	N	N	N	N	N	Y							
69174-08	28	85.9	N	N	N	Y												
69174-09	33	119.9	N	N	N	N	N	N	N	N	Y							
69177-07	33	103.6	N	N	N	N	N	N	N	N	Y							
MEAN	29.1	89.2																
S.D.	2.29	12.74																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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01/22/2005
R:02/02/2005

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 1: CORN OIL

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-01	N N N N N N N N N N D D P E D D D	A
69166-06	N N N N N N N N N N E M D D D E M	5.0
69167-07	N N N N N N N N N D D D D E D D D	A
69175-02	N N N N N N N N N E D D D P E D D D E	5.0
69168-04	N N N N N N N N N N E D D D D E E	A
69169-01	N	A
69169-08	N N N N N N N N N M D D P E M D D E	A
69170-05	N N N N N N N N N E D D D D E D D D	5.0
69171-03	N N N N N N N N N E D D D E E D D D	5.0
69171-09	N N N N N N N N N N E D D D D E E D	6.0
69173-07	N N N N N D P E D D D D E E D D D E D	5.0
69174-01	N N N N N N N N E D D D D E D D D E D	4.5
69175-01	N N N N N N N E M D D D D D D D D E	A
69175-04	N N N N N N N N D D D E D D D E D D D	4.0
69176-09	N N N N E D D D D E D D D D E D D P E	5.0
	MEAN	4.9
	S.D.	0.53
	N	9

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 2: [redacted] 60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-06	N D D E E D D D P E D D D E D D D	4.5
69165-10	N D D D E D D D P E D D D E E D D	5.0
69166-07	N N N N N D D D P E D D D D E D D	5.0
69168-08	N N N N N D E M D D P E D D D P E	5.0
69168-10	N N N N N N N N N N D D E E D D D	A
69170-02	N N N N N N N N D E D D D D P E D D	6.0
69170-10	N N N N N D D P E M D D D P E D D D	6.0
69171-05	N N N D D D D D E D D D E E D D D E	5.0
69172-04	N N N N D D D P E D D D D D E E M D	7.0
69172-07	N N D D D P E E D D D D E D D D P E	5.0
69173-03	N N N N D P E D D D D D D E D D D D E	7.0
69174-05	N N N N N D D D D D P E E D D D D E D	5.0
69174-06	N N N N N D D D D E D D D D E D D D D	5.0
69176-08	N N D P E D D D P E D D D E E D D P E	5.0
69177-06	N N N N N N N N N D D D E D D D P E D	5.0
	MEAN	5.4
	S.D.	0.79
	N	14

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 3: [redacted] 250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-03	D D E E E D D D D E E D D D P E D	5.5
69166-05	D E E E D D D D D D E D D D D E D	6.0
69166-09	N E E E E E E E D D D E D D D E E	4.0
69167-01	N D E E D D D D E E D D D P E D D	5.5
69168-06	N E E E D D D D D E D D D D E E D	6.0
69169-07	N N E E D D D D E	A
69176-10	N N N D D D E D D D D E E D D D D D E	6.0
69171-04	N N E E E E E D D D D E E D D D D E	6.0
69171-08	N N D E E E E D D E M D D D D M D D	3.0
69172-02	N N E E E E E E E D D D D E D D D P	5.0
69173-10	N N D E E D D D D D E D D D D P E D D	6.0
69175-03	N N E D E E E E E E E D D D D P E E D	7.5
69175-05	N N E E E E E D D D D E E D D D D P E	6.0
69175-06	N N D D D E E E D D D D D E D D D D D	5.0
69176-04	N N D E E D D D D D E E D D D P E D D D	5.5
	MEAN	5.5
	S.D.	1.06
	N	14

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 4: [redacted] 1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-09	N N N N E E E E D D E E E E E E E	A
69167-03	N E D E D D E E E D D D D D D D E	3.5
69167-06	N N N D E E E E E E E D E D E E E	2.0
69167-09	N E E D D E E D E E E E E E E D D	6.0
69168-02	N N E E D E E M E D D E E D D D D	3.0
69169-06	N N N N N E E E E E E E E E E E E	A
69170-04	N E E E E E E D E E E E D E D D E E	3.5
69170-07	N N E E E E E E E E E E D E D E E E	2.0
69171-01	N E E E E E E E E E E D E E E E E E	A
69172-03	N N E E E E E E E E E E E D E E E E	A
69173-09	N E E E E E E D E E E E D E D D D D D	3.5
69176-07	N N E E E E D E E D E E E E E E E E E	3.0
69177-03	N N N N N N E D E E D E D E E E E E E	2.5
69177-08	N N N N N N N N N N D D E E D D E E D E	4.0
69177-09	N N N N E D E D E E E E E E E E E E E	2.0
	MEAN	3.2
	S.D.	1.17
	N	11

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 5: [redacted] 5

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-04	N N N N N N E M D D E E D D D E	5.0
69173-05	N N N N N N N N N M D D P E M D D P E	A
69166-08	N N N N N E D D D P E E D D D E E	6.0
69168-05	N N N N N N N N N E M D D D E D	5.0
69168-09	N N N N N N E D D D D P E D D D D	6.0
69169-04	N N N N N N N N N E D D D P E M D D	5.0
69170-06	N N N N N N N N N N N N N N E D D	A
69170-08	N N N N N N N N N D D P E D D D P E	A
69171-06	N N N N N N N N E D D D P E D D D E D	4.5
69171-10	N N N N N N N E M D D D E E D D D E	6.0
69174-03	N N N N N N N D D D D P E D D P P E D	5.0
69174-07	N N N N N N N N D P E D D D D E D D D	5.0
69175-08	N N N N N N N N N N N E D D D E E D D	5.0
69175-10	N N N N N N N D D D P E D D D E D D D	4.0
69177-05	N N N N N N N N N E M D D D P E D D D	6.0
	MEAN	5.2
	S.D.	0.66
	N	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 6: [redacted] 20

FEMALE NUMBER	DETERMINATION DAY: 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-05	N	N	N	N	N	N	N	N	D	P	E	D	D	D	E	E				A
69166-03	N	N	N	N	N	D	D	D	D	E	M	D	D	D	P	M	D			5.0
69167-02	N	N	N	N	N	N	E	D	D	D	P	E	D	D	D	E	D			4.5
69167-08	N	N	N	N	N	N	N	N	N	D	D	E	D	D	D	P	E			A
69168-01	N	N	N	N	N	N	N	E	D	D	D	D	P	E	D	D	D			6.0
69169-02	N	N	N	N	N	N	N	N	N	M	D	D	P	E	M	D	D	E		A
69169-03	N	N	N	N	N	N	N	N	D	D	D	P	E	D	D	D	E	E		A
69169-10	N	N	N	N	N	E	D	D	D	P	E	D	D	P	E	D	D	D		4.5
69172-05	N	N	N	N	N	N	N	N	E	D	D	D	D	D	D	D	D	D		A
69172-09	N	N	N	N	N	N	D	P	E	D	D	D	E	E	D	D	D	E		5.0
69173-01	N	N	N	N	N	N	N	N	N	E	M	D	D	D	P	E	D	D	D	6.0
69173-04	N	N	N	N	N	N	N	N	N	D	M	D	D	D	E	M	D	D	E	A
69175-07	N	N	N	N	D	D	D	D	P	E	D	D	D	D	D	D	D	D	D	A
69176-05	N	N	N	N	N	N	N	N	N	N	N	N	E	M	D	D	D	P	E	A
69177-10	N	N	N	N	N	N	N	N	N	D	D	D	P	E	M	D	D	P	E	A

MEAN	5.2
S.D.	0.68
N	6

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 20

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 7: [redacted] 60

FEMALE NUMBER	DETERMINATION DAY: 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69165-07	N	D	D	D	D	D	D	D	D	P	E	D	D	D	P	E	D			5.0
69166-10	N	N	N	D	D	D	E	D	D	D	D	P	E	D	D	D	E			6.0
69167-04	N	N	N	D	D	D	E	D	D	D	D	E	D	D	D	P	E			5.0
69167-05	N	D	D	D	D	D	E	D	D	D	D	E	D	D	D	P	E			5.0
69168-07	N	N	N	N	N	D	D	D	E	D	D	D	D	E	D	D	D			5.0
69169-05	N	N	D	D	D	E	D	D	D	D	D	E	M	D	D	P	E	D		5.5
69169-09	N	N	N	N	D	D	E	E	D	D	D	D	D	E	E	D	D	D		7.0
69170-01	N	N	D	D	D	D	D	P	E	D	D	D	P	E	D	D	D	P		5.0
69171-02	N	N	D	D	D	P	E	D	D	D	D	E	D	D	D	D	E	D		5.0
69172-01	N	N	N	D	D	E	E	D	D	D	D	E	D	D	D	P	E	D		5.0
69173-06	N	N	N	N	N	D	P	E	D	D	D	D	P	E	D	D	D	P	E	6.0
69174-02	N	N	N	N	N	N	N	N	N	D	D	P	E	E	M	D	D	D	E	A
69174-08	N	N	N	N	D	D	E	E	D	D	D	D	P	E	D	D	D	E	D	5.0
69174-09	N	N	N	N	N	N	N	N	N	D	D	D	D	E	E	D	D	D	P	A
69177-07	N	N	N	N	N	N	N	N	N	D	E	E	D	D	D	E	E	D		6.0

MEAN	5.4
S.D.	0.64
N	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

PCYCv5.22
01/22/2005
R:04/14/2005

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP:	CORN OIL	FEMALES
69165-01	4.70	12.3
69166-06	3.70	22.6
69167-07	3.70	11.0
69175-02	5.40	7.9
69168-04	6.40	9.2
69169-08	5.20	12.1
69170-05	3.20	8.9
69171-03	3.60	15.2
69171-09	2.70	8.2
69173-07	5.30	8.6
69174-01	4.10	8.6
69175-01	5.30	8.0
69175-04	5.80	12.4
69176-09	4.30	12.6
MEAN	4.53	11.3
S.D.	1.079	3.96
N	14	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42

SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted] 60	FEMALES	
69165-06	3.60	22.1
69165-10	5.60	12.3
69166-07	4.90	7.4
69168-08	5.50	26.1
69168-10	3.90	6.9
69170-02	4.90	16.4
69170-10	4.10	8.6
69171-05	4.70	15.7
69172-04	3.40	7.9
69172-07	4.50	9.0
69173-03	5.10	11.4
69174-05	5.00	7.6
69174-06	5.70	18.6
69176-08	5.00	24.4
69177-06	3.60	10.9
MEAN	4.63	13.7
S.D.	0.754	6.51
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42

SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted] 250	FEMALES	
69165-03	SU	SU
69166-05	6.00	8.2
69166-09	5.10	9.7
69167-01	5.10	10.5
69168-06	4.60	6.9
69176-10	6.40	16.4
69171-04	4.80	9.4
69171-08	4.00	12.7
69172-02	3.70	14.9
69173-10	4.00	5.7
69175-03	2.50	17.0
69175-05	4.70	12.0
69175-06	4.90	15.7
69176-04	4.90	7.4
MEAN	4.67	11.3
S.D.	0.992	3.83
N	13	13

SU = SAMPLE UNOBTAINABLE

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted] 1000	FEMALES	
69165-09	5.70	12.7
69167-03	4.90	30.5
69167-06	5.10	16.8
69167-09	5.60	13.9
69168-02	7.30	9.4
69169-06	3.40	10.4
69170-04	4.90	17.1
69170-07	4.70	7.4
69171-01	3.80	15.4
69172-03	4.80	10.9
69173-09	5.40	10.9
69176-07	5.50	12.4
69177-03	7.90	10.1
69177-08	7.10	12.7
69177-09	6.70	14.6
MEAN	5.52	13.7
S.D.	1.264	5.40
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted] 5	FEMALES	
69165-04	6.20	10.9
69173-05	6.60	6.7
69166-08	SU	SU
69168-05	3.80	9.7
69168-09	4.10	10.1
69169-04	4.20	12.2
69170-06	5.40	8.8
69170-08	3.90	10.0
69171-06	3.60	12.5
69171-10	5.20	11.1
69174-03	3.70	9.9
69174-07	4.40	13.4
69175-08	4.20	8.3
69175-10	4.70	9.0
69177-05	4.50	16.7
MEAN	4.61	10.7
S.D.	0.925	2.48
N	14	14

SU = SAMPLE UNOBTAINABLE

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42

SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted] 20	FEMALES	
69165-05	3.60	8.4
69166-03	5.30	10.1
69167-02	4.40	11.7
69167-08	6.10	12.3
69168-01	3.30	9.3
69169-02	5.50	14.8
69169-03	3.50	12.0
69169-10	3.30	15.8
69172-05	4.80	12.3
69172-09	4.90	19.8
69173-01	5.60	11.7
69173-04	4.60	14.0
69175-07	3.40	12.6
69176-05	5.70	11.4
69177-10	6.60	9.3
MEAN	4.71	12.4
S.D.	1.095	2.89
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 21

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-023

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted] 60	FEMALES	
69165-07	4.40	10.9
69166-10	6.50	14.1
69167-04	5.50	8.9
69167-05	4.70	12.7
69168-07	4.90	10.6
69169-05	6.20	8.0
69169-09	3.00	12.3
69170-01	3.80	29.2
69171-02	4.00	9.3
69172-01	3.60	13.2
69173-06	7.10	9.3
69174-02	3.90	15.8
69174-08	5.60	9.3
69174-09	4.30	12.0
69177-07	3.80	11.8
MEAN	4.75	12.5
S.D.	1.189	5.10
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

PCHEv4.03
01/27/2005
R:01/27/2005

TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:04-023

ANIMAL NO.69169-01 GROUP 1: CORN OIL FEMALE FOUND DEAD 11/20/04 DATE OF DEATH: 11/20/04

			GRADE
	LUNGS	GROSS: MASS 15 X 15 X 10 MM, TAN, INVOLVES RIGHT APICAL, RIGHT INTERMEDIATE AND RIGHT DIAPHRAGMATIC LOBES, PERICARDIUM AND HEART, SOFT, MASS #1	P
	LUNGS	GROSS: ADHESIONS RIGHT DIAPHRAGMATIC AND LEFT LOBES ATTACHED TO DIAPHRAGM; LEFT LOBE ATTACHED TO PERICARDIUM	P
	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
		JUVENILE OVARY BILATERAL	P
	THYROID GLANDS	MICRO: DECREASED COLLOID BILATERAL	4
	UTERUS	MICRO: JUVENILE UTERUS BILATERAL	P
	CERVIX	MICRO: JUVENILE CERVIX	P
	CAUSE OF DEATH	MICRO: UNDETERMINED PARTIAL TISSUES EXAMINED, NO ATTEMPT MADE TO DETERMINE CAUSE OF DEATH	P

NO SIGNIFICANT CHANGES OBSERVED GROSS:

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS

ANIMAL NO.69169-01 GROUP 1: CORN OIL FEMALE FOUND DEAD 11/20/04 DATE OF DEATH: 11/20/04

	GRADE
CERVIX	
VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69169-07 GROUP 3: [redacted] 250 FEMALE FOUND DEAD 11/28/04 DATE OF DEATH: 11/28/04

			GRADE
LUNGS	GROSS:	AREA(S), DARK RED MULTIPLE, IRREGULARLY SHAPED, ALL LOBES	P
LUNGS	GROSS:	NOT FULLY COLLAPSED ALL LOBES	P
OVARIES	MICRO:	DECREASED CORPORA LUTEA BILATERAL	P
THYROID GLANDS	MICRO:	HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
UTERUS	MICRO:	HYPOPLASIA BILATERAL	1
CAUSE OF DEATH	MICRO:	UNDETERMINED PARTIAL TISSUES EXAMINED, NO ATTEMPT MADE TO DETERMINE CAUSE OF DEATH	P

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES, HEART, INTESTINE, KIDNEYS, LIVER, LYMPH NODE, MES, MAMMARY GLAND, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN, STOMACH, THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER, UTERUS, CERVIX, VAGINA

MICRO: CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.52
02/17/2005

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-01	152.	0.3895	0.3700	0.0195	7.4870	1.4155	0.0390	0.0837	0.0079	0.0228
69166-06	150.	0.2066	0.1824	0.0242	7.1012	1.4363	0.0302	0.0700	0.0019	0.0223
69167-07	159.	0.4360	0.3624	0.0736	8.2883	1.7530	0.0386	0.0998	0.0099	0.0193
69175-02	143.	0.6132	0.3787	0.2345	6.1914	1.5686	0.0358	0.0900	0.0103	0.0143
69168-04	132.	0.2656	0.2442	0.0214	6.0711	1.2169	0.0335	0.0795	0.0083	0.0237
69169-08	159.	0.3190	0.2979	0.0211	7.5316	1.6280	0.0489	0.0961	0.0100	0.0148
69170-05	164.	0.3456	0.3155	0.0301	8.2778	1.4804	0.0409	0.0866	0.0065	0.0200
69171-03	167.	0.6437	0.4360	0.2077	7.6301	1.5728	0.0395	0.0784	0.0094	0.0150
69171-09	159.	0.2532	0.2280	0.0252	7.7890	1.8465	0.0443	0.0848	0.0082	0.0175
69173-07	133.	0.2350	0.2127	0.0223	6.6479	1.4531	0.0362	0.0856	0.0085	0.0138
69174-01	141.	0.2621	0.2326	0.0295	5.5168	1.4322	0.0417	0.0894	0.0092	0.0170
69175-01	161.	0.3312	0.3145	0.0167	8.4218	1.7635	0.0416	0.0851	0.0096	0.0152
69175-04	165.	0.6320	0.4164	0.2156	7.4265	1.6430	0.0386	0.0924	0.0103	0.0157
69176-09	159.	0.7080	0.3562	0.3518	8.1483	1.7753	0.0448	0.0825	0.0121	0.0160
MEAN	153.	0.4029	0.3105	0.0924	7.3235	1.5704	0.0395	0.0860	0.0087	0.0177
S.D.	11.6	0.17372	0.08009	0.11073	0.90891	0.17658	0.00480	0.00753	0.00238	0.00336
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-06	155.	0.5545	0.4047	0.1498	7.2558	1.5538	0.0505	0.0875	0.0085	0.0175
69165-10	161.	0.2921	0.2720	0.0201	8.2631	1.7912	0.0382	0.1015	0.0103	0.0233
69166-07	120.	0.2612	0.2460	0.0152	4.4918	1.2229	0.0396	0.0726	0.0053	0.0203
69168-08	149.	0.3604	0.3337	0.0267	7.9547	1.4089	0.0404	0.0857	0.0097	0.0195
69168-10	151.	0.2797	0.2550	0.0247	8.5396	1.6664	0.0394	0.0832	0.0081	0.0197
69170-02	172.	0.2671	0.2519	0.0152	9.6732	1.6278	0.0335	0.0973	0.0097	0.0180
69170-10	158.	0.4187	0.3857	0.0330	7.2212	1.7300	0.0335	0.0791	0.0085	0.0116
69171-05	146.	0.8675	0.4855	0.3820	8.5854	1.6627	0.0423	0.1059	0.0092	0.0204
69172-04	166.	0.2919	0.2628	0.0291	10.6406	1.5765	0.0376	0.0771	0.0079	0.0150
69172-07	145.	0.3304	0.3166	0.0138	6.5640	1.5891	0.0501	0.1100	0.0096	0.0230
69173-03	150.	0.3790	0.3637	0.0153	7.9434	1.5189	0.0422	0.0752	0.0092	0.0158
69174-05	162.	0.2267	0.2055	0.0212	7.1044	1.5901	0.0328	0.0784	0.0089	0.0159
69174-06	152.	0.8752	0.4075	0.4677	7.9796	1.6880	0.0453	0.0938	0.0098	0.0180
69176-08	151.	0.3737	0.3570	0.0167	6.9034	1.3223	0.0455	0.0972	0.0084	0.0141
69177-06	148.	0.2455	0.1869	0.0586	6.9512	1.4992	0.0335	0.0769	0.0073	0.0212
MEAN	152.	0.4016	0.3156	0.0859	7.7381	1.5632	0.0403	0.0881	0.0087	0.0182
S.D.	11.8	0.20783	0.08471	0.14269	1.41640	0.15247	0.00578	0.01205	0.00125	0.00331
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-023 INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted] 250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-03	139.	0.2131	0.1948	0.0183	7.5869	1.3675	0.0396	0.0849	0.0080	0.0173
69166-05	147.	0.2650	0.2281	0.0369	6.6070	1.4075	0.0487	0.0871	0.0088	0.0262
69166-09	150.	0.2568	0.2418	0.0150	7.9473	1.6147	0.0560	0.0852	0.0095	0.0209
69167-01	145.	0.2218	0.2107	0.0111	6.1286	1.5258	0.0428	0.0791	0.0095	0.0135
69168-06	135.	0.2226	0.2019	0.0207	6.9866	1.3961	0.0366	0.0720	0.0080	0.0203
69176-10	144.	0.3237	0.3039	0.0198	6.8994	1.4063	0.0421	0.0769	0.0097	0.0144
69171-04	142.	0.2572	0.2359	0.0213	6.5762	1.4081	0.0436	0.0804	0.0070	0.0253
69171-08	168.	0.3203	0.2970	0.0233	8.7845	1.6822	0.0534	0.0781	0.0085	0.0344
69172-02	157.	0.4759	0.3286	0.1473	7.9549	1.5906	0.0440	0.0695	0.0099	0.0293
69173-10	147.	0.2517	0.2416	0.0101	7.4452	1.4004	0.0306	0.0811	0.0083	0.0157
69175-03	146.	0.2824	0.2543	0.0281	8.0237	1.5827	0.0453	0.0589	0.0094	0.0119
69175-05	137.	0.3045	0.2825	0.0220	6.4824	1.4613	0.0465	0.0985	0.0098	0.0088
69175-06	154.	0.3163	0.2990	0.0173	7.8506	1.4950	0.0425	0.0750	0.0104	0.0130
69176-04	154.	0.3766	0.3164	0.0602	6.8237	1.6219	0.0456	0.0778	0.0096	0.0180
MEAN	148.	0.2920	0.2598	0.0322	7.2926	1.4971	0.0441	0.0789	0.0090	0.0192
S.D.	8.7	0.07038	0.04435	0.03541	0.76014	0.10466	0.00636	0.00916	0.00095	0.00732
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-09	145.	0.2531	0.2329	0.0202	9.2203	1.4499	0.0469	0.0423	0.0076	0.0231
69167-03	157.	0.2433	0.2349	0.0084	9.5684	1.6525	0.0459	0.0896	0.0102	0.0200
69167-06	135.	0.1870	0.1635	0.0235	7.7636	1.3709	0.0393	0.0482	0.0069	0.0275
69167-09	147.	0.1747	0.1532	0.0215	8.3931	1.4481	0.0404	0.0501	0.0080	0.0183
69168-02	127.	0.2318	0.2098	0.0220	7.1266	1.3844	0.0472	0.0519	0.0071	0.0295
69169-06	162.	0.2344	0.2198	0.0146	10.0363	1.6491	0.0462	0.0622	0.0103	0.0345
69170-04	159.	0.2200	0.2052	0.0148	8.8305	1.5337	0.0416	0.0523	0.0085	0.0313
69170-07	152.	0.2341	0.2167	0.0174	7.9295	1.4158	0.0425	0.0387	0.0061	0.0189
69171-01	142.	0.2296	0.2002	0.0294	8.3322	1.3521	0.0307	0.0458	0.0067	0.0268
69172-03	161.	0.2285	0.2142	0.0143	10.1812	1.5438	0.0450	0.0481	0.0073	0.0384
69173-09	131.	0.2585	0.2414	0.0171	7.2087	1.4007	0.0481	0.0644	0.0081	0.0171
69176-07	153.	0.2651	0.2432	0.0219	7.8174	1.5936	0.0488	0.0473	0.0089	0.0150
69177-03	147.	0.2592	0.2447	0.0145	8.4421	1.3540	0.0498	0.0424	0.0066	0.0175
69177-08	155.	0.2252	0.2121	0.0131	8.3897	1.5450	0.0435	0.0522	0.0066	0.0179
69177-09	156.	0.2533	0.2382	0.0151	7.6536	1.4831	0.0557	0.0466	0.0083	0.0159
MEAN	149.	0.2332	0.2153	0.0179	8.4595	1.4784	0.0448	0.0521	0.0078	0.0234
S.D.	10.9	0.02545	0.02735	0.00522	0.94833	0.10282	0.00567	0.01241	0.00127	0.00740
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 5

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-04	146.	0.7656	0.4117	0.3539	7.8294	1.4589	0.0419	0.0691	0.0086	0.0194
69173-05	147.	0.3501	0.3318	0.0183	7.2003	1.5716	0.0400	0.0913	0.0104	0.0161
69166-08	129.	0.3682	0.3452	0.0230	6.1598	1.3746	0.0417	0.0732	0.0089	0.0211
69168-05	141.	0.2099	0.1971	0.0128	6.2321	1.2801	0.0351	0.0753	0.0068	0.0269
69168-09	145.	0.6149	0.4141	0.2008	7.3706	1.5024	0.0471	0.0945	0.0086	0.0215
69169-04	158.	0.3553	0.3207	0.0346	6.8416	1.4529	0.0326	0.0755	0.0084	0.0174
69170-06	159.	0.2056	0.1871	0.0185	7.8858	1.5050	0.0391	0.0607	0.0089	0.0266
69170-08	143.	0.3855	0.3521	0.0334	6.8817	1.5552	0.0409	0.0933	0.0101	0.0240
69171-06	150.	0.3034	0.2731	0.0303	7.1152	1.6028	0.0358	0.1090	0.0091	0.0226
69171-10	171.	0.4060	0.3658	0.0402	8.3689	1.7551	0.0482	0.1090	0.0071	0.0319
69174-03	158.	0.2615	0.2442	0.0173	7.2004	1.6078	0.0354	0.1031	0.0085	0.0171
69174-07	142.	0.4013	0.3577	0.0436	6.6139	1.6036	0.0390	0.0709	0.0073	0.0140
69175-08	152.	0.2627	0.2428	0.0199	7.1365	1.5910	0.0350	0.0658	0.0081	0.0152
69175-10	142.	0.4843	0.3645	0.1198	6.9300	1.3447	0.0404	0.0961	0.0084	0.0153
69177-05	159.	0.3842	0.3201	0.0641	7.7520	1.5521	0.0402	0.1061	0.0087	0.0181
MEAN	149.	0.3839	0.3152	0.0687	7.1679	1.5172	0.0395	0.0862	0.0085	0.0205
S.D.	10.3	0.14889	0.07116	0.09337	0.61105	0.12097	0.00436	0.01682	0.00098	0.00515
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 20

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-05	143.	0.3482	0.3315	0.0167	6.9479	1.6112	0.0427	0.0875	0.0085	0.0265
69166-03	145.	0.2317	0.2147	0.0170	6.4633	1.3572	0.0402	0.0738	0.0077	0.0246
69167-02	154.	0.2406	0.2276	0.0130	8.2010	1.6628	0.0392	0.1190	0.0096	0.0182
69167-08	134.	0.2873	0.2717	0.0156	5.9353	1.4725	0.0437	0.0882	0.0099	0.0208
69168-01	146.	0.3251	0.2973	0.0278	6.7894	1.3718	0.0392	0.0810	0.0079	0.0212
69169-02	155.	0.4372	0.3915	0.0457	7.3015	1.5280	0.0556	0.1047	0.0099	0.0190
69169-03	148.	0.3575	0.3345	0.0230	8.5928	1.5148	0.0398	0.0831	0.0094	0.0279
69169-10	170.	0.5204	0.4142	0.1062	7.7981	1.7411	0.0460	0.0804	0.0088	0.0228
69172-05	168.	0.3119	0.2816	0.0303	8.7270	1.9012	0.0525	0.0835	0.0101	0.0259
69172-09	168.	0.3490	0.3292	0.0198	8.5014	1.7215	0.0455	0.0919	0.0113	0.0225
69173-01	163.	0.3766	0.3422	0.0344	7.5091	1.6773	0.0418	0.0787	0.0085	0.0182
69173-04	141.	0.2899	0.2756	0.0143	6.0783	1.4463	0.0346	0.0811	0.0075	0.0171
69175-07	163.	0.2289	0.2190	0.0099	8.2213	1.7296	0.0376	0.0815	0.0105	0.0163
69176-05	153.	0.3145	0.2959	0.0186	6.9231	1.5364	0.0439	0.1019	0.0099	0.0102
69177-10	166.	0.3454	0.3242	0.0212	8.1176	1.6320	0.0485	0.1105	0.0112	0.0155
MEAN	154.	0.3309	0.3034	0.0276	7.4738	1.5936	0.0434	0.0898	0.0094	0.0204
S.D.	11.4	0.07722	0.05824	0.02367	0.92198	0.15119	0.00562	0.01319	0.00120	0.00478
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/OVIDUCTS	PITUITARY	THYROID GLANDS
69165-07	147.	0.2465	0.2290	0.0175	7.6951	1.6575	0.0438	0.1020	0.0108	0.0222
69166-10	149.	0.7805	0.3637	0.4168	6.9118	1.4273	0.0447	0.0594	0.0075	0.0207
69167-04	144.	0.3027	0.2772	0.0255	6.8563	1.3636	0.0385	0.0630	0.0088	0.0191
69167-05	144.	0.2304	0.2132	0.0172	7.1816	1.4109	0.0417	0.0681	0.0087	0.0172
69168-07	150.	0.3211	0.2522	0.0689	6.6717	1.4928	0.0359	0.0659	0.0073	0.0264
69169-05	160.	0.2389	0.2128	0.0261	6.9984	1.4977	0.0442	0.1043	0.0093	0.0262
69169-09	168.	0.3388	0.3107	0.0281	8.1816	1.6586	0.0526	0.0909	0.0093	0.0136
69170-01	167.	0.6108	0.3961	0.2147	7.3211	1.6858	0.0469	0.0692	0.0096	0.0154
69171-02	146.	0.2421	0.2258	0.0163	7.7838	1.5999	0.0371	0.0804	0.0088	0.0245
69172-01	151.	0.2546	0.2381	0.0165	7.5621	1.5364	0.0436	0.0946	0.0087	0.0226
69173-06	150.	A	A	A	7.3737	1.5293	0.0495	0.0999	0.0110	0.0166
69174-02	145.	0.8030	0.3874	0.4156	7.2939	1.6210	0.0382	0.0735	0.0086	0.0152
69174-08	158.	0.3482	0.3319	0.0163	7.5879	1.5432	0.0427	0.0857	0.0102	0.0164
69174-09	167.	0.5755	0.4005	0.1750	8.4343	1.7941	0.0516	0.1111	0.0102	0.0167
69177-07	146.	0.2444	0.2293	0.0151	6.9199	1.3537	0.0371	0.0659	0.0083	0.0173
MEAN	153.	0.3955	0.2906	0.1050	7.3849	1.5448	0.0432	0.0823	0.0091	0.0193
S.D.	8.8	0.20622	0.07245	0.14608	0.49966	0.12617	0.00530	0.01719	0.00108	0.00416
N	15	14	14	14	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT
A = BLOTTED UTERUS WEIGHT GREATER THAN WET WEIGHT, NOT INCLUDED IN CALCULATION OF MEAN; LUMINAL FLUID WEIGHT CALCULATION NOT POSSIBLE

POFBWv4.14
01/27/2005
R:02/16/2005

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-01	152.	0.256	0.243	4.926	0.931	0.026	0.055	0.005	0.015
69166-06	150.	0.138	0.122	4.734	0.958	0.020	0.047	0.001	0.015
69167-07	159.	0.274	0.228	5.213	1.103	0.024	0.063	0.006	0.012
69175-02	143.	0.429	0.265	4.330	1.097	0.025	0.063	0.007	0.010
69168-04	132.	0.201	0.185	4.599	0.922	0.025	0.060	0.006	0.018
69169-08	159.	0.201	0.187	4.737	1.024	0.031	0.060	0.006	0.009
69170-05	164.	0.211	0.192	5.047	0.903	0.025	0.053	0.004	0.012
69171-03	167.	0.385	0.261	4.569	0.942	0.024	0.047	0.006	0.009
69171-09	159.	0.159	0.143	4.899	1.161	0.028	0.053	0.005	0.011
69173-07	133.	0.177	0.160	4.998	1.093	0.027	0.064	0.006	0.010
69174-01	141.	0.186	0.165	3.913	1.016	0.030	0.063	0.007	0.012
69175-01	161.	0.206	0.195	5.231	1.095	0.026	0.053	0.006	0.009
69175-04	165.	0.383	0.252	4.501	0.996	0.023	0.056	0.006	0.010
69176-09	159.	0.445	0.224	5.125	1.117	0.028	0.052	0.008	0.010
MEAN	153.	0.261	0.202	4.773	1.026	0.026	0.056	0.006	0.012
S.D.	11.6	0.1051	0.0451	0.3697	0.0852	0.0029	0.0059	0.0016	0.0027
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-06	155.	0.358	0.261	4.681	1.002	0.033	0.056	0.005	0.011
69165-10	161.	0.181	0.169	5.132	1.113	0.024	0.063	0.006	0.014
69166-07	120.	0.218	0.205	3.743	1.019	0.033	0.061	0.004	0.017
69168-08	149.	0.242	0.224	5.339	0.946	0.027	0.058	0.007	0.013
69168-10	151.	0.185	0.169	5.655	1.104	0.026	0.055	0.005	0.013
69170-02	172.	0.155	0.146	5.624	0.946	0.019	0.057	0.006	0.010
69170-10	158.	0.265	0.244	4.570	1.095	0.021	0.050	0.005	0.007
69171-05	146.	0.594	0.333	5.880	1.139	0.029	0.073	0.006	0.014
69172-04	166.	0.176	0.158	6.410	0.950	0.023	0.046	0.005	0.009
69172-07	145.	0.228	0.218	4.527	1.096	0.035	0.076	0.007	0.016
69173-03	150.	0.253	0.242	5.296	1.013	0.028	0.050	0.006	0.011
69174-05	162.	0.140	0.127	4.385	0.982	0.020	0.048	0.005	0.010
69174-06	152.	0.576	0.268	5.250	1.111	0.030	0.062	0.006	0.012
69176-08	151.	0.247	0.236	4.572	0.876	0.030	0.064	0.006	0.009
69177-06	148.	0.166	0.126	4.697	1.013	0.023	0.052	0.005	0.014
MEAN	152.	0.266	0.208	5.051	1.027	0.027	0.058	0.006	0.012
S.D.	11.8	0.1407	0.0587	0.6850	0.0790	0.0050	0.0087	0.0008	0.0028
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted] 250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS- BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-03	139.	0.153	0.140	5.458	0.984	0.028	0.061	0.006	0.012
69166-05	147.	0.180	0.155	4.495	0.957	0.033	0.059	0.006	0.018
69166-09	150.	0.171	0.161	5.298	1.076	0.037	0.057	0.006	0.014
69167-01	145.	0.153	0.145	4.227	1.052	0.030	0.055	0.007	0.009
69168-06	135.	0.165	0.150	5.175	1.034	0.027	0.053	0.006	0.015
69176-10	144.	0.225	0.211	4.791	0.977	0.029	0.053	0.007	0.010
69171-04	142.	0.181	0.166	4.631	0.992	0.031	0.057	0.005	0.018
69171-08	168.	0.191	0.177	5.229	1.001	0.032	0.046	0.005	0.020
69172-02	157.	0.303	0.209	5.067	1.013	0.028	0.044	0.006	0.019
69173-10	147.	0.171	0.164	5.065	0.953	0.021	0.055	0.006	0.011
69175-03	146.	0.193	0.174	5.496	1.084	0.031	0.040	0.006	0.008
69175-05	137.	0.222	0.206	4.732	1.067	0.034	0.072	0.007	0.006
69175-06	154.	0.205	0.194	5.098	0.971	0.028	0.049	0.007	0.008
69176-04	154.	0.245	0.205	4.431	1.053	0.030	0.051	0.006	0.012
MEAN	148.	0.197	0.176	4.942	1.015	0.030	0.054	0.006	0.013
S.D.	8.7	0.0410	0.0252	0.3949	0.0453	0.0038	0.0079	0.0007	0.0046
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:04-023

FEMALE GROUP: [redacted] 1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-09	145.	0.175	0.161	6.359	1.000	0.032	0.029	0.005	0.016
69167-03	157.	0.155	0.150	6.095	1.053	0.029	0.057	0.006	0.013
69167-06	135.	0.139	0.121	5.751	1.015	0.029	0.036	0.005	0.020
69167-09	147.	0.119	0.104	5.710	0.985	0.027	0.034	0.005	0.012
69168-02	127.	0.183	0.165	5.611	1.090	0.037	0.041	0.006	0.023
69169-06	162.	0.145	0.136	6.195	1.018	0.029	0.038	0.006	0.021
69170-04	159.	0.138	0.129	5.554	0.965	0.026	0.033	0.005	0.020
69170-07	152.	0.154	0.143	5.217	0.931	0.028	0.025	0.004	0.012
69171-01	142.	0.162	0.141	5.868	0.952	0.022	0.032	0.005	0.019
69172-03	161.	0.142	0.133	6.324	0.959	0.028	0.030	0.005	0.024
69173-09	131.	0.197	0.184	5.503	1.069	0.037	0.049	0.006	0.013
69176-07	153.	0.173	0.159	5.109	1.042	0.032	0.031	0.006	0.010
69177-03	147.	0.176	0.166	5.743	0.921	0.034	0.029	0.004	0.012
69177-08	155.	0.145	0.137	5.413	0.997	0.028	0.034	0.004	0.012
69177-09	156.	0.162	0.153	4.906	0.951	0.036	0.030	0.005	0.010
MEAN	149.	0.158	0.145	5.691	0.997	0.030	0.035	0.005	0.016
S.D.	10.9	0.0206	0.0202	0.4326	0.0512	0.0043	0.0084	0.0007	0.0049
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted] 5

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-04	146.	0.524	0.282	5.363	0.999	0.029	0.047	0.006	0.013
69173-05	147.	0.238	0.226	4.898	1.069	0.027	0.062	0.007	0.011
69166-08	129.	0.285	0.268	4.775	1.066	0.032	0.057	0.007	0.016
69168-05	141.	0.149	0.140	4.420	0.908	0.025	0.053	0.005	0.019
69168-09	145.	0.424	0.286	5.083	1.036	0.032	0.065	0.006	0.015
69169-04	158.	0.225	0.203	4.330	0.920	0.021	0.048	0.005	0.011
69170-06	159.	0.129	0.118	4.960	0.947	0.025	0.038	0.006	0.017
69170-08	143.	0.270	0.246	4.812	1.088	0.029	0.065	0.007	0.017
69171-06	150.	0.202	0.182	4.743	1.069	0.024	0.073	0.006	0.015
69171-10	171.	0.237	0.214	4.894	1.026	0.028	0.064	0.004	0.019
69174-03	158.	0.166	0.155	4.557	1.018	0.022	0.065	0.005	0.011
69174-07	142.	0.283	0.252	4.658	1.129	0.027	0.050	0.005	0.010
69175-08	152.	0.173	0.160	4.695	1.047	0.023	0.043	0.005	0.010
69175-10	142.	0.341	0.257	4.880	0.947	0.028	0.068	0.006	0.011
69177-05	159.	0.242	0.201	4.875	0.976	0.025	0.067	0.005	0.011
MEAN	149.	0.259	0.213	4.796	1.016	0.026	0.058	0.006	0.014
S.D.	10.3	0.1056	0.0532	0.2553	0.0654	0.0033	0.0105	0.0009	0.0033
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted] 20

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-05	143.	0.243	0.232	4.859	1.127	0.030	0.061	0.006	0.019
69166-03	145.	0.160	0.148	4.457	0.936	0.028	0.051	0.005	0.017
69167-02	154.	0.156	0.148	5.325	1.080	0.025	0.077	0.006	0.012
69167-08	134.	0.214	0.203	4.429	1.099	0.033	0.066	0.007	0.016
69168-01	146.	0.223	0.204	4.650	0.940	0.027	0.055	0.005	0.015
69169-02	155.	0.282	0.253	4.711	0.986	0.036	0.068	0.006	0.012
69169-03	148.	0.242	0.226	5.806	1.024	0.027	0.056	0.006	0.019
69169-10	170.	0.306	0.244	4.587	1.024	0.027	0.047	0.005	0.013
69172-05	168.	0.186	0.168	5.195	1.132	0.031	0.050	0.006	0.015
69172-09	168.	0.208	0.196	5.060	1.025	0.027	0.055	0.007	0.013
69173-01	163.	0.231	0.210	4.607	1.029	0.026	0.048	0.005	0.011
69173-04	141.	0.206	0.195	4.311	1.026	0.025	0.058	0.005	0.012
69175-07	163.	0.140	0.134	5.044	1.061	0.023	0.050	0.006	0.010
69176-05	153.	0.206	0.193	4.525	1.004	0.029	0.067	0.006	0.007
69177-10	166.	0.208	0.195	4.890	0.983	0.029	0.067	0.007	0.009
MEAN	154.	0.214	0.197	4.830	1.032	0.028	0.058	0.006	0.013
S.D.	11.4	0.0446	0.0352	0.4010	0.0597	0.0033	0.0089	0.0007	0.0035
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 24

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:04-023 INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted] 60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	ADRENAL GLANDS	OVARIES/ OVIDUCTS	PITUITARY	THYROID GLANDS
69165-07	147.	0.168	0.156	5.235	1.128	0.030	0.069	0.007	0.015
69166-10	149.	0.524	0.244	4.639	0.958	0.030	0.040	0.005	0.014
69167-04	144.	0.210	0.193	4.761	0.947	0.027	0.044	0.006	0.013
69167-05	144.	0.160	0.148	4.987	0.980	0.029	0.047	0.006	0.012
69168-07	150.	0.214	0.168	4.448	0.995	0.024	0.044	0.005	0.018
69169-05	160.	0.149	0.133	4.374	0.936	0.028	0.065	0.006	0.016
69169-09	168.	0.202	0.185	4.870	0.987	0.031	0.054	0.006	0.008
69170-01	167.	0.366	0.237	4.384	1.009	0.028	0.041	0.006	0.009
69171-02	146.	0.166	0.155	5.331	1.096	0.025	0.055	0.006	0.017
69172-01	151.	0.169	0.158	5.008	1.017	0.029	0.063	0.006	0.015
69173-06	150.	0.150	0.189	4.916	1.020	0.033	0.067	0.007	0.011
69174-02	145.	0.554	0.267	5.030	1.118	0.026	0.051	0.006	0.010
69174-08	158.	0.220	0.210	4.802	0.977	0.027	0.054	0.006	0.010
69174-09	167.	0.345	0.240	5.050	1.074	0.031	0.067	0.006	0.010
69177-07	146.	0.167	0.157	4.740	0.927	0.025	0.045	0.006	0.012
MEAN	153.	0.251	0.189	4.838	1.011	0.028	0.054	0.006	0.013
S.D.	8.8	0.1341	0.0414	0.2892	0.0649	0.0026	0.0102	0.0005	0.0031
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

POFBWv4.14
01/27/2005
R:02/16/2005

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69165-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3895	0.256	
UTERUS- BLOTTED	0.3700	0.243	
LIVER	7.4870	4.926	
KIDNEYS	1.4155	0.931	
ADRENAL GLANDS	0.0390	0.026	
OVARIES/OVIDUCTS	0.0837	0.055	
PITUITARY	0.0079	0.005	
THYROID GLANDS	0.0228	0.015	
FINAL BODY WT(G)	152.		

OVARIES

NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE OVARY NOT EXAMINED, NOT FOUND AT TIME OF TRIMMING

MICRO:OVARIES THYROID GLANDS UTERUS CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69166-06 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	GENERAL COMMENT	GROSS: ORGAN DAMAGED AT NECROPSY	GRADE
UTERUS- WET	0.2066	0.138		PITUITARY	P
UTERUS- BLOTTED	0.1824	0.122	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	7.1012	4.734		MICRO:OVARIES THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.4363	0.958			
ADRENAL GLANDS	0.0302	0.020			
OVARIES/OVIDUCTS	0.0700	0.047			
PITUITARY	0.0019	0.001			
THYROID GLANDS	0.0223	0.015			
FINAL BODY WT(G)	150.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69167-07 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	UTERUS	MICRO: HEMORRHAGE	GRADE
UTERUS- WET	0.4360	0.274		BILATERAL	1
UTERUS- BLOTTED	0.3624	0.228	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	8.2883	5.213		MICRO:OVARIES THYROID GLANDS CERVIX	
KIDNEYS	1.7530	1.103			
ADRENAL GLANDS	0.0386	0.024			
OVARIES/OVIDUCTS	0.0998	0.063			
PITUITARY	0.0099	0.006			
THYROID GLANDS	0.0193	0.012			
FINAL BODY WT(G)	159.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-02 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6132	0.429
UTERUS- BLOTTED	0.3787	0.265
LIVER	6.1914	4.330
KIDNEYS	1.5686	1.097
ADRENAL GLANDS	0.0358	0.025
OVARIES/OVIDUCTS	0.0900	0.063
PITUITARY	0.0103	0.007
THYROID GLANDS	0.0143	0.010
FINAL BODY WT(G)	143.	

NO SIGNIFICANT CHANGES OBSERVED

MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX	GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69168-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2656	0.201	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
UTERUS- BLOTTED	0.2442	0.185	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	6.0711	4.599		MICRO:OVARIES THYROID GLANDS CERVIX	
KIDNEYS	1.2169	0.922			
ADRENAL GLANDS	0.0335	0.025			
OVARIES/OVIDUCTS	0.0795	0.060			
PITUITARY	0.0083	0.006			
THYROID GLANDS	0.0237	0.018			
FINAL BODY WT(G)	132.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69169-08 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3190	0.201	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2979	0.187		
LIVER	7.5316	4.737		
KIDNEYS	1.6280	1.024		
ADRENAL GLANDS	0.0489	0.031		
OVARIES/OVIDUCTS	0.0961	0.060		
PITUITARY	0.0100	0.006		
THYROID GLANDS	0.0148	0.009		
FINAL BODY WT(G)	159.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69170-05 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3456	0.211	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3155	0.192		
LIVER	8.2778	5.047		
KIDNEYS	1.4804	0.903		
ADRENAL GLANDS	0.0409	0.025		
OVARIES/OVIDUCTS	0.0866	0.053		
PITUITARY	0.0065	0.004		
THYROID GLANDS	0.0200	0.012		
FINAL BODY WT(G)	164.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-03 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.6437	0.385	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.4360	0.261		
LIVER	7.6301	4.569		
KIDNEYS	1.5728	0.942		
ADRENAL GLANDS	0.0395	0.024		
OVARIES/OVIDUCTS	0.0784	0.047		
PITUITARY	0.0094	0.006		
THYROID GLANDS	0.0150	0.009		
FINAL BODY WT(G)	167.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-09 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2532	0.159	OVARIES	MICRO: CYST, CORPORA LUTEA	
UTERUS- BLOTTED	0.2280	0.143		UNILATERAL	P
			NO SIGNIFICANT CHANGES OBSERVED		
LIVER	7.7890	4.899		MICRO:THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.8465	1.161			
ADRENAL GLANDS	0.0443	0.028			
OVARIES/OVIDUCTS	0.0848	0.053			
PITUITARY	0.0082	0.005			
THYROID GLANDS	0.0175	0.011			
FINAL BODY WT(G)	159.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-07 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2350	0.177	OVARIES	MICRO: CYST, CORPORA LUTEA UNILATERAL	P
UTERUS- BLOTTED	0.2127	0.160	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	6.6479	4.998			
KIDNEYS	1.4531	1.093	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0362	0.027		MICRO:UTERUS CERVIX	
OVARIES/OVIDUCTS	0.0856	0.064			
PITUITARY	0.0085	0.006			
THYROID GLANDS	0.0138	0.010			
FINAL BODY WT(G)	133.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69174-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2621	0.186	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2326	0.165		
LIVER	5.5168	3.913		
KIDNEYS	1.4322	1.016		
ADRENAL GLANDS	0.0417	0.030		
OVARIES/OVIDUCTS	0.0894	0.063		
PITUITARY	0.0092	0.007		
THYROID GLANDS	0.0170	0.012		
FINAL BODY WT(G)	141.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69175-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3312	0.206
UTERUS- BLOTTED	0.3145	0.195
LIVER	8.4218	5.231
KIDNEYS	1.7635	1.095
ADRENAL GLANDS	0.0416	0.026
OVARIES/OVIDUCTS	0.0851	0.053
PITUITARY	0.0096	0.006
THYROID GLANDS	0.0152	0.009
FINAL BODY WT(G)	161.	

	GRADE
UTERUS	
MICRO: HYPOPLASIA BILATERAL	1
NO SIGNIFICANT CHANGES OBSERVED	
MICRO:OVARIES	
THYROID GLANDS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69175-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6320	0.383
UTERUS- BLOTTED	0.4164	0.252
LIVER	7.4265	4.501
KIDNEYS	1.6430	0.996
ADRENAL GLANDS	0.0386	0.023
OVARIES/OVIDUCTS	0.0924	0.056
PITUITARY	0.0103	0.006
THYROID GLANDS	0.0157	0.010
FINAL BODY WT(G)	165.	

OVARIES — NO SIGNIFICANT CHANGES OBSERVED

		GRADE
MICRO: DECREASED CORPORA LUTEA BILATERAL		P
MICRO:THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69176-09 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.7080	0.445	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3562	0.224		
LIVER	8.1483	5.125		
KIDNEYS	1.7753	1.117		
ADRENAL GLANDS	0.0448	0.028		
OVARIES/OVIDUCTS	0.0825	0.052		
PITUITARY	0.0121	0.008		
THYROID GLANDS	0.0160	0.010		
FINAL BODY WT(G)	159.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69165-06 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.5545	0.358
UTERUS- BLOTTED	0.4047	0.261
LIVER	7.2558	4.681
KIDNEYS	1.5538	1.002
ADRENAL GLANDS	0.0505	0.033
OVARIES/OVIDUCTS	0.0875	0.056
PITUITARY	0.0085	0.005
THYROID GLANDS	0.0175	0.011
FINAL BODY WT(G)	155.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE			
MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 16

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69165-10 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2921	0.181
UTERUS- BLOTTED	0.2720	0.169
LIVER	8.2631	5.132
KIDNEYS	1.7912	1.113
ADRENAL GLANDS	0.0382	0.024
OVARIES/OVIDUCTS	0.1015	0.063
PITUITARY	0.0103	0.006
THYROID GLANDS	0.0233	0.014
FINAL BODY WT(G)	161.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69166-07 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	GRADE
UTERUS- WET	0.2612	0.218			P
UTERUS- BLOTTED	0.2460	0.205	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	4.4918	3.743		MICRO:THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.2229	1.019			
ADRENAL GLANDS	0.0396	0.033			
OVARIES/OVIDUCTS	0.0726	0.061			
PITUITARY	0.0053	0.004			
THYROID GLANDS	0.0203	0.017			
FINAL BODY WT(G)	120.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69168-08 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3604	0.242	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3337	0.224		
LIVER	7.9547	5.339		
KIDNEYS	1.4089	0.946		
ADRENAL GLANDS	0.0404	0.027		
OVARIES/OVIDUCTS	0.0857	0.058		
PITUITARY	0.0097	0.007		
THYROID GLANDS	0.0195	0.013		
FINAL BODY WT(G)	149.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69168-10 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2797	0.185	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2550	0.169		
LIVER	8.5396	5.655		
KIDNEYS	1.6664	1.104		
ADRENAL GLANDS	0.0394	0.026		
OVARIES/OVIDUCTS	0.0832	0.055		
PITUITARY	0.0081	0.005		
THYROID GLANDS	0.0197	0.013		
FINAL BODY WT(G)	151.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69170-02 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2671	0.155	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2519	0.146		
LIVER	9.6732	5.624		
KIDNEYS	1.6278	0.946		
ADRENAL GLANDS	0.0335	0.019		
OVARIES/OVIDUCTS	0.0973	0.057		
PITUITARY	0.0097	0.006		
THYROID GLANDS	0.0180	0.010		
FINAL BODY WT(G)	172.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69170-10 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4187	0.265
UTERUS- BLOTTED	0.3857	0.244
LIVER	7.2212	4.570
KIDNEYS	1.7300	1.095
ADRENAL GLANDS	0.0335	0.021
OVARIES/OVIDUCTS	0.0791	0.050
PITUITARY	0.0085	0.005
THYROID GLANDS	0.0116	0.007
FINAL BODY WT(G)	158.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE	MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 22

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-05 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.8675	0.594
UTERUS- BLOTTED	0.4855	0.333
LIVER	8.5854	5.880
KIDNEYS	1.6627	1.139
ADRENAL GLANDS	0.0423	0.029
OVARIES/OVIDUCTS	0.1059	0.073
PITUITARY	0.0092	0.006
THYROID GLANDS	0.0204	0.014
FINAL BODY WT(G)	146.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE	MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69172-04 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2919	0.176
UTERUS- BLOTTED	0.2628	0.158
LIVER	10.6406	6.410
KIDNEYS	1.5765	0.950
ADRENAL GLANDS	0.0376	0.023
OVARIES/OVIDUCTS	0.0771	0.046
PITUITARY	0.0079	0.005
THYROID GLANDS	0.0150	0.009
FINAL BODY WT(G)	166.	

OVARIES
NO SIGNIFICANT CHANGES OBSERVED

GRADE
P

MICRO: DECREASED CORPORA LUTEA
BILATERAL

MICRO:THYROID GLANDS UTERUS CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69172-07 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3304	0.228
UTERUS- BLOTTED	0.3166	0.218
LIVER	6.5640	4.527
KIDNEYS	1.5891	1.096
ADRENAL GLANDS	0.0501	0.035
OVARIES/OVIDUCTS	0.1100	0.076
PITUITARY	0.0096	0.007
THYROID GLANDS	0.0230	0.016
FINAL BODY WT(G)	145.	

NO SIGNIFICANT CHANGES OBSERVED	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 25

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-03 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3790	0.253	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3637	0.242		
LIVER	7.9434	5.296		
KIDNEYS	1.5189	1.013		
ADRENAL GLANDS	0.0422	0.028		
OVARIES/OVIDUCTS	0.0752	0.050		
PITUITARY	0.0092	0.006		
THYROID GLANDS	0.0158	0.011		
FINAL BODY WT(G)	150.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 26

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69174-05 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2267	0.140
UTERUS- BLOTTED	0.2055	0.127
LIVER	7.1044	4.385
KIDNEYS	1.5901	0.982
ADRENAL GLANDS	0.0328	0.020
OVARIES/OVIDUCTS	0.0784	0.048
PITUITARY	0.0089	0.005
THYROID GLANDS	0.0159	0.010
FINAL BODY WT(G)	162.	

		GRADE
OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS	MICRO: HYPOPLASIA BILATERAL	1
NO SIGNIFICANT CHANGES OBSERVED		
	MICRO:THYROID GLANDS CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69174-06 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	GRADE
UTERUS- WET	0.8752	0.576			1
UTERUS- BLOTTED	0.4075	0.268	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	7.9796	5.250		MICRO:OVARIES UTERUS CERVIX	
KIDNEYS	1.6880	1.111			
ADRENAL GLANDS	0.0453	0.030			
OVARIES/OVIDUCTS	0.0938	0.062			
PITUITARY	0.0098	0.006			
THYROID GLANDS	0.0180	0.012			
FINAL BODY WT(G)	152.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69176-08 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3737	0.247
UTERUS- BLOTTED	0.3570	0.236
LIVER	6.9034	4.572
KIDNEYS	1.3223	0.876
ADRENAL GLANDS	0.0455	0.030
OVARIES/OVIDUCTS	0.0972	0.064
PITUITARY	0.0084	0.006
THYROID GLANDS	0.0141	0.009
FINAL BODY WT(G)	151.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 29

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69177-06 GROUP 2: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
			MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX
UTERUS- WET	0.2455	0.166				
UTERUS- BLOTTED	0.1869	0.126				
LIVER	6.9512	4.697				
KIDNEYS	1.4992	1.013				
ADRENAL GLANDS	0.0335	0.023				
OVARIES/OVIDUCTS	0.0769	0.052				
PITUITARY	0.0073	0.005				
THYROID GLANDS	0.0212	0.014				
FINAL BODY WT(G)	148.					

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 30

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69165-03 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2131	0.153	OVARIES	MICRO: DECREASED CORPORA LUTEA	P
				BILATERAL	
UTERUS- BLOTTED	0.1948	0.140	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
LIVER	7.5869	5.458		BILATERAL	
KIDNEYS	1.3675	0.984	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0396	0.028		MICRO:UTERUS CERVIX	
OVARIES/OVIDUCTS	0.0849	0.061			
PITUITARY	0.0080	0.006			
THYROID GLANDS	0.0173	0.012			
FINAL BODY WT(G)	139.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 31

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69166-05 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2650	0.180
UTERUS- BLOTTED	0.2281	0.155
LIVER	6.6070	4.495
KIDNEYS	1.4075	0.957
ADRENAL GLANDS	0.0487	0.033
OVARIES/OVIDUCTS	0.0871	0.059
PITUITARY	0.0088	0.006
THYROID GLANDS	0.0262	0.018
FINAL BODY WT(G)	147.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE			
MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 32

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69166-09 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2568	0.171	OVARIES	MICRO: DECREASED CORPORA LUTEA	P
				BILATERAL	
UTERUS- BLOTTED	0.2418	0.161	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
				BILATERAL	
LIVER	7.9473	5.298	UTERUS	MICRO: HYPOPLASIA	1
KIDNEYS	1.6147	1.076		BILATERAL	
ADRENAL GLANDS	0.0560	0.037			
OVARIES/OVIDUCTS	0.0852	0.057	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0095	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0209	0.014			
FINAL BODY WT(G)	150.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69167-01 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2218	0.153
UTERUS- BLOTTED	0.2107	0.145
LIVER	6.1286	4.227
KIDNEYS	1.5258	1.052
ADRENAL GLANDS	0.0428	0.030
OVARIES/OVIDUCTS	0.0791	0.055
PITUITARY	0.0095	0.007
THYROID GLANDS	0.0135	0.009
FINAL BODY WT(G)	145.	

NO SIGNIFICANT CHANGES OBSERVED

	MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 34

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69168-06 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2226	0.165	OVARIES	MICRO: DECREASED CORPORA LUTEA	P
UTERUS- BLOTTED	0.2019	0.150		BILATERAL	
LIVER	6.9866	5.175	UTERUS	MICRO: HYPOPLASIA	1
KIDNEYS	1.3961	1.034		BILATERAL	
			NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0366	0.027		MICRO:THYROID GLANDS CERVIX	
OVARIES/OVIDUCTS	0.0720	0.053			
PITUITARY	0.0080	0.006			
THYROID GLANDS	0.0203	0.015			
FINAL BODY WT(G)	135.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69176-10 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3237	0.225
UTERUS- BLOTTED	0.3039	0.211
LIVER	6.8994	4.791
KIDNEYS	1.4063	0.977
ADRENAL GLANDS	0.0421	0.029
OVARIES/OVIDUCTS	0.0769	0.053
PITUITARY	0.0097	0.007
THYROID GLANDS	0.0144	0.010
FINAL BODY WT(G)	144.	

		GRADE
OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS	MICRO: HYPOPLASIA BILATERAL	1
NO SIGNIFICANT CHANGES OBSERVED		
	MICRO:THYROID GLANDS CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-04 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2572	0.181	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2359	0.166	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	6.5762	4.631		MICRO:THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.4081	0.992			
ADRENAL GLANDS	0.0436	0.031			
OVARIES/OVIDUCTS	0.0804	0.057			
PITUITARY	0.0070	0.005			
THYROID GLANDS	0.0253	0.018			
FINAL BODY WT(G)	142.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 37

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-08 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3203	0.191	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2970	0.177	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	8.7845	5.229	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.6822	1.001			
ADRENAL GLANDS	0.0534	0.032			
OVARIES/OVIDUCTS	0.0781	0.046	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0085	0.005		MICRO:CERVIX	
THYROID GLANDS	0.0344	0.020			
FINAL BODY WT(G)	168.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69172-02 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.4759	0.303	OVARIES	MICRO: DECREASED CORPORA LUTEA	P
UTERUS- BLOTTED	0.3286	0.209		BILATERAL	
LIVER	7.9549	5.067	UTERUS	MICRO: HYPOPLASIA	1
KIDNEYS	1.5906	1.013		BILATERAL	
			NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0440	0.028		MICRO:THYROID GLANDS CERVIX	
OVARIES/OVIDUCTS	0.0695	0.044			
PITUITARY	0.0099	0.006			
THYROID GLANDS	0.0293	0.019			
FINAL BODY WT(G)	157.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-10 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2517	0.171	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2416	0.164	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	7.4452	5.065		MICRO:THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.4004	0.953			
ADRENAL GLANDS	0.0306	0.021			
OVARIES/OVIDUCTS	0.0811	0.055			
PITUITARY	0.0083	0.006			
THYROID GLANDS	0.0157	0.011			
FINAL BODY WT(G)	147.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 40

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-03 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2824	0.193	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2543	0.174	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	8.0237	5.496	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.5827	1.084			
ADRENAL GLANDS	0.0453	0.031			
OVARIES/OVIDUCTS	0.0589	0.040	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0094	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0119	0.008			
FINAL BODY WT(G)	146.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-05 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3045	0.222	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2825	0.206	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	6.4824	4.732			
KIDNEYS	1.4613	1.067	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0465	0.034			
OVARIES/OVIDUCTS	0.0985	0.072	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0098	0.007		MICRO:CERVIX	
THYROID GLANDS	0.0088	0.006			
FINAL BODY WT(G)	137.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-06 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3163	0.205	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2990	0.194	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.8506	5.098			
KIDNEYS	1.4950	0.971	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0425	0.028			
OVARIES/OVIDUCTS	0.0750	0.049	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0104	0.007		MICRO:CERVIX	
THYROID GLANDS	0.0130	0.008			
FINAL BODY WT(G)	154.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 43

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69176-04 GROUP 3: [redacted] 250 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3766	0.245	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3164	0.205		
LIVER	6.8237	4.431		
KIDNEYS	1.6219	1.053		
ADRENAL GLANDS	0.0456	0.030		
OVARIES/OVIDUCTS	0.0778	0.051		
PITUITARY	0.0096	0.006		
THYROID GLANDS	0.0180	0.012		
FINAL BODY WT(G)	154.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 44

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69165-09 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2531	0.175	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2329	0.161	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	9.2203	6.359			
KIDNEYS	1.4499	1.000	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0469	0.032			
OVARIES/OVIDUCTS	0.0423	0.029	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0076	0.005		MICRO:CERVIX	
THYROID GLANDS	0.0231	0.016			
FINAL BODY WT(G)	145.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69167-03 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2433	0.155	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
UTERUS- BLOTTED	0.2349	0.150	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	9.5684	6.095	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.6525	1.053			
ADRENAL GLANDS	0.0459	0.029			
OVARIES/OVIDUCTS	0.0896	0.057	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0102	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0200	0.013			
FINAL BODY WT(G)	157.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69167-06 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.1870	0.139	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.1635	0.121		CYST, CORPORA LUTEA UNILATERAL	P
LIVER	7.7636	5.751			
KIDNEYS	1.3709	1.015	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
ADRENAL GLANDS	0.0393	0.029			
OVARIES/OVIDUCTS	0.0482	0.036	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
PITUITARY	0.0069	0.005			
THYROID GLANDS	0.0275	0.020	NO SIGNIFICANT CHANGES OBSERVED		
FINAL BODY WT(G)	135.			MICRO:CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 47

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69167-09 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.1747	0.119	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.1532	0.104	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	8.3931	5.710	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.4481	0.985			
ADRENAL GLANDS	0.0404	0.027			
OVARIES/OVIDUCTS	0.0501	0.034	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0080	0.005		MICRO:CERVIX	
THYROID GLANDS	0.0183	0.012			
FINAL BODY WT(G)	147.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69168-02 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2318	0.183	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2098	0.165	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.1266	5.611	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.3844	1.090			
ADRENAL GLANDS	0.0472	0.037			
OVARIES/OVIDUCTS	0.0519	0.041	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0071	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0295	0.023			
FINAL BODY WT(G)	127.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69169-06 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2344	0.145	OVARIES	MICRO: CORPORA LUTEA ABSENT	P
UTERUS- BLOTTED	0.2198	0.136		BILATERAL	
LIVER	10.0363	6.195	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
KIDNEYS	1.6491	1.018		BILATERAL	
			NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0462	0.029		MICRO:UTERUS CERVIX	
OVARIES/OVIDUCTS	0.0622	0.038			
PITUITARY	0.0103	0.006			
THYROID GLANDS	0.0345	0.021			
FINAL BODY WT(G)	162.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69170-04 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2200	0.138	OVARIES	MICRO: CORPORA LUTEA ABSENT	P
UTERUS- BLOTTED	0.2052	0.129		BILATERAL	
LIVER	8.8305	5.554	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
KIDNEYS	1.5337	0.965		BILATERAL	
ADRENAL GLANDS	0.0416	0.026	UTERUS	MICRO: HYPOPLASIA	1
OVARIES/OVIDUCTS	0.0523	0.033		BILATERAL	
			NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0085	0.005		MICRO:CERVIX	
THYROID GLANDS	0.0313	0.020			
FINAL BODY WT(G)	159.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 51

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69170-07 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2341	0.154	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
UTERUS- BLOTTED	0.2167	0.143	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.9295	5.217			
KIDNEYS	1.4158	0.931	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0425	0.028			
OVARIES/OVIDUCTS	0.0387	0.025	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0061	0.004		MICRO:CERVIX	
THYROID GLANDS	0.0189	0.012			
FINAL BODY WT(G)	152.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-01 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2296	0.162	KIDNEYS	GROSS: DILATED PELVIS	
UTERUS- BLOTTED	0.2002	0.141		RIGHT	2
LIVER	8.3322	5.868	OVARIES	MICRO: CORPORA LUTEA ABSENT	
KIDNEYS	1.3521	0.952		BILATERAL	P
ADRENAL GLANDS	0.0307	0.022	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	
OVARIES/OVIDUCTS	0.0458	0.032		BILATERAL	1
PITUITARY	0.0067	0.005	UTERUS	MICRO: HYPOPLASIA	
THYROID GLANDS	0.0268	0.019		BILATERAL	1
			NO SIGNIFICANT CHANGES OBSERVED		
FINAL BODY WT(G)	142.			MICRO:CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 53

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69172-03 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2285	0.142	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
UTERUS- BLOTTED	0.2142	0.133	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	10.1812	6.324			
KIDNEYS	1.5438	0.959	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0450	0.028			
OVARIES/OVIDUCTS	0.0481	0.030	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0073	0.005		MICRO:CERVIX	
THYROID GLANDS	0.0384	0.024			
FINAL BODY WT(G)	161.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 54

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-09 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2585	0.197	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2414	0.184	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.2087	5.503			
KIDNEYS	1.4007	1.069	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0481	0.037			
OVARIES/OVIDUCTS	0.0644	0.049	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0081	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0171	0.013			
FINAL BODY WT(G)	131.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 55

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69176-07 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2651	0.173	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
UTERUS- BLOTTED	0.2432	0.159	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.8174	5.109	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.5936	1.042			
ADRENAL GLANDS	0.0488	0.032			
OVARIES/OVIDUCTS	0.0473	0.031	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0089	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0150	0.010			
FINAL BODY WT(G)	153.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69177-03 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2592	0.176	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2447	0.166	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	8.4421	5.743			
KIDNEYS	1.3540	0.921	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0498	0.034		MICRO:UTERUS CERVIX	
OVARIES/OVIDUCTS	0.0424	0.029			
PITUITARY	0.0066	0.004			
THYROID GLANDS	0.0175	0.012			
FINAL BODY WT(G)	147.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69177-08 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2252	0.145	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
UTERUS- BLOTTED	0.2121	0.137	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	8.3897	5.413	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.5450	0.997			
ADRENAL GLANDS	0.0435	0.028			
OVARIES/OVIDUCTS	0.0522	0.034	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0066	0.004		MICRO:CERVIX	
THYROID GLANDS	0.0179	0.012			
FINAL BODY WT(G)	155.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 58

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69177-09 GROUP 4: [redacted] 1000 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2533	0.162	OVARIES	MICRO: CORPORA LUTEA ABSENT BILATERAL	P
UTERUS- BLOTTED	0.2382	0.153	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.6536	4.906	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.4831	0.951			
ADRENAL GLANDS	0.0557	0.036			
OVARIES/OVIDUCTS	0.0466	0.030	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0083	0.005		MICRO:CERVIX	
THYROID GLANDS	0.0159	0.010			
FINAL BODY WT(G)	156.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69165-04 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.7656	0.524	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.4117	0.282	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	7.8294	5.363		MICRO:THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.4589	0.999			
ADRENAL GLANDS	0.0419	0.029			
OVARIES/OVIDUCTS	0.0691	0.047			
PITUITARY	0.0086	0.006			
THYROID GLANDS	0.0194	0.013			
FINAL BODY WT(G)	146.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-05 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3501	0.238
UTERUS- BLOTTED	0.3318	0.226
LIVER	7.2003	4.898
KIDNEYS	1.5716	1.069
ADRENAL GLANDS	0.0400	0.027
OVARIES/OVIDUCTS	0.0913	0.062
PITUITARY	0.0104	0.007
THYROID GLANDS	0.0161	0.011
FINAL BODY WT(G)	147.	

NO SIGNIFICANT CHANGES OBSERVED

MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69166-08 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3682	0.285	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3452	0.268		
LIVER	6.1598	4.775		
KIDNEYS	1.3746	1.066		
ADRENAL GLANDS	0.0417	0.032		
OVARIES/OVIDUCTS	0.0732	0.057		
PITUITARY	0.0089	0.007		
THYROID GLANDS	0.0211	0.016		
FINAL BODY WT(G)	129.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69168-05 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2099	0.149	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.1971	0.140		
LIVER	6.2321	4.420		
KIDNEYS	1.2801	0.908		
ADRENAL GLANDS	0.0351	0.025		
OVARIES/OVIDUCTS	0.0753	0.053		
PITUITARY	0.0068	0.005		
THYROID GLANDS	0.0269	0.019		
FINAL BODY WT(G)	141.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69168-09 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6149	0.424
UTERUS- BLOTTED	0.4141	0.286
LIVER	7.3706	5.083
KIDNEYS	1.5024	1.036
ADRENAL GLANDS	0.0471	0.032
OVARIES/OVIDUCTS	0.0945	0.065
PITUITARY	0.0086	0.006
THYROID GLANDS	0.0215	0.015
FINAL BODY WT(G)	145.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69169-04 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3553	0.225
UTERUS- BLOTTED	0.3207	0.203
LIVER	6.8416	4.330
KIDNEYS	1.4529	0.920
ADRENAL GLANDS	0.0326	0.021
OVARIES/OVIDUCTS	0.0755	0.048
PITUITARY	0.0084	0.005
THYROID GLANDS	0.0174	0.011
FINAL BODY WT(G)	158.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

MICRO:OVARIES THYROID GLANDS UTERUS CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69170-06 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2056	0.129	THYMUS	GROSS: MASS	P
UTERUS- BLOTTED	0.1871	0.118		20 X 20 X 10 MM, TAN, ATTACHED TO LEFT LATERAL THORACIC WALL, FIRM, MASS #1	
LIVER	7.8858	4.960	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
KIDNEYS	1.5050	0.947		BILATERAL	
ADRENAL GLANDS	0.0391	0.025	LYMPH NODE, MED	GROSS: ENLARGED	P
OVARIES/OVIDUCTS	0.0607	0.038	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0089	0.006		MICRO:OVARIES UTERUS CERVIX	
THYROID GLANDS	0.0266	0.017			
FINAL BODY WT(G)	159.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 66

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69170-08 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3855	0.270
UTERUS- BLOTTED	0.3521	0.246
LIVER	6.8817	4.812
KIDNEYS	1.5552	1.088
ADRENAL GLANDS	0.0409	0.029
OVARIES/OVIDUCTS	0.0933	0.065
PITUITARY	0.0101	0.007
THYROID GLANDS	0.0240	0.017
FINAL BODY WT(G)	143.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69171-06 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3034	0.202
UTERUS- BLOTTED	0.2731	0.182
LIVER	7.1152	4.743
KIDNEYS	1.6028	1.069
ADRENAL GLANDS	0.0358	0.024
OVARIES/OVIDUCTS	0.1090	0.073
PITUITARY	0.0091	0.006
THYROID GLANDS	0.0226	0.015
FINAL BODY WT(G)	150.	

NO SIGNIFICANT CHANGES OBSERVED

MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX	GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 68

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-10 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4060	0.237	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3658	0.214		
LIVER	8.3689	4.894		
KIDNEYS	1.7551	1.026		
ADRENAL GLANDS	0.0482	0.028		
OVARIES/OVIDUCTS	0.1090	0.064		
PITUITARY	0.0071	0.004		
THYROID GLANDS	0.0319	0.019		
FINAL BODY WT(G)	171.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69174-03 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2615	0.166
UTERUS- BLOTTED	0.2442	0.155
LIVER	7.2004	4.557
KIDNEYS	1.6078	1.018
ADRENAL GLANDS	0.0354	0.022
OVARIES/OVIDUCTS	0.1031	0.065
PITUITARY	0.0085	0.005
THYROID GLANDS	0.0171	0.011
FINAL BODY WT(G)	158.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69174-07 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4013	0.283
UTERUS- BLOTTED	0.3577	0.252
LIVER	6.6139	4.658
KIDNEYS	1.6036	1.129
ADRENAL GLANDS	0.0390	0.027
OVARIES/OVIDUCTS	0.0709	0.050
PITUITARY	0.0073	0.005
THYROID GLANDS	0.0140	0.010
FINAL BODY WT(G)	142.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

MICRO:OVARIES THYROID GLANDS UTERUS CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-08 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2627	0.173	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2428	0.160		
LIVER	7.1365	4.695		
KIDNEYS	1.5910	1.047		
ADRENAL GLANDS	0.0350	0.023		
OVARIES/OVIDUCTS	0.0658	0.043		
PITUITARY	0.0081	0.005		
THYROID GLANDS	0.0152	0.010		
FINAL BODY WT(G)	152.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 72

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-10 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4843	0.341	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3645	0.257		
LIVER	6.9300	4.880		
KIDNEYS	1.3447	0.947		
ADRENAL GLANDS	0.0404	0.028		
OVARIES/OVIDUCTS	0.0961	0.068		
PITUITARY	0.0084	0.006		
THYROID GLANDS	0.0153	0.011		
FINAL BODY WT(G)	142.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69177-05 GROUP 5: [redacted] 5 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3842	0.242
UTERUS- BLOTTED	0.3201	0.201
LIVER	7.7520	4.875
KIDNEYS	1.5521	0.976
ADRENAL GLANDS	0.0402	0.025
OVARIES/OVIDUCTS	0.1061	0.067
PITUITARY	0.0087	0.005
THYROID GLANDS	0.0181	0.011
FINAL BODY WT(G)	159.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE			
MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69165-05 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3482	0.243
UTERUS- BLOTTED	0.3315	0.232
LIVER	6.9479	4.859
KIDNEYS	1.6112	1.127
ADRENAL GLANDS	0.0427	0.030
OVARIES/OVIDUCTS	0.0875	0.061
PITUITARY	0.0085	0.006
THYROID GLANDS	0.0265	0.019
FINAL BODY WT(G)	143.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 75

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69166-03 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2317	0.160	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2147	0.148		
LIVER	6.4633	4.457		
KIDNEYS	1.3572	0.936		
ADRENAL GLANDS	0.0402	0.028		
OVARIES/OVIDUCTS	0.0738	0.051		
PITUITARY	0.0077	0.005		
THYROID GLANDS	0.0246	0.017		
FINAL BODY WT(G)	145.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69167-02 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2406	0.156	KIDNEYS	GROSS: DILATED PELVIS RIGHT	3
UTERUS- BLOTTED	0.2276	0.148	OVARIES	MICRO: CYST, CORPORA LUTEA UNILATERAL	P
LIVER	8.2010	5.325			
KIDNEYS	1.6628	1.080	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0392	0.025		MICRO:THYROID GLANDS UTERUS CERVIX	
OVARIES/OVIDUCTS	0.1190	0.077			
PITUITARY	0.0096	0.006			
THYROID GLANDS	0.0182	0.012			
FINAL BODY WT(G)	154.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69167-08 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2873	0.214
UTERUS- BLOTTED	0.2717	0.203
LIVER	5.9353	4.429
KIDNEYS	1.4725	1.099
ADRENAL GLANDS	0.0437	0.033
OVARIES/OVIDUCTS	0.0882	0.066
PITUITARY	0.0099	0.007
THYROID GLANDS	0.0208	0.016
FINAL BODY WT(G)	134.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE			
MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69168-01 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3251	0.223
UTERUS- BLOTTED	0.2973	0.204
LIVER	6.7894	4.650
KIDNEYS	1.3718	0.940
ADRENAL GLANDS	0.0392	0.027
OVARIES/OVIDUCTS	0.0810	0.055
PITUITARY	0.0079	0.005
THYROID GLANDS	0.0212	0.015
FINAL BODY WT(G)	146.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE			
MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS
SPONSOR NO.:04-023

ANIMAL NO.69169-02 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4372	0.282	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3915	0.253		
LIVER	7.3015	4.711		
KIDNEYS	1.5280	0.986		
ADRENAL GLANDS	0.0556	0.036		
OVARIES/OVIDUCTS	0.1047	0.068		
PITUITARY	0.0099	0.006		
THYROID GLANDS	0.0190	0.012		
FINAL BODY WT(G)	155.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69169-03 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3575	0.242
UTERUS- BLOTTED	0.3345	0.226
LIVER	8.5928	5.806
KIDNEYS	1.5148	1.024
ADRENAL GLANDS	0.0398	0.027
OVARIES/OVIDUCTS	0.0831	0.056
PITUITARY	0.0094	0.006
THYROID GLANDS	0.0279	0.019
FINAL BODY WT(G)	148.	

NO SIGNIFICANT CHANGES OBSERVED

MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69169-10 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.5204	0.306
UTERUS- BLOTTED	0.4142	0.244
LIVER	7.7981	4.587
KIDNEYS	1.7411	1.024
ADRENAL GLANDS	0.0460	0.027
OVARIES/OVIDUCTS	0.0804	0.047
PITUITARY	0.0088	0.005
THYROID GLANDS	0.0228	0.013
FINAL BODY WT(G)	170.	

NO SIGNIFICANT CHANGES OBSERVED

MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX	GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-023
INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69172-05 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3119	0.186	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2816	0.168	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	8.7270	5.195			
KIDNEYS	1.9012	1.132	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0525	0.031		MICRO:UTERUS CERVIX	
OVARIES/OVIDUCTS	0.0835	0.050			
PITUITARY	0.0101	0.006			
THYROID GLANDS	0.0259	0.015			
FINAL BODY WT(G)	168.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69172-09 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	GRADE
UTERUS- WET	0.3490	0.208		BILATERAL	1
UTERUS- BLOTTED	0.3292	0.196	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	8.5014	5.060		MICRO:OVARIES UTERUS CERVIX	
KIDNEYS	1.7215	1.025			
ADRENAL GLANDS	0.0455	0.027			
OVARIES/OVIDUCTS	0.0919	0.055			
PITUITARY	0.0113	0.007			
THYROID GLANDS	0.0225	0.013			
FINAL BODY WT(G)	168.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-01 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3766	0.231	OVARIES	MICRO: DECREASED CORPORA LUTEA	P
UTERUS- BLOTTED	0.3422	0.210	NO SIGNIFICANT CHANGES OBSERVED	BILATERAL	
LIVER	7.5091	4.607		MICRO:THYROID GLANDS UTERUS CERVIX	
KIDNEYS	1.6773	1.029			
ADRENAL GLANDS	0.0418	0.026			
OVARIES/OVIDUCTS	0.0787	0.048			
PITUITARY	0.0085	0.005			
THYROID GLANDS	0.0182	0.011			
FINAL BODY WT(G)	163.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-04 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2899	0.206	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2756	0.195		
LIVER	6.0783	4.311		
KIDNEYS	1.4463	1.026		
ADRENAL GLANDS	0.0346	0.025		
OVARIES/OVIDUCTS	0.0811	0.058		
PITUITARY	0.0075	0.005		
THYROID GLANDS	0.0171	0.012		
FINAL BODY WT(G)	141.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69175-07 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	OVARIES	MICRO: DECREASED CORPORA LUTEA		GRADE
UTERUS- WET	0.2289	0.140		BILATERAL		P
UTERUS- BLOTTED	0.2190	0.134	NO SIGNIFICANT CHANGES OBSERVED			
LIVER	8.2213	5.044		MICRO:THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.7296	1.061				
ADRENAL GLANDS	0.0376	0.023				
OVARIES/OVIDUCTS	0.0815	0.050				
PITUITARY	0.0105	0.006				
THYROID GLANDS	0.0163	0.010				
FINAL BODY WT(G)	163.					

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69176-05 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3145	0.206
UTERUS- BLOTTED	0.2959	0.193
LIVER	6.9231	4.525
KIDNEYS	1.5364	1.004
ADRENAL GLANDS	0.0439	0.029
OVARIES/OVIDUCTS	0.1019	0.067
PITUITARY	0.0099	0.006
THYROID GLANDS	0.0102	0.007
FINAL BODY WT(G)	153.	

		GRADE
THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
	NO SIGNIFICANT CHANGES OBSERVED	
	MICRO:OVARIES UTERUS CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69177-10 GROUP 6: [redacted] 20 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3454	0.208
UTERUS- BLOTTED	0.3242	0.195
LIVER	8.1176	4.890
KIDNEYS	1.6320	0.983
ADRENAL GLANDS	0.0485	0.029
OVARIES/OVIDUCTS	0.1105	0.067
PITUITARY	0.0112	0.007
THYROID GLANDS	0.0155	0.009
FINAL BODY WT(G)	166.	

NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO:OVARIES	
THYROID GLANDS	
UTERUS	
CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MICROSCOPIC FINDINGS
SPONSOR NO.:04-023

ANIMAL NO.69165-07 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2465	0.168
UTERUS- BLOTTED	0.2290	0.156
LIVER	7.6951	5.235
KIDNEYS	1.6575	1.128
ADRENAL GLANDS	0.0438	0.030
OVARIES/OVIDUCTS	0.1020	0.069
PITUITARY	0.0108	0.007
THYROID GLANDS	0.0222	0.015
FINAL BODY WT(G)	147.	

NO SIGNIFICANT CHANGES OBSERVED

MICRO:OVARIES	THYROID GLANDS	UTERUS	CERVIX

GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69166-10 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.7805	0.524	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.3637	0.244	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	6.9118	4.639			
KIDNEYS	1.4273	0.958	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0447	0.030		MICRO:UTERUS CERVIX	
OVARIES/OVIDUCTS	0.0594	0.040			
PITUITARY	0.0075	0.005			
THYROID GLANDS	0.0207	0.014			
FINAL BODY WT(G)	149.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 91

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69167-04 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3027	0.210	OVARIES	MICRO: DECREASED CORPORA LUTEA	P
				BILATERAL	
UTERUS- BLOTTED	0.2772	0.193	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
				BILATERAL	
LIVER	6.8563	4.761	UTERUS	MICRO: HYPOPLASIA	1
KIDNEYS	1.3636	0.947		BILATERAL	
ADRENAL GLANDS	0.0385	0.027			
OVARIES/OVIDUCTS	0.0630	0.044	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0088	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0191	0.013			
FINAL BODY WT(G)	144.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69167-05 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2304	0.160	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.2132	0.148	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.1816	4.987	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
KIDNEYS	1.4109	0.980			
ADRENAL GLANDS	0.0417	0.029			
OVARIES/OVIDUCTS	0.0681	0.047	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0087	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0172	0.012			
FINAL BODY WT(G)	144.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69168-07 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/06/04 DATE OF DEATH: 12/06/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3211	0.214	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
UTERUS- BLOTTED	0.2522	0.168	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
LIVER	6.6717	4.448			
KIDNEYS	1.4928	0.995	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0359	0.024		MICRO:OVARIES CERVIX	
OVARIES/OVIDUCTS	0.0659	0.044			
PITUITARY	0.0073	0.005			
THYROID GLANDS	0.0264	0.018			
FINAL BODY WT(G)	150.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69169-05 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	GRADE
UTERUS- WET	0.2389	0.149		BILATERAL	1
UTERUS- BLOTTED	0.2128	0.133	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	6.9984	4.374		MICRO:OVARIES UTERUS CERVIX	
KIDNEYS	1.4977	0.936			
ADRENAL GLANDS	0.0442	0.028			
OVARIES/OVIDUCTS	0.1043	0.065			
PITUITARY	0.0093	0.006			
THYROID GLANDS	0.0262	0.016			
FINAL BODY WT(G)	160.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MICROSCOPIC FINDINGS
SPONSOR NO.:04-023

ANIMAL NO.69169-09 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3388	0.202	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3107	0.185		
LIVER	8.1816	4.870		
KIDNEYS	1.6586	0.987		
ADRENAL GLANDS	0.0526	0.031		
OVARIES/OVIDUCTS	0.0909	0.054		
PITUITARY	0.0093	0.006		
THYROID GLANDS	0.0136	0.008		
FINAL BODY WT(G)	168.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 96

SPONSOR:[redacted]

SPONSOR NO.:04-023

INDIVIDUAL MICROSCOPIC FINDINGS

ANIMAL NO.69170-01 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.6108	0.366	OVARIES	MICRO: DECREASED CORPORA LUTEA BILATERAL	P
UTERUS- BLOTTED	0.3961	0.237	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
LIVER	7.3211	4.384			
KIDNEYS	1.6858	1.009	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
ADRENAL GLANDS	0.0469	0.028			
OVARIES/OVIDUCTS	0.0692	0.041	NO SIGNIFICANT CHANGES OBSERVED		
PITUITARY	0.0096	0.006		MICRO:CERVIX	
THYROID GLANDS	0.0154	0.009			
FINAL BODY WT(G)	167.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 97

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69171-02 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2421	0.166	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
UTERUS- BLOTTED	0.2258	0.155	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
LIVER	7.7838	5.331			
KIDNEYS	1.5999	1.096	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0371	0.025		MICRO:OVARIES CERVIX	
OVARIES/OVIDUCTS	0.0804	0.055			
PITUITARY	0.0088	0.006			
THYROID GLANDS	0.0245	0.017			
FINAL BODY WT(G)	146.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 98

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69172-01 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/07/04 DATE OF DEATH: 12/07/04

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2546	0.169
UTERUS- BLOTTED	0.2381	0.158
LIVER	7.5621	5.008
KIDNEYS	1.5364	1.017
ADRENAL GLANDS	0.0436	0.029
OVARIES/OVIDUCTS	0.0946	0.063
PITUITARY	0.0087	0.006
THYROID GLANDS	0.0226	0.015
FINAL BODY WT(G)	151.	

THYROID GLANDS

NO SIGNIFICANT CHANGES OBSERVED

MICRO: HYPERTROPHY, FOLLICULAR CELL	GRADE
BILATERAL	1

MICRO:OVARIES UTERUS CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 99

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69173-06 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	UTERUS	MICRO: HYPOPLASIA BILATERAL	GRADE 1
UTERUS- WET	0.2254	0.150			
UTERUS- BLOTTED	0.2828	0.189	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	7.3737	4.916		MICRO:OVARIES THYROID GLANDS CERVIX	
KIDNEYS	1.5293	1.020			
ADRENAL GLANDS	0.0495	0.033			
OVARIES/OVIDUCTS	0.0999	0.067			
PITUITARY	0.0110	0.007			
THYROID GLANDS	0.0166	0.011			
FINAL BODY WT(G)	150.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 100

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69174-02 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.8030	0.554	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.3874	0.267		
LIVER	7.2939	5.030		
KIDNEYS	1.6210	1.118		
ADRENAL GLANDS	0.0382	0.026		
OVARIES/OVIDUCTS	0.0735	0.051		
PITUITARY	0.0086	0.006		
THYROID GLANDS	0.0152	0.010		
FINAL BODY WT(G)	145.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO.69174-08 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3482	0.220	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL BILATERAL	1
UTERUS- BLOTTED	0.3319	0.210	UTERUS	MICRO: HYPOPLASIA BILATERAL	1
LIVER	7.5879	4.802			
KIDNEYS	1.5432	0.977	NO SIGNIFICANT CHANGES OBSERVED		
ADRENAL GLANDS	0.0427	0.027		MICRO:OVARIES CERVIX	
OVARIES/OVIDUCTS	0.0857	0.054			
PITUITARY	0.0102	0.006			
THYROID GLANDS	0.0164	0.010			
FINAL BODY WT(G)	158.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MICROSCOPIC FINDINGS
SPONSOR NO.:04-023

ANIMAL NO.69174-09 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	GRADE
UTERUS- WET	0.5755	0.345		BILATERAL	1
UTERUS- BLOTTED	0.4005	0.240	NO SIGNIFICANT CHANGES OBSERVED		
LIVER	8.4343	5.050	MICRO:OVARIES	UTERUS	CERVIX
KIDNEYS	1.7941	1.074			
ADRENAL GLANDS	0.0516	0.031			
OVARIES/OVIDUCTS	0.1111	0.067			
PITUITARY	0.0102	0.006			
THYROID GLANDS	0.0167	0.010			
FINAL BODY WT(G)	167.				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 25 (SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187041 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 103

SPONSOR:[redacted]

INDIVIDUAL MICROSCOPIC FINDINGS

SPONSOR NO.:04-023

ANIMAL NO.69177-07 GROUP 7: [redacted] 60 FEMALE SCHEDULED EUTH 12/08/04 DATE OF DEATH: 12/08/04

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2444	0.167	MICRO:OVARIES	THYROID GLANDS UTERUS CERVIX
UTERUS- BLOTTED	0.2293	0.157		
LIVER	6.9199	4.740		
KIDNEYS	1.3537	0.927		
ADRENAL GLANDS	0.0371	0.025		
OVARIES/OVIDUCTS	0.0659	0.045		
PITUITARY	0.0083	0.006		
THYROID GLANDS	0.0173	0.012		
FINAL BODY WT(G)	146.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.52
02/17/2005
R:02/17/2005

APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

[redacted]

[redacted]

[redacted]

Test Substance Certificate

[redacted]

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown, viscous liquid

Storage Conditions
Ambient, store under nitrogen blanket

Expiration Date
1 July 2005

Additional Comments
None

[redacted]

14 October 2004
Date

[redacted]

[redacted] 396

[redacted]

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown, opaque, very viscous liquid

Storage Conditions
Ambient

Expiration Date
1 May 2005

Additional Comments
None

[redacted]

7 September 2004
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

[redacted]

TITLE

The Analytical Report in Support of a Female Pubertal Assay [redacted] Administered Orally in Juvenile Female Rats

[redacted]

SUBMITTED TO SUPPORT THE TESTING OF:

[redacted]

WIL Research Study #WIL-187041

[redacted] Reference #04-023

[redacted]

STUDY INITIATION DATE

2 September 2004

ANALYTICAL START DATE

2 November 2004

ANALYTICAL END DATE

30 December 2004

ANALYTICAL STUDY COMPLETION DATE

18 November 2005

PERFORMING LABORATORY

[redacted]

TOTAL PAGES

14

[redacted]

[redacted]

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[redacted]

[redacted]

[redacted]

ANALYTICAL STUDY GLP COMPLIANCE STATEMENT

[redacted]

All analytical tests performed by [redacted] WIL Research Study #WIL-187041 [redacted] Reference #04-023) were conducted in compliance with current EPA Good Laboratory Practice (GLP) standards as described by the Toxic Substances Control Act (TSCA) 40 CFR Part 792.

[redacted]

Principal Investigato[redacted] Date: 10 November 2015

[redacted]

[redacted]

ANALYTICAL STUDY QUALITY ASSURANCE UNIT STATEMENT

The analytical raw data and final report for the [redacted] study have been reviewed by the [redacted] Quality Assurance Team.

The report appears to accurately describe the methods and Standard Operating Procedures (SOPs) used in the study. The reported results accurately reflect the raw data of the study.

Study #
WIL Research Study #WIL-187041
[redacted]#04-023

Study Title
The Analytical Report in Support of a Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

		Dates Reported to	
	Study Director	WIL Research Mgmt	ILT Mgmt
Study In-progress Inspection 10 December 2004	8 November 2005	8 November, 2005	8 November, 2005
Analytical Draft Report Review 9-11, 14 November 2005	18 November 2005	18 November 2005	18 November 2005
Analytical Final Report Review 18 November 2005	18 November 2005	18 November 2005	18 November 2005

[redacted]

Date: April 19, 2005

Quality Assurance Specialist
[redacted]

[redacted]

ABSTRACT

Samples of suspensions ([redacted] corn oil) used in a female pubertal assay in rats, WIL Research Study #WIL-187041 [redacted] 04-023), were analyzed at [redacted] verify their homogeneity, stability, and nominal concentrations. A direct dilution procedure was employed to prepare the samples for elemental analysis by Inductively Coupled Plasma-Atomic Emission Spectroscopy (ICP-AES). Homogeneity and stability of [redacted] corn oil were established. The nominal concentrations of all dosing suspensions were verified by the analytical data.

TEST SUBSTANCES

The test substances used in the preparation of the dosing suspensions are identified as [redacted] and [redacted]. The CAS numbers are confidential; contact [redacted] for further information. The test substances were characterized and their stabilities were established prior to the initiation of the study.

INTRODUCTION

The purpose of this analytical study was the determination and verification of test substance homogeneity, stability, and concentration in corn oil. The concentration study samples were aliquots taken from mixtures prepared as dosing suspensions for a female pubertal assay in rats as outlined in the protocol for WIL Research Study #WIL-187041.

The analytical portion of the study was performed by the High Volume Services team located in the [redacted]. The analytical start and end dates were 2 November and 30 December 2004 respectively.

EXPERIMENTAL

SAMPLES
Samples were shipped from WIL Research to ILT's Principal Investigator. Samples were stored at room temperature and in the dark prior to analysis.

The first batch of samples was transferred to the laboratory on 2 November 2004. The analysis of the last set of samples was completed on 14 December 2004. Densities for [redacted] and corn oil were determined on 30 December 2004. The density of [redacted] was determined during a previous study.

STANDARDS
Calibration standards for the ICP-AES were made from certified commercially prepared elemental concentrates (Conostan Division of Conoco, Inc.). Standard preparation data is archived by ILT.

[redacted]

[redacted]

[redacted]

[redacted]

ANALYTICAL METHOD

Samples were prepared as stated in ILT's Test Code 30176, SOP ME-125 "Elemental Analysis of Additives or Additive Mixtures by Direct Dilution and ICP Analysis." The procedures outlined in SOP EQ-130, "IRIS Intrepid XDL II Radial Inductively Coupled Plasma Spectrometer," were followed during the instrumental analysis of the samples.

The approach employed in this method was to verify concentration based on the known elemental composition of [redacted] Aliquots of the dosing suspensions were diluted in an o-xylene diluent and the elemental composition was determined by ICP-AES. The calcium concentration of the samples was then used to ascertain the concentration of the test substance in the dosing suspensions.

DISCUSSION

METHOD VALIDATION

Method validation was performed following the recommendations outlined in the International Conference on Harmonisation's Q2B document: Guideline on the Validation of Analytical Procedures: Methodology. The limit of detection (LOD) and limit of quantitation (LOQ) were calculated to be 0.063 and 0.192 wt ppm calcium respectively. A reporting limit of 2 wt ppm calcium was determined to be appropriate for vehicle results.

SAMPLE ANALYSIS

The analytical results for the suspensions of [redacted] n corn oil are summarized in the tables located on pages 8 through 14. Seven calibration standards were analyzed to generate a linear calibration curve with inverse concentration weighting. All instrument control checks and quality control samples were within acceptable limits. Known amounts of calcium were spiked into 26 samples throughout the duration of the study and gave acceptable percent recoveries of 93 to 107%.

The dosing suspensions were analyzed for calcium, an element present in known concentrations in the test substances. Dosing suspension estimates of weight percent calcium were derived by the following formula:

$$Wt\%\ Ca = \left[\frac{x}{x + \left(D_2 - \frac{xD_2}{D_1}\right)}\right] \%\ Ca\ in\ [redacted]\ or\ [redacted]$$

where x is the solute test substance concentration in mg/µL; D_1 is the test substance density (0.9325 g/mL for [redacted]3 and 0.9810 g/mL for [redacted]); and D_2 is the vehicle or solvent density (corn oil, 0.9192 g/mL). The concentration of calcium in [redacted]3 is 3.530 wt% and 5.152 wt% in [redacted]3. The measured results of calcium were obtained by ICP-AES and compared against the estimated values. For [redacted]3 suspensions, results were converted to wt% from ppm by multiplying by 10^{-4}.

Homogeneity was confirmed if the percent differences between the overall dose level mean and individual strata means were 10% or less. Stability and concentration data were evaluated using percent difference. The acceptable tolerance was 15%. Duplicate analyses were compared using the Contract Laboratories Program (CLP) Guidelines for Inorganic Analyses relative percent difference limit of 20%

[redacted]

[redacted]

RESULTS AND CONCLUSIONS

The confirmation of dosing suspension homogeneity is supported by the data presented on pages 8 and 9. The percent difference of all strata means with their respective overall mean is well below the 10% tolerance.

The stabilities of [redacted] corn oil over a 10-day period are established on pages 10 and 11. The percent difference between the estimated and measured concentrations is less than 15% for all dosing levels.

The analytical result summaries for the concentration studies are found on pages 12 and 13. The nominal concentrations of all dosing suspensions were verified by the analytical data. The percent difference between the estimated and measured concentrations is less than 15% for all dosing levels.

The table on page 14 presents the duplicate precision data. The agreement between the duplicates is excellent and well under the CLP relative percent difference guideline of 20%.

ARCHIVES

SAMPLES
The unused portion of all samples shall be stored in room [redacted] for a minimum of one year after the final analytical report is issued.

RAW DATA
Calibration data; and instrument, chemical, and standard logbook documentation shall be archived by [redacted]. All other raw data shall be archived in the Analytical Study File [redacted] Analytical Study Archives.

FINAL REPORT
A copy of the final report shall be archived with the Analytical Study File in [redacted]

PROTOCOL AND SOP DEVIATIONS

There were no protocol deviations.

SOP ME-125 states a duplicate sample shall be prepared for every batch of 20 samples. No duplicates were prepared for samples analyzed on 26 November, 30 November, or 10 December. All QCs and instrument control samples were within acceptable limits on these dates. This did not affect the outcome of the analytical results.

STUDY PERSONNEL

PRINCIPAL INVESTIGATOR

ANALYSTS

SUPERVISORY PERSONNEL

[redacted]

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187041
[redacted]: Reference #04-023

Homogeneity Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted] mg/mL wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
438365001	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0001	1	Middle	0	0.000	<2 wt ppm		
438365020	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0020	1	Middle	0	0.000	<2 wt ppm	<2 wt ppm	0.0
438365002	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0002	2	Top	12	0.046	0.046		
438365021	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0021	2	Top	12	0.046	0.046	0.046	0.0
438365003	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0003	2	Middle	12	0.046	0.046	0.046	
438365022	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0022	2	Middle	12	0.046	0.046	0.046	0.0
438365004	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0004	2	Bottom	12	0.046	0.046		
438365023	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0023	2	Bottom	12	0.046	0.046	0.046	0.0
438365005	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0005	3	Top	50	0.192	0.195		
438365024	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0024	3	Top	50	0.192	0.196	0.196	0.0
438365006	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0006	3	Middle	50	0.192	0.196	0.196	
438365025	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0025	3	Middle	50	0.192	0.195	0.196	0.0
438365007	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0007	3	Bottom	50	0.192	0.195		
438365026	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0026	3	Bottom	50	0.192	0.196	0.196	0.0
438365008	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0008	4	Top	200	0.766	0.758		
438365027	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0027	4	Top	200	0.766	0.757	0.758	0.3
438365009	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0009	4	Middle	200	0.766	0.759	0.760	
438365028	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0028	4	Middle	200	0.766	0.763	0.761	0.1
438365010	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0010	4	Bottom	200	0.766	0.759		
438365029	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0029	4	Bottom	200	0.766	0.762	0.761	0.1

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187041
[redacted] Reference #04-023

Homogeneity Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated [redacted] mL	Concentration wt ppm Ca	Measured Concentration, wt ppm Ca	Strata Mean, wt ppm Ca	Overall Mean, wt ppm Ca	Percent Difference, %
438365011	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0002	5	Top	1	56.0	54.5			
438365030	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0012	5	Top	1	56.0	55.7	55.1		0.9
438365012	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0003	5	Middle	1	56.0	54.5		54.6	
438365031	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0013	5	Middle	1	56.0	53.8	54.2		0.7
438365013	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0004	5	Bottom	1	56.0	55.0			
438365032	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0014	5	Bottom	1	56.0	54.2	54.6		0.0
438365014	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0005	6	Top	4	224	229			
438365033	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0015	6	Top	4	224	218	224		1.3
438365015	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0006	6	Middle	4	224	233		227	
438365034	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0016	6	Middle	4	224	226	230		1.3
438365016	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0007	6	Bottom	4	224	229			
438365035	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0017	6	Bottom	4	224	225	227		0.0
438365017	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0008	7	Top	12	672	693			
438365036	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0018	7	Top	12	672	671	682		0.9
438365018	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0009	7	Middle	12	672	696		688	
438365037	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0019	7	Middle	12	672	663	680		1.2
438365019	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0010	7	Bottom	12	672	721			
438365038	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0020	7	Bottom	12	672	685	703		2.2

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187041
[redacted]: Reference #04-023

10-Day Stability Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated Concentration mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
438365001	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0001	1	Middle	0	0 000	<2 wt ppm	*
438365001	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0001	1	Middle	0	0 000	<2 wt ppm	*
438365020	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0020	1	Middle	0	0.000	<2 wt ppm	*
438365020	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0020	1	Middle	0	0 000	<2 wt ppm	*
438365002	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0002	2	Top	12	0 046	0.046	0.0
438365002	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0002	2	Top	12	0 046	0 045	2 2
438365021	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0021	2	Top	12	0.046	0 046	0.0
438365021	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0021	2	Top	12	0.046	0 045	2 2
438365003	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0003	2	Middle	12	0 046	0 046	0 0
438365003	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0003	2	Middle	12	0.046	0 045	2 2
438365022	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0022	2	Middle	12	0 046	0.046	0.0
438365022	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0022	2	Middle	12	0 046	0 046	0 0
438365004	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0004	2	Bottom	12	0 046	0.046	0.0
438365004	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0004	2	Bottom	12	0.046	0 045	2 2
438365023	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0023	2	Bottom	12	0 046	0.046	0 0
438365023	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0023	2	Bottom	12	0 046	0 046	0.0
438365005	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0005	3	Top	50	0.192	0 195	1 6
438365005	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0005	3	Top	50	0 192	0.194	1 0
438365024	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0024	3	Top	50	0.192	0.196	2.1
438365024	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0024	3	Top	50	0.192	0.195	1 6
438365006	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0006	3	Middle	50	0.192	0 196	2 1
438365006	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0006	3	Middle	50	0 192	0 194	1.0
438365025	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0025	3	Middle	50	0 192	0 195	1.6
438365025	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0025	3	Middle	50	0 192	0 195	1.6
438365007	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0007	3	Bottom	50	0 192	0 195	1 6
438365007	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0007	3	Bottom	50	0 192	0 194	1 0
438365026	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0026	3	Bottom	50	0 192	0.196	2 1
438365026	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0026	3	Bottom	50	0 192	0.195	1.6
438365008	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0008	4	Top	200	0.766	0 758	1 0
438365008	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0008	4	Top	200	0 766	0 749	2.2
438365027	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0027	4	Top	200	0 766	0 757	1.2
438365027	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0027	4	Top	200	0 766	0 760	0 8
438365009	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0009	4	Middle	200	0.766	0 759	0 9
438365009	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0009	4	Middle	200	0 766	0.759	0 9
438365028	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0028	4	Middle	200	0 766	0 763	0 4
438365028	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0028	4	Middle	200	0 766	0 759	0 9
438365010	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0010	4	Bottom	200	0 766	0 759	0 9
438365010	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0010	4	Bottom	200	0.766	0 758	1 0
438365029	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0029	4	Bottom	200	0.766	0 762	0 5
438365029	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0029	4	Bottom	200	0 766	0.762	0 5

PERCENT DIFFERENCE CALCULATION
Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

* Not a significant difference

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187041
[redacted]: Reference #04-023

10-Day Stability Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted], mg/mL	wt ppm Ca	Measured Concentration, wt ppm Ca	Percent Difference, %
438365011	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0002	5	Top	1	56.0	54.5	2.7
438365011	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0002	5	Top	1	56 0	54.7	2 3
438365030	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0012	5	Top	1	56.0	55 7	0 5
438365030	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0012	5	Top	1	56.0	60 4	7.9
438365012	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0003	5	Middle	1	56 0	54.5	2.7
438365012	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0003	5	Middle	1	56 0	53.4	4 6
438365031	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0013	5	Middle	1	56 0	53 8	3 9
438365031	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0013	5	Middle	1	56 0	55 8	0.4
438365013	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0004	5	Bottom	1	56.0	55.0	1.8
438365013	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0004	5	Bottom	1	56 0	52 4	6 4
438365032	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0014	5	Bottom	1	56.0	54 2	3 2
438365032	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0014	5	Bottom	1	56.0	55.8	0.4
438365014	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0005	6	Top	4	224	229	2 2
438365014	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0005	6	Top	4	224	230	2 7
438365033	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0015	6	Top	4	224	218	2.7
438365033	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0015	6	Top	4	224	223	0 4
438365015	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0006	6	Middle	4	224	233	4 0
438365015	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0006	6	Middle	4	224	219	2 2
438365034	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0016	6	Middle	4	224	226	0 9
438365034	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0016	6	Middle	4	224	230	2.7
438365016	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0007	6	Bottom	4	224	229	2.2
438365016	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0007	6	Bottom	4	224	229	2 2
438365035	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0017	6	Bottom	4	224	225	0.4
438365035	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0017	6	Bottom	4	224	228	1 8
438365017	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0008	7	Top	12	672	693	3.1
438365017	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0008	7	Top	12	672	685	1.9
438365036	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0018	7	Top	12	672	671	0.1
438365036	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0018	7	Top	12	672	680	1 2
438365018	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0009	7	Middle	12	672	697	3.7
438365018	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0009	7	Middle	12	672	721	7.3
438365037	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0019	7	Middle	12	672	663	1 3
438365037	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0019	7	Middle	12	672	702	4.5
438365019	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0010	7	Bottom	12	672	721	7 3
438365019	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0010	7	Bottom	12	672	681	1 3
438365038	25-Oct-04	25-Oct-04	02-Nov-04	RX-187041L-0020	7	Bottom	12	672	685	1.9
438365038	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0020	7	Bottom	12	672	688	2 4

PERCENT DIFFERENCE CALCULATION

Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187041
[redacted] Reference #04-023

Concentration Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted] mg/mL	wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
441944001	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0058	1	Middle	0	0 000	<2 wt ppm	*
441944002	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0059	2	Middle	12	0 046	0 045	2.2
441944003	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0060	3	Middle	50	0.193	0 189	2.1
441944004	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0061	4	Middle	200	0.767	0 754	1.7
441945001	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0079	1	Middle	0	0.000	<2 wt ppm	*
441945002	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0080	2	Middle	12	0.046	0.045	2.2
441945003	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0081	3	Middle	50	0.193	0.190	1.6
441945004	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0082	4	Middle	200	0.767	0.720	6.1
441945008	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0093	1	Middle	0	0.000	<2 wt ppm	*
441945009	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0094	2	Middle	12	0.046	0.043	6.5
441945010	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0095	3	Middle	50	0.193	0.192	0.5
441945011	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0096	4	Middle	200	0 767	0.756	1.4
443584001	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0107	1	Middle	0	0.000	<2 wt ppm	*
443584002	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0108	2	Middle	12	0.046	0.045	2.2
443584003	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0109	3	Middle	50	0.193	0 191	1.0
443584004	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0110	4	Middle	200	0.767	0 718	6.4
443584008	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0114	1	Middle	0	0.000	<2 wt ppm	*
443584009	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0115	2	Middle	12	0.046	0 045	2.2
443584010	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0116	3	Middle	50	0.193	0.191	1 0
443584011	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0117	4	Middle	200	0.767	0.748	2.5
444084001	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0128	1	Middle	0	0.000	<2 wt ppm	*
444084002	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0129	2	Middle	12	0.046	0.046	0.0
444084003	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0130	3	Middle	50	0 193	0.196	1.6
444084004	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0131	4	Middle	200	0 767	0 762	0.7

PERCENT DIFFERENCE CALCULATION
Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

* Not a significant difference

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187041
[redacted] Reference #04-023

Concentration Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted], mg/mL	wt ppm Ca	Measured Concentration, wt ppm Ca	Percent Difference, %
441944005	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0062	5	Middle	1	56.0	53.4	4 6
441944006	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0063	6	Middle	4	224	224	0 0
441944007	15-Nov-04	16-Nov-04	26-Nov-04	RX-187041L-0064	7	Middle	12	672	675	0 4
441945005	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0083	5	Middle	1	56.0	54.2	3.2
441945006	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0084	6	Middle	4	224	222	0.9
441945007	15-Nov-04	22-Nov-04	26-Nov-04	RX-187041L-0085	7	Middle	12	672	671	0.1
441945012	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0097	5	Middle	1	56.0	54.7	2.3
441945013	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0098	6	Middle	4	224	225	0.4
441945014	22-Nov-04	23-Nov-04	26-Nov-04	RX-187041L-0099	7	Middle	12	672	672	0.0
443584005	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0111	5	Middle	1	56.0	53 0	5.4
443584006	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0112	6	Middle	4	224	216	3 6
443584007	22-Nov-04	29-Nov-04	10-Dec-04	RX-187041L-0113	7	Middle	12	672	634	5 7
443584012	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0118	5	Middle	1	56.0	52 0	7.1
443584013	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0119	6	Middle	4	224	218	2.7
443584014	29-Nov-04	30-Nov-04	10-Dec-04	RX-187041L-0120	7	Middle	12	672	655	2 5
444084005	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0132	5	Middle	1	56.0	53.1	5 2
444084006	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0133	6	Middle	4	224	228	1 8
444084007	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0134	7	Middle	12	672	691	2 8

PERCENT DIFFERENCE CALCULATION

Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN DOSING SUSPENSIONS
WIL Research #WIL-187041
[redacted]: Reference #04-023

Duplicate Analysis

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	Aliquot Phase	Estimated Concentration Amount of test substance	Amount of Ca	Measured Concentration, amount of Ca	Relative Percent Difference, %
438365016	25-Oct-04	25-Oct-04	2-Nov-04	RX-187041L-0007	6	Bottom	4 mg/mL [redacted]	224 wt ppm	229 wt ppm	
438365016 Dup	25-Oct-04	25-Oct-04	2-Nov-04	RX-187041L-0007	6	Bottom	4 mg/mL	224 wt ppm	229 wt ppm	0 0
438365032	25-Oct-04	25-Oct-04	2-Nov-04	RX-187041L-0014	5	Bottom	1 mg/mL	56.0 wt ppm	54 2 wt ppm	
438365032 Dup	25-Oct-04	25-Oct-04	2-Nov-04	RX-187041L-0014	5	Bottom	1 mg/mL	56.0 wt ppm	54 1 wt ppm	0.2
438365010	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0010	4	Bottom	200 mg/mL	0.766 wt%	0 758 wt%	
438365010 Dup	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0010	4	Bottom	200 mg/mL	0.766 wt%	0 755 wt%	0.4
438365031	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0013	5	Middle	1 mg/mL	56.0 wt ppm	55 8 wt ppm	
438365031 Dup	25-Oct-04	25-Oct-04	12-Nov-04	RX-187041L-0013	5	Middle	1 mg/mL	56.0 wt ppm	55 7 wt ppm	0 2
444084007	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0134	7	Middle	12 mg/mL	672 wt ppm	691 wt ppm	
444084007 Dup	29-Nov-04	07-Dec-04	14-Dec-04	RX-187041L-0134	7	Middle	12 mg/mL	672 wt ppm	692 wt ppm	0 1

RELATIVE PERCENT DIFFERENCE CALCULATION

Absolute value (((First Measured Concentration-Duplicate Measured Concentration)/((First Measured Concentration+Duplicate Measured Concentration)/2))*100)

APPENDIX C

Animal Room Environmental Conditions

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO.:WIL- 187041 TEMPERATURE/HUMIDITY - DAILY SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187041 DATE IN: 11/02/04 TIME IN: 11:00
DATE OUT: 12/08/04 TIME OUT: 11:00

ROOM SPECIFICATIONS: B ROOM 23 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
02-Nov-04	70.6	21.4	44.4
03-Nov-04	70.4	21.4	37.2
04-Nov-04	70.5	21.4	39.8
05-Nov-04	70.5	21.4	36.0
06-Nov-04	70.5	21.4	35.8
07-Nov-04	70.5	21.4	38.3
08-Nov-04	70.6	21.4	35.3
09-Nov-04	70.6	21.4	35.9
10-Nov-04	70.6	21.4	36.3
11-Nov-04	70.5	21.4	37.2
12-Nov-04	70.6	21.4	37.3
13-Nov-04	70.5	21.4	36.8
14-Nov-04	70.4	21.4	37.0
15-Nov-04	70.4	21.3	38.0
16-Nov-04	70.6	21.4	39.5
17-Nov-04	70.4	21.3	42.0
18-Nov-04	70.7	21.5	44.6
19-Nov-04	70.6	21.5	44.7
20-Nov-04	70.6	21.4	42.4
21-Nov-04	70.7	21.5	40.6
22-Nov-04	70.6	21.4	39.2
23-Nov-04	70.6	21.5	41.9
24-Nov-04	70.8	21.6	45.6

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.08
2/16/05 07:14

STUDY SPECIFICATIONS: 187041 DATE IN: 11/02/04 TIME IN: 11:00
DATE OUT: 12/08/04 TIME OUT: 11:00

ROOM SPECIFICATIONS: B ROOM 23 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
25-Nov-04	70.5	21.4	38.1
26-Nov-04	70.5	21.4	38.1
27-Nov-04	70.4	21.3	38.1
28-Nov-04	70.6	21.4	37.6
29-Nov-04	70.7	21.5	38.0
30-Nov-04	70.5	21.4	39.9
01-Dec-04	70.7	21.5	39.5
02-Dec-04	70.4	21.3	39.0
03-Dec-04	70.7	21.5	37.6
04-Dec-04	70.6	21.4	37.8
05-Dec-04	70.7	21.5	38.4
06-Dec-04	70.5	21.4	41.8
07-Dec-04	70.7	21.5	46.6
08-Dec-04	70.6	21.4	39.3

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.6	70.4	70.8
TEMPERATURE °C	21.4	21.3	21.6
HUMIDITY (%RH)	39.3	35.3	46.6
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

ROOM SPECIFICATIONS:	B ROOM 23				
SPECIES:	RAT				
LOW TEMPERATURE:	66.0	DATE IN:	11/02/04		
HIGH TEMPERATURE:	76.0	TIME IN:	11:00		
LOW HUMIDITY:	30.0	DATE OUT:	12/08/04		
HIGH HUMIDITY:	70.0	TIME OUT:	11:00		

ROOM B ROOM 23 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.6	39.3
MIN	68.2	33.0
MAX	72.8	58.3
SD	1.29	3.62
N SAMPLES	863	863
FIRST DAY	11/02/04	
LAST DAY	12/08/04	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

STUDY 187041 SUMMARY

MEAN	70.6	39.3
MIN	68.2	33.0
MAX	72.8	58.3
SD	1.29	3.62
N SAMPLES	863	863
FIRST DAY	11/02/04	
LAST DAY	12/08/04	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

APPENDIX D

Clinical Pathology Methods, Procedures And References

CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Immunoassay- DPC Immulite®

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

References:

Immulite®. Diagnostics Products Corporation. Package Insert.

APPENDIX E

WIL Reproductive Historical Control Data [Crl:CD®(SD) Rats]

WIL Reproductive Historical Control Data
Crl:CD(SD) Rat*

Grand Mean Summary
Parental and Neonatal Observations

ENDPOINT	TOTAL	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
TOTAL NUMBER OF DATASETS	**107**							
NO. MALES IN CONTROL GROUP	2141	27.1	3.95	79	15	40	25	30
MALE MATING INDEX (%)		96.3	4.72	77	72.0	100.0	95.7	100.0
MALE FERTILITY INDEX (%)		89.6	8.10	79	56.7	100.0	86.5	95.7
NO. FEMALES IN CONTROL GROUP	2815	26.6	3.57	106	15	40	25	30
FEMALE MATING INDEX (%)		97.5	3.60	83	84.0	100.0	96.0	100.0
FEMALE FERTILITY INDEX (%)		92.0	7.47	105	56.7	100.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	1755	27.0	3.10	65	22	40	25	30
NO. THAT DELIVERED	1583	24.4	3.22	65	17	38	23	26
NO. THAT DID NOT DELIVER	172	2.6	2.44	65	0	13	1	3
NO. THAT DIED	13	0.1	0.36	106	0	2	0	0
NO. WITH TOTAL LITTER LOSS	13	0.2	0.44	65	0	2	0	0
NO. WITH DYSTOCIA	6	0.1	0.29	65	0	1	0	0
MEAN PRE-COITAL INTERVAL (DAYS)		3.0	0.56	81	1.8	4.7	2.6	3.3
MEAN GESTATION LENGTH (DAYS)		21.8	0.15	65	21.6	22.3	21.7	21.9
MEAN NO. PUPS BORN		14.5	0.94	65	12.0	16.5	13.7	15.0
MEAN VIABLE LITTER SIZE ON PND 0		14.2	0.94	65	11.6	16.0	13.4	14.9
PUP SEX RATIO								
MEAN % MALE		49.7	2.83	65	42.7	56.6	47.7	51.8
MEAN % FEMALE		50.3	2.86	65	43.4	57.3	48.2	52.3
MEAN NO. OF FORMER IMPLANTATION SITES AT WEANING		15.3	0.83	58	13.7	17.1	14.7	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING		0.8	0.21	58	0.3	1.3	0.7	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY		15.5	0.90	40	13.8	16.8	15.1	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)		4.5	0.41	59	4.0	5.8	4.2	4.6
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM		96.4	23.11	13	50.4	132.9	87.8	107.8

EXPERIMENTAL START DATE OF OLDEST DATASET 6/17/96
DATE OF LAST NECROPSY OF MOST RECENT DATASET 2/3/04

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN NO. PUPS BORN	14.5	0.94	65	12.0	16.5	13.7	15.0
PUP SURVIVAL INDICES (% PER LITTER)							
PND 0 (RELATIVE TO NO. BORN)	98.0	1.42	65	92.3	100.0	97.4	99.0
PND 0 TO PND 1	99.0	1.24	65	94.3	100.0	98.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	1.08	64	93.5	100.0	98.8	99.6
PND 4 (AFTER SELECTION) TO PND 7	99.5	0.94	57	95.8	100.0	99.5	100.0
PND 7 TO PND 14	99.4	1.38	53	93.5	100.0	99.5	100.0
PND 14 TO PND 21	99.7	0.97	54	94.7	100.0	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.1	2.01	62	91.3	99.3	95.0	97.5
PND 4 (AFTER SELECTION) TO PND 21	98.7	1.96	53	91.1	100.0	98.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)							
PND 1	7.1	0.25	65	6.5	7.6	6.9	7.2
PND 4 (BEFORE SELECTION)	9.9	0.59	64	8.6	11.4	9.5	10.4
PND 7	15.4	1.34	57	11.7	17.8	15.1	16.4
PND 14	31.0	3.50	53	22.5	36.5	29.2	33.1
PND 21	48.7	5.47	54	34.9	58.0	45.4	52.1
PND 28	81.5	8.23	18	65.4	94.0	74.6	87.6
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)							
PND 1	6.7	0.25	65	6.1	7.2	6.5	6.8
PND 4 (BEFORE SELECTION)	9.4	0.57	64	8.1	10.9	8.9	9.7
PND 7	14.6	1.32	57	11.0	17.1	14.1	15.5
PND 14	29.8	3.41	53	21.2	35.1	27.6	32.1
PND 21	46.6	5.07	54	33.3	55.6	43.9	49.7
PND 28	75.3	7.25	18	59.8	86.2	69.0	79.5
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.4365	0.0509	21	1.3451	1.5175	1.4000	1.4775
SPLEEN	0.1938	0.0343	21	0.1189	0.2480	0.1755	0.2211
THYMUS GLAND	0.1933	0.0269	21	0.1392	0.2446	0.1723	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.3886	0.0459	21	1.2903	1.4597	1.3623	1.4242
SPLEEN	0.1923	0.0321	21	0.1182	0.2408	0.1722	0.2200
THYMUS GLAND	0.1969	0.0281	21	0.1338	0.2479	0.1778	0.2113

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)							
MALE	4.6	0.92	10	2.5	5.7	4.3	5.3
FEMALE	2.7	0.70	10	1.3	3.9	2.4	3.2
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.8	1.83	41	41.6	49.0	44.0	45.8
MEAN BODY WEIGHT AT ACQUISITION (G)	228.4	10.21	38	210.5	248.6	221.9	235.5
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	1.39	41	31.7	38.8	32.7	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	112.4	7.79	38	99.0	133.0	107.0	117.6
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)							
MALE	5.1	0.08	7	5.0	5.2	5.0	5.1
FEMALE	5.2	0.10	7	5.0	5.3	5.1	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)							
MALE	4.0	0.08	6	4.0	4.2	4.0	4.0
FEMALE	4.0	0.08	6	4.0	4.2	4.0	4.0
MEAN DAY OF EYE OPENING (PND)							
MALE	16.1	1.35	6	15.1	18.7	15.3	16.0
FEMALE	16.0	1.37	6	14.8	18.6	15.2	16.0
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)							
MALE	14.9	NA	1	14.9	14.9	14.9	14.9
FEMALE	14.9	NA	1	14.9	14.9	14.9	14.9
MEAN DAY OF HAIR GROWTH (PND)							
MALE	12.4	0.99	2	11.7	13.1	12.1	12.8
FEMALE	12.4	0.85	2	11.8	13.0	12.1	12.7
MEAN DAY OF INCISOR ERUPTION (PND)							
MALE	9.8	0.44	3	9.3	10.1	9.7	10.1
FEMALE	9.7	0.38	3	9.3	10.0	9.6	10.0

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ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHT (G)	2.20	0.295	37	1.76	2.80	1.95	2.30
MEAN RIGHT TESTIS WEIGHT (G)	1.79	0.067	55	1.65	1.93	1.73	1.84
MEAN LEFT TESTIS WEIGHT (G)	1.79	0.065	55	1.67	1.92	1.74	1.84
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.73	0.039	55	0.64	0.81	0.71	0.75
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.040	55	0.62	0.80	0.70	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3249	0.0227	55	0.2629	0.3693	0.3159	0.3366
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3282	0.0206	55	0.2714	0.3712	0.3183	0.3413
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)							
LEFT TESTIS	86.8	9.3	49	69.6	106.9	79.2	93.2
LEFT EPIDIDYMIS	460.7	54.6	49	343.6	640.1	421.3	477.0
LEFT CAUDA EPIDIDYMIS	677.5	50.3	4	618.7	738.9	651.8	701.9
MEAN SPERM PRODUCTION RATE							
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	1.5	49	11.4	17.5	13.0	15.3
% MOTILE SPERM	84.6	4.4	53	71.3	91.9	82.0	87.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)							
NORMAL	98.9	1.3	50	91.9	99.9	98.8	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.6	50	0.0	3.4	0.2	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.7	50	0.0	4.7	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)							
NORMAL	198.0	2.6	50	183.8	200.0	197.9	199.3
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.3	1.7	50	0.0	10.0	0.4	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	1.5	50	0.0	9.4	0.2	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0

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DATASET NO.	1	2	3	4	5
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
MALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
FEMALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	30
NO. THAT DELIVERED	25	17	28	27	28
NO. THAT DID NOT DELIVER	5	13	2	3	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	0
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	3.0	2.3	2.4	2.2
MEAN GESTATION LENGTH (DAYS)	22.3	22.0	21.8	21.8	21.8
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
MEAN VIABLE LITTER SIZE ON PND 0	11.6	12.5	13.5	13.4	13.0
PUP SEX RATIO					
MEAN % MALE	49.7	52.1	51.1	51.8	52.1
MEAN % FEMALE	50.3	47.9	48.9	48.2	47.9
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.5	14.2	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.9	0.7	1.2
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	4.2	4.1	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	11/19/97	2/23/98	11/3/98	2/3/99	9/24/98
DATE OF LAST NECROPSY	4/7/98	8/18/98	3/16/99	7/23/99	2/5/99
ROUTE	Diet	Diet	Diet	Diet	Inhalation
VEHICLE	Basal Feed	Basal Feed	Basal Feed	Basal Feed	Filtered Air

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DATASET NO.	6	7	8	9	10
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	29	30	30
NO. THAT DELIVERED	29	24	26	28	28
NO. THAT DID NOT DELIVER	1	6	3	2	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	1	1	0	0	0
NO. WITH DYSTOCIA	0	1	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.5	2.6	2.7	2.7	2.8
MEAN GESTATION LENGTH (DAYS)	21.7	22.0	21.8	22.1	21.8
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
MEAN VIABLE LITTER SIZE ON PND 0	13.1	14.5	12.9	12.9	13.1
PUP SEX RATIO					
MEAN % MALE	48.6	49.2	48.6	44.0	45.0
MEAN % FEMALE	51.4	50.8	51.4	56.0	55.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	15.7	14.0	13.7	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	0.8	0.6	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.1	4.2	4.3	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	96.7	54.4	98.1	---	85.5
EXPERIMENTAL START DATE	12/24/98	2/9/99	5/27/99	11/23/98	2/25/99
DATE OF LAST NECROPSY	6/11/99	7/9/99	11/12/99	4/7/99	8/19/99
ROUTE	Inhalation	Gavage	Gavage	Diet	Diet
VEHICLE	Filtered Air	DI Water	DI Water	Basal Feed	Basal Feed

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DATASET NO.	11	12	13	14	15
NO. MALES IN CONTROL GROUP	30	30	30	30	---
MALE MATING INDEX (%)	96.6	96.7	93.3	100.0	---
MALE FERTILITY INDEX (%)	89.7	96.7	86.7	100.0	---
NO. FEMALES IN CONTROL GROUP	30	30	30	30	25
FEMALE MATING INDEX (%)	96.7	96.7	93.3	100.0	---
FEMALE FERTILITY INDEX (%)	90.0	96.7	86.7	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	25
NO. THAT DELIVERED	27	29	26	30	25
NO. THAT DID NOT DELIVER	3	1	4	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	1
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.7	3.3	2.6	2.0	---
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	21.8	21.6	21.8
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
MEAN VIABLE LITTER SIZE ON PND 0	13.3	13.1	13.2	14.4	14.4
PUP SEX RATIO					
MEAN % MALE	56.4	50.6	51.3	50.0	49.0
MEAN % FEMALE	43.6	49.4	48.7	50.0	51.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	---	15.6	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	---	0.8	0.8
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	87.8	96.9	---	---	---
EXPERIMENTAL START DATE	1/14/97	4/15/97	4/15/97	11/4/97	8/31/98
DATE OF LAST NECROPSY	6/3/97	11/29/97	11/29/97	11/25/97	10/9/98
ROUTE	Inhalation	Inhalation	Inhalation	Inhalation	Gavage
VEHICLE	Filtered Air	Filtered Air	Filtered Air	Filtered Air	0.4% MC

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DATASET NO.	16	17	18	19	20
NO. MALES IN CONTROL GROUP	25	24	---	25	25
MALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	92.0	95.8	---	100.0	96.0
NO. FEMALES IN CONTROL GROUP	25	24	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	95.8	92.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	24	25	---	---
NO. THAT DELIVERED	23	23	23	---	---
NO. THAT DID NOT DELIVER	2	1	2	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	---
NO. WITH DYSTOCIA	0	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	2.4	---	2.8	2.7
MEAN GESTATION LENGTH (DAYS)	21.8	21.6	21.8	---	---
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
MEAN VIABLE LITTER SIZE ON PND 0	13.9	15.0	14.7	---	---
PUP SEX RATIO					
MEAN % MALE	52.1	49.7	51.9	---	---
MEAN % FEMALE	47.9	50.3	48.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.1	15.9	15.7	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	0.9	1.0	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	16.4	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/14/98	7/7/98	9/23/98	10/27/98	3/29/99
DATE OF LAST NECROPSY	2/1/99	10/1/98	11/23/98	3/1/99	5/4/99
ROUTE	Gavage	Diet	Gavage	Gavage	Gavage
VEHICLE	0.4% MC	Basal Feed	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80

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DATASET NO.	21	22	23	24	25
NO. MALES IN CONTROL GROUP	---	25	---	25	---
MALE MATING INDEX (%)	---	96.0	---	72.0	---
MALE FERTILITY INDEX (%)	---	88.0	---	72.0	---
NO. FEMALES IN CONTROL GROUP	25	25	22	25	25
FEMALE MATING INDEX (%)	---	96.0	---	84.0	---
FEMALE FERTILITY INDEX (%)	100.0	88.0	95.5	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25	22	---	25
NO. THAT DELIVERED	25	22	21	---	25
NO. THAT DID NOT DELIVER	0	3	1	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	0
NO. WITH DYSTOCIA	0	0	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	2.2	---	3.5	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.8	21.8	---	22.0
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	13.8	14.9	14.6	---	14.7
PUP SEX RATIO					
MEAN % MALE	47.7	49.8	47.7	---	47.7
MEAN % FEMALE	52.3	50.2	52.3	---	52.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.9	15.4	---	15.7
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.8	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	13.9	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.2	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	10/26/98	11/17/98	1/12/99	2/3/99	7/27/98
DATE OF LAST NECROPSY	12/13/98	4/13/99	3/1/99	6/15/99	9/12/98
ROUTE	SubQ	SubQ	SubQ	SubQ	Gavage
VEHICLE	20 mM Na Phosphate	21 mM Na Phosphate	Sponsor-Supplied	Sponsor-Supplied	0.75% MC

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DATASET NO.	26	27	28	29	30
NO. MALES IN CONTROL GROUP	25	---	---	25	---
MALE MATING INDEX (%)	96.0	---	---	96.0	---
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	96.0	---
FEMALE FERTILITY INDEX (%)	92.0	88.0	96.0	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	25	25	25
NO. THAT DELIVERED	---	22	23	24	25
NO. THAT DID NOT DELIVER	---	3	2	1	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	0	0
NO. WITH DYSTOCIA	---	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	---	---	2.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.7	21.7	21.7	21.7
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	15.9	14.7	15.0
PUP SEX RATIO					
MEAN % MALE	---	50.8	54.0	50.8	48.5
MEAN % FEMALE	---	49.2	46.0	49.2	51.5
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.8	16.7	---	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.6	0.5	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	13.8	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/18/98	9/13/99	8/2/99	8/17/99	8/9/99
DATE OF LAST NECROPSY	12/29/98	10/31/99	9/12/99	1/10/00	9/25/99
ROUTE	Gavage	Gavage	Gavage	Gavage	Intranasal
VEHICLE	0.75% MC	0.1 M Na Phosphate	0.4% MC	0.4% MC	MC

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DATASET NO.	31	32	33	34	35
NO. MALES IN CONTROL GROUP	25	40	---	---	40
MALE MATING INDEX (%)	82.6	97.5	---	---	---
MALE FERTILITY INDEX (%)	73.9	95.0	---	---	75.0
NO. FEMALES IN CONTROL GROUP	25	40	25	25	40
FEMALE MATING INDEX (%)	95.8	97.5	100.0	100.0	---
FEMALE FERTILITY INDEX (%)	87.5	95.0	92.0	96.0	---
NO. FEMALES SELECTED TO DELIVER	---	40	---	---	---
NO. THAT DELIVERED	---	38	---	---	---
NO. THAT DID NOT DELIVER	---	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	---	---	---
NO. WITH DYSTOCIA	---	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	2.8	2.6	3.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.6	---	---	---
MEAN NO. PUPS BORN	---	15.4	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	---	48.8	---	---	---
MEAN % FEMALE	---	51.2	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.9	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.1	---	15.4	15.6	16.5
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/31/99	6/17/96	9/29/98	11/6/98	3/4/99
DATE OF LAST NECROPSY	1/11/00	11/15/96	11/24/98	12/31/98	4/14/99
ROUTE	Intranasal	Inhalation	Gavage	Gavage	Dermal
VEHICLE	MC	Filtered Air	1% Avicel-5% Tween 80 50mM Sodium Acetate	0.5% Aqueous MC	Fire Pond Water

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DATASET NO.	36	37	38	39	40
NO. MALES IN CONTROL GROUP	20	25	---	25	25
MALE MATING INDEX (%)	---	96.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	95.0	88.0	---	92.0	100.0
NO. FEMALES IN CONTROL GROUP	20	25	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	92.0	96.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	---	25	25	---
NO. THAT DELIVERED	---	---	24	23	---
NO. THAT DID NOT DELIVER	---	---	1	2	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	1	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.2	---	2.6	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	21.6	21.7	---
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	14.8	14.4	---
PUP SEX RATIO					
MEAN % MALE	---	---	55.2	50.9	---
MEAN % FEMALE	---	---	44.8	49.1	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	15.4	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.9	15.3	---	---	15.8
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/15/99	4/9/99	6/15/99	6/17/96	11/18/99
DATE OF LAST NECROPSY	6/24/99	6/17/99	7/31/99	11/17/99	1/28/00
ROUTE	Dermal	Gavage	Gavage	Untreated	Untreated
VEHICLE	Fire Pond Water	10mM Lactic Acid in DI Water	5% Acacia	Not Applicable	Not Applicable

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DATASET NO.	41	42	43	44	45
NO. MALES IN CONTROL GROUP	---	24	35	15	30
MALE MATING INDEX (%)	---	95.7	97.1	100.0	100.0
MALE FERTILITY INDEX (%)	---	91.3	91.4	86.7	96.7
NO. FEMALES IN CONTROL GROUP	25	24	35	15	30
FEMALE MATING INDEX (%)	---	100.0	97.1	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	95.7	94.3	86.7	96.7
NO. FEMALES SELECTED TO DELIVER	25	23	---	---	30
NO. THAT DELIVERED	24	21	---	---	28
NO. THAT DID NOT DELIVER	1	2	---	---	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	1
NO. WITH TOTAL LITTER LOSS	0	0	---	---	0
NO. WITH DYSTOCIA	0	0	---	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.3	2.2	2.2	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	21.8	---	---	21.7
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	15.5	15.0	---	---	14.7
PUP SEX RATIO					
MEAN % MALE	53.1	47.3	---	---	46.7
MEAN % FEMALE	46.9	52.7	---	---	53.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.3	16.0	---	---	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	---	---	0.6
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	15.4	16.6	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.3	---	---	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/21/99	11/3/99	10/1/99	1/12/00	10/1/99
DATE OF LAST NECROPSY	11/7/99	3/9/00	1/17/00	8/17/00	2/11/00
ROUTE	Gavage	Untreated	Dermal	Untreated Recovery	Gavage
VEHICLE	10% Aqueous Acacia	Not Applicable	Sponsor-Supplied Placebo	Not Applicable	Citric Acid Solution

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DATASET NO.	46	47	48	49	50
NO. MALES IN CONTROL GROUP	29	25	25	24	25
MALE MATING INDEX (%)	93.1	100.0	96.0	100.0	96.0
MALE FERTILITY INDEX (%)	79.3	84.0	92.0	87.5	92.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	93.1	100.0	96.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	79.3	84.0	92.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	29	---	25	25	---
NO. THAT DELIVERED	23	---	23	22	---
NO. THAT DID NOT DELIVER	6	---	2	3	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	---
NO. WITH DYSTOCIA	0	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	4.3	2.6	3.4	3.8	2.9
MEAN GESTATION LENGTH (DAYS)	21.8	---	22.0	22.0	---
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
MEAN VIABLE LITTER SIZE ON PND 0	14.7	---	14.4	14.5	---
PUP SEX RATIO					
MEAN % MALE	48.3	---	53.7	44.7	---
MEAN % FEMALE	51.7	---	46.3	56.3	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.7	---	15.3	15.5	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.3	0.5	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.2	---	---	16.3
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.4	4.1	4.2	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	107.8	105.6	---
EXPERIMENTAL START DATE	1/25/00	10/25/99	11/3/99	2/29/00	11/19/99
DATE OF LAST NECROPSY	6/22/00	12/30/99	3/20/00	7/25/00	1/21/00
ROUTE	Gavage	SubQ	Inhalation	Inhalation	Intranasal
VEHICLE	Citric Acid Solution	Sponsor-Supplied Placebo	Filtered Air	Filtered Air	Sponsor-Supplied Placebo

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DATASET NO.	51	52	53	54	55
NO. MALES IN CONTROL GROUP	25	25	30	30	25
MALE MATING INDEX (%)	96.0	92.0	93.3	93.3	96.0
MALE FERTILITY INDEX (%)	88.0	92.0	83.3	80.0	92.0
NO. FEMALES IN CONTROL GROUP	25	25	30	30	25
FEMALE MATING INDEX (%)	100.0	100.0	93.3	93.3	96.0
FEMALE FERTILITY INDEX (%)	92.0	100.0	83.3	80.0	92.0
NO. FEMALES SELECTED TO DELIVER	---	---	30	30	---
NO. THAT DELIVERED	---	---	25	24	---
NO. THAT DID NOT DELIVER	---	---	5	6	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	0	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.6	3.6	3.5	3.7	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	22.0	21.6	---
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	13.0	13.9	---
PUP SEX RATIO					---
MEAN % MALE	---	---	49.7	50.3	---
MEAN % FEMALE	---	---	50.3	49.7	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.0	15.3	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.8	1.0	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.2	16.7	---	---	15.9
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.3	---	4.4	4.9	4.5
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	114.9	---
EXPERIMENTAL START DATE	1/14/00	1/25/00	2/4/00	5/30/00	2/7/00
DATE OF LAST NECROPSY	3/20/00	3/8/00	6/16/00	10/23/00	3/19/00
ROUTE	Gavage	Dermal	Diet	Diet	Gavage
VEHICLE	0.5% CMC	Sponsor-Supplied Placebo	Basal Feed	Basal Feed	0.5% MC-0.10% Tween 80

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DATASET NO.	56	57	58	59	60
NO. MALES IN CONTROL GROUP	25	---	25	25	---
MALE MATING INDEX (%)	95.8	---	100.0	84.0	---
MALE FERTILITY INDEX (%)	95.8	---	96.0	84.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	95.8	---	100.0	84.0	---
FEMALE FERTILITY INDEX (%)	95.8	92.0	96.0	84.0	96.0
NO. FEMALES SELECTED TO DELIVER	---	25	---	---	25
NO. THAT DELIVERED	---	23	---	---	24
NO. THAT DID NOT DELIVER	---	2	---	---	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	---	---	0
NO. WITH DYSTOCIA	---	0	---	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.6	---	2.9	2.4	---
MEAN GESTATION LENGTH (DAYS)	---	21.8	---	---	21.8
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	---	---	16.0
PUP SEX RATIO					
MEAN % MALE	---	50.4	---	---	52.0
MEAN % FEMALE	---	49.6	---	---	48.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	16.0	---	---	17.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.9	---	---	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.3	---	13.9	16.1	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.0	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/7/00	2/8/00	2/7/00	3/31/00	5/15/00
DATE OF LAST NECROPSY	6/6/00	3/26/00	7/11/00	6/12/00	7/4/00
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.5% MC-0.10% Tween 80	0.5% CMC	0.5% CMC	0.5% CMC	0.5% Aqueous CMC

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DATASET NO.	61	62	63	64	65
NO. MALES IN CONTROL GROUP	25	----	23	25	25
MALE MATING INDEX (%)	100.0	----	95.7	100.0	100.0
MALE FERTILITY INDEX (%)	100.0	----	91.3	84.0	100.0
NO. FEMALES IN CONTROL GROUP	25	25	23	25	25
FEMALE MATING INDEX (%)	100.0	---	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	96.0	91.3	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	23	---	---
NO. THAT DELIVERED	---	24	20	---	---
NO. THAT DID NOT DELIVER	---	1	3	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	---	---
NO. WITH DYSTOCIA	---	1	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	----	3.1	---	2.1
MEAN GESTATION LENGTH (DAYS)	---	21.8	21.9	---	---
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.0	13.1	---	---
PUP SEX RATIO					
MEAN % MALE	---	50.5	51.8	---	---
MEAN % FEMALE	---	49.5	48.2	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.7	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.0	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.0	---	---	15.4	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.3	4.1	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	6/28/00	7/4/00	8/15/00	8/25/00	9/25/00
DATE OF LAST NECROPSY	10/12/00	8/21/00	12/21/00	10/6/00	11/10/00
ROUTE	Untreated	Gavage	Untreated	Diet	Diet
VEHICLE	Not Applicable	10% Aqueous Acacia	Not Applicable	Basal Feed	Basal Feed

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DATASET NO.	66	67	68	69	70
NO. MALES IN CONTROL GROUP	---	25	25	25	---
MALE MATING INDEX (%)	----	100.0	92.0	96.0	---
MALE FERTILITY INDEX (%)	----	87.5	80.0	92.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	---	100.0	92.0	96.0	---
FEMALE FERTILITY INDEX (%)	76.0	88.0	80.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	23
NO. THAT DELIVERED	19	---	20	---	23
NO. THAT DID NOT DELIVER	6	---	5	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	2
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	----	3.8	2.7	2.2	---
MEAN GESTATION LENGTH (DAYS)	21.9	---	22.0	---	22.0
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
MEAN VIABLE LITTER SIZE ON PND 0	14.0	---	14.6	---	14.3
PUP SEX RATIO					
MEAN % MALE	46.9	---	51.9	---	51.2
MEAN % FEMALE	53.1	---	48.1	---	48.8
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.3	---	15.4	---	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.7	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.6	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.2	4.8	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/22/00	10/4/00	10/27/00	12/5/00	1/19/01
DATE OF LAST NECROPSY	10/8/00	1/23/01	3/3/01	1/31/01	3/6/01
ROUTE	Gavage	Untreated	Gavage	IV	Gavage
VEHICLE	Aqueous 10% Lactic Acid	Not Applicable	Sesame Oil	Saline	DI Water

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DATASET NO.	71	72	73	74	75
NO. MALES IN CONTROL GROUP	23	---	25	25	40
MALE MATING INDEX (%)	95.5	---	88.0	96.0	97.5
MALE FERTILITY INDEX (%)	90.9	---	84.0	87.5	90.0
NO. FEMALES IN CONTROL GROUP	23	25	25	25	40
FEMALE MATING INDEX (%)	95.7	---	92.0	100.0	97.5
FEMALE FERTILITY INDEX (%)	91.3	100.0	88.0	92.0	90.0
NO. FEMALES SELECTED TO DELIVER	23	25	---	---	---
NO. THAT DELIVERED	21	25	---	---	---
NO. THAT DID NOT DELIVER	2	0	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	---	---	---
NO. WITH DYSTOCIA	0	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.3	---	3.1	3.1	2.7
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	---	---	---
MEAN NO. PUPS BORN	12.6	15.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	12.6	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	47.6	50.5	---	---	---
MEAN % FEMALE	52.4	49.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	16.2	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.3	0.7	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.3	16.6	16.6
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.4	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/3/01	2/19/01	3/28/01	2/20/01	3/20/01
DATE OF LAST NECROPSY	7/2/01	4/2/01	7/10/01	4/26/01	7/5/01
ROUTE	Untreated	Gavage	Untreated	Gavage	Gavage
VEHICLE	Not Applicable	Reverse Osmosis-Purified Water	Not Applicable	Reverse Osmosis-Purified Water	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water

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DATASET NO.	76	77	78	79	80
NO. MALES IN CONTROL GROUP	---	30	29	---	30
MALE MATING INDEX (%)	---	100.0	96.6	---	100.0
MALE FERTILITY INDEX (%)	---	96.7	86.2	---	93.3
NO. FEMALES IN CONTROL GROUP	25	30	30	25	30
FEMALE MATING INDEX (%)	96.0	100.0	96.6	92.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	96.7	86.2	92.0	93.3
NO. FEMALES SELECTED TO DELIVER	---	30	29	---	---
NO. THAT DELIVERED	---	29	25	---	---
NO. THAT DID NOT DELIVER	---	1	4	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	---	2	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.1	2.7	2.6	3.4	2.8
MEAN GESTATION LENGTH (DAYS)	---	21.6	21.8	---	---
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.2	13.9	---	---
PUP SEX RATIO					
MEAN % MALE	---	51.2	49.2	---	---
MEAN % FEMALE	---	48.8	50.8	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.6	15.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	0.9	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.6	---	---	14.9	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.5	4.9	5.5	5.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	132.9	---	---
EXPERIMENTAL START DATE	4/20/01	6/12/01	10/4/01	6/15/01	7/12/01
DATE OF LAST NECROPSY	6/11/01	10/22/01	3/8/02	7/30/01	10/5/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water	0.5% MC

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DATASET NO.	81	82	83	84	85
NO. MALES IN CONTROL GROUP	25	25	25	25	25
MALE MATING INDEX (%)	92.0	92.0	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	84.0	92.0	100.0	91.7	100.0
NO. FEMALES IN CONTROL GROUP	25	25	25	24	25
FEMALE MATING INDEX (%)	100.0	96.0	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	88.0	92.0	100.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	25	---	---	---
NO. THAT DELIVERED	20	23	---	---	---
NO. THAT DID NOT DELIVER	5	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	1	0	0	0
NO. WITH TOTAL LITTER LOSS	1	1	---	---	---
NO. WITH DYSTOCIA	0	1	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.8	4.7	2.8	2.5	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	22.0	---	---	---
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	14.3	12.7	---	---	---
PUP SEX RATIO					
MEAN % MALE	46.6	47.1	---	---	---
MEAN % FEMALE	53.4	52.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	14.3	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.8	15.1	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.8	4.9	5.2	---	5.0
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	50.4	---	---	---
EXPERIMENTAL START DATE	8/6/01	11/28/01	8/6/01	9/7/01	7/17/01
DATE OF LAST NECROPSY	12/10/01	4/27/02	9/18/01	11/21/01	10/16/01
ROUTE	Inhalation/ Gavage	Inhalation/ Gavage	Gavage	Gavage	Gavage
VEHICLE	Filtered Air/ Olive Oil	Filtered Air/ Olive Oil	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	PEG 1000/ Carbowax PEG 400 in DI Water

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DATASET NO.	86	87	88	89	90
NO. MALES IN CONTROL GROUP	---	30	30	25	25
MALE MATING INDEX (%)	---	86.7	96.7	100.0	100.0
MALE FERTILITY INDEX (%)	---	73.3	73.3	96.0	100.0
NO. FEMALES IN CONTROL GROUP	25	30	30	25	25
FEMALE MATING INDEX (%)	100.0	86.7	96.7	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	73.3	73.3	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	30	30	---	---
NO. THAT DELIVERED	---	22	22	---	---
NO. THAT DID NOT DELIVER	---	8	8	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	2.8	4.0	2.5	2.6
MEAN GESTATION LENGTH (DAYS)	---	22.0	22.0	---	---
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	13.6	13.0	---	---
PUP SEX RATIO					
MEAN % MALE	---	49.6	46.9	---	---
MEAN % FEMALE	---	50.4	53.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.1	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	1.2	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.7	---	---	16.8	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	5.3	4.7	4.6	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	114.6	---	---
EXPERIMENTAL START DATE	8/26/01	9/2/01	1/2/02	10/12/01	10/19/01
DATE OF LAST NECROPSY	10/21/01	1/15/02	5/31/02	12/14/01	12/27/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	DI Water	2.5%HPMC in 50mM Sodium Acetate

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	91	92	93	94	95
NO. MALES IN CONTROL GROUP	---	25	30	30	30
MALE MATING INDEX (%)	---	95.5	96.7	96.7	100.0
MALE FERTILITY INDEX (%)	---	95.5	93.3	80.0	93.3
NO. FEMALES IN CONTROL GROUP	25	25	30	30	30
FEMALE MATING INDEX (%)	---	95.8	96.7	96.7	100.0
FEMALE FERTILITY INDEX (%)	100.0	95.8	93.3	80.0	93.3
NO. FEMALES SELECTED TO DELIVER	25	---	30	30	30
NO. THAT DELIVERED	25	---	28	24	27
NO. THAT DID NOT DELIVER	0	---	2	6	3
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	0
NO. WITH DYSTOCIA	0	---	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.0	3.5	3.1	1.8
MEAN GESTATION LENGTH (DAYS)	21.7	---	21.9	22.1	21.7
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
MEAN VIABLE LITTER SIZE ON PND 0	14.9	---	14.7	13.0	14.8
PUP SEX RATIO					
MEAN % MALE	49.1	---	42.7	56.6	45.9
MEAN % FEMALE	50.9	---	57.3	43.4	54.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.0	---	15.7	13.9	15.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	---	0.8	0.8	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	13.9	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.0	4.5	4.5	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	107.0	---
EXPERIMENTAL START DATE	12/3/01	1/8/02	2/15/02	6/21/02	12/26/01
DATE OF LAST NECROPSY	1/14/02	4/24/02	7/11/02	11/6/02	5/7/02
ROUTE	Gavage	Untreated	Diet	Diet	Drinking Water
VEHICLE	DI Water	Not Applicable	Basal Feed	Basal Feed	Drinking Water

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	96	97	98	99	100
NO. MALES IN CONTROL GROUP	30	---	25	---	25
MALE MATING INDEX (%)	96.7	---	96.0	---	96.0
MALE FERTILITY INDEX (%)	86.7	---	92.0	---	96.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	96.7	---	100.0	---	100.0
FEMALE FERTILITY INDEX (%)	86.7	96.0	96.0	88.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	25	---	25	25
NO. THAT DELIVERED	26	24	---	22	24
NO. THAT DID NOT DELIVER	4	1	---	3	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	1	0
NO. WITH TOTAL LITTER LOSS	0	0	---	0	0
NO. WITH DYSTOCIA	0	0	---	1	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.9	---	3.1	---	4.0
MEAN GESTATION LENGTH (DAYS)	22.0	21.7	---	21.8	21.8
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
MEAN VIABLE LITTER SIZE ON PND 0	14.3	15.0	---	15.3	14.2
PUP SEX RATIO					
MEAN % MALE	53.5	48.4	---	45.8	48.9
MEAN % FEMALE	46.5	51.6	---	54.2	51.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.7	---	17.1	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.7	---	1.1	1.1
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.5	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.0	---	4.2	---	4.3
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/18/02	10/22/02	2/11/03	11/18/02	3/10/03
DATE OF LAST NECROPSY	9/12/02	12/9/02	3/20/03	12/30/02	5/8/03
ROUTE	Drinking Water	Gavage	Gavage	Gavage	Gavage
VEHICLE	Drinking Water	2.5%HPMC in 50mM Sodium Acetate	2.5%HPMC in 50mM Sodium Acetate	0.5% MC	0.5% MC

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DATASET NO.	101	102	103	104	105
NO. MALES IN CONTROL GROUP	25	---	---	25	25
MALE MATING INDEX (%)	96.0	---	---	96.0	96.0
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	72.0
NO. FEMALES IN CONTROL GROUP	25	---	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	100.0	96.0
FEMALE FERTILITY INDEX (%)	92.0	---	96.0	100.0	72.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	25
NO. THAT DELIVERED	23	---	24	---	18
NO. THAT DID NOT DELIVER	2	---	1	---	7
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	---	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	---	---	3.5	3.4
MEAN GESTATION LENGTH (DAYS)	22.0	---	21.9	---	21.9
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
MEAN VIABLE LITTER SIZE ON PND 0	13.9	---	15.3	---	13.4
PUP SEX RATIO					
MEAN % MALE	52.6	---	47.9	---	53.7
MEAN % FEMALE	47.4	---	52.1	---	46.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.5	---	16.1	---	14.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	---	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	15.4	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	4.2	4.7
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	1/7/03	1/7/03	7/22/03	11/10/03	6/10/03
DATE OF LAST NECROPSY	5/30/03	6/20/03	10/28/03	12/16/03	10/12/03
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.10% Sodium Phosphate Buffer	0.10% Sodium Phosphate Buffer	DI Water	DI Water	1.0% MC

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DATASET NO.	106	107
NO. MALES IN CONTROL GROUP	---	---
MALE MATING INDEX (%)	---	---
MALE FERTILITY INDEX (%)	---	---
NO. FEMALES IN CONTROL GROUP	25	25
FEMALE MATING INDEX (%)	---	---
FEMALE FERTILITY INDEX (%)	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25
NO. THAT DELIVERED	25	25
NO. THAT DID NOT DELIVER	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0
NO. WITH TOTAL LITTER LOSS	0	0
NO. WITH DYSTOCIA	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.7
MEAN NO. PUPS BORN	15.9	15.5
MEAN VIABLE LITTER SIZE ON PND 0	15.7	15.3
PUP SEX RATIO		
MEAN % MALE	49.4	46.3
MEAN % FEMALE	50.6	53.7
MEAN NO. OF IMPLANTATION SITES AT WEANING	17.0	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---
EXPERIMENTAL START DATE	10/27/03	10/28/03
DATE OF LAST NECROPSY	2/2/04	2/3/04
ROUTE	Gavage	Gavage
VEHICLE	1.0% MC	1.0% MC

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DATASET NO.	1	2	3	4	5
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	92.3	97.5	99.3	99.2	99.4
PND 0 TO PND 1	100.0	99.6	99.2	99.4	99.2
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	98.6	99.3	100.0	99.3
PND 4 (AFTER SELECTION) TO PND 7	99.5	100.0	100.0	99.1	100.0
PND 7 TO PND 14	100.0	100.0	100.0	100.0	100.0
PND 14 TO PND 21	100.0	98.5	100.0	100.0	99.6
BIRTH TO PND 4 (BEFORE SELECTION)	92.3	95.9	97.8	98.7	97.9
PND 4 (AFTER SELECTION) TO PND 21	99.5	98.5	100.0	99.1	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.4	7.1	7.2	7.0	7.2
PND 4 (BEFORE SELECTION)	10.6	10.6	10.1	10.2	10.4
PND 7	17.2	17.2	16.4	16.8	15.1
PND 14	33.7	35.8	29.9	35.0	27.8
PND 21	53.8	58.0	45.4	53.1	44.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.8	6.8	6.6	6.7
PND 4 (BEFORE SELECTION)	10.0	10.0	9.5	9.7	9.7
PND 7	16.1	16.3	15.5	16.2	14.1
PND 14	32.1	34.3	28.9	33.9	26.3
PND 21	51.6	54.8	44.1	51.0	42.2
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3915
SPLEEN	---	---	---	---	0.1698
THYMUS GLAND	---	---	---	---	0.1690
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3530
SPLEEN	---	---	---	---	0.1722
THYMUS GLAND	---	---	---	---	0.1743

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DATASET NO.	6	7	8	9	10
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.3	96.6	97.7	98.2	97.7
PND 0 TO PND 1	99.8	94.5	99.4	99.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	97.8	99.4	97.8	99.7	100.0
PND 4 (AFTER SELECTION) TO PND 7	100.0	100.0	99.5	100.0	100.0
PND 7 TO PND 14	96.6	100.0	100.0	100.0	96.9
PND 14 TO PND 21	99.6	100.0	100.0	100.0	97.8
BIRTH TO PND 4 (BEFORE SELECTION)	96.0	91.3	95.2	97.7	97.4
PND 4 (AFTER SELECTION) TO PND 21	96.1	100.0	99.5	100.0	96.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	6.8	6.8	7.3	7.1
PND 4 (BEFORE SELECTION)	10.2	9.6	9.6	10.5	10.4
PND 7	15.3	15.3	15.4	16.4	16.6
PND 14	28.5	31.1	31.8	33.1	33.4
PND 21	45.3	51.0	49.5	50.6	52.1
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.5	6.3	6.9	6.7
PND 4 (BEFORE SELECTION)	9.5	9.1	9.0	10.0	9.7
PND 7	14.3	14.5	14.6	15.7	15.6
PND 14	27.5	29.7	30.8	32.2	31.2
PND 21	43.5	47.9	47.7	49.2	49.0
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4000	1.4926	1.4660	---	---
SPLEEN	0.1805	0.2106	0.1901	---	---
THYMUS GLAND	0.1790	0.2155	0.2076	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3682	1.4242	1.4214	---	---
SPLEEN	0.1846	0.1975	0.1929	---	---
THYMUS GLAND	0.1853	0.2113	0.2099	---	---

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DATASET NO.	11	12	13	14	15
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.4	97.6	97.8	97.0	95.7
PND 0 TO PND 1	99.3	98.9	99.4	99.6	95.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	99.6	99.2	98.8	100.0
PND 4 (AFTER SELECTION) TO PND 7	97.2	99.6	---	---	100.0
PND 7 TO PND 14	96.3	---	---	---	99.5
PND 14 TO PND 21	100.0	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.5	96.2	96.4	95.4	94.0
PND 4 (AFTER SELECTION) TO PND 21	95.4	98.5	---	---	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.6	7.0	6.9	7.1
PND 4 (BEFORE SELECTION)	9.1	8.9	9.3	9.5	10.0
PND 7	11.7	12.3	---	---	16.2
PND 14	22.5	24.6	---	---	32.5
PND 21	34.9	38.2	---	---	51.4
PND 28	65.4	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	6.2	6.5	6.4	6.7
PND 4 (BEFORE SELECTION)	8.5	8.4	8.8	9.0	9.5
PND 7	11.0	11.5	---	---	15.4
PND 14	21.2	23.4	---	---	31.7
PND 21	33.3	37.0	---	---	49.1
PND 28	59.8	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3616	1.4033	---	---	---
SPLEEN	0.1189	0.1544	---	---	---
THYMUS GLAND	0.1392	0.1640	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.2903	1.3390	---	---	---
SPLEEN	0.1182	0.1539	---	---	---
THYMUS GLAND	0.1338	0.1612	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.5	97.3	99.0	---	---
PND 0 TO PND 1	100.0	98.5	98.8	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.4	99.0	99.6	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	94.9	97.5	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	100.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	6.7	7.1	---	---
PND 4 (BEFORE SELECTION)	10.3	9.2	10.2	---	---
PND 7	---	13.1	16.5	---	---
PND 14	---	25.1	34.9	---	---
PND 21	---	39.5	54.7	---	---
PND 28	---	70.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.3	6.7	---	---
PND 4 (BEFORE SELECTION)	9.8	8.7	9.7	---	---
PND 7	---	12.6	15.9	---	---
PND 14	---	24.1	33.7	---	---
PND 21	---	38.0	52.4	---	---
PND 28	---	66.8	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.6	98.7	99.0	---	99.8
PND 0 TO PND 1	99.7	99.1	100.0	---	100.0
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	99.8	98.8	---	99.5
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	---	100.0
PND 7 TO PND 14	99.5	---	100.0	---	100.0
PND 14 TO PND 21	100.0	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.4	97.5	97.8	---	99.3
PND 4 (AFTER SELECTION) TO PND 21	99.5	---	100.0	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.1	7.4	---	6.8
PND 4 (BEFORE SELECTION)	10.2	10.4	10.7	---	9.6
PND 7	16.7	---	17.8	---	15.7
PND 14	34.8	---	36.5	---	32.4
PND 21	53.3	---	55.3	---	52.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.7	6.9	---	6.5
PND 4 (BEFORE SELECTION)	9.7	9.7	10.0	---	9.1
PND 7	16.1	---	16.8	---	14.9
PND 14	33.5	---	34.7	---	31.2
PND 21	50.9	---	53.1	---	50.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.9	97.7	98.9	99.5
PND 0 TO PND 1	---	94.3	96.7	98.2	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.6	98.8	98.8	99.4
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	99.5
PND 7 TO PND 14	---	99.3	100.0	---	98.5
PND 14 TO PND 21	---	100.0	100.0	---	98.8
BIRTH TO PND 4 (BEFORE SELECTION)	---	92.1	93.8	96.0	98.0
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	100.0	---	97.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	6.7	7.1	6.5
PND 4 (BEFORE SELECTION)	---	9.4	9.4	9.8	8.6
PND 7	---	15.1	15.1	---	13.0
PND 14	---	31.3	32.9	---	27.1
PND 21	---	48.1	50.9	---	41.3
PND 28	---	86.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.4	6.4	6.6	6.1
PND 4 (BEFORE SELECTION)	---	8.9	8.8	9.1	8.1
PND 7	---	14.1	14.3	---	12.2
PND 14	---	29.4	31.2	---	25.7
PND 21	---	45.0	48.0	---	39.4
PND 28	---	79.4	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN NO. PUPS BORN	---	15.4	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.3	---	---	---
PND 0 TO PND 1	---	99.3	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	99.7	---	---	---
PND 7 TO PND 14	---	99.7	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	97.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	---	---	---
PND 4 (BEFORE SELECTION)	---	10.1	---	---	---
PND 7	---	14.8	---	---	---
PND 14	---	27.2	---	---	---
PND 21	---	45.5	---	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	---	---	---
PND 4 (BEFORE SELECTION)	---	9.6	---	---	---
PND 7	---	14.0	---	---	---
PND 14	---	26.3	---	---	---
PND 21	---	43.8	---	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	36	37	38	39	40
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	95.8	97.7	---
PND 0 TO PND 1	---	---	98.7	98.9	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	97.7	98.1	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	---	---
PND 7 TO PND 14	---	---	99.5	---	---
PND 14 TO PND 21	---	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	92.4	94.8	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.8	6.8	---
PND 4 (BEFORE SELECTION)	---	---	9.5	9.2	---
PND 7	---	---	15.0	---	---
PND 14	---	---	31.8	---	---
PND 21	---	---	48.9	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.4	6.3	---
PND 4 (BEFORE SELECTION)	---	---	8.9	8.8	---
PND 7	---	---	14.1	---	---
PND 14	---	---	30.5	---	---
PND 21	---	---	46.7	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.5	98.6	---	---	99.1
PND 0 TO PND 1	99.7	99.6	---	---	98.6
PND 1 TO PND 4 (BEFORE SELECTION)	99.1	98.4	---	---	99.8
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.7	---	---	99.6
PND 7 TO PND 14	100.0	---	---	---	100.0
PND 14 TO PND 21	100.0	---	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	---	---	97.5
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	---	---	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	7.4	---	---	6.6
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	9.0
PND 7	15.3	15.2	---	---	14.9
PND 14	32.5	---	---	---	31.1
PND 21	51.4	---	---	---	45.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.9	---	---	6.2
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	8.5
PND 7	14.5	14.4	---	---	14.2
PND 14	31.3	---	---	---	30.0
PND 21	49.5	---	---	---	44.5
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.4163
SPLEEN	---	---	---	---	0.1822
THYMUS GLAND	---	---	---	---	0.1758
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3876
SPLEEN	---	---	---	---	0.1915
THYMUS GLAND	---	---	---	---	0.1852

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DATASET NO.	46	47	48	49	50
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.5	---	96.6	97.3	---
PND 0 TO PND 1	100.0	---	100.0	99.7	---
PND 1 TO PND 4 (BEFORE SELECTION)	98.4	---	99.5	99.7	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	100.0	---
PND 7 TO PND 14	100.0	---	99.5	100.0	---
PND 14 TO PND 21	100.0	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	---	96.1	96.8	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	99.5	100.0	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	---	7.3	7.1	---
PND 4 (BEFORE SELECTION)	9.3	---	10.7	10.3	---
PND 7	15.1	---	15.4	15.5	---
PND 14	32.1	---	28.8	29.2	---
PND 21	51.1	---	48.4	49.5	---
PND 28	---	---	88.1	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.2	---	6.9	6.7	---
PND 4 (BEFORE SELECTION)	8.7	---	10.1	9.6	---
PND 7	14.0	---	14.5	14.5	---
PND 14	30.4	---	27.4	27.6	---
PND 21	47.5	---	45.9	46.6	---
PND 28	---	---	79.5	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4763	---	1.4897	1.4728	---
SPLEEN	0.2176	---	0.2063	0.2189	---
THYMUS GLAND	0.1990	---	0.1951	0.1958	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4261	---	1.4332	1.3957	---
SPLEEN	0.2042	---	0.1977	0.2087	---
THYMUS GLAND	0.1986	---	0.2001	0.1895	---

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DATASET NO.	51	52	53	54	55
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	98.7	97.6	---
PND 0 TO PND 1	---	---	100.0	99.5	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	99.3	99.2	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	99.5	---
PND 7 TO PND 14	---	---	100.0	100.0	---
PND 14 TO PND 21	---	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	98.0	96.3	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	100.0	99.5	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.6	7.2	---
PND 4 (BEFORE SELECTION)	---	---	11.2	10.2	---
PND 7	---	---	17.7	16.9	---
PND 14	---	---	35.1	35.2	---
PND 21	---	---	57.6	55.2	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.2	6.8	---
PND 4 (BEFORE SELECTION)	---	---	10.7	9.7	---
PND 7	---	---	17.1	16.2	---
PND 14	---	---	35.1	33.7	---
PND 21	---	---	55.6	52.2	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.5175	1.4836	---
SPLEEN	---	---	0.2476	0.2227	---
THYMUS GLAND	---	---	0.2372	0.2446	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4597	1.4341	---
SPLEEN	---	---	0.2302	0.2200	---
THYMUS GLAND	---	---	0.2479	0.2407	---

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DATASET NO.	56	57	58	59	60
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.9	---	---	97.3
PND 0 TO PND 1	---	98.6	---	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	---	93.5	---	---	100.0
PND 4 (AFTER SELECTION) TO PND 7	---	99.4	---	---	100.0
PND 7 TO PND 14	---	100.0	---	---	100.0
PND 14 TO PND 21	---	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	---	91.6	---	---	95.9
PND 4 (AFTER SELECTION) TO PND 21	---	99.4	---	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.0	---	---	7.1
PND 4 (BEFORE SELECTION)	---	9.6	---	---	9.7
PND 7	---	16.1	---	---	16.1
PND 14	---	33.9	---	---	34.4
PND 21	---	52.4		---	54.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.6	---	---	6.7
PND 4 (BEFORE SELECTION)	---	9.2	---	---	9.2
PND 7	---	15.1	---	---	15.2
PND 14	---	32.5	---	---	32.8
PND 21	---	49.2	---	---	52.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	95.6	95.8	---	---
PND 0 TO PND 1	---	95.4	98.1	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	98.9	99.3	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	93.1	93.3	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	7.1	---	---
PND 4 (BEFORE SELECTION)	---	9.9	10.7	---	---
PND 7	---	15.7	---	---	---
PND 14	---	30.0	---	---	---
PND 21	---	48.4	---	---	---
PND 28	---	88.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	6.8	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.1	---	---
PND 7	---	14.9	---	---	---
PND 14	---	28.9	---	---	---
PND 21	---	46.6	---	---	---
PND 28	---	80.5	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.0	---	98.8	---	97.8
PND 0 TO PND 1	99.0	---	98.1	---	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	95.7	---	99.7	---	99.3
PND 4 (AFTER SELECTION) TO PND 7	95.8	---	100.0	---	98.4
PND 7 TO PND 14	100.0	---	100.0	---	99.4
PND 14 TO PND 21	99.2	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	91.9	---	96.6	---	96.7
PND 4 (AFTER SELECTION) TO PND 21	95.2	---	100.0	---	97.8
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	---	7.1	---	7.2
PND 4 (BEFORE SELECTION)	10.3	---	9.8	---	10.1
PND 7	16.3	---	15.3	---	15.1
PND 14	32.5	---	32.3	---	30.9
PND 21	49.4	---	52.1	---	48.2
PND 28	89.8	---	---	---	83.2
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	---	6.6	---	6.8
PND 4 (BEFORE SELECTION)	9.7	---	9.1	---	9.4
PND 7	15.8	---	14.5	---	14.1
PND 14	32.8	---	31.1	---	29.5
PND 21	50.2	---	49.7	---	46.3
PND 28	86.2	---	---	---	77.9
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	71	72	73	74	75
MEAN NO. PUPS BORN	12.6	15.5	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.6	97.4	---	---	---
PND 0 TO PND 1	98.5	99.8	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	99.0	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.4	99.5	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.1	96.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	7.0	---	---	---
PND 4 (BEFORE SELECTION)	10.8	9.7	---	---	---
PND 7	17.4	15.4	---	---	---
PND 14	---	32.4	---	---	---
PND 21	---	50.0	---	---	---
PND 28	---	87.8	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.6	---	---	---
PND 4 (BEFORE SELECTION)	10.4	9.1	---	---	---
PND 7	16.5	14.4	---	---	---
PND 14	---	30.9	---	---	---
PND 21	---	47.3	---	---	---
PND 28	---	82.1	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.3	97.5	---	---
PND 0 TO PND 1	---	98.0	99.5	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	98.8	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	96.6	100.0	---	---
PND 7 TO PND 14	---	94.4	99.0	---	---
PND 14 TO PND 21	---	95.9	99.5	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	94.9	95.7	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	92.2	98.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	7.2	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.5	---	---
PND 7	---	12.8	15.0	---	---
PND 14	---	24.8	29.7	---	---
PND 21	---	39.1	45.1	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	8.9	9.9	---	---
PND 7	---	11.8	14.3	---	---
PND 14	---	23.6	28.3	---	---
PND 21	---	39.1	42.9	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3553	1.4080	---	---
SPLEEN	---	0.1471	0.1755	---	---
THYMUS GLAND	---	0.1723	0.1901	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3241	1.3683	---	---
SPLEEN	---	0.1471	0.1850	---	---
THYMUS GLAND	---	0.1710	0.2032	---	---

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DATASET NO.	81	82	83	84	85
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.0	93.3	---	---	---
PND 0 TO PND 1	100.0	100.0	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.6	99.3	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.0	100.0	---	---	---
PND 7 TO PND 14	93.5	100.0	---	---	---
PND 14 TO PND 21	94.7	99.5	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.7	92.7	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	91.1	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.4	---	---	---
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	---
PND 7	12.8	15.2	---	---	---
PND 14	23.3	---	---	---	---
PND 21	38.4	42.6	---	---	---
PND 28	74.0	79.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	7.1	---	---	---
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	---
PND 7	12.2	14.3	---	---	---
PND 14	22.7	---	---	---	---
PND 21	37.6	40.5	---	---	---
PND 28	69.3	73.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3451	1.4458	---	---	---
SPLEEN	0.1503	0.1817	---	---	---
THYMUS GLAND	0.1617	0.1971	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3142	1.3833	---	---	---
SPLEEN	0.1515	0.1686	---	---	---
THYMUS GLAND	0.1669	0.1948	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.8	98.8	---	---
PND 0 TO PND 1	---	100.0	99.4	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.7	99.7	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	99.4	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	95.5	97.9	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.4	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.9	7.3	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.4	---	---
PND 7	---	12.9	14.6	---	---
PND 14	---	24.0	27.3	---	---
PND 21	---	38.5	43.9	---	---
PND 28	---	72.0	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	9.0	9.8	---	---
PND 7	---	12.5	13.9	---	---
PND 14	---	23.3	26.2	---	---
PND 21	---	36.9	41.9	---	---
PND 28	---	66.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3987	---	---
SPLEEN	---	---	0.1815	---	---
THYMUS GLAND	---	---	0.1678	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3623	---	---
SPLEEN	---	---	0.1905	---	---
THYMUS GLAND	---	---	0.1778	---	---

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DATASET NO.	91	92	93	94	95
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	96.8	---	99.1	98.7	98.7
PND 0 TO PND 1	100.0	---	98.9	97.0	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	99.8	---	99.0	99.2	99.8
PND 4 (AFTER SELECTION) TO PND 7	99.0	---	99.6	99.5	100.0
PND 7 TO PND 14	98.0	---	100.0	100.0	100.0
PND 14 TO PND 21	99.0	---	99.6	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.5	---	97.1	94.9	97.6
PND 4 (AFTER SELECTION) TO PND 21	96.0	---	99.1	99.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	7.1	7.5	6.9
PND 4 (BEFORE SELECTION)	9.2	---	9.9	10.8	9.5
PND 7	14.0	---	15.7	17.3	15.5
PND 14	24.6	---	32.2	35.3	32.6
PND 21	37.8	---	50.5	56.7	51.3
PND 28	69.8	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	---	6.7	7.0	6.4
PND 4 (BEFORE SELECTION)	8.8	---	9.4	10.1	8.9
PND 7	13.3	---	15.0	16.3	14.6
PND 14	24.2	---	31.3	33.9	31.2
PND 21	36.9	---	48.9	53.5	49.3
PND 28	67.4	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4143	1.4899	1.4775
SPLEEN	---	---	0.2232	0.2480	0.2220
THYMUS GLAND	---	---	0.1943	0.2330	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3958	1.4378	1.4216
SPLEEN	---	---	0.2335	0.2408	0.2229
THYMUS GLAND	---	---	0.2120	0.2363	0.2265

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DATASET NO.	96	97	98	99	100
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.9	100.0	---	96.1	99.0
PND 0 TO PND 1	99.5	99.5	---	99.7	98.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	97.4	---	96.8	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	97.3	---	96.9	---
PND 7 TO PND 14	100.0	99.4	---	99.3	---
PND 14 TO PND 21	100.0	100.0	---	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.2	96.9	---	92.4	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	96.8	---	96.3	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.9	---	7.0	7.3
PND 4 (BEFORE SELECTION)	9.9	9.3	---	9.5	---
PND 7	16.2	14.5	---	15.4	---
PND 14	33.0	30.7	---	32.7	---
PND 21	50.0	49.7	---	51.6	---
PND 28	---	83.5	---	87.1	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.6	---	6.6	6.9
PND 4 (BEFORE SELECTION)	9.4	8.9	---	9.0	---
PND 7	15.5	13.9	---	14.4	---
PND 14	31.9	29.5	---	30.7	---
PND 21	48.5	47.6	---	48.6	---
PND 28	---	77.7	---	78.4	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4605	---	---	---	---
SPLEEN	0.2211	---	---	---	---
THYMUS GLAND	0.2123	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4199	---	---	---	---
SPLEEN	0.2261	---	---	---	---
THYMUS GLAND	0.2078	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.7	---	99.2	---	98.3
PND 0 TO PND 1	99.4	---	99.4	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	99.2	---	99.2	---	99.2
PND 4 (AFTER SELECTION) TO PND 7	99.6	---	99.5	---	100.0
PND 7 TO PND 14	99.6	---	99.5	---	---
PND 14 TO PND 21	100.0	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	97.8	---	---
PND 4 (AFTER SELECTION) TO PND 21	99.1	---	99.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	---	7.3	---	7.6
PND 4 (BEFORE SELECTION)	10.5	---	10.1	---	11.4
PND 7	16.1	---	16.4	---	16.4
PND 14	31.1	---	34.0	---	---
PND 21	49.0	---	53.8	---	---
PND 28	76.4	---	94.0	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	6.9	---	7.2
PND 4 (BEFORE SELECTION)	9.9	---	9.6	---	10.9
PND 7	15.4	---	15.5	---	15.7
PND 14	29.9	---	32.8	---	---
PND 21	47.0	---	51.6	---	---
PND 28	68.9	---	85.3	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	106	107
MEAN NO. PUPS BORN	15.9	15.5
PUP SURVIVAL INDICES (% PER LITTER)		
PND 0 (RELATIVE TO NO. BORN)	98.6	98.6
PND 0 TO PND 1	99.2	99.5
PND 1 TO PND 4 (BEFORE SELECTION)	99.5	98.7
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.5
PND 7 TO PND 14	100.0	100.0
PND 14 TO PND 21	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.3	96.8
PND 4 (AFTER SELECTION) TO PND 21	100.0	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)		
PND 1	7.0	6.8
PND 4 (BEFORE SELECTION)	9.5	9.4
PND 7	15.1	15.3
PND 14	31.8	31.6
PND 21	50.5	50.2
PND 28	86.6	85.3
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)		
PND 1	6.5	6.3
PND 4 (BEFORE SELECTION)	8.9	8.8
PND 7	14.0	14.4
PND 14	30.0	30.4
PND 21	48.0	47.7
PND 28	79.1	77.0
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---

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DATASET NO.	1	2	3	4	5
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	43.3	---	46.7	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	230.4	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.2	---	33.1	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	106.9	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	6	7	8	9	10
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	5.3	5.7	---	---
FEMALE	---	3.2	3.9	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.0	---	44.6	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	217.9	---	223.0	---	232.0
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	---	34.4	---	32.6
MEAN BODY WEIGHT AT ACQUISITION (G)	105.1	---	118.9	---	112.2
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	11	12	13	14	15
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	5.3	5.3	---	---	---
FEMALE	3.3	3.1	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	47.0	47.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	38.8	32.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	5.2
FEMALE	---	---	---	---	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	4.8	---	---	---
FEMALE	---	2.7	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	41.6	---	41.8	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	210.5	---	212.2	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	32.5	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	107.4	---	117.7	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	4.0	---	---
FEMALE	---	---	4.0	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	16.1	---	---
FEMALE	---	---	16.1	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.0	---	42.4	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	227.1	---	229.0	---	226.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.4	---	31.9	---	33.2
MEAN BODY WEIGHT AT ACQUISITION (G)	115.2	---	109.9	---	119.1
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.0	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.2	---	---	---	---
FEMALE	14.8	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.1	---	43.8	49.0
MEAN BODY WEIGHT AT ACQUISITION (G)	---	247.9	---	229.2	248.0
MEAN DAY OF VAGINAL PATENCY (PND)	---	31.9	---	33.2	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	103.8	---	119.5	102.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	49.0	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	248.0	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	33.7	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	102.8	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	36	37	38	39	40
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.7	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	235.1	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	112.1	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.1	---	---	---	46.3
MEAN BODY WEIGHT AT ACQUISITION (G)	240.3	---	---	---	231.0
MEAN DAY OF VAGINAL PATENCY (PND)	32.7	---	---	---	31.7
MEAN BODY WEIGHT AT ACQUISITION (G)	114.7	---	---	---	99.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.1	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	18.7	---	---	---	---
FEMALE	18.6	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	46	47	48	49	50
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.2	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	228.9	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	36.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	130.3	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	51	52	53	54	55
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	42.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	227.0	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	34.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	133.0	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	56	57	58	59	60
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	42.0	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	---	215.7	---	---	248.6
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.9	---	---	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	112.6	---	---	125.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.7	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	238.3	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	107.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	5.1	---	---	---
FEMALE	---	5.2	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	4.2	---	---	---
FEMALE	---	4.2	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	15.5	---	---	---
FEMALE	---	15.5	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.7	---	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	224.7	---	---	---	220.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.1	---	---	---	33.1
MEAN BODY WEIGHT AT ACQUISITION (G)	114.4	---	---	---	107.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	14.9
FEMALE	---	---	---	---	14.9
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	10.1
FEMALE	---	---	---	---	10.0

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DATASET NO.	71	72	73	74	75
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.4	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	231.8	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.2	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	117.2	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	2.45	4.41	---	---
FEMALE	---	1.34	2.57	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	219.5	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	37.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	119.8	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	81	82	83	84	85
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.6	45.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	223.2	222.2	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	35.1	33.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	114.0	109.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.2	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	4.0	---	---	---
FEMALE	4.0	4.0	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.7	15.1	---	---	---
FEMALE	15.7	15.1	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	13.1	11.7	---	---	---
FEMALE	13.0	11.8	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	10.0	9.3	---	---	---
FEMALE	9.9	9.3	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	49.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	236.1	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	35.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	109.0	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	91	92	93	94	95
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	4.34	4.32	---
FEMALE	---	---	2.41	2.37	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.8	---	46.1	---	44.4
MEAN BODY WEIGHT AT ACQUISITION (G)	213.8	---	236.6	---	212.8
MEAN DAY OF VAGINAL PATENCY (PND)	33.8	---	34.2	---	33.0
MEAN BODY WEIGHT AT ACQUISITION (G)	99.5	---	121.9	---	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	96	97	98	99	100
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	4.36	---	---	---	---
FEMALE	2.28	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.0	---	44.8	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	220.2	---	235.6	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.9	---	33.5	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	115.1	---	111.5	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.7	---	42.3	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	221.8	---	223.8	---	225.2
MEAN DAY OF VAGINAL PATENCY (PND)	33.0	---	33.0	---	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	103.4	---	119.0	---	109.7
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	106	107
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.4	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	238.2	228.2
MEAN DAY OF VAGINAL PATENCY (PND)	32.9	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	112.1	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)		
MALE	5.1	5.0
FEMALE	5.3	5.1
MEAN DAY OF PINNAL DETACHMENT (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF EYE OPENING (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF HAIR GROWTH (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF INCISOR ERUPTION (PND)		
MALE	---	---
FEMALE	---	---

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DATASET NO.	1	2	3	4	5
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.55	2.64	2.73	1.95	2.70
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.85	1.72	1.84	1.71
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.88	1.74	1.85	1.71
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.71	0.75	0.74	0.74	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.76	0.72	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3266	0.3293	0.3185	0.3164	0.3022
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3197	0.3423	0.3280	0.3295	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	85.2	89.1	99.3	87.0	87.3
LEFT EPIDIDYMIS	449.0	407.9	436.1	413.4	343.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.0	14.6	16.3	14.3	14.3
% MOTILE SPERM	84.9	82.4	85.5	87.6	80.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.6	99.4	99.9	99.6	99.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	0.5	0.0	0.3	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.1	0.0	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.2	198.8	199.9	199.1	198.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.4	0.9	0.1	0.6	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	1.3	0.3	0.1	0.3	0.9
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	6	7	8	9	10
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.05	1.88	1.82	2.80	1.76
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.72	1.72	1.73	1.79
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.73	1.75	1.75	1.81
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.75	0.68	0.71	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.70	0.69	0.74	0.76
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3269	0.3364	0.2812	0.3157	0.3210
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3225	0.3242	0.3057	0.3280	0.3271
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.6	81.7	104.8	90.8	95.8
LEFT EPIDIDYMIS	517.5	410.6	534.3	452.1	416.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	13.4	17.2	14.9	15.7
% MOTILE SPERM	80.8	85.3	82.3	87.6	85.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.7	99.8	99.0	99.8	96.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.8	0.1	0.7	0.2	2.0
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.1	0.3	0.1	1.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.4	199.6	198.0	199.5	192.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.6	0.3	1.5	0.3	4.0
HEAD ABSENT WITH NORMAL FLAGELLUM	1.0	0.1	0.5	0.2	3.2
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	11	12	13	14	15
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.64	2.73	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.76	1.73	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.76	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	0.72	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.70	0.70	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3262	0.3174	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3064	0.2950	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	72.9	94.1	---	---	---
LEFT EPIDIDYMIS	456.0	467.9	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	11.9	15.4	---	---	---
% MOTILE SPERM	80.2	75.4	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.5	99.6	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.9	0.1	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.3	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.0	199.2	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.9	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	1.1	0.6	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.1	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.65	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.67	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2807	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2943	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	96.6	---	---	---
LEFT EPIDIDYMIS	---	438.8	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.8	---	---	---
% MOTILE SPERM	---	80.9	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.8	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.0	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.9	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.		22	23	24	25
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.45	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.73	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3160	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3293	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	91.7	---	---	---
LEFT EPIDIDYMIS	---	478.5	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.0	---	---	---
% MOTILE SPERM	---	86.2	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.1	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.3	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	1.77
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.68
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3092
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	106.7
LEFT EPIDIDYMIS	---	---	---	---	442.7
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	17.5
% MOTILE SPERM	---	---	---	---	81.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0

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DATASET NO.	36	37	38	39	40
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.80	1.76	---	---	1.93
MEAN LEFT TESTIS WEIGHT (G)	1.88	1.75	---	---	1.90
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.78	0.67	---	---	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.80	0.67	---	---	0.77
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3402	0.2857	---	---	0.3552
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3712	0.3061	---	---	0.3380
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.0	95.5	---	---	83.8
LEFT EPIDIDYMIS	393.1	556.7	---	---	418.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.1	15.7	---	---	13.7
% MOTILE SPERM	77.3	79.3	---	---	86.4
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.8	---	---	---	98.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.4	---	---	---	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.5	---	---	---	197.6
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	---	---	---	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	1.8	---	---	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0

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DATASET NO.	41	42	43	44	45
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	1.79	1.87	1.83	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.90	1.82	1.76	1.79
MEAN LEFT TESTIS WEIGHT (G)	---	1.89	1.84	1.82	1.80
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.81	0.78	0.78	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.77	0.77	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3586	0.3495	0.3272	0.3338
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3374	0.3555	0.3487	0.3149
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	95.5	76.7	74.1	---
LEFT EPIDIDYMIS	---	476.1	421.3	407.1	477.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.7	12.6	12.1	---
% MOTILE SPERM	---	85.9	87.1	75.9	89.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.8	99.4	99.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.3	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.5	198.8	199.4	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	0.7	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.6	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---

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DATASET NO.	46	47	48	49	50
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.15	2.14	---
MEAN RIGHT TESTIS WEIGHT (G)	1.83	1.70	1.79	1.84	1.69
MEAN LEFT TESTIS WEIGHT (G)	1.84	1.71	1.79	1.80	1.72
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.75	0.67	0.72	0.74	0.67
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.68	0.74	0.72	0.66
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3291	0.2817	0.3327	0.3178	0.3080
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3298	0.2967	0.3252	0.3304	0.3025
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	94.7	84.8	106.9	82.4
LEFT EPIDIDYMIS	539.2	500.8	471.9	640.1	503.2
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.5	13.9	17.5	13.5
% MOTILE SPERM	88.1	89.2	86.8	88.9	79.2
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.5	99.7	99.5	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.3	0.2	0.2	0.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.3	0.1	0.2	0.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	198.9	199.4	199.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.5	0.4	0.0	0.9
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.6	0.1	0.0	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	51	52	53	54	55
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.24	2.28
MEAN RIGHT TESTIS WEIGHT (G)	1.73	---	1.82	1.89	1.77
MEAN LEFT TESTIS WEIGHT (G)	1.69	---	1.80	1.92	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	---	0.81	0.75	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.69	---	0.76	0.78	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3121	---	0.3548	0.3431	0.3396
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3084	---	0.3387	0.3504	0.3475
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	90.5	---	105.4	83.8	---
LEFT EPIDIDYMIS	462.7	---	454.6	412.9	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.8	---	17.3	13.7	
% MOTILE SPERM	91.6	---	91.1	85.3	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.8	---	99.8	99.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.1	---	0.2	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	199.6	199.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	---	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---

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DATASET NO.	56	57	58	59	60
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---		---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.73	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.69	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.2962	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3168	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	91.0	---
LEFT EPIDIDYMIS	447.6	---	---	585.8	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	14.9	---
% MOTILE SPERM	86.3	---	---	84.2	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.3	---	---	99.5	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	---	---	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	198.6	---	---	199.1	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.1	---	---	0.4	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.3	---	---	0.5	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---

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DATASET NO.	61	62	63	64	65
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	----	1.92	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	----	1.80	---	1.80
MEAN LEFT TESTIS WEIGHT (G)	---	----	1.79	---	1.75
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.67
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3189	---	0.3368
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3449	---	0.3239
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	----	79.8	---	77.8
LEFT EPIDIDYMIS	---	----	506.2	---	417.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	----	13.1	---	12.8
% MOTILE SPERM	---	----	91.9	---	71.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	----	99.4	---	91.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.4	---	3.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.2	---	4.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	----	198.8	---	183.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.8	---	6.7
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.4	---	9.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0

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DATASET NO.	66	67	68	69	70
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	----	----	1.95	1.82	---
MEAN RIGHT TESTIS WEIGHT (G)	----	----	1.85	1.71	---
MEAN LEFT TESTIS WEIGHT (G)	----	----	1.83	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	----	----	0.71	0.64	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	----	----	0.70	0.62	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.2972	0.2629	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.3065	0.2714	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	----	----	81.0	---	---
LEFT EPIDIDYMIS	----	----	443.9	480.0	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	----	----	13.3	---	---
% MOTILE SPERM	----	----	87.3	82.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	----	----	98.9	97.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	0.7	1.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.4	0.9	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	----	----	197.9	195.8	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	1.4	1.7	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.8	2.4	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.1	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---

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DATASET NO.	71	72	73	74	75
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.68	1.90
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.69	1.91
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.68	0.78
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3057	0.3564
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3143	0.3693
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	75.0	69.6
LEFT EPIDIDYMIS	---	---	---	458.8	466.3
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	12.3	11.4
% MOTILE SPERM	---	---	---	82.0	83.1
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	99.0	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	0.5	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	0.5	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	198.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	1.0	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	1.0	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0

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DATASET NO.	76	77	78	79	80
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.26	2.29	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.84	---	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	1.84	1.87	---	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.74	---	0.74
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.76	---	0.74
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3354	0.3364	---	0.3397
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3460	0.3498	---	0.3377
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	77.7	90.8	---	74.3
LEFT EPIDIDYMIS	---	454.3	436.0	---	353.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	12.6	14.9	---	12.2
% MOTILE SPERM	---	87.5	87.0	---	84.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	96.1	99.2	---	98.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.6	0.4	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	2.3	0.5	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	192.2	198.3	---	197.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	3.1	0.7	---	1.2
HEAD ABSENT WITH NORMAL FLAGELLUM	---	4.6	0.9	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0

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DATASET NO.	81	82	83	84	85
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.13	2.15	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.84	1.80	---	1.76	1.75
MEAN LEFT TESTIS WEIGHT (G)	1.81	1.80	---	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.80	0.73	---	0.79	0.70
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.76	0.73	---	0.78	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3686	0.3270	---	0.3682	0.3326
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3595	0.3243	---	0.3706	0.3286
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	79.1	96.6	---	79.2	84.6
LEFT EPIDIDYMIS	---	---	---	469.0	452.3
LEFT CAUDA EPIDIDYMIS	738.9	618.7	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	13.0	15.8	---	13.0	13.9
% MOTILE SPERM	88.6	84.3	---	89.7	78.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.5	99.3	---	99.3	97.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	0.4	---	0.5	1.8
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	0.2	---	0.3	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	199.0	198.7	---	198.6	195.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.9	---	0.9	3.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.4	0.4	---	0.5	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0

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DATASET NO.	86	87	88	89	90
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	2.30		---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.79	1.76	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	1.83	1.80	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.69	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.71	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3055	0.3194	0.3257	0.3352
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3306	0.3226	0.3384	0.3310
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	88.8	81.6	86.7	87.4
LEFT EPIDIDYMIS	---	476.2	434.0	475.8	461.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	14.5	13.4	14.2	14.3
% MOTILE SPERM	---	83.0	87.0	83.4	81.7
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.9	97.3	99.7	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.3	0.4	0.1	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.8	0.3	0.2	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.8	198.6	199.4	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.6	0.8	0.3	10.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.6	0.6	0.3	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	91	92	93	94	95
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.22	2.09
MEAN RIGHT TESTIS WEIGHT (G)	---	---	1.85	1.90	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	---	1.82	1.91	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.76	0.72
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.77	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3234	0.3424	0.3162
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3421	0.3460	0.3212
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	75.9	93.2	78.1
LEFT EPIDIDYMIS	---	---	---	---	406.0
LEFT CAUDA EPIDIDYMIS	---	---	689.5	662.8	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	12.4	15.3	12.8
% MOTILE SPERM	---	---	91.0	82.0	88.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	99.4	99.7	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.4	0.2	0.3
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.2	0.1	0.1
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	198.9	199.4	199.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.8	0.4	1.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.3	0.2	0.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0

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DATASET NO.	96	97	98	99	100
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	1.98	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.86	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.82	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.63	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3264	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3232	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	76.2	---	---	---	---
LEFT EPIDIDYMIS	548.6	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	12.5	---	---	---	---
% MOTILE SPERM	89.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.7	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.2	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	101	102	103	104	105
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.23	2.04	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.87	1.92	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.73	1.85	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.78	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.68	0.74	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3336	0.3693	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.2858	0.3405	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	106	107
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)		
LEFT TESTIS	---	---
LEFT EPIDIDYMIS	---	---
LEFT CAUDA EPIDIDYMIS	---	---
MEAN SPERM PRODUCTION RATE		
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---
% MOTILE SPERM	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

APPENDIX F

Study Protocol

[redacted]

Study Number: WIL-187041

PROTOCOL AMENDMENT III

Sponsor: [redacted]

Sponsor Study No.: 04-023

A. Title of Study:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modifications:

1) **9.1** **Macroscopic Examination:**

Change cervix and uterine body (two sections) to cervix and uterine body (one longitudinal section).

2) **9.3** **Microscopic Examination:**

Change cervix and uterine body (two sections) to cervix and uterine body (one longitudinal section).

C. Reasons for Protocol Modifications:

1 & 2) The procedure for sectioning the cervix and uterine body has been revised.

Approved By:

[redacted]

[redacted] 30 January 2005
Sponsor Representative Date

Prepared By:
WIL Research Laboratories, LLC

[redacted] 12/21/2004
B.S. Date
Study Director

[redacted] 12/21/04
Director, Developmental and Date
Reproductive Toxicology

Study Number: WIL-187041

PROTOCOL AMENDMENT II

Sponsor: [redacted]

Sponsor Study No.: 04-023

A. Title of Study:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modifications:

1) On the cover page, in the study title, chang[redacted] to [redacted]

2) **4.1 Identification:**

[redacted]

4.1.1 Lot Number:

[redacted]

4.1.5 Storage Conditions:

Store at ambient conditions under nitrogen.

3) **7.4.1 Organization of Test Groups:**

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/ml)	Dose Volume (ml/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[redacted]	60	12	5	15
3		250	50	5	15
4		1000	200	5	15
5		5	1	5	15
6		20	4	5	15
7		60	12	5	15

C. Reasons for Protocol Modifications:

1) The Sponsor has elected to replace one of the test articles in this assay.

2) Due to the change in test article, the identification, lot number and storage conditions are corrected.

3) The test article has been changed in the table which presents the study group arrangement.

Approved By:

[redacted]co

[redacted]

11/2/04
Date

Sponsor Representative

Prepared By:

WIL Research Laboratories, LLC

[redacted]

10/18/2004
Date

Study Director

[redacted]

10/18/2004
Date

Director, Developmental and
Reproductive Toxicology

Study Number: WIL-187041

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor Study No.: 04-023

A. Title of Study:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Addition:

1) **3. STUDY SCHEDULE:**

Proposed Animal Receipt Date: (Experimental Starting Date):	November 2, 2004
Proposed Experimental Start Date:	November 16, 2004
Proposed Experimental Termination/Completion Date:	December 8, 2004
Proposed Audited Report Date:	February 16, 2005

C. Reasons for Protocol Modifications:

1) Study dates have been determined.

Approved By:

[redacted]

Sponsor Representative

11 October 2004
Date

Prepared By:
WIL Research Laboratories, Inc.

[redacted]

Study Director

10/8/2004
Date

[redacted]

Director, Developmental and Reproductive Toxicology

10/8/2004
Date

PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 04-023

Submitted To:

[redacted]

WIL Research Laboratories, Inc.
1407 George Road
Ashland, OH 44805-9281

1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]

2.2 WIL Study Director:

[redacted]

2.3 WIL Deputy Director:

[redacted]

2.4 WIL Departmental Responsibilities:

[redacted]

3 STUDY SCHEDULE:

Proposed Animal Receipt Date: (Experimental Starting Date)	To be determined.
Proposed Experimental Start Date:	To be determined.
Proposed Experimental Termination/Completion Date:	To be determined.
Proposed Audited Report Date:	To be determined.

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

4.1.1 Lot Number:

[redacted]

4.1.2 Purity:

100%

4.1.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.1.4 Physical Description:

Dark brown, very viscous liquid.

4.1.5 Storage Conditions:

Store at ambient conditions.

4.1.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, Inc. indefinitely unless otherwise specified.

4.1.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) should accompany the test article upon arrival at the laboratory.

4.2 Identification:

[redacted]

4.2.1 Lot Number:

[redacted]

4.2.2 Purity:

100%

4.2.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.2.4 Physical Description:

Dark brown, opaque, very viscous liquid.

4.2.5 Storage Conditions:

Store at ambient conditions.

4.2.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, Inc. indefinitely unless otherwise specified.

4.2.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) should accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Sprague-Dawley Crl:CD®(SD)IGS BR

5.3 Source:

Charles River Laboratories
Portage, Michigan

5.4 Number on Study:

105 Females (maximum of 130 immature females and 13 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 8-10 days old upon receipt. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and discarded.

5.5 Body Weight Range:

At randomization: 30-50 g. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal eartag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, Inc. has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed-O'Cobs®). Following randomization, the juvenile female animals will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL Standard Operating Procedures. The facilities at WIL Research Laboratories, Inc. are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol-specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, Inc. by the manufacturer and will be placed in the study records. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Each of 7 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, disposable plastic dosing cannulae will be used for the oral administration by gavage. Any losses or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/ml)	Dose Volume (ml/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[redacted]	60	12	5	15
3	[redacted]	250	50	5	15
4	[redacted]	1000	200	5	15
5	[redacted]	5	1	5	15
6	[redacted]	20	4	5	15
7	[redacted]	60	12	5	15

7.4.2 Vehicle Control Article:

Corn oil

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 of age and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Article Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity will be collected prior to the initiation of test article administration. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control,

three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Two of the three samples will be sent to [redacted], for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. The methods employed will be one or more of the following:

[redacted] SOP #ME-125

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of $\pm$ 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] phone at [redacted] or by email [redacted]). This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will be observed also approximately one hour following dosing and the observations will be recorded. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory,

autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded.

7.6.2 Body Weights:

Daily body weights will be recorded individually (to the nearest 0.1 gram PND 22-42, with the exception of the weight collected the day prior to dosing and the final body weight) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized as described above.

8 HOROMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH) Thyroxine (T_4)

9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized *in extremis*. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. The following tissues will be collected and placed in 10% neutral-buffered formalin:

Cervix and Uterine Body (two sections)	Thyroid
Ovaries	Uterine horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized *in extremis*.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in the same sequence as which dosing occurred. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

9.2.2 Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Ovaries and oviducts
Kidneys	Pituitary gland
Liver	Thyroid

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 Microscopic Examination:

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination.

The vagina, ovaries, and thyroid from each animal will be similarly preserved with the uterus.

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the following tissues from all animals.

Ovaries	Thyroid
Cervix and Uterine Body (two sections)	Uterine Horns (four sections per horn)

10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age of first estrous and estrous cycle length will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of EPA/TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Good Laboratory Practice Regulations [C (97) 186/Final]. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, Inc.

14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, Inc. to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, Inc. will not be responsible for shipment following delivery to the common carrier.

15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional paper copies of the final report may result in additional charges.

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory Standard Operating Procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via **e-mail** on **August 31, 2004.**

[redacted]

7 September 2004
Date

Team Leader, Toxicology Testing

WIL Research Laboratories, Inc.

[redacted]

9/2/2004
Date

Study Director

[redacted]

9/2/2004
Date

Director, Developmental and
Reproductive Toxicology

FINAL REPORT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187042

COMPANY SANITIZED

STUDY DIRECTOR

[redacted]

STUDY INITIATION DATE

November 4, 2004

STUDY COMPLETION DATE

November 30, 2005

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

04-027

SPONSOR

[redacted]

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] or [ ], in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to three groups each of 15 Crl:CD®(SD)[1] immature female rats. Dosage levels for each test article were 60, 250 and 1000 mg/kg/day, and the dosage volume was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director.

Dosing procedures were performed from November 26 through December 17, 2004, when the animals were 22 to 41 days of age; the study start was staggered, based on age. At the initiation of dose administration, body weights ranged from 43.9 g to 70.2 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[ ]	60	12	5	15
3	[ ]	250	50	5	15
4	[ ]	1000	200	5	15
5	[ ]	60	12	5	15
6	[ ]	250	50	5	15
7	[ ]	1000	200	5	15

Due to spacing constraints, the dose group names are presented on the tables and figures as corn oil, [ ]/60, [ ]/250, [ ]/1000, [ ]/60, [ ]/250 and [

[1] Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

]/1000 for the vehicle control, 60, 250 and 1000 mg/kg/day [ ] and 60, 250 and 1000 mg/kg/day [ ] groups, respectively.

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (100% pure corn oil, exp. dates 2/17/06, 3/19/06 and 4/6/06) was dispensed into a storage container and stirred throughout use. The [ ] and [ ] dosing formulations were prepared by weighing an appropriate amount of test article for each group into a tared, calibrated storage container. A stir bar and approximately 80% of the vehicle were added to the storage container, and the mixture was stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The [ ] and [ ] dosing formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature. Three samples from the control group and three sets of samples from the test article formulations were collected prior to the initiation of dose administration. Two sets of samples for concentration verification were collected on each day of preparation and two sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and six sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC, for possible future analysis.

Thirteen dams with 10 female pups each (130 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on November 9, 2004. The pups were 3 to 5 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam) during the acclimation period (17 to 19 days) until randomization of the pups on postnatal day (PND) 21. Following randomization, the female pups were weaned, identified by metal eartag and housed three per cage in plastic maternity cages. Environmental controls were set to

maintain an average daily temperature of 71±5°F and an average daily relative humidity of 50±20%. Actual mean daily temperatures ranged from 70.4°F to 70.8°F (21.3°C to 21.6°C) and mean daily relative humidity ranged from 36.0% to 46.6%. Light timers were calibrated to provide a 12-hour light (6 a.m. to 6 p.m.)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse-osmosis-purified water were offered *ad libitum*.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on PND 25 (Adams, *et al.*, 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (*i.e.*, the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia), beginning on the day vaginal patency was observed. Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A gross necropsy was performed only on animals that were found dead or euthanized *in extremis*. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum thyroxine (T_4) and thyroid stimulating hormone (TSH) levels. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, adrenal glands, pituitary gland and thyroid

glands were weighed. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The ovaries, uterus (horns and body), cervix, vagina, pituitary gland, thyroid glands and gross lesions were retained from all females, including those found dead.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. Mean body weights, body weight changes, days of acquisition of vaginal patency, estrous cycle lengths, ages at the first occurrence of estrus, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
November 9, 2004	Experimental starting date (animal receipt)
November 26, 2004	Experimental start date (first day of dose administration)
November 26 - December 17, 2004	Test article administration
December 30, 2004	Experimental termination/completion date (last analytical analyses)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS - [ ]

Female no. 69638-07 in the 1000 mg/kg/day [ ] group was euthanized *in extremis* near the end of the dose administration period at 40 days of age; no internal findings were noted at necropsy. This female had labored respiration, red material around the eyes, nose and/or mouth and was gasping at the daily examinations on PND 38, 39 and/or 40. At the time of dose administration and/or 1 hour following administration, this female had salivation and/or clear material around the mouth and was wiping its mouth on the walls and/or floor occasionally throughout the study. This female lost 21 g of body weight at 37-40 days of age. At necropsy, this female was internally normal. The moribund condition of this animal was attributed to the test article. All other animals in the [ ]-treated groups survived to the scheduled euthanasia. Test article-related salivation and/or clear material around the mouth and wiping the mouth on the cage floor and/or walls were observed at the time of and 1 hour following dose administration in the 250 and 1000 mg/kg/day [ ] groups. These findings did not persist to the daily observations and were not considered adverse. One female in the 1000 mg/kg/day [ ] group had hypoactivity and hypothermia (body cool to the touch) and was pale at 33, 34 and/or 35 days of age. These findings were considered test article-related because this female also lost weight during this period. However, they were not considered adverse because the female was clinically normal and gained weight during the remainder of the study. Salivation prior to dose administration occurred once or twice in up to four animals in the 60 mg/kg/day [ ] group. This finding was considered test article-related but not adverse. No other [ ]-related findings were observed.

Mean body weight gains in the 1000 mg/kg/day [ ] group were reduced compared to the control group values following the first 2 days of dose administration. The differences were statistically significant ($p<0.05$ or $p<0.01$) on PND 22-23 and 23-24.

Throughout the remainder of the dosing period, mean body weight gains in this group were generally similar to those in the control group. However, occasional decreases in mean body weight gains were observed; the difference during PND 31-32 was statistically significant ($p<0.01$) compared to that in the control group. When the entire treatment period (PND 22-42) was evaluated, mean body weight gain in the 1000 mg/kg/day [ ] group was statistically significantly ($p<0.05$) reduced compared to the control group value. Mean body weights in this group were 4.6% to 10.6% lower than the control group values from PND 24-42. The differences were statistically significant ($p<0.05$) on PND 38 and 39. Mean body weights and body weight gains in the 60 and 250 mg/kg/day [ ] groups were similar to those in the control group throughout the study; none of the differences were statistically significant.

Vaginal patency in the 250 and 1000 mg/kg/day [ ] groups was achieved at an earlier age than in the control group; the differences were significant ($p<0.01$). Mean ages of acquisition were 31.8, 31.1, 27.0 and 26.1 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. The values in the 60, 250 and 1000 mg/kg/day [ ] groups were below the minimum mean value in the WIL historical control data (31.7 days); however, the 60 mg/kg/day [ ] value was considered similar to the concurrent control group value. Because the females were younger on the day that vaginal patency was observed, mean body weights at the age of acquisition in the 250 and 1000 mg/kg/day [ ] groups were also lower (statistically significant, $p<0.01$) than the control group value. These differences were consistent with an interpretation of estrogenic effects resulting from the test article.

No differences in mean estrous cycle length were observed when the [ ]-treated groups were compared to the control group. Estrous cycle lengths in females of this age are highly variable. In the 1000 mg/kg/day [ ] group, estrous cycle length could only be determined for six females due to an increase in the number of females in persistent diestrus following vaginal opening; persistent diestrus in these females was attributed to the test article. The age of the first occurrence of estrus in the 60, 250 and

1000 mg/kg/day [ ] groups was earlier (32.9, 32.9 and 32.4 days of age, respectively) than in the control group (34.1 days of age); the differences were not statistically significant. While vaginal patency was observed approximately 4.5 days earlier (observed in all females by 28 days of age) in the 1000 mg/kg/day [ ] group, the age at the first occurrence of estrus in this group was PND 38 or later for four females; four other females in this group had no occurrence of estrus prior to euthanasia.

Mean total T_4 and TSH levels in the 60, 250 and 1000 mg/kg/day [ ] groups were similar to those in the control group.

Test article-related reductions in mean absolute and relative (to final body weight) ovary/oviduct and uterus (wet and blotted) weights were observed in the 1000 mg/kg/day [ ] group; the differences from the control group were statistically significant ($p<0.05$ or $p<0.01$). These decreases in uterus and ovary/oviduct weights corresponded to the increased number of females in persistent diestrus. Luminal fluid data were highly variable; no attempt was made to euthanize the females at the same stage of estrous. However, mean luminal fluid weight in the 1000 mg/kg/day [ ] group was reduced (not statistically significant) compared to the control group value. Mean absolute and relative liver weights in the 1000 mg/kg/day [ ] group were increased compared to the control group values; the differences were statistically significant ($p<0.01$). Mean absolute pituitary gland weight in the 1000 mg/kg/day [ ] group was reduced compared to the control group value (statistically significant, $p<0.01$). Although the relative pituitary weight was similar to that in the control group, the lower mean pituitary weight was attributed to the test article. No test article-related or statistically significant differences in organ weights were observed in the 60 and 250 mg/kg/day [ ] groups.

1.6. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in estrogenic effects in the 250 and 1000 mg/kg/day groups, as evidenced by early attainment of vaginal patency. The decreased mean ovary and uterus

(wet and blotted) weights, fewer number of animals cycling normally (persistent diestrus) and decreased pituitary weight at 1000 mg/kg/day [ ] were attributed to test article.

1.7. RESULTS - [ ]

Female no. 69629-03 in the 1000 mg/kg/day [ ] group was found dead at 30 days of age, following nine doses. This animal was prostrate immediately following dose administration on the day of death. The only other clinical finding for this female was clear material around the mouth noted at the time of dose administration at 25 days of age. No test article-related decreases in body weight gain were observed for this female prior to death. At necropsy, this female had dark red discoloration of one lobe of the lung. The relationship of this mortality to [ ] administration is unclear. All other animals survived to the scheduled euthanasia. Salivation and/or clear material around the mouth and wiping the mouth on the cage walls and/or floor were observed at the time of dose administration and/or 1 hour following dose administration in the majority of the animals in the 1000 mg/kg/day [ ] group. These findings were attributed to the test article but not considered adverse. Clear material around the mouth and/or salivation prior to dose administration were observed in one or two animals in the 60 and 250 mg/kg/day [ ] groups at the time of dose administration and/or 1 hour following dose administration.

A slight decrease in mean body weight gain was observed in the 1000 mg/kg/day [ ] group following the first day of test article administration (PND 22-23). The difference from the control group value was statistically significant ($p<0.05$). Mean body weight gains in this group were similar to those in the control group throughout the remainder of the study. The reduction in mean body weight gain on PND 22-23 was not of sufficient magnitude to result in any statistically significant decreases in mean body weights in this group throughout the study. Therefore, this transient reduction was not considered adverse. No [ ]-related effects on mean body weights or body weight gains were observed in the 60 and 250 mg/kg/day groups. The only statistically significant ($p<0.05$) difference from the control group was an increase in mean body weight gain in the 250 mg/kg/day [ ] group during PND 30-31.

There were no test article-related effects on the mean age of acquisition of vaginal patency. Vaginal patency was achieved slightly later in the 60, 250 and 1000 mg/kg/day [ ] groups than in the control group. Mean days of acquisition were 31.8, 33.6, 32.8 and 33.4 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. However, the differences were not statistically significant, and the values in all [ ]-treated groups were similar to the mean value in the WIL historical control data (33.4 days), and no dose-related trends were evident. Since the females were slightly older on the day that vaginal patency was observed, mean body weights on the day of acquisition in the 60, 250 and 1000 mg/kg/day [ ] groups were also higher than the control group value. The differences were statistically significant ($p<0.05$) in the 60 and 1000 mg/kg/day [ ] groups. None of these differences were attributed to the test article.

No test article-related differences in mean estrous cycle length were observed when comparing the [ ]-treated groups to the control group. The age of the first occurrence of estrus in the 60, 250 and 1000 mg/kg/day [ ] groups was slightly later (36.5, 35.6 and 35.3 days of age, respectively) than in the control group (34.1 days of age). The differences were not statistically significant, but were related to the slightly later age at which vaginal patency was observed compared to the control group.

Mean T_4 and TSH levels in the 60, 250 and 1000 mg/kg/day [ ] groups were similar to the control group values. No statistically significant differences or dose-related trends were evident.

No test article-related or statistically significant differences in organ weights were observed in the [ ]-treated groups. Slight reductions (not statistically significant) in absolute and relative uterus (wet and blotted) weights were observed in 1000 mg/kg/day [ ] group. These reductions were attributed to biological variation. Luminal fluid data were highly variable; no statistically significant differences in mean luminal fluid weights were observed in the [ ]-treated groups, and no dose-related trends were evident.

1.8. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in no estrogenic effects in the 60, 250 and 1000 mg/kg/day groups.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____
[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____
[ ] Date
Senior Study Analyst

Report Reviewed By:

_____ _____
[ ] Date
Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

[ ]	Manager, Clinical Pathology
[ ]	Senior Operations Manager, Vivarium
[ ]	Manager, Gross Pathology and Developmental Toxicology Laboratory
[ ]	QC Coordinator, Regulatory Affairs and Services
[ ]	Group Supervisor, Formulations Laboratory
[ ]	Director, Metabolism and Analytical Chemistry
[ ]	Operations Manager, Developmental, Reproductive and Neurotoxicology

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
12/16/04	Blood Collection	12/16/04	1/27/05	[ ]
2/10/05	Study Records (Rx-1)	2/10/05	3/25/05	[ ]
2/11,14/05	Study Records (I-1)	2/14/05	3/25/05	[ ]
2/15/05	Study Records (C-1)	2/15/05	3/25/05	[ ]
2/16/05	Study Records (C-2)	2/16/05	3/25/05	[ ]
2/16/05	Study Records (N-1)	2/16/05	3/25/05	[ ]
2/17-18/05	Draft Report	2/18/05	3/25/05	[ ]
2/22/05	Study Records (N-1 Supplemental)	2/22/05	3/25/05	[ ]

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Parts 160 and 792), the OECD Principles of Good Laboratory Practice, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendments with the following exceptions. The data located in Appendices A (Certificates of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____
[ ] Date
Compliance Specialist

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 5.3** states that animals were to be supplied by Charles River Laboratories, Inc., Portage, Michigan. However, animals were received from the Raleigh, North Carolina facility of Charles River Laboratories.
- **Protocol Section 5.4** states that the immature female pups were to be 4-6 days old upon receipt. However, the pups were 3-5 days old at the time of receipt.
- **Protocol Section 5.5** states that the body weight range at randomization was to be 30 g to 50 g and animals assigned to study would weigh ± 5 g of the mean. However, the actual body weights of animals assigned to study were 42 g to 63 g, and individual body weights ranged from -13 g to +8 g of the mean.
- **Protocol Section 7.5.4** states that [ ]was to be notified prior to shipping dosing formulation samples; the notification was to include test article and study identifications. However, the e-mail notifications sent to [ ]on November 8 and 23, 2004, did not include test article identification.
- **Protocol Sections 9.1 and 9.2.2** state that the thyroid glands were to be retained and weighed. However, the thyroid glands from female no. 69636-09 (control group) and 69626-08 (60 mg/kg/day [ ] group, left thyroid gland only) were lost at necropsy, and therefore were not retained or weighed.
- **Protocol Section 9.2.1** states that the harvesting of uteri was to be performed in the same sequence as the animals were dosed. Due to the normal diurnal fluctuation in circulating concentrations of thyroid hormone levels, the necropsy order was randomized to minimize the potential effect, across all groups, that the time of day of sample collection may have had on thyroid hormone levels.

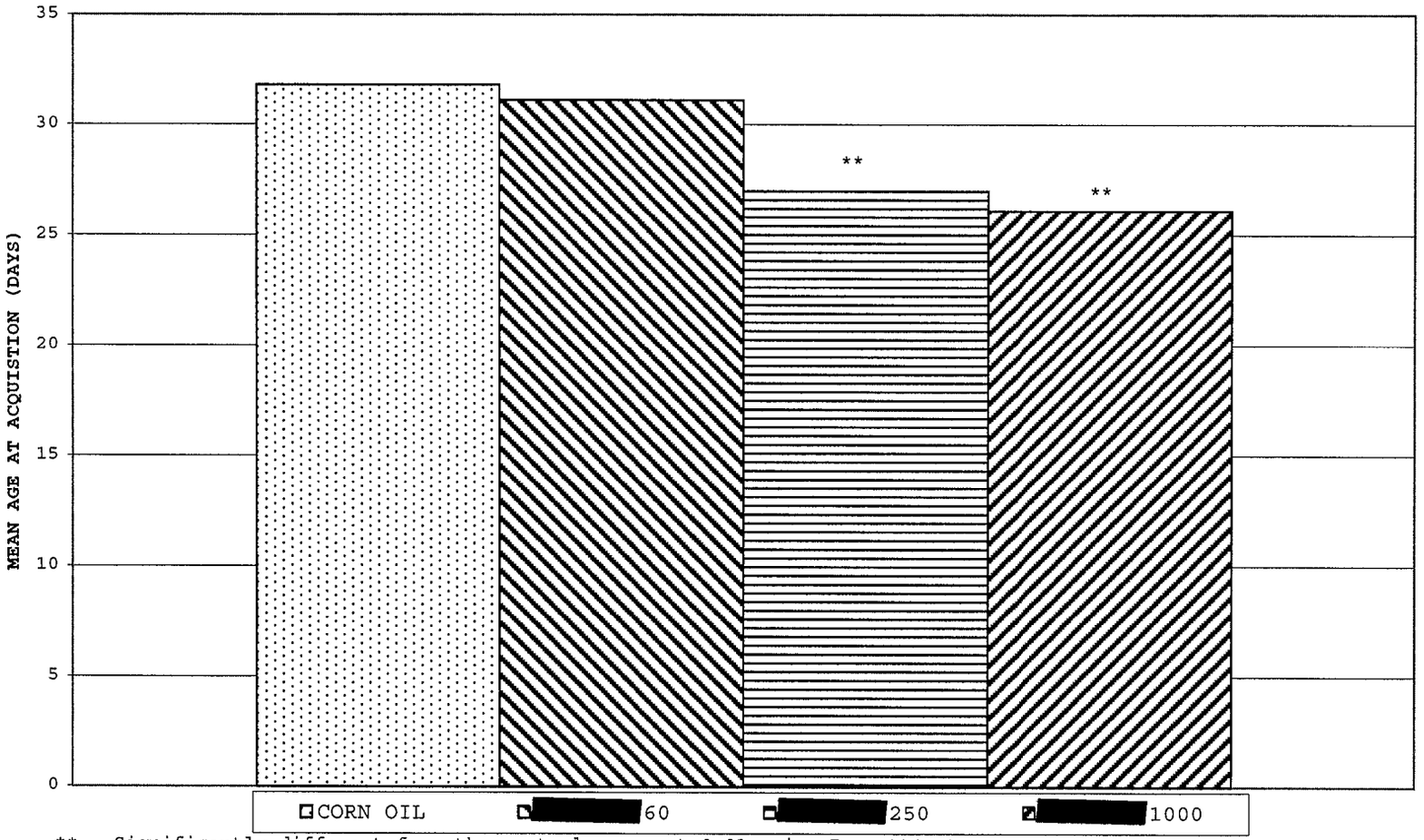
These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1-12

PROJECT NO.:WIL-187042 FIGURE 1 ([redacted]

SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR NO.:04-027 MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY

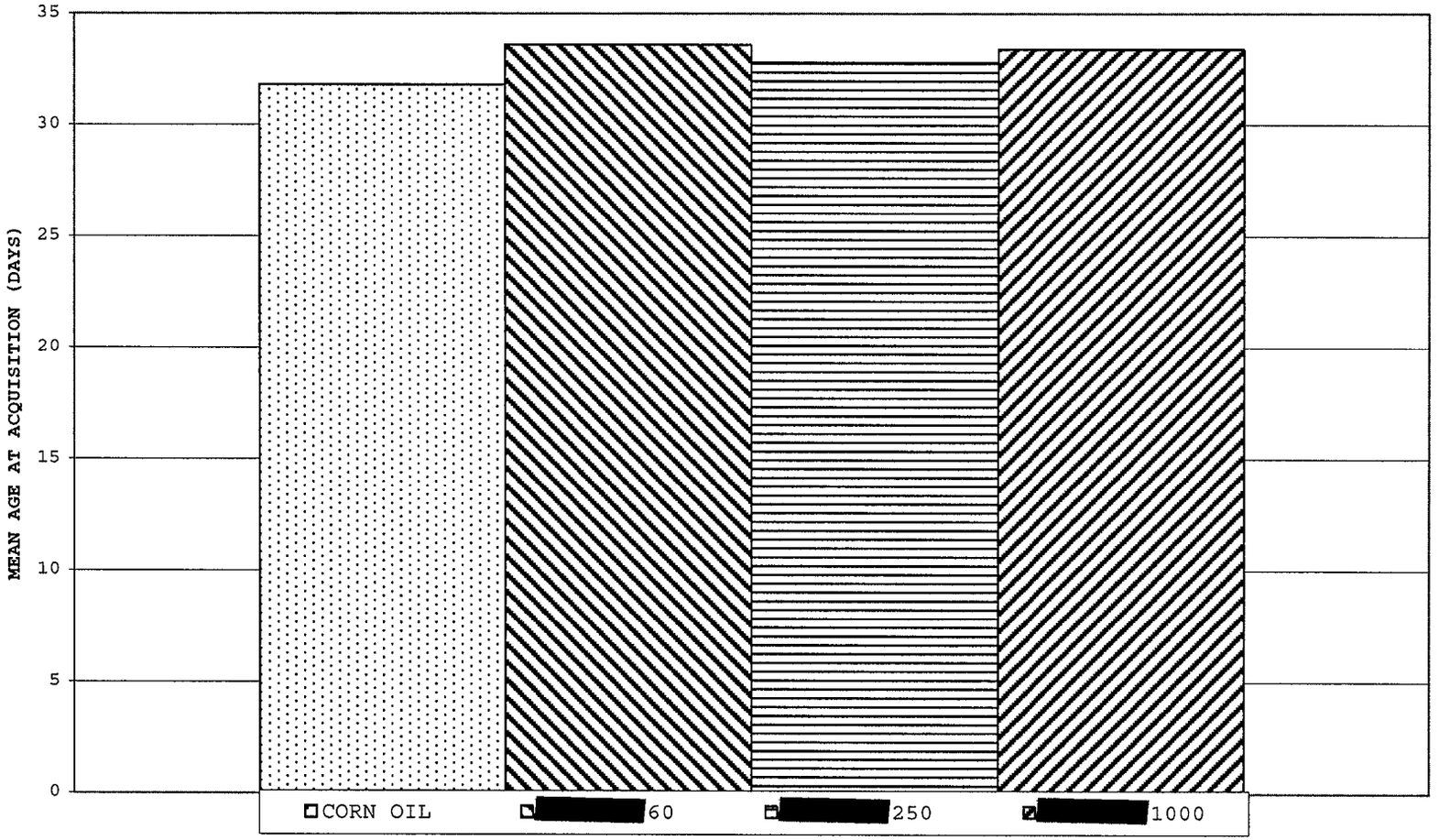


** = Significantly different from the control group at 0.01 using Dunnett's test

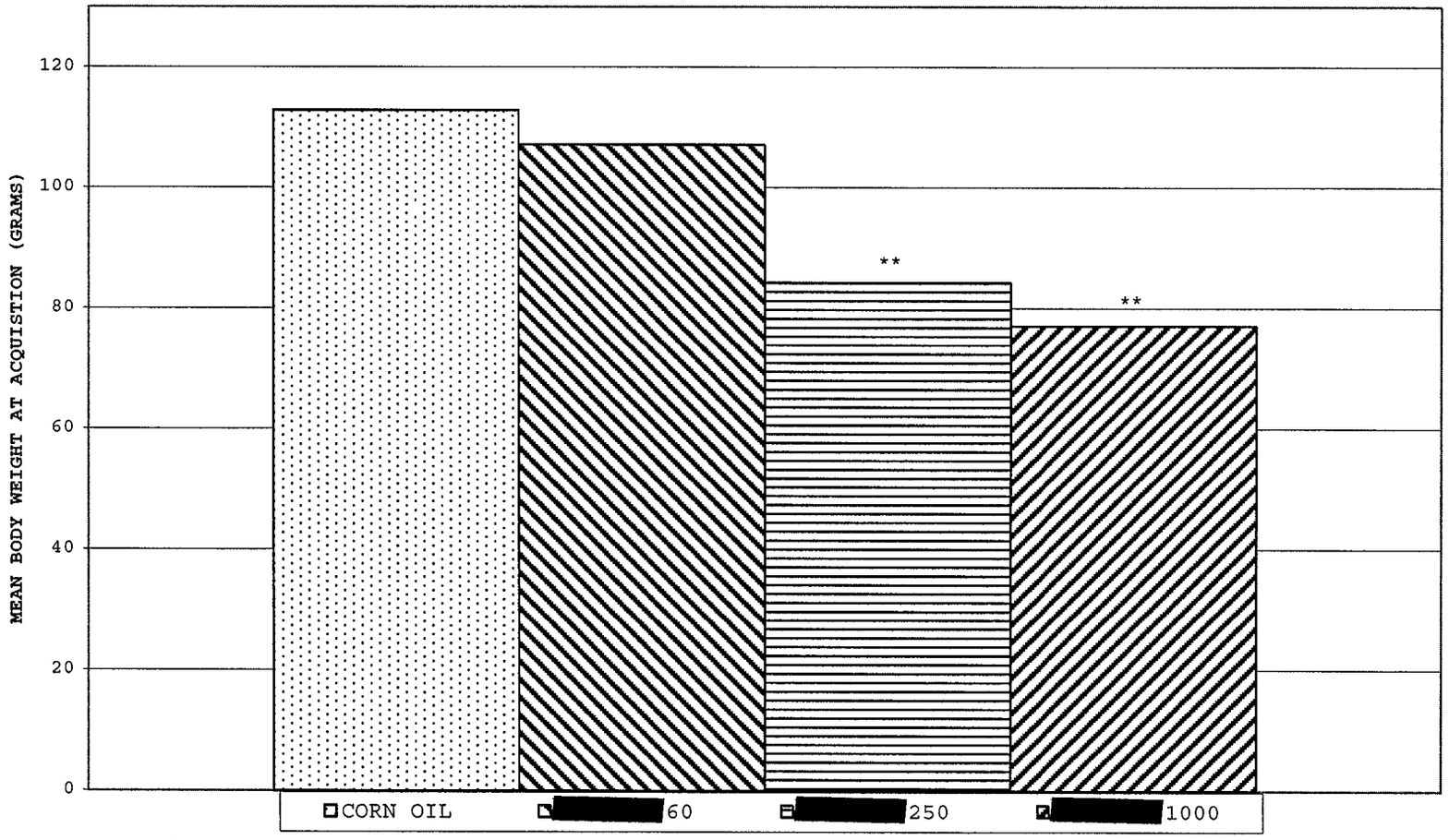
PROJECT NO.:WIL-187042 FIGURE 2 ([redacted]

SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR NO.:04-027 MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



PROJECT NO.:WIL-187042 FIGURE 3 ([redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN BODY WEIGHTS(GRAMS) AT ACQUISITION OF VAGINAL PATENCY

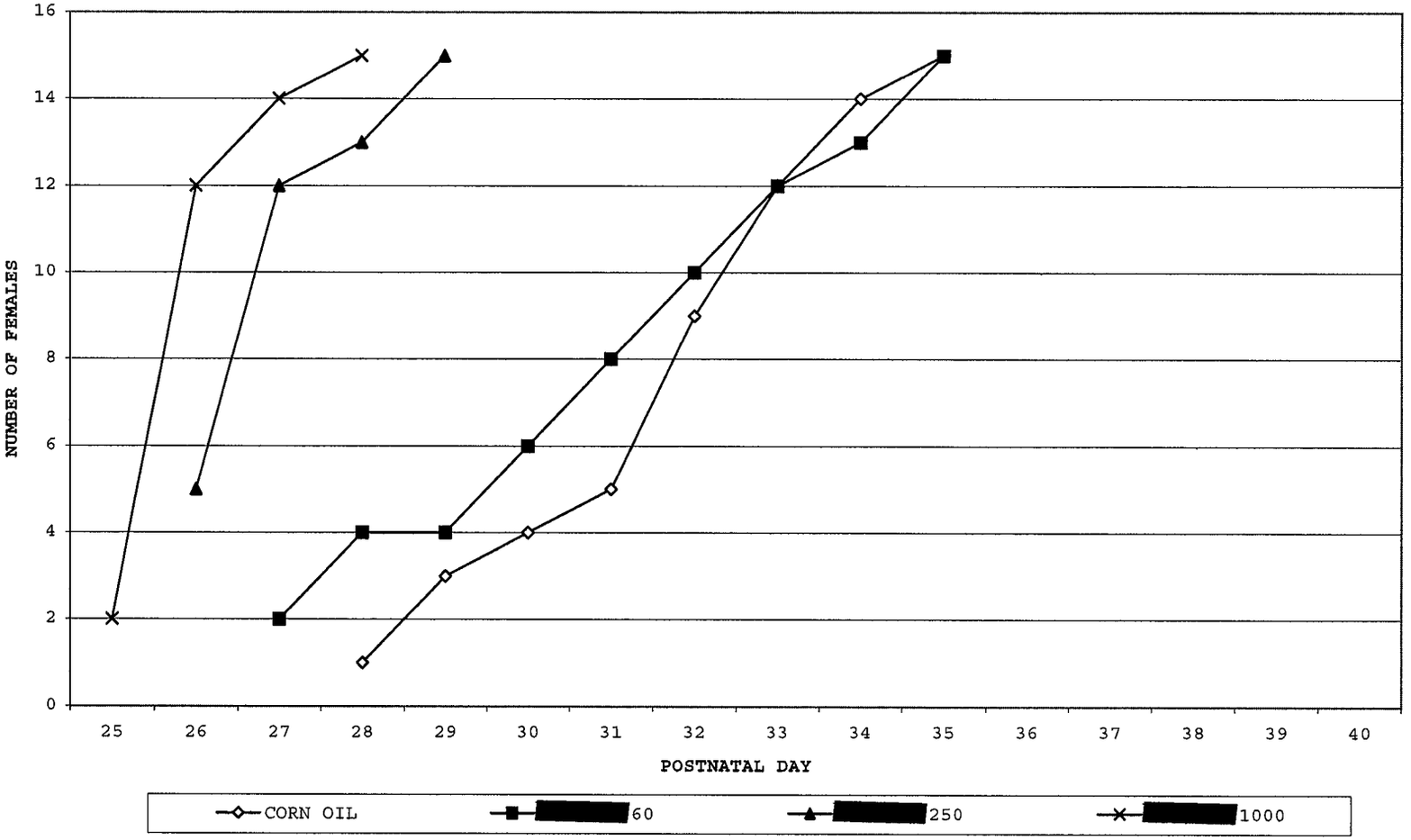


** = Significantly different from control group at 0.01 using Dunnett's test

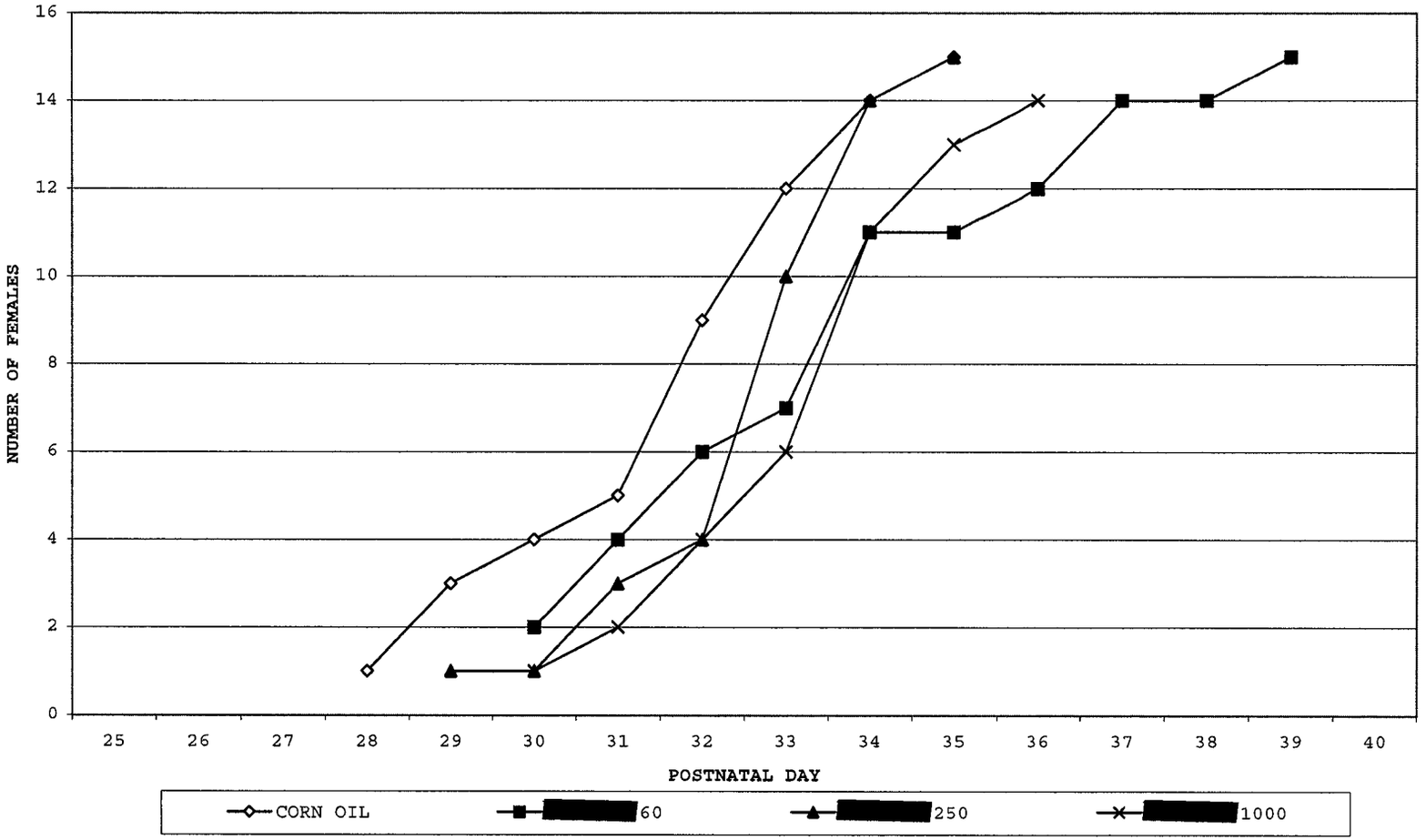
PROJECT NO.:WIL-187042 FIGURE 4 ([redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN BODY WEIGHT (GRAMS) AT ACQUISITION OF VAGINAL PATENCY

* = Significantly different from control group at 0.05 using Dunnett's test

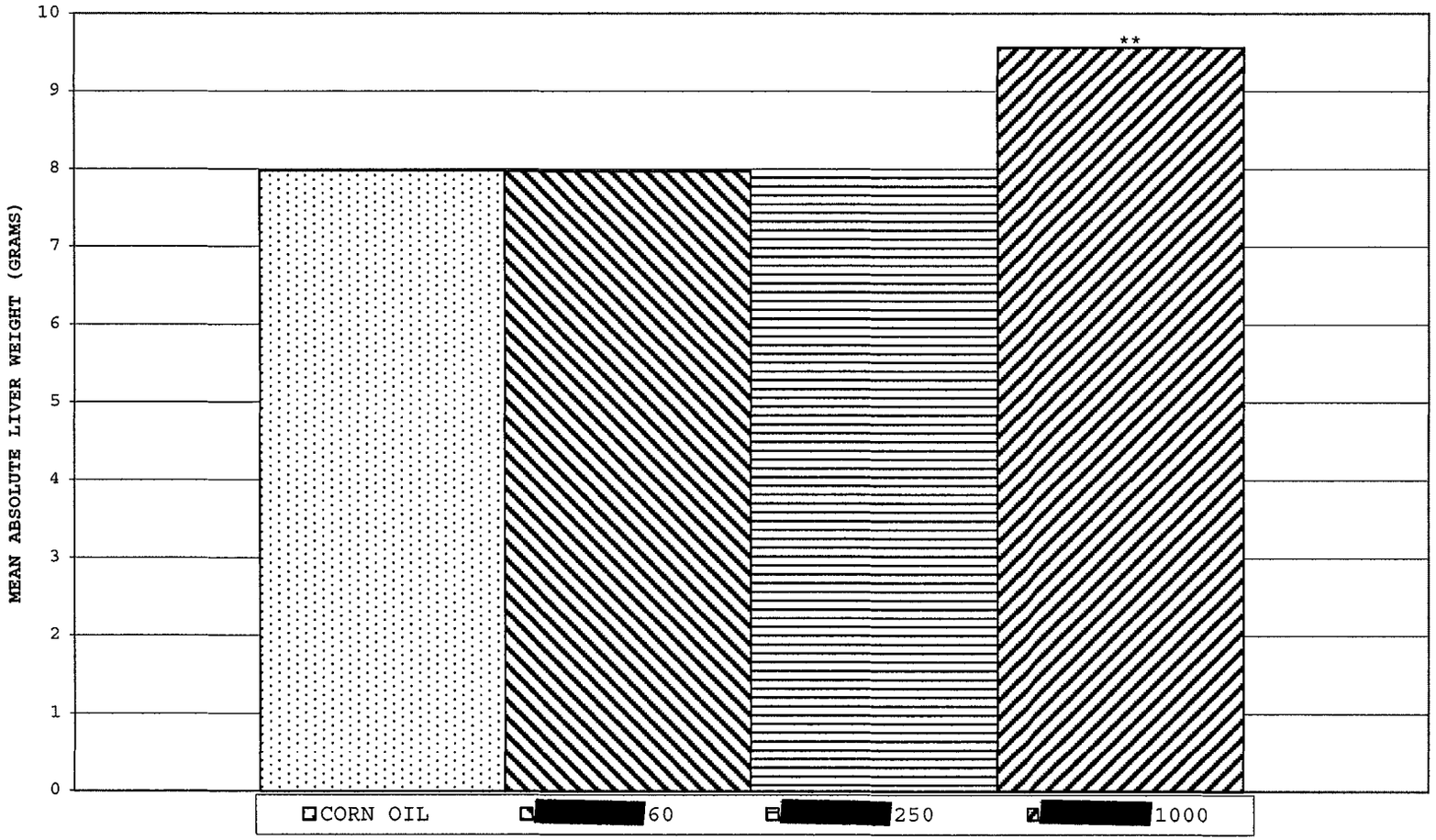
SPONSOR NO.:WIL-187042 FIGURE 5 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY



PROJECT NO.:WIL-187042 FIGURE 6 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY

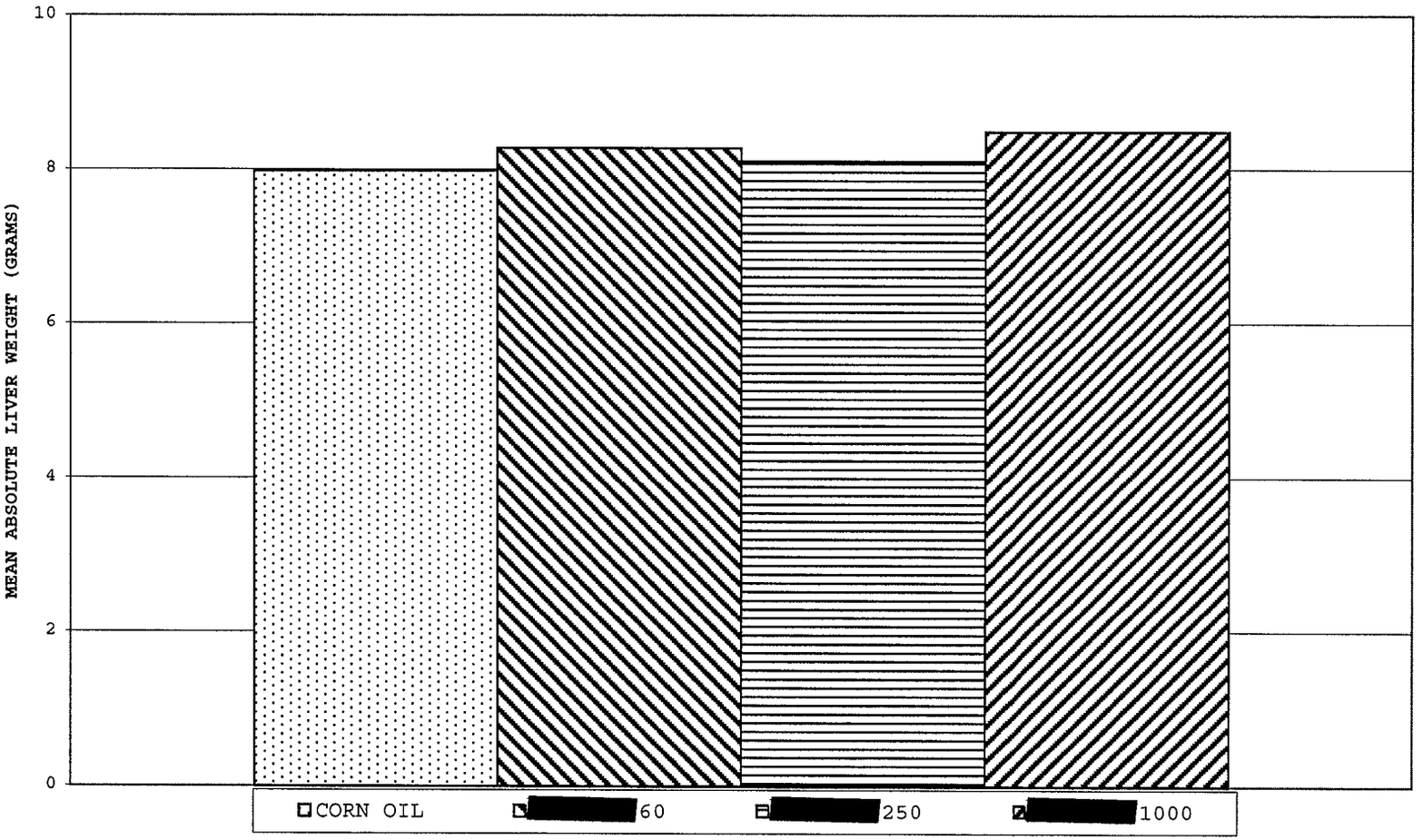


PROJECT NO.:WIL-187042 FIGURE 7 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN ABSOLUTE LIVER WEIGHT (GRAMS)

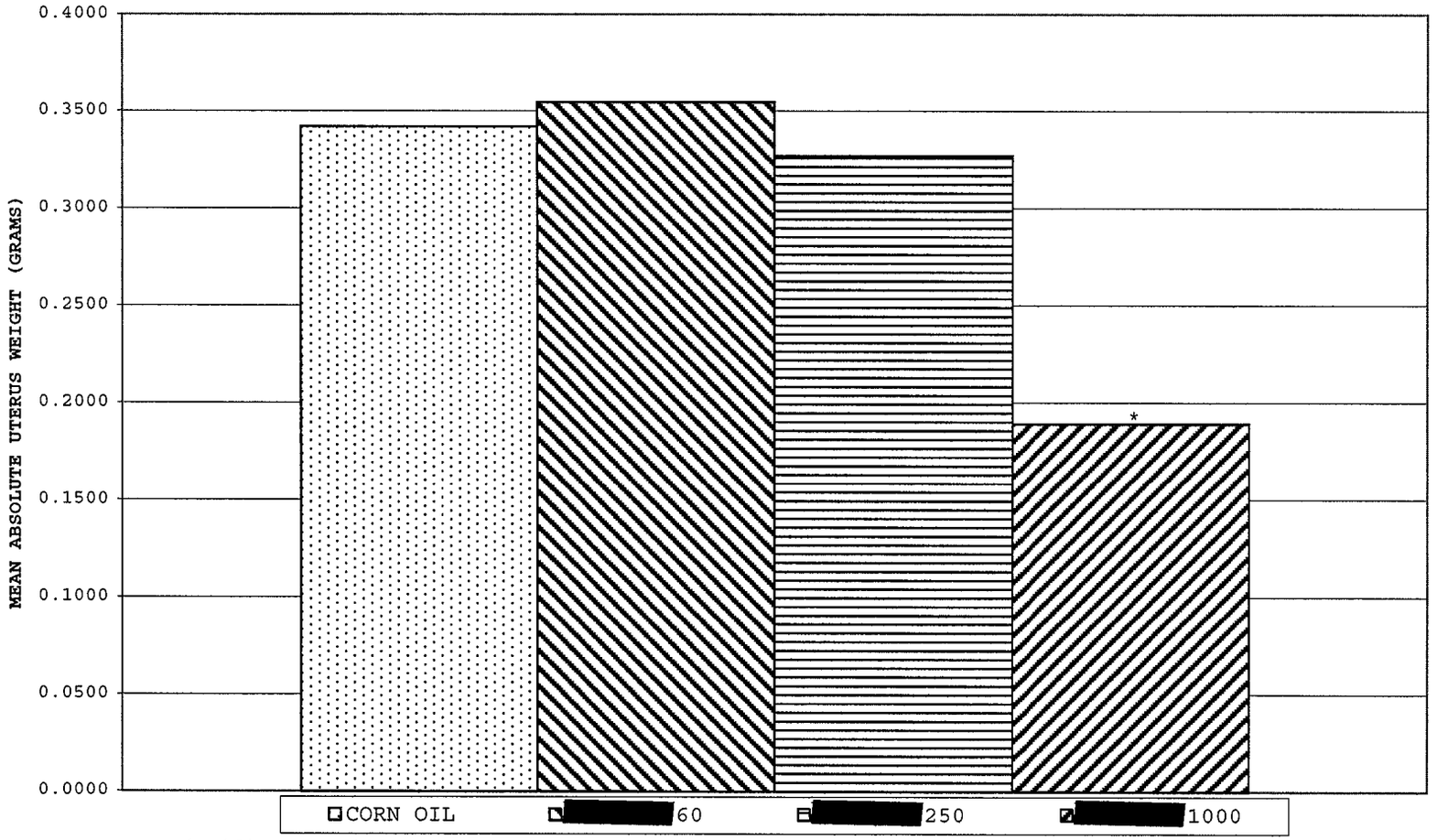


** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187042 FIGURE 8 ([redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN ABSOLUTE LIVER WEIGHT (GRAMS)

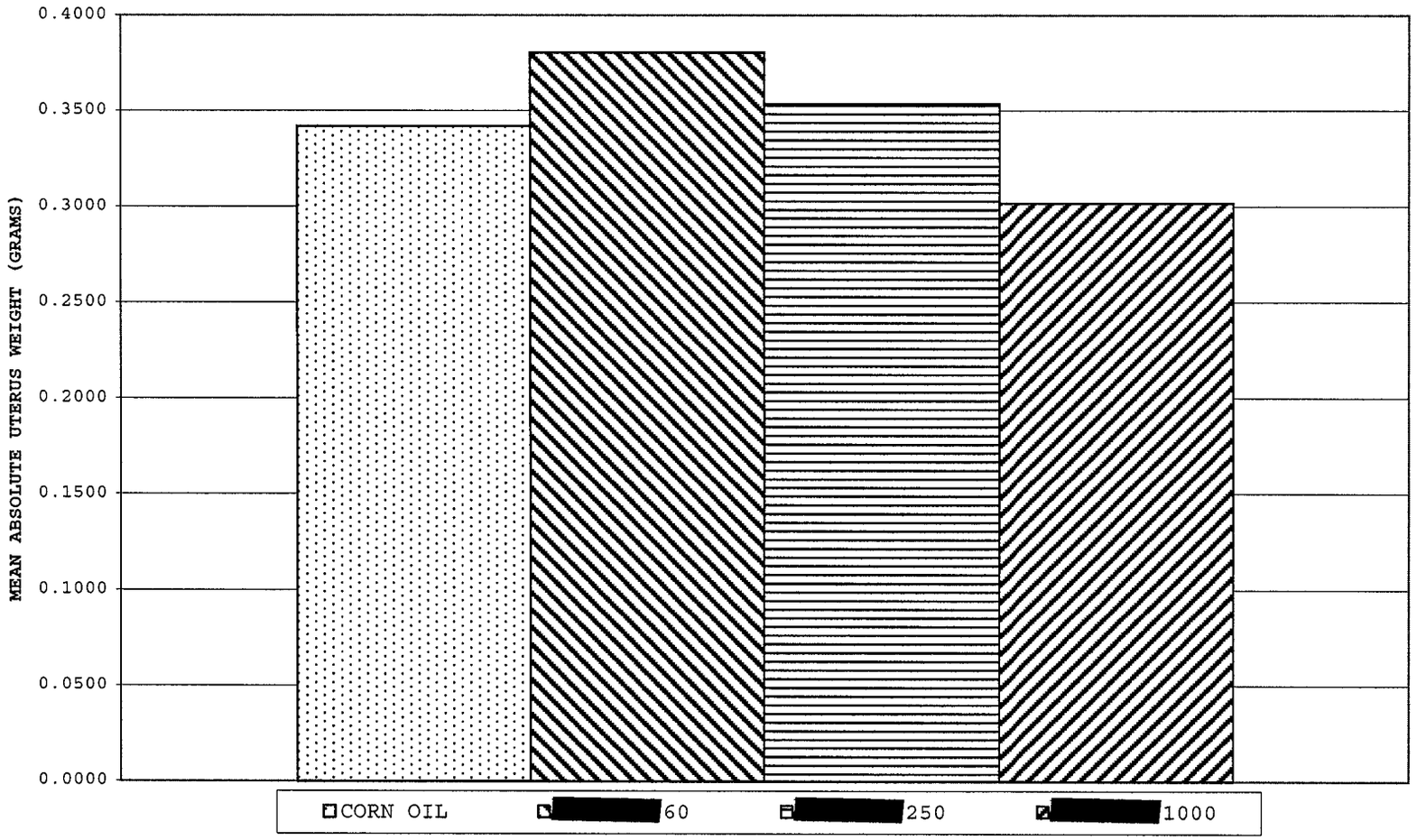


PROJECT NO.:WIL-187042 FIGURE 9 ([redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN ABSOLUTE UTERUS WEIGHT (GRAMS)

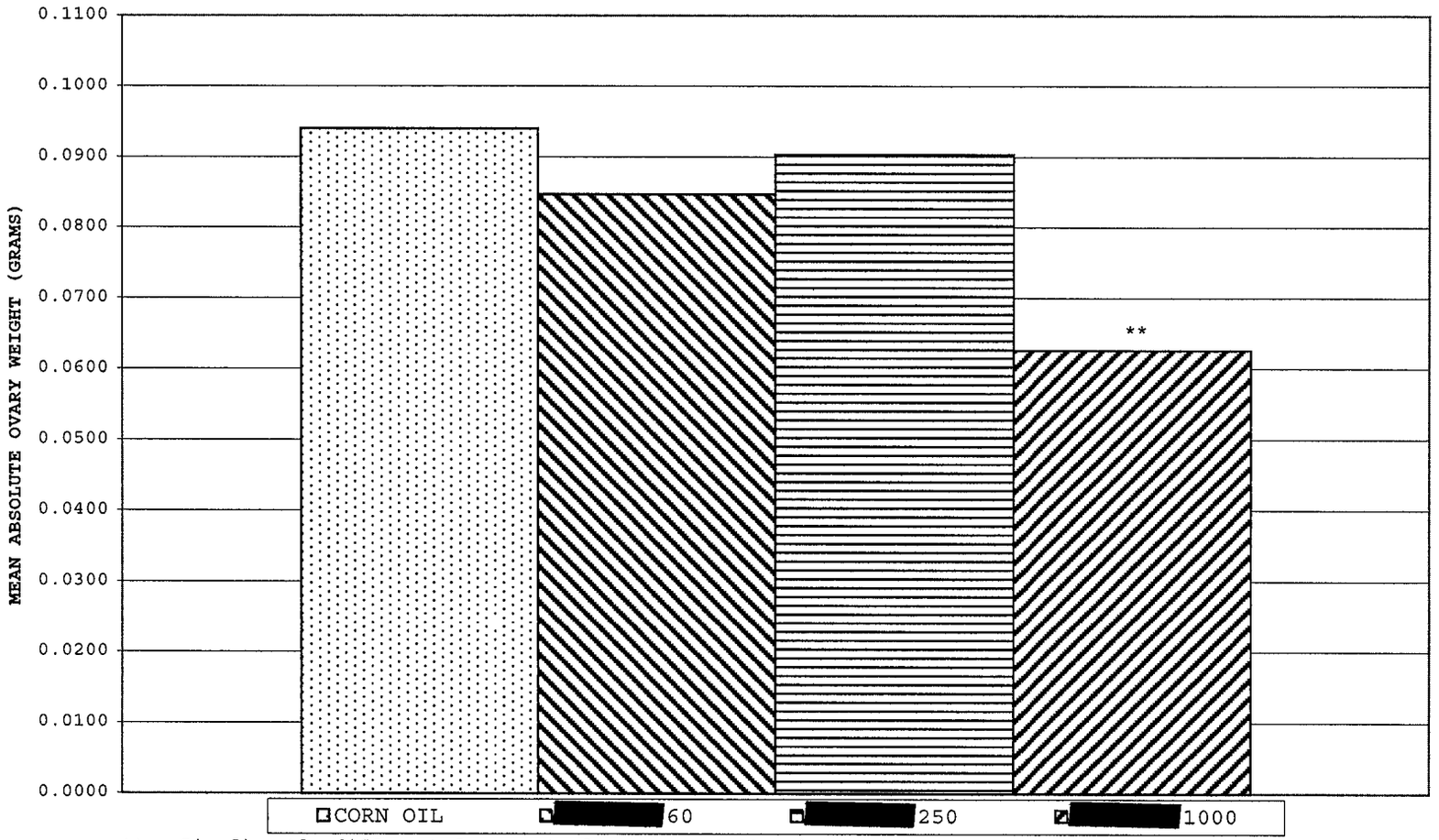


* = Significantly different from control group at 0.05 using Dunnett's test

PROJECT NO.:WIL-187042 FIGURE 10 ([redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN ABSOLUTE UTERUS WEIGHT (GRAMS)



PROJECT NO.:WIL-187042 FIGURE 11 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:04-027 MEAN ABSOLUTE OVARY WEIGHT (GRAMS)

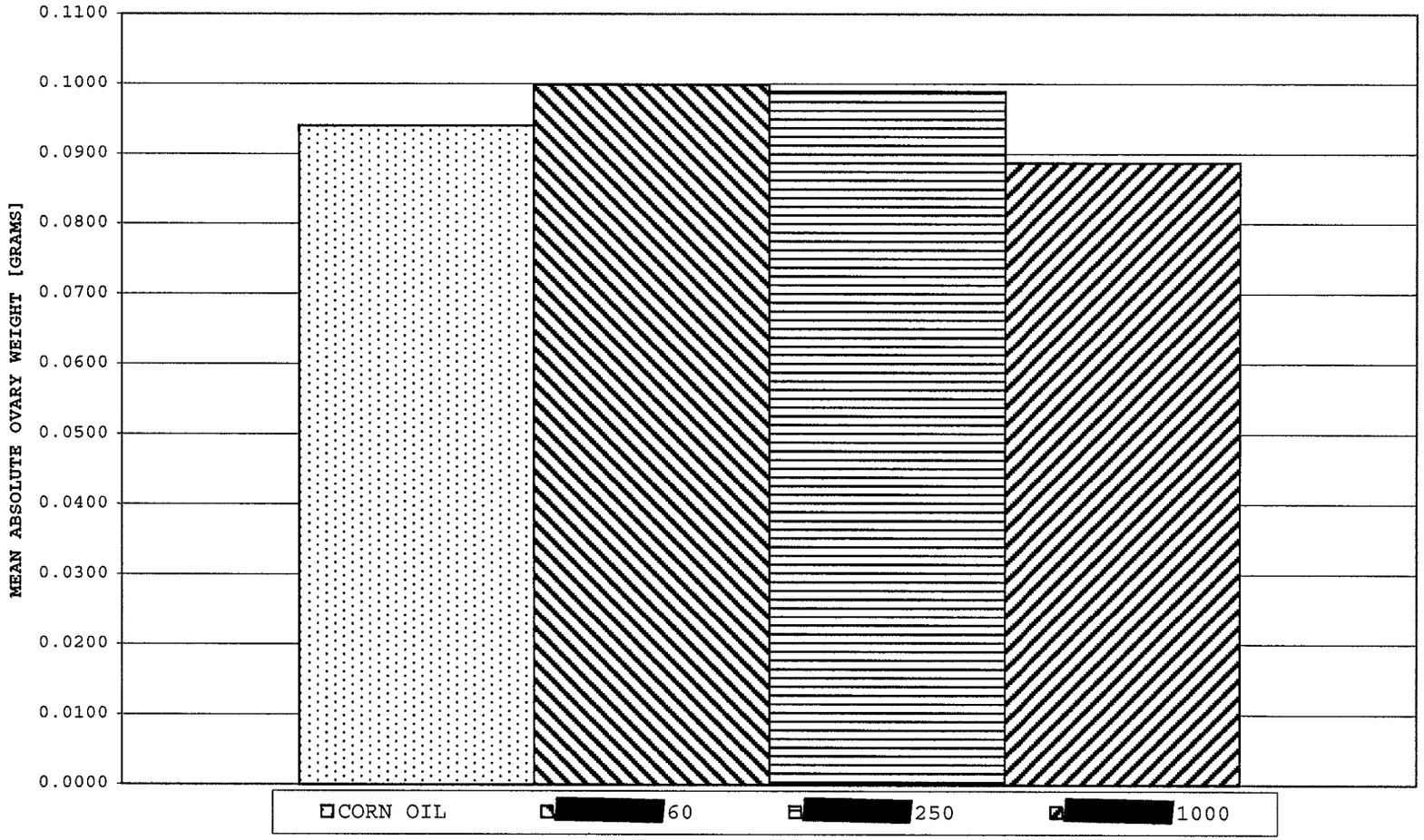


** = Signficantly different from control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187042 FIGURE 12 ([redacted]

SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR NO.:04-027 MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



TABLES 1-23

TABLE 1

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF SURVIVAL AND DISPOSITION

SPONSOR NO.:04-027

FEMALES

GROUP :	1				2				3				4			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
30	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
31	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
32	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
33	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
34	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
35	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
36	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
37	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
38	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
39	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
40	15	0	0	0	15	0	0	0	15	0	0	0	14	0	1	0
41	15	0	0	0	15	0	0	0	15	0	0	0	14	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	14

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000

TABLE 1

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SUMMARY OF SURVIVAL AND DISPOSITION

SPONSOR NO.:04-027

FEMALES

GROUP :	5				6				7			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0
30	15	0	0	0	15	0	0	0	14	1	0	0
31	15	0	0	0	15	0	0	0	14	0	0	0
32	15	0	0	0	15	0	0	0	14	0	0	0
33	15	0	0	0	15	0	0	0	14	0	0	0
34	15	0	0	0	15	0	0	0	14	0	0	0
35	15	0	0	0	15	0	0	0	14	0	0	0
36	15	0	0	0	15	0	0	0	14	0	0	0
37	15	0	0	0	15	0	0	0	14	0	0	0
38	15	0	0	0	15	0	0	0	14	0	0	0
39	15	0	0	0	15	0	0	0	14	0	0	0
40	15	0	0	0	15	0	0	0	14	0	0	0
41	15	0	0	0	15	0	0	0	14	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	14

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

5- [redacted]60 6- [redacted]250 7- [redacted]1000

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01/20/2005

TABLE 2 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	11-26-04 TO 12-18-04						
GROUP:	1	2	3	4	5	6	7
NORMAL							
-NO SIGNIFICANT CLINICAL OBSERVATIONS	315/15	308/15	315/15	297/15	315/15	304/15	303/15
DISPOSITION							
-FOUND DEAD	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-SCHEDULED EUTHANASIA	15/15	15/15	15/15	14/14	15/15	15/15	14/14
-EUTHANIZED IN EXTREMIS	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
BEHAVIOR/CNS							
-BODY COOL TO TOUCH	0/ 0	0/ 0	0/ 0	3/ 1	0/ 0	0/ 0	0/ 0
-HYPOACTIVITY	0/ 0	0/ 0	0/ 0	3/ 1	0/ 0	0/ 0	0/ 0
-PALE IN COLOR	0/ 0	0/ 0	0/ 0	2/ 1	0/ 0	0/ 0	0/ 0
BODY/INTEGUMENT							
-HAIR LOSS RIGHT FORELIMB	0/ 0	4/ 2	0/ 0	5/ 3	0/ 0	5/ 2	0/ 0
-HAIR LOSS LEFT FORELIMB	0/ 0	6/ 2	0/ 0	9/ 3	0/ 0	10/ 3	0/ 0
CARDIO-PULMONARY							
-LABORED RESPIRATION	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
-GASPING	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
EYES/EARS/NOSE							
-DRIED RED MATERIAL AROUND LEFT EYE	0/ 0	0/ 0	0/ 0	4/ 2	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

TABLE 2 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:04-027

----- F E M A L E -----

TABLE RANGE:	11-26-04 TO 12-18-04						
GROUP:	1	2	3	4	5	6	7
EYES/EARS/NOSE							
-DRIED RED MATERIAL AROUND RIGHT EYE	0/ 0	0/ 0	0/ 0	3/ 1	0/ 0	0/ 0	0/ 0
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	3/ 1	0/ 0	0/ 0	0/ 0
ORAL/DENTAL							
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	2/ 1	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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01/20/2005

TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:04-027

----- F E M A L E -----

TABLE RANGE:	11-26-04 TO 12-17-04						
GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING	0/ 0	0/ 0	34/13	140/15	0/ 0	0/ 0	11/ 9
-PROSTRATE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
ORAL/DENTAL							
-SALIVATION	0/ 0	1/ 1	18/ 8	31/15	0/ 0	0/ 0	11/ 7
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	24/12	78/15	2/ 2	1/ 1	19/10
-SALIVATION PRIOR TO DOSING	6/ 1	5/ 4	52/ 9	105/13	0/ 0	15/ 2	39/ 7
-WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING	0/ 0	0/ 0	0/ 0	9/ 7	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.05
01/20/2005
R:01/24/2005

TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	11-26-04 TO 12-17-04						
GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-WIPES MOUTH ON CAGE FLOOR AND/OR WALLS	0/ 0	0/ 0	3/ 3	40/14	0/ 0	0/ 0	14/ 8
ORAL/DENTAL							
-SALIVATION	0/ 0	0/ 0	2/ 2	13/ 8	0/ 0	0/ 0	5/ 3
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	22/ 8	163/15	1/ 1	0/ 0	35/10

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.05
01/20/2005
R:01/24/2005

TABLE 5

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHTS [G]

FEMALES

	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22								
	MEAN	59.0	58.6	58.9	58.5	58.9	58.6	58.5
	S.D.	5.16	6.01	5.03	4.34	5.19	4.94	4.44
	N	15	15	15	15	15	15	15
PND 23								
	MEAN	64.9	63.8	63.8	62.9	64.0	64.0	63.5
	S.D.	5.58	6.79	5.02	5.18	5.36	5.22	4.65
	N	15	15	15	15	15	15	15
PND 24								
	MEAN	70.3	69.1	68.5	66.5	69.5	69.4	69.0
	S.D.	5.43	6.61	5.75	5.41	5.86	5.49	4.84
	N	15	15	15	15	15	15	15
PND 25								
	MEAN	75.4	74.3	74.0	71.5	74.6	74.2	74.0
	S.D.	6.21	7.69	5.85	5.39	6.25	5.84	5.14
	N	15	15	15	15	15	15	15
PND 26								
	MEAN	80.9	80.0	78.9	76.7	80.2	79.6	79.6
	S.D.	7.20	8.42	6.06	5.89	7.26	6.68	5.44
	N	15	15	15	15	15	15	15
PND 27								
	MEAN	86.2	85.1	84.4	81.9	85.2	84.5	85.2
	S.D.	8.08	9.05	6.24	5.67	7.69	6.73	5.64
	N	15	15	15	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

TABLE 5

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28								
	MEAN	91.9	90.4	90.7	87.3	91.4	90.0	90.6
	S.D.	8.96	10.01	7.01	6.75	8.80	7.30	6.37
	N	15	15	15	15	15	15	15
PND 29								
	MEAN	97.1	96.7	96.1	92.6	97.2	95.9	96.2
	S.D.	8.98	11.66	7.09	6.38	9.59	8.17	6.53
	N	15	15	15	15	15	15	15
PND 30								
	MEAN	103.5	101.8	101.7	96.8	103.0	101.3	103.0
	S.D.	9.96	12.37	7.36	6.95	10.49	8.33	7.40
	N	15	15	15	15	15	15	15
PND 31								
	MEAN	108.3	107.3	107.2	101.0	109.2	108.2	108.5
	S.D.	9.91	13.21	7.68	8.71	11.70	9.07	8.24
	N	15	15	15	15	15	15	14
PND 32								
	MEAN	115.0	113.0	112.8	104.9	115.6	114.5	115.3
	S.D.	10.79	12.80	8.23	10.21	11.41	9.08	8.45
	N	15	15	15	15	15	15	14
PND 33								
	MEAN	120.7	118.9	118.9	109.7	121.9	120.3	121.9
	S.D.	11.92	14.05	8.27	12.25	11.95	9.04	9.60
	N	15	15	15	15	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

TABLE 5

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34								
	MEAN	127.6	124.7	125.1	115.3	128.4	126.3	128.0
	S.D.	13.51	15.18	9.03	13.52	13.24	9.46	10.28
	N	15	15	15	15	15	15	14
PND 35								
	MEAN	134.2	131.5	131.6	121.7	136.2	133.8	135.4
	S.D.	13.43	16.35	9.19	14.93	13.13	8.95	10.91
	N	15	15	15	15	15	15	14
PND 36								
	MEAN	139.8	136.6	137.6	127.0	141.8	140.9	140.6
	S.D.	13.28	17.35	9.77	14.06	13.86	11.19	11.29
	N	15	15	15	15	15	15	14
PND 37								
	MEAN	145.0	141.3	143.5	132.5	147.6	145.9	146.5
	S.D.	13.05	16.71	10.11	14.23	14.86	10.60	11.25
	N	15	15	15	15	15	15	14
PND 38								
	MEAN	151.1	146.4	147.5	136.0a	152.2	149.8	151.6
	S.D.	14.44	16.97	9.88	15.98	14.69	11.50	11.88
	N	15	15	15	15	15	15	14
PND 39								
	MEAN	156.9	151.8	151.9	140.2a	157.4	155.5	156.1
	S.D.	16.01	17.68	10.08	16.30	12.92	11.66	12.44
	N	15	15	15	15	15	15	14

MODIFIED STATISTICS USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

a = Significantly different from control group 1 at 0.05 using Dunnett's test

TABLE 5

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40								
	MEAN	159.7	155.4	154.7	144.4	162.4	160.0	159.1
	S.D.	16.44	18.76	9.35	17.01	14.56	12.00	11.91
	N	15	15	15	15	15	15	14
PND 41								
	MEAN	164.0	160.9	158.8	151.4	166.5	162.7	163.5
	S.D.	15.99	19.70	10.27	15.71	13.27	12.65	13.38
	N	15	15	15	14	15	15	14
PND 42								
	MEAN	168.7	165.6	162.6	154.3	170.5	168.2	169.7
	S.D.	16.62	19.97	9.76	14.82	12.94	11.48	12.43
	N	15	15	15	14	15	15	14

MODIFIED STATISTICS USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

None significantly different from control group

PJTBWSUv5.11
01/20/2005
R:01/24/2005

TABLE 6

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22- 23							
MEAN	5.9	5.2	4.8	4.4a	5.1	5.4	5.0c
S.D.	1.20	1.43	1.06	1.73	0.91	0.82	0.67
N	15	15	15	15	15	15	15
PND 23- 24							
MEAN	5.4	5.3	4.7	3.6b	5.5	5.4	5.5
S.D.	1.03	0.85	1.27	1.52	1.16	1.36	0.89
N	15	15	15	15	15	15	15
PND 24- 25							
MEAN	5.1	5.1	5.5	5.0	5.2	4.8	5.0
S.D.	1.23	1.44	1.38	1.40	1.25	1.08	0.93
N	15	15	15	15	15	15	15
PND 25- 26							
MEAN	5.4	5.7	4.9	5.2	5.6	5.4	5.6
S.D.	1.33	1.26	0.89	1.67	1.17	1.22	1.03
N	15	15	15	15	15	15	15
PND 26- 27							
MEAN	5.3	5.2	5.5	5.1	5.0	4.9	5.6
S.D.	1.32	1.75	1.30	1.29	3.02	1.01	0.60
N	15	15	15	15	15	15	15
PND 27- 28							
MEAN	5.7	5.3	6.3	5.4	6.2	5.5	5.4
S.D.	1.41	1.36	1.24	1.77	3.32	1.64	1.67
N	15	15	15	15	15	15	15

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test
c = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

TABLE 6

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28- 29							
MEAN	5.2	6.3	5.5	5.4	5.8	5.9	5.6
S.D.	1.78	2.17	0.95	1.24	1.34	2.08	1.60
N	15	15	15	15	15	15	15
PND 29- 30							
MEAN	6.4	5.1	5.6	4.2	5.8	5.4	6.9
S.D.	2.12	1.92	1.26	3.69	1.69	1.82	1.68
N	15	15	15	15	15	15	15
PND 30- 31							
MEAN	4.8	5.5	5.4	4.1	6.2	6.9c	5.4
S.D.	1.95	1.46	1.49	3.04	2.16	2.43	1.45
N	15	15	15	15	15	15	14
PND 31- 32							
MEAN	6.7	5.7	5.6	4.0b	6.4	6.4	6.8
S.D.	1.75	1.69	1.75	3.08	1.16	2.47	2.10
N	15	15	15	15	15	15	14
PND 32- 33							
MEAN	5.7	5.9	6.1	4.8	6.3	5.7	6.6
S.D.	1.91	1.86	2.83	2.72	1.74	2.33	1.85
N	15	15	15	15	15	15	14
PND 33- 34							
MEAN	6.9	5.8	6.2	5.6	6.5	6.0	6.1
S.D.	2.42	2.23	2.73	2.06	2.39	1.78	1.67
N	15	15	15	15	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test
c = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

TABLE 6

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34- 35							
MEAN	6.6	6.8	6.5	6.4	7.8	7.5	7.3
S.D.	2.24	3.02	2.89	3.19	2.04	2.48	2.31
N	15	15	15	15	15	15	14
PND 35- 36							
MEAN	5.6	5.0	6.0	5.3	5.6	7.1	5.3
S.D.	2.61	3.00	3.41	1.40	3.54	3.20	2.57
N	15	15	15	15	15	15	14
PND 36- 37							
MEAN	5.2	4.8	6.0	5.5	5.8	5.0	5.9
S.D.	2.79	2.52	3.83	1.95	2.04	3.20	1.74
N	15	15	15	15	15	15	14
PND 37- 38							
MEAN	6.1	5.0	4.0	3.5	4.6	3.8	5.1
S.D.	2.85	2.38	2.69	7.05	3.00	2.03	1.80
N	15	15	15	15	15	15	14
PND 38- 39							
MEAN	5.8	5.4	4.4	4.3	5.2	5.7	4.5
S.D.	3.05	2.62	1.98	2.73	3.07	2.33	1.92
N	15	15	15	15	15	15	14
PND 39- 40							
MEAN	2.9	3.7	2.8	4.1	4.9	4.5	3.0
S.D.	3.00	2.43	4.20	3.47	2.78	2.80	3.04
N	15	15	15	15	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

TABLE 6

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40- 41								
	MEAN	4.2	5.5	4.1	4.8	4.1	2.7	4.4
	S.D.	2.86	2.98	3.59	2.50	4.63	2.81	4.84
	N	15	15	15	14	15	15	14
PND 41- 42								
	MEAN	4.7	4.7	3.8	2.9	4.0	5.5	6.2
	S.D.	3.64	3.28	3.41	2.86	3.09	4.63	4.02
	N	15	15	15	14	15	15	14
PND 22- 42								
	MEAN	109.7	107.0	103.7	95.6a	111.6	109.6	111.2
	S.D.	14.20	16.01	8.96	15.25	8.41	10.16	11.70
	N	15	15	15	14	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.11
01/20/2005
R:01/24/2005

TABLE 7

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
VAGINAL PATENCY (PND)							
MEAN	31.8	31.1	27.0b	26.1b	33.6	32.8	33.4
S.D.	2.04	2.71	1.00	0.74	2.72	1.52	1.65
N	15	15	15	15	15	15	14
BODY WEIGHT (GRAMS)							
MEAN	112.8	107.1	84.2b	77.1b	124.6c	119.0	123.6c
S.D.	10.09	16.91	8.25	7.43	15.36	9.13	12.42
N	15	15	15	15	15	15	14

MODIFIED STATISTICS USED.

PND= POSTNATAL DAY

b = Significantly difference from control group 1 at 0.01 using Dunnett's test

c = Significantly difference from control group 1 at 0.05 using Dunnett's test

PJTBBv1.11
01/20/2005
R:01/26/2005

TABLE 8

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ESTROUS CYCLE DATA
SPONSOR NO.:04-027

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ESTROUS CYCLE LENGTH (DAYS)							
MEAN	5.2	5.7	5.8	5.9	4.7	5.0	5.4
S.D.	0.41	0.81	1.93	3.45	0.52	0.00	1.30
N	11	12	10	6	6	6	8
MEAN AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)							
MEAN	34.1	32.9	32.9	32.4	36.5	35.6	35.4
S.D.	2.84	1.96	3.09	6.79	3.27	3.02	2.84
N	13	15	15	11	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PCYCv5.22
01/20/2005
R:02/23/2005

TABLE 9

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF SPECIAL CHEMISTRY VALUES

SPONSOR NO.:04-027

			FEMALES					
ANALYSIS	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
TOTAL T4 (uG/dL)								
DAY 42	MEAN	4.51	5.02	5.29	5.33	4.69	4.90	4.56
	S.D.	1.217	0.976	0.718	1.664	1.324	0.976	0.921
	N	15	15	15	15	15	15	14
TSH (ng/ml)								
DAY 42	MEAN	11.4	12.0	10.0	11.4	10.5	10.7	11.1
	S.D.	3.80	5.01	2.74	3.97	3.93	5.16	4.49
	N	15	15	15	15	15	15	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

MODIFIED STATISTIC USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

None significantly different from control group

PCPSv5.2
02/25/2005

TABLE 10 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:04-027

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	0	0	0	1	0	0	1
LUNGS							
-DISCOLORATION, DARK RED	0	0	0	0	0	0	1
SKIN							
-MATTING, RED	0	0	0	1	0	0	0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PGRSI2v4.05
01/20/2005

TABLE 11

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS [G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
UTERUS- WET (G)							
MEAN	0.3420	0.3544	0.3270	0.1890a	0.3804	0.3534	0.3017
S.D.	0.15255	0.20453	0.13692	0.03843	0.14476	0.08257	0.11461
N	15	15	15	14	15	15	14
UTERUS- BLOTTED (G)							
MEAN	0.2810	0.2711	0.2626	0.1757b	0.3193	0.3249	0.2566
S.D.	0.07266	0.09204	0.05630	0.03491	0.07829	0.07627	0.06348
N	15	15	15	14	15	15	14
LUMINAL FLUID (G)							
MEAN	0.0610	0.0833	0.0644	0.0133	0.0610	0.0285	0.0451
S.D.	0.10757	0.12224	0.08540	0.00539	0.09315	0.01244	0.05531
N	15	15	15	14	15	15	14
LIVER (G)							
MEAN	7.9780	7.9686	7.8945	9.5595b	8.2722	8.1028	8.4845
S.D.	1.02781	1.32512	0.70578	0.98729	0.91463	0.94154	1.06062
N	15	15	15	14	15	15	14
KIDNEYS (G)							
MEAN	1.6541	1.5895	1.6182	1.5549	1.6837	1.6690	1.7380
S.D.	0.20746	0.22863	0.11141	0.14577	0.16412	0.13857	0.15786
N	15	15	15	14	15	15	14
OVARIES/OVIDUCTS (G)							
MEAN	0.0940	0.0847	0.0903	0.0626b	0.0998	0.0989	0.0887
S.D.	0.02767	0.02368	0.01155	0.02061	0.02324	0.01895	0.02739
N	15	15	15	14	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
			FEMALES				
ADRENAL GLANDS (G)							
MEAN	0.0428	0.0396	0.0464	0.0445	0.0449	0.0442	0.0422
S.D.	0.00666	0.00916	0.00394	0.00859	0.00727	0.00675	0.00852
N	15	15	15	14	15	15	14
PITUITARY (G)							
MEAN	0.0093	0.0085	0.0089	0.0073b	0.0091	0.0092	0.0091
S.D.	0.00144	0.00166	0.00097	0.00106	0.00143	0.00127	0.00102
N	15	15	15	14	15	15	14
THYROID GLANDS (G)							
MEAN	0.0213	0.0180	0.0172	0.0189	0.0181	0.0202	0.0210
S.D.	0.00556	0.00221	0.00312	0.00466	0.00424	0.00245	0.00244
N	14	14	15	14	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test

POFBSTv5.05
01/20/2005
R:02/25/2005

TABLE 12

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
FINAL BODY WT (G)							
MEAN	169.	166.	163.	154.	171.	168.	170.
S.D.	16.6	20.0	9.8	14.9	12.9	11.3	12.6
N	15	15	15	14	15	15	14
UTERUS- WET							
MEAN	0.205	0.210	0.203	0.123a	0.224	0.211	0.179
S.D.	0.0995	0.1089	0.0898	0.0218	0.0917	0.0529	0.0712
N	15	15	15	14	15	15	14
UTERUS- BLOTTED							
MEAN	0.167	0.163	0.162	0.114b	0.187	0.194	0.152
S.D.	0.0402	0.0466	0.0392	0.0200	0.0430	0.0490	0.0395
N	15	15	15	14	15	15	14
LIVER							
MEAN	4.723	4.797	4.849	6.210b	4.848	4.807	4.991
S.D.	0.2399	0.4182	0.2857	0.4779	0.3582	0.3417	0.3643
N	15	15	15	14	15	15	14
KIDNEYS							
MEAN	0.979	0.959	0.995	1.010	0.987	0.992	1.025
S.D.	0.0518	0.0641	0.0507	0.0664	0.0584	0.0477	0.0528
N	15	15	15	14	15	15	14

MODIFIED STATISTICS USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

TABLE 12

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

	FEMALES						
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
OVARIES/OVIDUCTS							
MEAN	0.056	0.051	0.056	0.040b	0.058	0.059	0.052
S.D.	0.0151	0.0110	0.0067	0.0109	0.0113	0.0094	0.0157
N	15	15	15	14	15	15	14
ADRENAL GLANDS							
MEAN	0.025	0.024	0.029	0.029	0.026	0.026	0.025
S.D.	0.0034	0.0044	0.0025	0.0050	0.0032	0.0031	0.0049
N	15	15	15	14	15	15	14
PITUITARY							
MEAN	0.005	0.005	0.006	0.005	0.005	0.005	0.005
S.D.	0.0006	0.0007	0.0008	0.0007	0.0006	0.0006	0.0005
N	15	15	15	14	15	15	14
THYROID GLANDS							
MEAN	0.013	0.011	0.011	0.012	0.011	0.012	0.013
S.D.	0.0037	0.0013	0.0021	0.0030	0.0026	0.0015	0.0018
N	14	14	15	14	15	15	14

MODIFIED STATISTICS USED.

For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.

b = Significantly different from control group 1 at 0.01 using Dunnett's test

POFBSTv5.05
01/20/2005
R:01/24/2005

TABLE 13 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:04-027

TABLE RANGE: 11-26-04 TO 12-18-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69626-09	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69627-04	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69627-05	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69629-07	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69629-09	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69630-03	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69630-04	F	CORN OIL	DISPOSITION	12-16-04	7:35	P	SCHEDULED EUTHANASIA
69631-03	F	CORN OIL	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69631-04	F	CORN OIL	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69632-02	F	CORN OIL	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69633-05	F	CORN OIL	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69634-09	F	CORN OIL	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69636-06	F	CORN OIL	DISPOSITION	12-18-04	6:47	P	SCHEDULED EUTHANASIA
69636-09	F	CORN OIL	DISPOSITION	12-18-04	6:47	P	SCHEDULED EUTHANASIA
69638-09	F	CORN OIL	DISPOSITION	12-18-04	6:47	P	SCHEDULED EUTHANASIA
69626-03	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69626-03	F	[redacted]60	BODY/INTEGUMENT	11-29-04	7:36	1	HAIR LOSS LEFT FORELIMB
				11-30-04	7:52	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	7:52	1	HAIR LOSS LEFT FORELIMB
				12-03-04	7:01	1	HAIR LOSS LEFT FORELIMB
				12-04-04	6:59	1	HAIR LOSS LEFT FORELIMB
69626-08	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69626-08	F	[redacted]60	BODY/INTEGUMENT	11-29-04	7:36	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:36	1	HAIR LOSS LEFT FORELIMB
				12-03-04	7:01	1	HAIR LOSS RIGHT FORELIMB
				12-03-04	7:01	1	HAIR LOSS LEFT FORELIMB
				12-04-04	7:00	1	HAIR LOSS RIGHT FORELIMB
69627-07	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69628-06	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 13 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:04-027

TABLE RANGE: 11-26-04 TO 12-18-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69629-10	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69630-06	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69630-10	F	[redacted]60	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69631-05	F	[redacted]60	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69632-03	F	[redacted]60	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69632-07	F	[redacted]60	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69632-09	F	[redacted]60	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69634-07	F	[redacted]60	DISPOSITION	12-17-04	7:17	P	SCHEDULED EUTHANASIA
69635-01	F	[redacted]60	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69637-01	F	[redacted]60	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69637-09	F	[redacted]60	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69627-08	F	[redacted]250	DISPOSITION	12-16-04	7:36	P	SCHEDULED EUTHANASIA
69628-02	F	[redacted]250	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69628-08	F	[redacted]250	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69629-02	F	[redacted]250	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69629-04	F	[redacted]250	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69629-06	F	[redacted]250	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69629-08	F	[redacted]250	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69631-02	F	[redacted]250	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69631-07	F	[redacted]250	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69632-01	F	[redacted]250	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69633-07	F	[redacted]250	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69633-08	F	[redacted]250	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69635-02	F	[redacted]250	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69636-10	F	[redacted]250	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69637-08	F	[redacted]250	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69626-01	F	[redacted]1000	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69626-01	F	[redacted]1000	BODY/INTEGUMENT	11-29-04	7:42	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:42	1	HAIR LOSS LEFT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 13 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:04-027

TABLE RANGE: 11-26-04 TO 12-18-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69626-01	F	[redacted]1000	BODY/INTEGUMENT	11-30-04	8:00	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	8:00	1	HAIR LOSS LEFT FORELIMB
69626-05	F	[redacted]1000	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69626-05	F	[redacted]1000	BODY/INTEGUMENT	11-30-04	8:00	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	8:00	1	HAIR LOSS LEFT FORELIMB
				12-03-04	7:14	1	HAIR LOSS RIGHT FORELIMB
				12-03-04	7:14	1	HAIR LOSS LEFT FORELIMB
				12-04-04	7:11	1	HAIR LOSS LEFT FORELIMB
69626-06	F	[redacted]1000	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69626-06	F	[redacted]1000	BODY/INTEGUMENT	11-29-04	7:42	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:42	2	HAIR LOSS LEFT FORELIMB
				12-03-04	7:14	1	HAIR LOSS LEFT FORELIMB
				12-04-04	7:11	1	HAIR LOSS LEFT FORELIMB
				12-05-04	6:54	1	HAIR LOSS LEFT FORELIMB
69627-03	F	[redacted]1000	DISPOSITION	12-16-04	7:37	P	SCHEDULED EUTHANASIA
69628-07	F	[redacted]1000	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69628-10	F	[redacted]1000	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69630-07	F	[redacted]1000	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69631-09	F	[redacted]1000	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69632-06	F	[redacted]1000	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69633-02	F	[redacted]1000	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69633-02	F	[redacted]1000	BEHAVIOR/CNS	12-08-04	8:53	P	BODY COOL TO TOUCH
				12-08-04	8:53	P	HYPOACTIVITY
				12-09-04	6:20	P	BODY COOL TO TOUCH
				12-09-04	6:20	P	HYPOACTIVITY
				12-09-04	6:20	P	PALE IN COLOR
				12-10-04	6:24	P	BODY COOL TO TOUCH
				12-10-04	6:24	P	HYPOACTIVITY
				12-10-04	6:24	P	PALE IN COLOR

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 13 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027 INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 11-26-04 TO 12-18-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69633-02	F	[redacted]1000	EYES/EARS/NOSE	12-05-04	6:57	1	DRIED RED MATERIAL AROUND LEFT EYE
69633-10	F	1000	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69634-05	F	1000	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69637-10	F	1000	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69638-01	F	1000	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69638-07	F	1000	DISPOSITION	12-16-04	10:19	P	EUTHANIZED IN EXTREMIS
69638-07	F	1000	CARDIO-PULMONARY	12-15-04	6:54	P	LABORED RESPIRATION
				12-16-04	7:01	P	GASPING
69638-07	F	[redacted]1000	EYES/EARS/NOSE	12-14-04	7:06	1	DRIED RED MATERIAL AROUND LEFT EYE
				12-14-04	7:06	1	DRIED RED MATERIAL AROUND RIGHT EYE
				12-14-04	7:07	1	DRIED RED MATERIAL AROUND NOSE
				12-15-04	6:53	2	DRIED RED MATERIAL AROUND LEFT EYE
				12-15-04	6:53	2	DRIED RED MATERIAL AROUND RIGHT EYE
				12-15-04	6:53	2	DRIED RED MATERIAL AROUND NOSE
				12-16-04	7:02	1	DRIED RED MATERIAL AROUND LEFT EYE
				12-16-04	7:02	1	DRIED RED MATERIAL AROUND RIGHT EYE
				12-16-04	7:02	1	DRIED RED MATERIAL AROUND NOSE
69638-07	F	[redacted]1000	ORAL/DENTAL	12-14-04	7:07	1	DRIED RED MATERIAL AROUND MOUTH
				12-15-04	6:54	2	DRIED RED MATERIAL AROUND MOUTH
69627-01	F	[redacted]60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69627-02	F	60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69627-06	F	60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69627-10	F	60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69628-01	F	60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69630-08	F	60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69630-09	F	60	DISPOSITION	12-16-04	7:38	P	SCHEDULED EUTHANASIA
69631-06	F	60	DISPOSITION	12-17-04	7:18	P	SCHEDULED EUTHANASIA
69631-08	F	60	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA
69632-08	F	60	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 13 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:04-027

TABLE RANGE: 11-26-04 TO 12-18-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69634-02	F	[redacted]60	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA
69634-08	F	[redacted]60	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA
69635-09	F	[redacted]60	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69637-04	F	[redacted]60	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69638-04	F	[redacted]60	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69626-02	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69626-02	F	[redacted]250	BODY/INTEGUMENT	11-29-04	7:48	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:48	1	HAIR LOSS LEFT FORELIMB
				12-03-04	7:24	1	HAIR LOSS LEFT FORELIMB
				12-04-04	7:21	1	HAIR LOSS LEFT FORELIMB
				12-05-04	7:03	1	HAIR LOSS LEFT FORELIMB
69626-04	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69626-04	F	[redacted]250	BODY/INTEGUMENT	11-29-04	7:49	1	HAIR LOSS RIGHT FORELIMB
				11-29-04	7:49	1	HAIR LOSS LEFT FORELIMB
				11-30-04	8:10	1	HAIR LOSS RIGHT FORELIMB
				11-30-04	8:10	1	HAIR LOSS LEFT FORELIMB
				12-03-04	7:24	1	HAIR LOSS RIGHT FORELIMB
				12-03-04	7:24	1	HAIR LOSS LEFT FORELIMB
				12-04-04	7:21	1	HAIR LOSS RIGHT FORELIMB
69626-10	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69626-10	F	[redacted]250	BODY/INTEGUMENT	11-29-04	7:49	1	HAIR LOSS LEFT FORELIMB
				11-30-04	8:10	1	HAIR LOSS LEFT FORELIMB
				12-04-04	7:22	1	HAIR LOSS LEFT FORELIMB
69628-05	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69628-09	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69629-01	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69630-05	F	[redacted]250	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69632-04	F	[redacted]250	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA
69632-10	F	[redacted]250	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 11-26-04 TO 12-18-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69633-03	F	250	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA
69633-04	F	250	DISPOSITION	12-17-04	7:19	P	SCHEDULED EUTHANASIA
69634-10	F	250	DISPOSITION	12-17-04	7:20	P	SCHEDULED EUTHANASIA
69635-10	F	250	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69637-02	F	250	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69638-08	F	250	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69626-07	F	1000	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69628-03	F	1000	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69628-04	F	1000	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69629-03	F	1000	DISPOSITION	12-04-04	13:33	P	FOUND DEAD
69629-05	F	1000	DISPOSITION	12-16-04	7:39	P	SCHEDULED EUTHANASIA
69630-01	F	1000	DISPOSITION	12-16-04	7:40	P	SCHEDULED EUTHANASIA
69630-02	F	1000	DISPOSITION	12-16-04	7:40	P	SCHEDULED EUTHANASIA
69631-01	F	1000	DISPOSITION	12-17-04	7:20	P	SCHEDULED EUTHANASIA
69631-10	F	1000	DISPOSITION	12-17-04	7:20	P	SCHEDULED EUTHANASIA
69632-05	F	1000	DISPOSITION	12-17-04	7:20	P	SCHEDULED EUTHANASIA
69634-01	F	1000	DISPOSITION	12-17-04	7:20	P	SCHEDULED EUTHANASIA
69634-03	F	1000	DISPOSITION	12-17-04	7:20	P	SCHEDULED EUTHANASIA
69637-03	F	1000	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69638-02	F	1000	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA
69638-10	F	1000	DISPOSITION	12-18-04	6:48	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:04-027

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69638-09	F	CORN OIL	ORAL/DENTAL	12-04-04	11:29	1	SALIVATION PRIOR TO DOSING
				12-08-04	11:47	1	SALIVATION PRIOR TO DOSING
				12-09-04	11:47	1	SALIVATION PRIOR TO DOSING
				12-10-04	11:51	1	SALIVATION PRIOR TO DOSING
				12-11-04	10:58	1	SALIVATION PRIOR TO DOSING
				12-12-04	10:55	1	SALIVATION PRIOR TO DOSING
69626-03	F	[redacted]60	ORAL/DENTAL	12-13-04	11:42	1	SALIVATION PRIOR TO DOSING
69630-06	F	[redacted]60	ORAL/DENTAL	12-04-04	11:34	2	SALIVATION
				12-08-04	11:49	1	SALIVATION PRIOR TO DOSING
				12-14-04	12:28	1	SALIVATION PRIOR TO DOSING
69634-07	F	[redacted]60	ORAL/DENTAL	12-13-04	11:46	1	SALIVATION PRIOR TO DOSING
69637-09	F	[redacted]60	ORAL/DENTAL	12-14-04	12:32	1	SALIVATION PRIOR TO DOSING
69627-08	F	[redacted]250	BEHAVIOR/CNS	12-13-04	11:55	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69627-08	F	[redacted]250	ORAL/DENTAL	11-29-04	12:01	1	WET CLEAR MATERIAL AROUND MOUTH
69628-02	F	[redacted]250	ORAL/DENTAL	12-01-04	11:52	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	11:52	1	SALIVATION
				12-02-04	12:03	1	SALIVATION
				12-02-04	12:03	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:01	2	SALIVATION PRIOR TO DOSING
				12-09-04	11:55	2	SALIVATION PRIOR TO DOSING
				12-10-04	11:59	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:05	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:02	2	SALIVATION PRIOR TO DOSING
				12-13-04	11:49	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:33	1	SALIVATION PRIOR TO DOSING
				12-15-04	12:32	2	SALIVATION PRIOR TO DOSING
69628-08	F	[redacted]250	BEHAVIOR/CNS	12-02-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-05-04	11:44	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69628-08	F	[redacted]250	ORAL/DENTAL	12-02-04	12:03	1	SALIVATION
				12-02-04	12:03	1	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	12:15	1	SALIVATION
				12-04-04	11:44	1	SALIVATION PRIOR TO DOSING
				12-07-04	11:56	1	SALIVATION PRIOR TO DOSING
				12-09-04	11:55	2	SALIVATION PRIOR TO DOSING
				12-10-04	12:00	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:06	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:02	2	SALIVATION PRIOR TO DOSING
				12-13-04	11:49	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:34	3	SALIVATION PRIOR TO DOSING
				12-15-04	12:33	2	SALIVATION PRIOR TO DOSING
69629-02	F	[redacted]250	BEHAVIOR/CNS	12-02-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:08	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:01	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:55	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69629-02	F	[redacted]250	ORAL/DENTAL	12-02-04	12:04	1	WET CLEAR MATERIAL AROUND MOUTH
69629-04	F	[redacted]250	BEHAVIOR/CNS	12-09-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:55	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69629-04	F	[redacted]250	ORAL/DENTAL	12-01-04	11:53	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69629-04	F	[redacted]250	ORAL/DENTAL	12-02-04	12:04	1	SALIVATION
				12-02-04	12:04	1	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	12:16	1	SALIVATION
				12-09-04	11:56	2	SALIVATION PRIOR TO DOSING
69629-06	F	[redacted]250	BEHAVIOR/CNS	12-02-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:09	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:10	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:55	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69629-06	F	[redacted]250	ORAL/DENTAL	12-02-04	12:04	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	11:47	1	SALIVATION PRIOR TO DOSING
				12-07-04	11:58	2	SALIVATION PRIOR TO DOSING
				12-08-04	11:57	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:01	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:07	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:03	1	SALIVATION PRIOR TO DOSING
				12-13-04	11:50	1	SALIVATION PRIOR TO DOSING
				12-14-04	12:35	3	SALIVATION PRIOR TO DOSING
69629-08	F	[redacted]250	BEHAVIOR/CNS	12-11-04	11:11	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69631-02	F	[redacted]250	BEHAVIOR/CNS	12-02-04	12:08	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:11	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027 INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69631-02	F	[redacted]250	BEHAVIOR/CNS	12-16-04	12:33	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69631-02	F	[redacted]250	ORAL/DENTAL	11-27-04	12:34	1	SALIVATION
				11-28-04	11:50	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	12:04	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	11:54	1	SALIVATION
				12-01-04	11:54	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:08	1	SALIVATION
				12-02-04	12:08	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:03	2	SALIVATION PRIOR TO DOSING
				12-07-04	11:59	2	SALIVATION PRIOR TO DOSING
				12-13-04	11:51	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:33	1	SALIVATION
				12-16-04	12:33	1	WET CLEAR MATERIAL AROUND MOUTH
69631-07	F	[redacted]250	BEHAVIOR/CNS	12-06-04	12:08	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:11	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69631-07	F	[redacted]250	ORAL/DENTAL	11-28-04	11:50	1	SALIVATION
				11-28-04	11:50	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:08	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	11:49	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:04	2	SALIVATION PRIOR TO DOSING
				12-07-04	12:00	3	SALIVATION PRIOR TO DOSING
				12-08-04	11:58	1	SALIVATION PRIOR TO DOSING
				12-09-04	11:57	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:02	1	SALIVATION PRIOR TO DOSING
				12-11-04	11:08	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69631-07	F	[redacted]250	ORAL/DENTAL	12-12-04	11:04	2	SALIVATION PRIOR TO DOSING
				12-13-04	11:52	3	SALIVATION PRIOR TO DOSING
				12-14-04	12:36	2	SALIVATION PRIOR TO DOSING
				12-15-04	12:35	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:32	1	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	12:32	1	SALIVATION
69632-01	F	[redacted]250	BEHAVIOR/CNS	12-09-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69632-01	F	[redacted]250	ORAL/DENTAL	12-02-04	12:08	2	SALIVATION
				12-02-04	12:08	2	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	11:50	1	SALIVATION PRIOR TO DOSING
				12-09-04	11:58	2	SALIVATION PRIOR TO DOSING
				12-13-04	11:52	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:34	2	SALIVATION
				12-16-04	12:34	2	WET CLEAR MATERIAL AROUND MOUTH
69633-07	F	[redacted]250	BEHAVIOR/CNS	12-11-04	11:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69633-08	F	[redacted]250	BEHAVIOR/CNS	12-09-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69633-08	F	[redacted]250	ORAL/DENTAL	12-09-04	11:59	2	SALIVATION PRIOR TO DOSING
				12-10-04	12:03	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:09	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:05	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69633-08	F	[redacted]250	ORAL/DENTAL	12-13-04	11:53	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:37	3	SALIVATION PRIOR TO DOSING
				12-15-04	12:36	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:30	1	SALIVATION PRIOR TO DOSING
				12-16-04	12:34	2	WET CLEAR MATERIAL AROUND MOUTH
69635-02	F	[redacted]250	BEHAVIOR/CNS	12-06-04	12:09	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69636-10	F	[redacted]250	BEHAVIOR/CNS	12-08-04	12:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69636-10	F	[redacted]250	ORAL/DENTAL	12-01-04	11:59	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	11:59	2	SALIVATION
				12-02-04	12:11	1	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	12:00	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:34	1	SALIVATION
				12-16-04	12:34	1	WET CLEAR MATERIAL AROUND MOUTH
				12-17-04	11:56	1	SALIVATION
				12-17-04	11:56	2	WET CLEAR MATERIAL AROUND MOUTH
69637-08	F	[redacted]250	ORAL/DENTAL	12-01-04	11:59	2	SALIVATION
				12-01-04	11:59	1	WET CLEAR MATERIAL AROUND MOUTH
69626-01	F	[redacted]1000	BEHAVIOR/CNS	12-01-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69626-01	F	[redacted]1000	BEHAVIOR/CNS	12-07-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:11	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:45	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69626-01	F	[redacted]1000	ORAL/DENTAL	11-27-04	12:41	1	SALIVATION
				11-29-04	12:09	1	SALIVATION
				11-29-04	12:09	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:11	1	SALIVATION PRIOR TO DOSING
				11-30-04	12:15	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:04	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:04	1	SALIVATION
				12-02-04	12:16	1	SALIVATION
				12-02-04	12:16	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:20	3	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	11:08	1	SALIVATION PRIOR TO DOSING
				12-13-04	11:57	1	SALIVATION PRIOR TO DOSING
69626-05	F	[redacted]1000	BEHAVIOR/CNS	12-02-04	12:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:23	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69626-05	F	[redacted]1000	BEHAVIOR/CNS	12-07-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:45	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69626-05	F	[redacted]1000	ORAL/DENTAL	11-27-04	12:41	2	SALIVATION
				11-29-04	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:04	1	SALIVATION
				12-01-04	12:04	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:16	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:21	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:07	1	SALIVATION PRIOR TO DOSING
				12-08-04	12:03	2	SALIVATION PRIOR TO DOSING
				12-09-04	12:04	2	SALIVATION PRIOR TO DOSING
				12-10-04	12:06	2	SALIVATION PRIOR TO DOSING
69626-06	F	[redacted]1000	BEHAVIOR/CNS	11-30-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:03	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69626-06	F	[redacted]1000	BEHAVIOR/CNS	12-02-04	12:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:45	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69626-06	F	[redacted]1000	ORAL/DENTAL	11-28-04	11:58	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	12:10	1	SALIVATION
				11-29-04	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:03	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:14	2	SALIVATION PRIOR TO DOSING
				12-02-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	11:57	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:11	2	SALIVATION PRIOR TO DOSING
				12-06-04	12:21	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:08	3	SALIVATION PRIOR TO DOSING
				12-08-04	12:04	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69626-06	F	[redacted]1000	ORAL/DENTAL	12-09-04	12:05	3	SALIVATION PRIOR TO DOSING
				12-11-04	11:14	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:09	3	SALIVATION PRIOR TO DOSING
				12-13-04	11:58	3	SALIVATION PRIOR TO DOSING
				12-14-04	12:40	3	SALIVATION PRIOR TO DOSING
				12-15-04	12:39	2	SALIVATION PRIOR TO DOSING
				12-15-04	12:39	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69627-03	F	[redacted]1000	BEHAVIOR/CNS	11-29-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-30-04	12:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 11
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69627-03	F	[redacted]1000	BEHAVIOR/CNS	12-15-04	12:45	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69627-03	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:13	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:17	1	SALIVATION
				12-01-04	12:05	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:17	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:23	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	12:05	1	SALIVATION PRIOR TO DOSING
69628-07	F	[redacted]1000	BEHAVIOR/CNS	11-30-04	12:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:04	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-05-04	11:59	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:48	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69628-07	F	[redacted]1000	ORAL/DENTAL	11-28-04	11:58	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69628-07	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:12	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:17	1	SALIVATION
				11-30-04	12:17	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:05	2	SALIVATION
				12-01-04	12:05	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:18	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:18	2	SALIVATION
				12-03-04	12:28	1	SALIVATION PRIOR TO DOSING
				12-04-04	11:59	1	SALIVATION PRIOR TO DOSING
				12-05-04	11:59	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:12	2	SALIVATION PRIOR TO DOSING
				12-06-04	12:23	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:10	2	SALIVATION PRIOR TO DOSING
				12-09-04	12:06	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:10	2	SALIVATION PRIOR TO DOSING
				12-15-04	12:40	1	SALIVATION PRIOR TO DOSING
69628-10	F	[redacted]1000	BEHAVIOR/CNS	11-29-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:11	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69628-10	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:48	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69628-10	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:12	1	SALIVATION
				11-29-04	12:12	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:19	3	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:19	2	SALIVATION
				12-01-04	12:05	2	SALIVATION
				12-01-04	12:05	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:15	2	SALIVATION PRIOR TO DOSING
				12-02-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	12:29	2	SALIVATION PRIOR TO DOSING
				12-04-04	12:00	1	SALIVATION PRIOR TO DOSING
				12-05-04	11:59	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:13	3	SALIVATION PRIOR TO DOSING
				12-06-04	12:14	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	12:24	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:11	3	SALIVATION PRIOR TO DOSING
				12-08-04	12:05	3	SALIVATION PRIOR TO DOSING
				12-09-04	12:06	3	SALIVATION PRIOR TO DOSING
				12-10-04	12:07	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:10	3	SALIVATION PRIOR TO DOSING
				12-13-04	11:59	3	SALIVATION PRIOR TO DOSING
				12-14-04	12:41	3	SALIVATION PRIOR TO DOSING
				12-15-04	12:41	3	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69630-07	F	[redacted]1000	BEHAVIOR/CNS	11-28-04	12:01	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-29-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:07	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-05-04	12:00	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:17	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69630-07	F	[redacted]1000	ORAL/DENTAL	11-28-04	12:01	1	WET CLEAR MATERIAL AROUND MOUTH
				11-29-04	12:15	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:07	2	SALIVATION
				12-01-04	12:07	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 15

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69630-07	F	[redacted]1000	ORAL/DENTAL	12-02-04	12:21	2	SALIVATION
				12-02-04	12:21	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:24	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	12:07	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:11	3	SALIVATION PRIOR TO DOSING
				12-13-04	12:00	2	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
69631-09	F	[redacted]1000	BEHAVIOR/CNS	12-01-04	12:08	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:22	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:48	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-16-04	12:39	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69631-09	F	[redacted]1000	ORAL/DENTAL	12-01-04	12:08	1	SALIVATION
				12-01-04	12:08	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:22	2	SALIVATION
				12-02-04	12:22	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:15	3	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 16

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69631-09	F	[redacted]1000	ORAL/DENTAL	12-06-04	12:15	2	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	12:25	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:12	3	SALIVATION PRIOR TO DOSING
				12-08-04	12:06	1	SALIVATION PRIOR TO DOSING
				12-09-04	12:07	2	SALIVATION PRIOR TO DOSING
				12-10-04	12:08	1	SALIVATION PRIOR TO DOSING
				12-11-04	11:16	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:11	3	SALIVATION PRIOR TO DOSING
				12-13-04	12:00	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:42	2	SALIVATION PRIOR TO DOSING
				12-15-04	12:41	1	SALIVATION PRIOR TO DOSING
				12-16-04	12:39	1	WET CLEAR MATERIAL AROUND MOUTH
69632-06	F	[redacted]1000	BEHAVIOR/CNS	11-29-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:22	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:24	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:06	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:48	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 17

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69632-06	F	[redacted]1000	BEHAVIOR/CNS	12-16-04	12:39	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69632-06	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:15	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:08	2	SALIVATION
				12-01-04	12:08	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:20	2	SALIVATION PRIOR TO DOSING
				12-02-04	12:23	3	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	12:31	2	SALIVATION PRIOR TO DOSING
				12-05-04	12:03	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:16	3	SALIVATION PRIOR TO DOSING
				12-06-04	12:16	3	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-06-04	12:24	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:13	3	SALIVATION PRIOR TO DOSING
				12-08-04	12:06	3	SALIVATION PRIOR TO DOSING
				12-09-04	12:08	3	SALIVATION PRIOR TO DOSING
				12-10-04	12:09	3	SALIVATION PRIOR TO DOSING
				12-11-04	11:17	3	SALIVATION PRIOR TO DOSING
				12-12-04	11:12	3	SALIVATION PRIOR TO DOSING
				12-12-04	11:12	3	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-13-04	12:01	3	SALIVATION PRIOR TO DOSING
				12-13-04	12:01	3	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-14-04	12:43	3	SALIVATION PRIOR TO DOSING
				12-15-04	12:42	3	SALIVATION PRIOR TO DOSING
				12-16-04	12:39	2	SALIVATION
				12-16-04	12:39	2	WET CLEAR MATERIAL AROUND MOUTH
69633-02	F	[redacted]1000	BEHAVIOR/CNS	11-30-04	12:25	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:10	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69633-02	F	[redacted]1000	BEHAVIOR/CNS	12-02-04	12:23	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:09	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:48	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-16-04	12:40	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69633-02	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:25	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:10	1	SALIVATION
				12-01-04	12:10	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:23	1	SALIVATION
				12-02-04	12:23	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:26	3	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	12:40	1	SALIVATION
				12-16-04	12:40	3	WET CLEAR MATERIAL AROUND MOUTH
69633-10	F	[redacted]1000	BEHAVIOR/CNS	12-02-04	12:23	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
							DOSING
69633-10	F	[redacted]1000	BEHAVIOR/CNS	12-09-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:49	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69633-10	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:25	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:10	2	SALIVATION
				12-01-04	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:23	1	SALIVATION
				12-02-04	12:23	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:06	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:17	3	SALIVATION PRIOR TO DOSING
				12-06-04	12:26	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:14	3	SALIVATION PRIOR TO DOSING
				12-08-04	12:08	2	SALIVATION PRIOR TO DOSING
				12-09-04	12:09	3	SALIVATION PRIOR TO DOSING
				12-10-04	12:09	1	SALIVATION PRIOR TO DOSING
				12-11-04	11:18	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:13	2	SALIVATION PRIOR TO DOSING
				12-13-04	12:02	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:44	3	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69633-10	F	[redacted]1000	ORAL/DENTAL	12-15-04	12:43	1	SALIVATION PRIOR TO DOSING
				12-16-04	12:37	1	SALIVATION PRIOR TO DOSING
				12-16-04	12:40	1	WET CLEAR MATERIAL AROUND MOUTH
69634-05	F	[redacted]1000	BEHAVIOR/CNS	11-29-04	12:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				11-30-04	12:25	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-01-04	12:10	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-05-04	12:05	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-06-04	12:25	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:06	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:49	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69634-05	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:16	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:25	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:21	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69634-05	F	[redacted]1000	ORAL/DENTAL	12-02-04	12:23	2	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:07	1	SALIVATION PRIOR TO DOSING
				12-05-04	12:05	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:18	3	SALIVATION PRIOR TO DOSING
				12-06-04	12:25	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:15	2	SALIVATION PRIOR TO DOSING
				12-08-04	12:08	3	SALIVATION PRIOR TO DOSING
				12-09-04	12:10	3	SALIVATION PRIOR TO DOSING
				12-10-04	12:10	1	SALIVATION PRIOR TO DOSING
				12-11-04	11:18	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:13	3	SALIVATION PRIOR TO DOSING
				12-12-04	11:13	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING
				12-13-04	12:02	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:45	3	SALIVATION PRIOR TO DOSING
				12-15-04	12:43	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:40	2	SALIVATION
				12-16-04	12:40	2	WET CLEAR MATERIAL AROUND MOUTH
69637-10	F	[redacted]1000	BEHAVIOR/CNS	12-01-04	12:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-02-04	12:26	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-07-04	12:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-13-04	12:06	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69637-10	F	[redacted]1000	ORAL/DENTAL	12-01-04	12:13	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69637-10	F	[redacted]1000	ORAL/DENTAL	12-02-04	12:26	1	SALIVATION
				12-02-04	12:26	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:26	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	12:41	1	WET CLEAR MATERIAL AROUND MOUTH
				12-17-04	11:57	1	SALIVATION
				12-17-04	11:57	1	WET CLEAR MATERIAL AROUND MOUTH
69638-01	F	[redacted]1000	BEHAVIOR/CNS	12-07-04	12:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-09-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-14-04	12:49	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-17-04	11:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69638-01	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:26	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:13	1	SALIVATION
				12-01-04	12:13	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:26	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	12:19	3	SALIVATION PRIOR TO DOSING
				12-06-04	12:27	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	12:16	2	SALIVATION PRIOR TO DOSING
				12-09-04	12:11	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:11	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 23

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69638-01	F	[redacted]1000	ORAL/DENTAL	12-11-04	11:21	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:15	1	SALIVATION PRIOR TO DOSING
				12-13-04	12:03	1	SALIVATION PRIOR TO DOSING
				12-14-04	12:45	2	SALIVATION PRIOR TO DOSING
				12-15-04	12:44	2	SALIVATION PRIOR TO DOSING
				12-16-04	12:41	1	SALIVATION PRIOR TO DOSING
				12-16-04	12:41	1	WET CLEAR MATERIAL AROUND MOUTH
				12-17-04	11:56	1	SALIVATION
				12-17-04	11:56	2	WET CLEAR MATERIAL AROUND MOUTH
69638-07	F	[redacted]1000	BEHAVIOR/CNS	12-07-04	12:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-08-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-10-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-12-04	11:18	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-15-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69638-07	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:26	3	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:13	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:27	1	SALIVATION
				12-02-04	12:27	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:09	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:27	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	12:12	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:22	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:15	3	SALIVATION PRIOR TO DOSING
				12-12-04	11:15	1	WET CLEAR MATERIAL AROUND MOUTH PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69638-07	F	[redacted]1000	ORAL/DENTAL	12-13-04	12:04	1	SALIVATION PRIOR TO DOSING
69630-09	F	[redacted]60	ORAL/DENTAL	12-06-04	12:35	1	WET CLEAR MATERIAL AROUND MOUTH
69635-09	F	[redacted]60	ORAL/DENTAL	12-06-04	12:36	2	WET CLEAR MATERIAL AROUND MOUTH
69629-01	F	[redacted]250	ORAL/DENTAL	11-29-04	12:31	1	WET CLEAR MATERIAL AROUND MOUTH
69632-10	F	[redacted]250	ORAL/DENTAL	12-08-04	12:23	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:26	1	SALIVATION PRIOR TO DOSING
				12-11-04	11:33	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:29	2	SALIVATION PRIOR TO DOSING
				12-14-04	12:59	2	SALIVATION PRIOR TO DOSING
				12-15-04	12:58	2	SALIVATION PRIOR TO DOSING
69638-08	F	[redacted]250	ORAL/DENTAL	12-07-04	12:37	1	SALIVATION PRIOR TO DOSING
				12-08-04	12:26	1	SALIVATION PRIOR TO DOSING
				12-09-04	12:28	2	SALIVATION PRIOR TO DOSING
				12-10-04	12:28	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:35	2	SALIVATION PRIOR TO DOSING
				12-12-04	11:31	2	SALIVATION PRIOR TO DOSING
				12-13-04	12:19	1	SALIVATION PRIOR TO DOSING
				12-14-04	13:01	2	SALIVATION PRIOR TO DOSING
				12-15-04	13:00	2	SALIVATION PRIOR TO DOSING
69628-03	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:46	2	SALIVATION
				11-30-04	12:46	2	WET CLEAR MATERIAL AROUND MOUTH
69628-04	F	[redacted]1000	BEHAVIOR/CNS	12-02-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:41	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69628-04	F	[redacted]1000	ORAL/DENTAL	12-01-04	12:35	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:47	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:47	1	SALIVATION
				12-05-04	12:27	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 25

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69628-04	F	[redacted]1000	ORAL/DENTAL	12-07-04	12:39	1	SALIVATION PRIOR TO DOSING
				12-08-04	12:28	1	SALIVATION PRIOR TO DOSING
				12-09-04	12:30	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:37	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:33	1	SALIVATION PRIOR TO DOSING
				12-13-04	12:21	2	SALIVATION PRIOR TO DOSING
				12-14-04	13:03	1	SALIVATION PRIOR TO DOSING
				12-15-04	13:02	2	SALIVATION PRIOR TO DOSING
69629-03	F	[redacted]1000	BEHAVIOR/CNS	12-04-04	12:52	P	PROSTRATE
69629-03	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:39	1	WET CLEAR MATERIAL AROUND MOUTH
69629-05	F	[redacted]1000	BEHAVIOR/CNS	11-30-04	12:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
				12-11-04	11:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69629-05	F	[redacted]1000	ORAL/DENTAL	11-29-04	12:39	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:47	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	12:47	1	SALIVATION
				12-01-04	12:35	1	WET CLEAR MATERIAL AROUND MOUTH
69630-01	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69630-02	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69630-02	F	[redacted]1000	ORAL/DENTAL	11-27-04	13:03	1	SALIVATION
				11-30-04	12:48	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	12:35	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:48	1	SALIVATION
				12-02-04	12:48	2	WET CLEAR MATERIAL AROUND MOUTH
69631-01	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69631-01	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:48	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 26

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69631-01	F	[redacted]1000	ORAL/DENTAL	12-09-04	12:31	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:31	2	SALIVATION PRIOR TO DOSING
				12-11-04	11:38	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:34	1	SALIVATION PRIOR TO DOSING
				12-13-04	12:22	2	SALIVATION PRIOR TO DOSING
				12-14-04	13:04	1	SALIVATION PRIOR TO DOSING
				12-15-04	13:03	2	SALIVATION PRIOR TO DOSING
69631-10	F	[redacted]1000	ORAL/DENTAL	12-09-04	12:31	1	SALIVATION PRIOR TO DOSING
69632-05	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69632-05	F	[redacted]1000	ORAL/DENTAL	11-28-04	12:29	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:50	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	12:32	1	SALIVATION PRIOR TO DOSING
69634-01	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:43	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69634-01	F	[redacted]1000	ORAL/DENTAL	12-01-04	12:36	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:50	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	12:33	2	SALIVATION PRIOR TO DOSING
				12-13-04	12:23	3	SALIVATION PRIOR TO DOSING
				12-14-04	13:06	1	SALIVATION PRIOR TO DOSING
				12-15-04	13:05	1	SALIVATION PRIOR TO DOSING
69634-03	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:43	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69634-03	F	[redacted]1000	ORAL/DENTAL	12-08-04	12:31	1	SALIVATION PRIOR TO DOSING
				12-09-04	12:32	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:33	3	SALIVATION PRIOR TO DOSING
				12-12-04	11:35	2	SALIVATION PRIOR TO DOSING
				12-13-04	12:24	2	SALIVATION PRIOR TO DOSING
				12-14-04	13:06	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 27

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69634-03	F	[redacted]1000	ORAL/DENTAL	12-15-04	13:05	2	SALIVATION PRIOR TO DOSING
69637-03	F	[redacted]1000	ORAL/DENTAL	12-17-04	11:59	1	SALIVATION
				12-17-04	11:59	1	WET CLEAR MATERIAL AROUND MOUTH
69638-02	F	[redacted]1000	ORAL/DENTAL	11-30-04	12:51	1	SALIVATION
				12-01-04	12:37	1	SALIVATION
				12-01-04	12:37	1	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:51	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	12:51	1	SALIVATION
				12-04-04	12:56	1	SALIVATION PRIOR TO DOSING
				12-06-04	12:49	3	SALIVATION PRIOR TO DOSING
				12-07-04	12:44	1	SALIVATION PRIOR TO DOSING
				12-08-04	12:32	2	SALIVATION PRIOR TO DOSING
				12-09-04	12:33	1	SALIVATION PRIOR TO DOSING
				12-10-04	12:34	1	SALIVATION PRIOR TO DOSING
				12-11-04	11:41	1	SALIVATION PRIOR TO DOSING
				12-12-04	11:36	2	SALIVATION PRIOR TO DOSING
				12-14-04	13:07	2	SALIVATION PRIOR TO DOSING
				12-15-04	13:06	1	SALIVATION PRIOR TO DOSING
				12-17-04	11:59	2	SALIVATION
				12-17-04	11:59	1	WET CLEAR MATERIAL AROUND MOUTH
69638-10	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	11:43	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS FOLLOWING DOSING
69638-10	F	[redacted]1000	ORAL/DENTAL	12-11-04	11:43	P	SALIVATION

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69628-02	F	[redacted]250	BEHAVIOR/CNS	12-10-04	12:50	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69628-02	F	[redacted]250	ORAL/DENTAL	12-13-04	12:40	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:23	2	SALIVATION
69628-08	F	[redacted]250	ORAL/DENTAL	12-14-04	13:23	2	WET CLEAR MATERIAL AROUND MOUTH
69629-06	F	[redacted]250	BEHAVIOR/CNS	12-12-04	11:51	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69631-02	F	[redacted]250	ORAL/DENTAL	12-09-04	12:45	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:41	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:24	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:25	2	WET CLEAR MATERIAL AROUND MOUTH
69631-07	F	[redacted]250	ORAL/DENTAL	12-13-04	12:40	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
69632-01	F	[redacted]250	ORAL/DENTAL	12-09-04	12:46	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:24	1	SALIVATION
				12-14-04	13:24	1	WET CLEAR MATERIAL AROUND MOUTH
69633-08	F	[redacted]250	ORAL/DENTAL	12-09-04	12:46	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	11:56	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:24	1	WET CLEAR MATERIAL AROUND MOUTH
69635-02	F	[redacted]250	BEHAVIOR/CNS	12-10-04	12:50	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69636-10	F	[redacted]250	ORAL/DENTAL	12-10-04	12:49	2	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	11:56	3	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	11:51	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:41	3	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:25	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:27	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:24	2	WET CLEAR MATERIAL AROUND MOUTH
				12-17-04	12:49	2	WET CLEAR MATERIAL AROUND MOUTH
69637-08	F	[redacted]250	ORAL/DENTAL	12-07-04	12:50	1	WET CLEAR MATERIAL AROUND MOUTH
69626-01	F	[redacted]1000	BEHAVIOR/CNS	12-10-04	13:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-11-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69626-01	F	[redacted]1000	BEHAVIOR/CNS	12-12-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69626-01	F	[redacted]1000	ORAL/DENTAL	11-29-04	13:11	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:06	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:19	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:19	1	SALIVATION
				12-04-04	12:57	2	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:18	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:15	3	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:09	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:09	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:58	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:44	1	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:39	1	WET CLEAR MATERIAL AROUND MOUTH
69626-05	F	[redacted]1000	BEHAVIOR/CNS	12-08-04	13:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-12-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69626-05	F	[redacted]1000	ORAL/DENTAL	12-04-04	12:57	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:18	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:09	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:11	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:15	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:10	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:57	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69626-05	F	[redacted]1000	ORAL/DENTAL	12-14-04	13:44	1	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
69626-06	F	[redacted]1000	BEHAVIOR/CNS	12-14-04	13:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69626-06	F	[redacted]1000	ORAL/DENTAL	12-01-04	13:06	3	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:56	2	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:19	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:14	2	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:09	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:09	3	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:15	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:10	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:57	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:43	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
69627-03	F	[redacted]1000	BEHAVIOR/CNS	12-08-04	13:12	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-09-04	13:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-13-04	13:01	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-14-04	13:46	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69627-03	F	[redacted]1000	ORAL/DENTAL	12-06-04	13:19	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:15	1	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:09	1	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:10	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
69628-07	F	[redacted]1000	BEHAVIOR/CNS	12-13-04	13:01	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69628-07	F	[redacted]1000	ORAL/DENTAL	11-29-04	13:12	2	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	3	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:20	1	SALIVATION
				12-01-04	13:06	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:20	3	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:44	2	SALIVATION
				12-04-04	12:57	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:13	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:19	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:15	3	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:10	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:10	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:12	2	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:16	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:58	3	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:39	2	WET CLEAR MATERIAL AROUND MOUTH
69628-10	F	[redacted]1000	BEHAVIOR/CNS	12-09-04	13:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-12-04	12:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-13-04	13:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69628-10	F	[redacted]1000	ORAL/DENTAL	11-29-04	13:11	1	WET CLEAR MATERIAL AROUND MOUTH
				11-30-04	13:21	1	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:07	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:20	1	SALIVATION
				12-03-04	13:45	1	SALIVATION
				12-04-04	12:58	2	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:13	2	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:19	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69628-10	F	[redacted]1000	ORAL/DENTAL	12-07-04	13:15	3	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:09	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:09	3	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:12	3	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:16	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:58	3	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:39	2	WET CLEAR MATERIAL AROUND MOUTH
69630-07	F	[redacted]1000	BEHAVIOR/CNS	12-07-04	13:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-08-04	13:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-09-04	13:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-10-04	13:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-14-04	13:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:42	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69630-07	F	[redacted]1000	ORAL/DENTAL	11-30-04	13:21	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:07	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:20	2	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:58	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:20	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:16	3	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:10	3	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:16	1	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:11	3	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:45	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:39	2	WET CLEAR MATERIAL AROUND MOUTH
69631-09	F	[redacted]1000	ORAL/DENTAL	12-06-04	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69632-06	F	[redacted]1000	BEHAVIOR/CNS	12-02-04	13:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-13-04	13:02	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69632-06	F	[redacted]1000	ORAL/DENTAL	12-02-04	13:21	1	SALIVATION
				12-02-04	13:21	3	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:20	3	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:20	2	SALIVATION
				12-07-04	13:16	3	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:10	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:10	3	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:12	3	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:16	1	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:11	3	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:59	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:45	3	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:25	1	SALIVATION
				12-16-04	13:25	2	WET CLEAR MATERIAL AROUND MOUTH
69633-02	F	[redacted]1000	BEHAVIOR/CNS	12-10-04	13:16	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-11-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-12-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-14-04	13:47	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:43	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69633-02	F	[redacted]1000	ORAL/DENTAL	12-01-04	13:07	1	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:46	1	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:12	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69633-02	F	[redacted]1000	ORAL/DENTAL	12-14-04	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:26	3	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:26	1	SALIVATION
69633-10	F	[redacted]1000	BEHAVIOR/CNS	11-30-04	13:22	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-09-04	13:14	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-12-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69633-10	F	[redacted]1000	ORAL/DENTAL	11-30-04	13:22	2	WET CLEAR MATERIAL AROUND MOUTH
				12-01-04	13:08	3	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:21	1	SALIVATION
				12-02-04	13:21	3	WET CLEAR MATERIAL AROUND MOUTH
				12-03-04	13:46	1	WET CLEAR MATERIAL AROUND MOUTH
				12-04-04	12:59	2	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:21	3	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:21	2	SALIVATION
				12-07-04	13:16	3	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:11	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:12	3	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:59	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
69634-05	F	[redacted]1000	BEHAVIOR/CNS	12-11-04	12:19	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-12-04	12:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69634-05	F	[redacted]1000	ORAL/DENTAL	11-29-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69634-05	F	[redacted]1000	ORAL/DENTAL	12-01-04	13:08	2	WET CLEAR MATERIAL AROUND MOUTH
				12-02-04	13:22	3	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:21	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:11	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:11	3	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:12	3	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	12:59	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:45	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:26	2	SALIVATION
				12-16-04	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
69637-10	F	[redacted]1000	BEHAVIOR/CNS	12-09-04	13:15	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-17-04	12:52	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69637-10	F	[redacted]1000	ORAL/DENTAL	12-06-04	13:21	1	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:12	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:40	1	WET CLEAR MATERIAL AROUND MOUTH
69638-01	F	[redacted]1000	BEHAVIOR/CNS	12-17-04	12:52	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69638-01	F	[redacted]1000	ORAL/DENTAL	12-02-04	13:22	1	WET CLEAR MATERIAL AROUND MOUTH
				12-05-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-06-04	13:22	3	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:18	1	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:13	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69638-01	F	[redacted]1000	ORAL/DENTAL	12-13-04	12:59	1	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				12-16-04	13:28	1	SALIVATION
				12-16-04	13:28	2	WET CLEAR MATERIAL AROUND MOUTH
				12-17-04	12:50	1	WET CLEAR MATERIAL AROUND MOUTH
69638-07	F	[redacted]1000	BEHAVIOR/CNS	12-08-04	13:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69638-07	F	[redacted]1000	ORAL/DENTAL	12-06-04	13:22	1	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:13	1	WET CLEAR MATERIAL AROUND MOUTH
69630-09	F	[redacted]60	ORAL/DENTAL	12-09-04	13:10	3	WET CLEAR MATERIAL AROUND MOUTH
69626-07	F	[redacted]1000	BEHAVIOR/CNS	12-12-04	12:25	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69628-03	F	[redacted]1000	BEHAVIOR/CNS	12-10-04	13:20	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69628-03	F	[redacted]1000	ORAL/DENTAL	12-11-04	12:28	1	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	13:12	2	WET CLEAR MATERIAL AROUND MOUTH
69628-04	F	[redacted]1000	ORAL/DENTAL	12-09-04	13:18	1	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:29	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:54	1	SALIVATION
				12-14-04	13:54	2	WET CLEAR MATERIAL AROUND MOUTH
69629-05	F	[redacted]1000	ORAL/DENTAL	12-10-04	13:19	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:54	1	WET CLEAR MATERIAL AROUND MOUTH
69630-02	F	[redacted]1000	BEHAVIOR/CNS	12-12-04	12:24	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-14-04	13:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69630-02	F	[redacted]1000	ORAL/DENTAL	12-08-04	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:20	2	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:29	2	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:23	1	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69630-02	F	[redacted]1000	ORAL/DENTAL	12-14-04	13:55	2	WET CLEAR MATERIAL AROUND MOUTH
69631-01	F	[redacted]1000	ORAL/DENTAL	12-10-04	13:19	2	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:29	1	WET CLEAR MATERIAL AROUND MOUTH
				12-12-04	12:23	1	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:55	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:52	2	WET CLEAR MATERIAL AROUND MOUTH
69632-05	F	[redacted]1000	ORAL/DENTAL	12-14-04	13:55	1	WET CLEAR MATERIAL AROUND MOUTH
69634-01	F	[redacted]1000	BEHAVIOR/CNS	12-14-04	13:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-15-04	13:52	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69634-01	F	[redacted]1000	ORAL/DENTAL	12-02-04	13:38	2	WET CLEAR MATERIAL AROUND MOUTH
				12-07-04	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				12-08-04	13:17	2	WET CLEAR MATERIAL AROUND MOUTH
				12-10-04	13:20	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:55	3	WET CLEAR MATERIAL AROUND MOUTH
69634-03	F	[redacted]1000	BEHAVIOR/CNS	12-14-04	13:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69634-03	F	[redacted]1000	ORAL/DENTAL	12-10-04	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
69637-03	F	[redacted]1000	BEHAVIOR/CNS	12-12-04	12:25	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-17-04	12:57	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69637-03	F	[redacted]1000	ORAL/DENTAL	12-11-04	12:29	2	WET CLEAR MATERIAL AROUND MOUTH
				12-11-04	12:29	2	SALIVATION
				12-16-04	13:48	2	WET CLEAR MATERIAL AROUND MOUTH
69638-02	F	[redacted]1000	BEHAVIOR/CNS	12-10-04	13:21	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-13-04	13:13	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-14-04	13:57	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
				12-17-04	12:56	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS
69638-02	F	[redacted]1000	ORAL/DENTAL	12-09-04	13:19	3	WET CLEAR MATERIAL AROUND MOUTH
				12-09-04	13:19	2	SALIVATION
				12-11-04	12:30	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 11-26-04 TO 12-17-04

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
69638-02	F	[redacted]1000	ORAL/DENTAL	12-11-04	12:30	2	SALIVATION
				12-12-04	12:24	2	WET CLEAR MATERIAL AROUND MOUTH
				12-13-04	13:11	2	WET CLEAR MATERIAL AROUND MOUTH
				12-14-04	13:56	2	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:52	1	WET CLEAR MATERIAL AROUND MOUTH
				12-15-04	13:52	1	SALIVATION
				12-17-04	12:54	2	WET CLEAR MATERIAL AROUND MOUTH
69638-10	F	[redacted]1000	BEHAVIOR/CNS	12-17-04	12:57	P	WIPES MOUTH ON CAGE FLOOR AND/OR WALLS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.08
01/20/2005
R:01/26/2005

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: CORN OIL												
69626-09	59.2	64.9	70.8	75.4	80.4	84.7	90.1	96.5	102.5	108.2	114.7	119.5
69627-04	59.9	64.4	71.3	76.6	81.7	86.0	90.4	93.1	98.5	102.5	109.6	115.1
69627-05	54.8	60.8	65.7	70.3	74.4	78.6	81.5	87.0	92.2	97.5	104.5	108.2
69629-07	58.1	62.2	68.0	72.0	75.9	80.5	85.9	91.2	96.9	100.6	106.6	111.8
69629-09	64.7	71.1	76.4	83.9	89.4	97.6	105.1	111.2	116.7	123.7	132.5	137.6
69630-03	48.0	53.7	61.0	64.5	68.5	73.3	78.9	83.0	87.9	94.1	100.8	104.0
69630-04	56.3	60.4	65.0	68.4	71.8	76.6	79.7	85.3	90.4	93.2	98.8	102.4
69631-03	57.7	64.4	70.0	75.2	81.0	85.3	91.5	97.9	102.2	110.7	115.9	121.0
69631-04	57.0	63.7	67.8	73.8	80.0	83.8	90.4	96.5	101.9	109.0	112.4	117.4
69632-02	61.0	66.3	71.7	76.3	83.2	90.6	98.3	104.1	109.8	114.0	122.6	127.9
69633-05	67.9	73.5	78.0	82.8	89.9	95.4	101.6	108.6	114.8	116.8	123.8	129.0
69634-09	64.7	70.7	77.6	82.5	87.9	94.5	99.7	105.6	112.5	113.8	117.8	127.8
69636-06	63.9	72.4	76.7	84.4	91.2	98.0	104.8	104.8	117.5	122.1	131.4	138.8
69636-09	60.2	67.7	72.3	77.9	85.7	91.2	97.9	104.0	113.2	118.4	127.4	136.5
69638-09	52.2	57.7	62.1	67.3	71.8	76.7	82.9	88.3	95.8	100.2	106.2	112.8
MEAN	59.0	64.9	70.3	75.4	80.9	86.2	91.9	97.1	103.5	108.3	115.0	120.7
S.D.	5.16	5.58	5.43	6.21	7.20	8.08	8.96	8.98	9.96	9.91	10.79	11.92
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: CORN OIL									
69626-09	123.1	130.2	137.4	142.3	145.1	152.3	156.6	159.5	162.1
69627-04	124.0	129.8	137.1	142.7	147.8	156.1	157.1	164.3	168.2
69627-05	113.4	122.6	126.3	131.7	138.3	140.0	144.3	149.8	151.5
69629-07	117.1	123.2	129.9	134.9	140.3	140.1	147.1	152.8	161.2
69629-09	146.1	153.3	157.5	166.2	172.0	179.6	181.9	183.5	191.2
69630-03	108.4	117.3	122.0	131.3	134.5	138.3	140.1	147.2	152.8
69630-04	106.3	113.5	122.0	127.9	132.9	137.6	143.7	147.3	153.8
69631-03	132.3	138.3	141.7	146.3	151.0	156.0	157.5	158.5	165.3
69631-04	124.3	130.7	133.3	137.2	142.5	147.1	147.3	148.4	154.4
69632-02	133.4	133.1	145.4	153.8	155.1	167.3	164.4	167.9	174.3
69633-05	139.0	146.3	149.0	148.5	158.8	163.8	164.6	170.3	167.1
69634-09	134.6	140.0	143.8	145.9	155.1	162.0	164.0	174.3	172.0
69636-06	146.3	154.7	161.7	162.8	174.5	178.5	183.6	182.9	191.8
69636-09	146.7	155.0	161.1	169.1	177.9	187.2	195.9	200.9	208.2
69638-09	118.3	124.6	129.0	134.4	140.3	146.9	148.1	152.3	157.1
MEAN	127.6	134.2	139.8	145.0	151.1	156.9	159.7	164.0	168.7
S.D.	13.51	13.43	13.28	13.05	14.44	16.01	16.44	15.99	16.62
N	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: [redacted]60												
69626-03	59.2	66.4	70.1	74.8	79.2	84.3	87.7	92.3	97.5	101.3	108.4	113.8
69626-08	56.4	60.9	67.0	71.7	75.2	80.6	85.0	90.2	94.6	96.8	103.2	107.0
69627-07	59.5	66.0	71.4	76.9	84.3	89.6	96.1	104.7	110.7	118.2	126.1	131.2
69628-06	43.9	48.9	55.2	57.4	61.9	67.4	70.4	76.1	81.1	85.7	90.5	93.6
69629-10	54.4	57.5	63.9	67.4	73.6	78.8	84.2	90.9	95.7	102.1	108.4	114.9
69630-06	65.8	73.4	78.6	83.7	89.3	97.7	104.4	112.3	120.6	126.0	131.2	138.3
69630-10	57.4	62.6	68.6	73.3	77.8	84.0	88.0	93.6	99.3	105.8	111.6	117.7
69631-05	55.2	60.5	65.9	70.3	74.6	78.2	82.7	86.7	90.6	95.7	101.1	103.4
69632-03	63.6	70.6	76.2	81.8	89.2	95.8	101.8	107.6	115.3	122.9	129.4	136.0
69632-07	61.1	64.7	69.0	74.3	80.2	85.6	89.7	96.1	99.2	105.0	111.4	116.4
69632-09	62.8	67.4	72.2	77.6	84.9	91.9	97.2	104.3	104.5	110.7	115.8	122.0
69634-07	70.2	76.5	82.3	90.8	97.8	101.7	109.5	121.8	128.3	134.7	135.4	144.5
69635-01	56.8	61.3	65.2	72.5	78.2	83.4	88.9	95.2	99.6	105.4	112.8	120.2
69637-01	54.9	58.2	63.8	68.9	74.4	75.0	80.9	84.4	90.2	93.9	98.2	104.6
69637-09	58.5	62.8	67.3	72.4	78.9	83.2	89.8	94.4	100.2	105.4	111.2	119.6
MEAN	58.6	63.8	69.1	74.3	80.0	85.1	90.4	96.7	101.8	107.3	113.0	118.9
S.D.	6.01	6.79	6.61	7.69	8.42	9.05	10.01	11.66	12.37	13.21	12.80	14.05
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: [redacted]60									
69626-03	117.7	127.9	130.2	138.3	139.8	149.8	151.9	159.6	163.7
69626-08	109.7	117.5	115.5	121.4	126.5	128.0	131.1	132.1	134.8
69627-07	137.6	147.3	155.2	161.1	164.1	171.9	180.1	187.1	186.7
69628-06	97.6	102.7	106.8	110.9	114.8	121.3	125.8	131.3	133.2
69629-10	119.7	128.4	134.9	138.6	147.2	154.3	159.7	166.4	177.0
69630-06	144.3	153.1	158.9	163.2	166.5	171.6	177.2	185.1	187.5
69630-10	120.1	132.0	136.8	143.8	149.1	155.7	155.3	162.9	169.3
69631-05	110.9	113.8	118.8	120.7	128.8	127.6	132.0	134.0	140.9
69632-03	146.2	151.9	156.7	159.4	165.4	169.0	174.0	179.9	184.7
69632-07	123.4	127.5	129.1	138.0	140.5	146.4	150.7	150.8	156.9
69632-09	127.6	133.0	143.2	147.4	151.0	157.0	159.3	162.7	166.6
69634-07	150.7	161.6	165.4	164.2	174.3	179.5	184.4	187.0	196.0
69635-01	129.2	132.3	141.2	146.6	151.7	157.9	161.8	172.0	171.7
69637-01	108.7	113.5	118.7	123.0	128.1	134.0	132.3	140.4	144.0
69637-09	127.1	130.7	137.3	143.6	147.5	152.4	155.7	162.6	171.4
MEAN	124.7	131.5	136.6	141.3	146.4	151.8	155.4	160.9	165.6
S.D.	15.18	16.35	17.35	16.71	16.97	17.68	18.76	19.70	19.97
N	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: [redacted]250												
69627-08	60.7	65.6	70.1	76.3	81.3	87.7	95.8	101.2	106.0	111.7	122.1	123.9
69628-02	52.6	57.7	62.1	66.1	71.6	78.3	83.8	90.0	95.4	101.1	107.7	111.7
69628-08	57.1	62.7	66.7	71.5	76.5	82.7	88.4	92.1	99.0	103.0	107.8	112.0
69629-02	62.2	67.6	73.4	78.8	82.1	88.5	95.8	101.3	105.4	108.3	113.1	118.2
69629-04	54.8	59.8	64.2	67.5	71.7	76.4	81.5	86.5	91.6	96.0	98.0	106.0
69629-06	62.8	69.5	75.5	81.2	87.4	91.4	97.9	104.4	112.1	117.1	123.6	126.2
69629-08	54.4	60.2	66.6	70.3	75.1	80.9	86.1	91.7	97.6	105.4	110.8	114.8
69631-02	61.9	67.2	74.2	80.2	86.2	91.4	99.2	104.9	112.2	118.9	123.0	130.4
69631-07	53.8	58.3	62.2	67.7	73.8	77.1	82.3	87.2	92.5	98.3	103.7	108.7
69632-01	58.4	61.4	66.4	72.2	77.3	83.0	89.5	96.2	100.5	108.4	113.7	121.4
69633-07	66.3	70.6	75.4	81.7	85.9	94.1	99.8	106.3	110.6	115.8	120.9	126.6
69633-08	69.9	73.4	78.9	82.7	88.2	91.8	100.5	103.9	108.9	114.0	119.8	127.4
69635-02	59.5	64.2	67.6	75.4	80.6	86.9	91.3	97.2	104.3	111.5	116.9	130.0
69636-10	55.3	61.1	63.4	71.2	74.9	80.3	86.7	92.1	98.8	102.8	109.5	117.3
69637-08	54.4	57.3	60.6	67.0	70.9	75.7	81.4	87.2	91.2	95.1	100.9	109.1
MEAN	58.9	63.8	68.5	74.0	78.9	84.4	90.7	96.1	101.7	107.2	112.8	118.9
S.D.	5.03	5.02	5.75	5.85	6.06	6.24	7.01	7.09	7.36	7.68	8.23	8.27
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: [redacted]250									
69627-08	131.8	141.0	145.7	154.8	161.5	165.9	169.5	171.5	178.6
69628-02	117.0	123.0	130.6	135.9	142.2	143.2	150.2	150.2	155.2
69628-08	113.7	120.1	126.0	128.9	129.3	133.0	139.7	142.6	146.6
69629-02	124.2	130.8	136.6	142.2	147.4	151.3	151.4	156.6	161.1
69629-04	110.8	119.6	124.2	130.0	133.3	139.6	146.2	151.2	154.7
69629-06	134.0	143.9	152.8	156.5	160.1	164.0	171.5	180.1	174.9
69629-08	122.7	132.4	132.0	149.1	148.9	154.8	163.8	161.9	168.3
69631-02	139.3	141.7	144.3	149.2	152.8	157.2	156.5	158.0	165.1
69631-07	117.9	118.4	124.7	130.9	139.0	142.7	142.1	147.7	149.9
69632-01	129.9	132.2	146.1	146.8	152.9	152.9	155.4	158.8	163.4
69633-07	136.4	141.9	145.3	154.0	154.3	160.6	157.9	163.3	161.0
69633-08	131.6	137.3	141.5	144.5	150.8	154.1	158.3	159.8	164.6
69635-02	130.6	139.5	150.3	157.8	158.6	165.3	159.9	172.5	178.8
69636-10	122.6	131.0	136.8	139.8	146.0	152.7	152.9	159.8	163.7
69637-08	113.8	121.0	126.4	132.7	135.8	141.3	144.9	147.9	153.7
MEAN	125.1	131.6	137.6	143.5	147.5	151.9	154.7	158.8	162.6
S.D.	9.03	9.19	9.77	10.11	9.88	10.08	9.35	10.27	9.76
N	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: [redacted]1000												
69626-01	58.1	63.4	68.3	73.9	78.2	82.9	89.2	95.5	99.3	103.7	108.7	111.7
69626-05	63.5	68.8	73.1	78.4	84.4	87.1	92.5	98.5	103.4	108.1	113.6	117.7
69626-06	59.6	64.7	66.7	70.6	77.2	80.8	86.6	92.0	94.4	101.7	107.1	114.1
69627-03	57.9	61.9	66.7	74.7	80.0	84.4	90.0	96.2	101.9	106.8	113.2	119.0
69628-07	55.7	58.4	61.0	66.0	72.5	77.4	83.1	88.5	94.8	100.4	104.0	110.2
69628-10	49.7	52.5	56.2	61.8	66.3	71.2	75.3	81.2	87.6	92.0	98.5	102.0
69630-07	56.3	63.4	65.8	71.2	72.7	79.2	82.7	87.8	92.4	95.7	100.2	105.9
69631-09	59.7	68.1	72.8	77.2	82.8	88.1	96.7	102.0	107.6	115.2	121.6	126.9
69632-06	59.5	63.5	68.3	69.8	74.6	80.6	88.3	92.0	97.4	103.4	107.5	113.0
69633-02	64.6	68.5	68.8	74.4	82.1	87.3	93.9	97.2	89.0	83.7	78.3	74.3
69633-10	67.0	72.2	76.7	81.7	87.5	93.6	100.4	104.6	112.4	117.1	117.2	124.1
69634-05	55.0	59.5	60.8	65.3	71.0	76.1	79.4	84.5	90.7	93.4	98.1	102.5
69637-10	54.9	56.9	60.4	66.8	73.3	77.3	83.4	89.3	93.8	97.9	100.5	107.1
69638-01	60.3	63.1	67.1	72.4	77.8	83.2	85.9	90.1	94.4	96.2	100.2	105.0
69638-07	55.9	59.0	64.6	68.6	70.5	78.7	81.6	90.0	93.2	99.0	104.9	111.6
MEAN	58.5	62.9	66.5	71.5	76.7	81.9	87.3	92.6	96.8	101.0	104.9	109.7
S.D.	4.34	5.18	5.41	5.39	5.89	5.67	6.75	6.38	6.95	8.71	10.21	12.25
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: [redacted]1000									
69626-01	117.3	124.3	128.7	133.6	137.9	143.2	146.1	150.3	154.4
69626-05	123.0	128.9	134.8	139.1	143.2	147.8	152.6	158.4	159.3
69626-06	120.2	129.9	133.7	141.4	145.5	154.0	159.4	161.6	169.6
69627-03	125.2	137.1	141.8	149.6	153.3	155.5	161.2	166.5	166.3
69628-07	114.1	124.8	129.2	133.7	140.2	142.7	145.4	153.0	152.2
69628-10	109.1	116.6	123.1	130.5	136.3	138.4	146.8	150.5	154.5
69630-07	110.4	115.5	121.1	126.9	132.6	139.1	144.7	148.7	152.1
69631-09	134.6	143.7	148.8	156.9	165.0	171.4	175.4	186.0	183.8
69632-06	118.5	126.4	130.1	131.9	139.9	145.9	148.0	151.6	158.0
69633-02	75.0	80.2	89.4	96.7	100.3	106.3	113.3	119.7	124.8
69633-10	129.6	135.2	140.1	145.6	150.7	154.9	159.1	159.4	163.7
69634-05	110.7	111.3	116.7	121.5	127.7	130.6	134.1	140.0	144.2
69637-10	110.7	115.2	119.5	123.2	128.9	126.7	134.2	137.0	139.0
69638-01	110.3	111.4	115.9	121.6	124.9	126.7	131.6	136.8	138.1
69638-07	120.8	125.7	132.3	134.8	113.4	120.4	113.8		
MEAN	115.3	121.7	127.0	132.5	136.0	140.2	144.4	151.4	154.3
S.D.	13.52	14.93	14.06	14.23	15.98	16.30	17.01	15.71	14.82
N	15	15	15	15	15	15	15	14	14

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHTS [G]

SPONSOR NO.:04-027

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: [redacted]60												
69627-01	65.2	69.7	75.4	78.8	85.1	90.8	98.3	102.8	108.2	116.6	123.2	130.3
69627-02	59.8	64.9	70.0	75.0	81.3	87.8	94.1	98.7	103.8	111.6	117.7	121.7
69627-06	62.7	68.1	74.7	79.5	85.3	91.8	99.3	106.1	111.5	118.7	126.8	134.0
69627-10	53.4	58.2	63.1	67.3	71.2	75.3	79.0	84.3	89.6	93.3	100.6	106.0
69628-01	59.5	64.3	70.7	75.6	81.6	87.6	95.2	101.4	111.1	114.6	121.7	125.9
69630-08	48.8	53.5	57.6	61.5	64.4	68.4	72.6	77.0	81.9	86.9	91.7	98.4
69630-09	52.5	59.4	65.6	68.9	75.1	79.4	81.6	87.1	91.2	98.5	105.5	108.5
69631-06	58.5	64.2	68.2	73.0	78.9	82.2	89.1	95.1	101.4	106.1	112.2	119.4
69631-08	58.3	63.6	69.2	75.3	81.0	86.0	94.3	101.5	107.2	114.0	120.7	128.8
69632-08	64.1	69.4	75.3	79.7	86.2	98.9	98.1	106.9	111.9	121.2	126.0	134.7
69634-02	62.8	67.6	73.2	79.7	85.2	90.3	95.9	102.4	109.2	114.1	120.7	128.0
69634-08	67.7	74.2	80.6	87.7	95.5	93.1	107.2	114.1	122.4	132.5	136.2	142.9
69635-09	56.5	59.6	67.4	73.2	78.2	82.0	88.5	92.6	97.1	102.7	109.8	115.8
69637-04	54.2	59.4	63.2	70.5	75.0	79.6	87.9	92.0	95.2	100.2	107.5	116.1
69638-04	59.6	63.7	67.7	73.6	79.5	85.5	90.4	95.9	103.6	106.7	113.6	118.2
MEAN	58.9	64.0	69.5	74.6	80.2	85.2	91.4	97.2	103.0	109.2	115.6	121.9
S.D.	5.19	5.36	5.86	6.25	7.26	7.69	8.80	9.59	10.49	11.70	11.41	11.95
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: [redacted]60									
69627-01	138.1	143.8	151.6	158.0	163.2	167.5	174.7	180.9	186.4
69627-02	128.6	138.8	146.1	150.3	155.9	160.2	164.9	172.3	172.9
69627-06	142.5	149.8	159.1	166.5	174.2	174.2	181.1	186.3	191.8
69627-10	110.6	118.0	125.1	128.5	133.2	142.1	144.9	151.5	159.3
69628-01	129.5	140.5	147.0	153.8	154.6	156.5	163.9	171.5	173.1
69630-08	99.6	109.7	115.9	121.0	123.2	132.3	135.2	141.6	143.0
69630-09	114.9	122.7	129.7	135.0	137.5	147.4	151.3	156.0	160.6
69631-06	127.2	131.6	137.3	142.3	149.1	152.9	161.6	163.2	162.6
69631-08	136.9	144.5	142.2	151.5	159.1	163.4	169.5	166.2	174.2
69632-08	140.3	145.0	153.0	161.7	164.8	165.1	165.4	176.0	178.0
69634-02	134.8	142.9	148.7	151.7	160.0	164.8	168.7	174.6	176.0
69634-08	150.4	161.0	169.5	176.4	173.8	182.2	191.2	186.2	188.4
69635-09	124.1	130.3	136.5	144.4	150.2	156.4	162.4	161.4	166.7
69637-04	119.9	128.1	131.3	133.9	138.0	144.8	144.5	153.7	159.2
69638-04	128.9	137.0	134.5	139.6	146.9	151.5	156.2	156.1	166.0
MEAN	128.4	136.2	141.8	147.6	152.2	157.4	162.4	166.5	170.5
S.D.	13.24	13.13	13.86	14.86	14.69	12.92	14.56	13.27	12.94
N	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 11

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 6: [redacted]250												
69626-02	62.3	67.0	72.7	77.8	81.9	85.6	90.4	98.3	105.3	108.6	117.2	118.8
69626-04	60.5	65.3	71.1	75.2	79.7	83.5	89.2	93.8	98.0	107.9	110.9	117.1
69626-10	57.5	63.0	70.4	74.5	79.4	84.9	91.6	96.3	102.2	106.9	109.1	117.5
69628-05	50.6	55.9	61.4	66.2	70.9	77.8	82.7	88.4	92.7	103.2	109.9	118.2
69628-09	55.2	60.7	64.4	69.0	73.2	77.1	83.9	91.1	94.1	101.6	109.6	113.3
69629-01	62.7	69.2	75.9	79.2	85.9	90.3	96.8	103.8	110.0	118.1	127.3	131.2
69630-05	56.6	61.8	68.2	71.5	76.7	82.1	86.3	91.6	96.0	103.0	109.2	113.1
69632-04	60.0	66.0	72.7	77.6	84.3	90.1	94.9	100.6	105.3	113.7	121.9	127.6
69632-10	57.2	64.7	67.6	73.5	79.0	83.8	84.5	95.2	96.8	98.7	107.2	111.4
69633-03	64.9	69.9	75.7	82.3	88.2	91.8	99.5	106.1	112.8	121.9	123.8	133.5
69633-04	69.8	76.0	80.4	86.6	94.4	100.5	107.1	114.4	119.8	127.5	134.1	139.1
69634-10	54.6	59.0	65.8	68.9	75.7	81.6	86.8	92.0	97.1	104.2	113.4	116.6
69635-10	54.4	59.3	62.8	68.1	72.0	76.2	81.8	83.6	92.7	96.9	103.9	111.3
69637-02	53.8	58.5	62.8	67.7	71.6	76.1	81.6	84.8	91.4	97.6	101.9	109.6
69638-08	59.2	64.3	69.3	75.2	81.1	86.2	92.8	98.2	104.9	112.6	118.6	125.9
MEAN	58.6	64.0	69.4	74.2	79.6	84.5	90.0	95.9	101.3	108.2	114.5	120.3
S.D.	4.94	5.22	5.49	5.84	6.68	6.73	7.30	8.17	8.33	9.07	9.08	9.04
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 6: [redacted]250									
69626-02	127.8	136.7	142.3	151.3	154.5	156.6	161.3	166.7	171.0
69626-04	121.9	133.5	138.9	144.8	147.2	151.8	157.2	159.9	161.6
69626-10	120.1	127.8	136.6	136.0	139.8	144.4	146.9	147.9	154.5
69628-05	125.7	131.9	140.0	149.1	151.7	161.2	166.8	172.2	177.4
69628-09	120.9	127.6	135.3	143.1	147.9	155.0	164.3	166.3	166.8
69629-01	136.0	143.5	153.7	160.9	166.5	175.6	178.3	175.3	187.1
69630-05	118.6	127.3	131.9	138.3	143.5	148.3	153.4	156.5	159.6
69632-04	136.5	136.8	148.7	150.6	159.1	164.2	161.9	167.5	176.0
69632-10	116.0	122.5	122.4	130.0	130.4	137.6	140.7	138.4	148.6
69633-03	138.5	144.3	155.8	156.1	158.8	165.2	170.7	174.8	173.1
69633-04	145.9	154.9	163.0	167.2	170.8	175.1	180.4	185.3	183.0
69634-10	124.0	132.7	139.6	146.1	150.8	152.2	161.3	166.6	171.8
69635-10	116.8	125.2	127.9	131.9	135.2	143.2	145.5	147.6	156.8
69637-02	114.3	123.7	129.9	135.4	136.3	141.1	144.8	149.6	156.4
69638-08	131.6	139.1	147.8	148.2	153.9	161.1	166.5	166.3	179.1
MEAN	126.3	133.8	140.9	145.9	149.8	155.5	160.0	162.7	168.2
S.D.	9.46	8.95	11.19	10.60	11.50	11.66	12.00	12.65	11.48
N	15	15	15	15	15	15	15	15	15

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHTS [G]

SPONSOR NO.:04-027

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 7: [redacted]1000												
69626-07	64.6	70.3	74.3	78.6	84.8	91.1	95.4	101.7	109.6	116.4	121.7	128.6
69628-03	53.8	59.3	64.1	69.4	75.4	81.9	87.0	95.1	101.5	109.2	117.5	124.1
69628-04	53.2	58.7	64.2	68.5	72.9	78.2	84.4	90.0	94.3	98.9	108.8	113.2
69629-03	58.8	64.1	69.5	74.8	79.7	85.5	88.9	95.3	101.0			
69629-05	60.8	66.3	73.1	77.9	85.1	90.3	95.0	101.6	107.9	112.4	121.6	128.9
69630-01	57.9	61.2	68.2	73.6	78.2	83.3	88.5	94.2	102.9	106.3	113.6	121.2
69630-02	54.7	59.4	63.9	68.6	72.8	77.5	81.7	84.6	88.9	92.7	98.8	102.3
69631-01	55.6	61.2	66.3	69.0	75.2	80.2	85.7	90.7	96.3	102.5	109.5	116.7
69631-10	61.4	66.7	72.8	78.8	85.5	91.1	100.6	104.8	110.9	116.2	126.3	132.5
69632-05	57.3	61.9	67.9	72.0	77.3	83.9	86.5	90.5	97.1	99.9	103.1	109.5
69634-01	66.9	72.2	78.5	84.6	90.6	96.2	102.7	105.4	115.3	121.3	125.3	133.0
69634-03	64.6	69.4	75.5	81.1	85.4	91.5	98.3	105.8	111.9	117.4	123.5	130.2
69637-03	54.4	58.4	64.0	69.9	74.7	79.5	84.3	89.5	97.1	103.4	109.7	113.8
69638-02	59.9	64.9	69.1	73.6	79.6	85.1	90.0	97.1	105.1	110.1	114.9	121.7
69638-10	53.6	58.1	63.6	69.5	76.7	82.7	89.7	96.2	105.5	112.7	120.2	131.3
MEAN	58.5	63.5	69.0	74.0	79.6	85.2	90.6	96.2	103.0	108.5	115.3	121.9
S.D.	4.44	4.65	4.84	5.14	5.44	5.64	6.37	6.53	7.40	8.24	8.45	9.60
N	15	15	15	15	15	15	15	15	15	14	14	14

TABLE 16

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 7: [redacted]1000									
69626-07	135.5	145.6	150.2	157.5	163.1	168.3	174.3	180.1	182.3
69628-03	130.8	140.0	144.3	153.7	157.9	163.4	165.3	173.6	177.3
69628-04	117.4	127.2	134.4	140.0	146.8	150.1	148.5	159.3	162.4
69629-05	132.6	140.0	146.7	153.1	158.1	164.5	169.3	175.2	176.9
69630-01	127.2	133.9	141.7	146.5	153.0	156.0	162.6	168.8	174.3
69630-02	107.4	112.2	115.5	123.0	127.3	130.5	133.1	138.2	144.4
69631-01	121.4	127.2	133.3	137.8	141.9	149.4	154.5	158.3	158.2
69631-10	142.0	144.8	152.1	159.4	163.4	166.9	164.6	170.5	177.9
69632-05	116.1	121.7	126.8	133.1	137.0	138.6	145.2	141.3	152.4
69634-01	141.0	148.2	150.3	152.9	162.4	168.8	169.4	165.2	177.0
69634-03	135.4	142.7	144.2	149.2	151.8	152.9	159.3	158.3	170.0
69637-03	119.4	126.8	133.1	137.1	141.5	147.9	150.4	158.6	163.5
69638-02	130.0	136.9	138.2	145.2	148.5	153.4	156.2	156.8	168.4
69638-10	136.2	147.9	157.9	163.1	169.8	174.4	174.4	184.9	190.5
MEAN	128.0	135.4	140.6	146.5	151.6	156.1	159.1	163.5	169.7
S.D.	10.28	10.91	11.29	11.25	11.88	12.44	11.91	13.38	12.43
N	14	14	14	14	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: CORN OIL												
69626-09	5.7	5.9	4.6	5.0	4.3	5.4	6.4	6.0	5.7	6.5	4.8	3.6
69627-04	4.5	6.9	5.3	5.1	4.3	4.4	2.7	5.4	4.0	7.1	5.5	8.9
69627-05	6.0	4.9	4.6	4.1	4.2	2.9	5.5	5.2	5.3	7.0	3.7	5.2
69629-07	4.1	5.8	4.0	3.9	4.6	5.4	5.3	5.7	3.7	6.0	5.2	5.3
69629-09	6.4	5.3	7.5	5.5	8.2	7.5	6.1	5.5	7.0	8.8	5.1	8.5
69630-03	5.7	7.3	3.5	4.0	4.8	5.6	4.1	4.9	6.2	6.7	3.2	4.4
69630-04	4.1	4.6	3.4	3.4	4.8	3.1	5.6	5.1	2.8	5.6	3.6	3.9
69631-03	6.7	5.6	5.2	5.8	4.3	6.2	6.4	4.3	8.5	5.2	5.1	11.3
69631-04	6.7	4.1	6.0	6.2	3.8	6.6	6.1	5.4	7.1	3.4	5.0	6.9
69632-02	5.3	5.4	4.6	6.9	7.4	7.7	5.8	5.7	4.2	8.6	5.3	5.5
69633-05	5.6	4.5	4.8	7.1	5.5	6.2	7.0	6.2	2.0	7.0	5.2	10.0
69634-09	6.0	6.9	4.9	5.4	6.6	5.2	5.9	6.9	1.3	4.0	10.0	6.8
69636-06	8.5	4.3	7.7	6.8	6.8	6.8	0.0	12.7	4.6	9.3	7.4	7.5
69636-09	7.5	4.6	5.6	7.8	5.5	6.7	6.1	9.2	5.2	9.0	9.1	10.2
69638-09	5.5	4.4	5.2	4.5	4.9	6.2	5.4	7.5	4.4	6.0	6.6	5.5
MEAN	5.9	5.4	5.1	5.4	5.3	5.7	5.2	6.4	4.8	6.7	5.7	6.9
S.D.	1.20	1.03	1.23	1.33	1.32	1.41	1.78	2.12	1.95	1.75	1.91	2.42
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: CORN OIL									
69626-09	7.1	7.2	4.9	2.8	7.2	4.3	2.9	2.6	102.9
69627-04	5.8	7.3	5.6	5.1	8.3	1.0	7.2	3.9	108.3
69627-05	9.2	3.7	5.4	6.6	1.7	4.3	5.5	1.7	96.7
69629-07	6.1	6.7	5.0	5.4	-0.2	7.0	5.7	8.4	103.1
69629-09	7.2	4.2	8.7	5.8	7.6	2.3	1.6	7.7	126.5
69630-03	8.9	4.7	9.3	3.2	3.8	1.8	7.1	5.6	104.8
69630-04	7.2	8.5	5.9	5.0	4.7	6.1	3.6	6.5	97.5
69631-03	6.0	3.4	4.6	4.7	5.0	1.5	1.0	6.8	107.6
69631-04	6.4	2.6	3.9	5.3	4.6	0.2	1.1	6.0	97.4
69632-02	-0.3	12.3	8.4	1.3	12.2	-2.9	3.5	6.4	113.3
69633-05	7.3	2.7	-0.5	10.3	5.0	0.8	5.7	-3.2	99.2
69634-09	5.4	3.8	2.1	9.2	6.9	2.0	10.3	-2.3	107.3
69636-06	8.4	7.0	1.1	11.7	4.0	5.1	-0.7	8.9	127.9
69636-09	8.3	6.1	8.0	8.8	9.3	8.7	5.0	7.3	148.0
69638-09	6.3	4.4	5.4	5.9	6.6	1.2	4.2	4.8	104.9
MEAN	6.6	5.6	5.2	6.1	5.8	2.9	4.2	4.7	109.7
S.D.	2.24	2.61	2.79	2.85	3.05	3.00	2.86	3.64	14.20
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: [redacted]60												
69626-03	7.2	3.7	4.7	4.4	5.1	3.4	4.6	5.2	3.8	7.1	5.4	3.9
69626-08	4.5	6.1	4.7	3.5	5.4	4.4	5.2	4.4	2.2	6.4	3.8	2.7
69627-07	6.5	5.4	5.5	7.4	5.3	6.5	8.6	6.0	7.5	7.9	5.1	6.4
69628-06	5.0	6.3	2.2	4.5	5.5	3.0	5.7	5.0	4.6	4.8	3.1	4.0
69629-10	3.1	6.4	3.5	6.2	5.2	5.4	6.7	4.8	6.4	6.3	6.5	4.8
69630-06	7.6	5.2	5.1	5.6	8.4	6.7	7.9	8.3	5.4	5.2	7.1	6.0
69630-10	5.2	6.0	4.7	4.5	6.2	4.0	5.6	5.7	6.5	5.8	6.1	2.4
69631-05	5.3	5.4	4.4	4.3	3.6	4.5	4.0	3.9	5.1	5.4	2.3	7.5
69632-03	7.0	5.6	5.6	7.4	6.6	6.0	5.8	7.7	7.6	6.5	6.6	10.2
69632-07	3.6	4.3	5.3	5.9	5.4	4.1	6.4	3.1	5.8	6.4	5.0	7.0
69632-09	4.6	4.8	5.4	7.3	7.0	5.3	7.1	0.2	6.2	5.1	6.2	5.6
69634-07	6.3	5.8	8.5	7.0	3.9	7.8	12.3	6.5	6.4	0.7	9.1	6.2
69635-01	4.5	3.9	7.3	5.7	5.2	5.5	6.3	4.4	5.8	7.4	7.4	9.0
69637-01	3.3	5.6	5.1	5.5	0.6	5.9	3.5	5.8	3.7	4.3	6.4	4.1
69637-09	4.3	4.5	5.1	6.5	4.3	6.6	4.6	5.8	5.2	5.8	8.4	7.5
MEAN	5.2	5.3	5.1	5.7	5.2	5.3	6.3	5.1	5.5	5.7	5.9	5.8
S.D.	1.43	0.85	1.44	1.26	1.75	1.36	2.17	1.92	1.46	1.69	1.86	2.23
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: [redacted]60									
69626-03	10.2	2.3	8.1	1.5	10.0	2.1	7.7	4.1	104.5
69626-08	7.8	-2.0	5.9	5.1	1.5	3.1	1.0	2.7	78.4
69627-07	9.7	7.9	5.9	3.0	7.8	8.2	7.0	-0.4	127.2
69628-06	5.1	4.1	4.1	3.9	6.5	4.5	5.5	1.9	89.3
69629-10	8.7	6.5	3.7	8.6	7.1	5.4	6.7	10.6	122.6
69630-06	8.8	5.8	4.3	3.3	5.1	5.6	7.9	2.4	121.7
69630-10	11.9	4.8	7.0	5.3	6.6	-0.4	7.6	6.4	111.9
69631-05	2.9	5.0	1.9	8.1	-1.2	4.4	2.0	6.9	85.7
69632-03	5.7	4.8	2.7	6.0	3.6	5.0	5.9	4.8	121.1
69632-07	4.1	1.6	8.9	2.5	5.9	4.3	0.1	6.1	95.8
69632-09	5.4	10.2	4.2	3.6	6.0	2.3	3.4	3.9	103.8
69634-07	10.9	3.8	-1.2	10.1	5.2	4.9	2.6	9.0	125.8
69635-01	3.1	8.9	5.4	5.1	6.2	3.9	10.2	-0.3	114.9
69637-01	4.8	5.2	4.3	5.1	5.9	-1.7	8.1	3.6	89.1
69637-09	3.6	6.6	6.3	3.9	4.9	3.3	6.9	8.8	112.9
MEAN	6.8	5.0	4.8	5.0	5.4	3.7	5.5	4.7	107.0
S.D.	3.02	3.00	2.52	2.38	2.62	2.43	2.98	3.28	16.01
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: [redacted]250												
69627-08	4.9	4.5	6.2	5.0	6.4	8.1	5.4	4.8	5.7	10.4	1.8	7.9
69628-02	5.1	4.4	4.0	5.5	6.7	5.5	6.2	5.4	5.7	6.6	4.0	5.3
69628-08	5.6	4.0	4.8	5.0	6.2	5.7	3.7	6.9	4.0	4.8	4.2	1.7
69629-02	5.4	5.8	5.4	3.3	6.4	7.3	5.5	4.1	2.9	4.8	5.1	6.0
69629-04	5.0	4.4	3.3	4.2	4.7	5.1	5.0	5.1	4.4	2.0	8.0	4.8
69629-06	6.7	6.0	5.7	6.2	4.0	6.5	6.5	7.7	5.0	6.5	2.6	7.8
69629-08	5.8	6.4	3.7	4.8	5.8	5.2	5.6	5.9	7.8	5.4	4.0	7.9
69631-02	5.3	7.0	6.0	6.0	5.2	7.8	5.7	7.3	6.7	4.1	7.4	8.9
69631-07	4.5	3.9	5.5	6.1	3.3	5.2	4.9	5.3	5.8	5.4	5.0	9.2
69632-01	3.0	5.0	5.8	5.1	5.7	6.5	6.7	4.3	7.9	5.3	7.7	8.5
69633-07	4.3	4.8	6.3	4.2	8.2	5.7	6.5	4.3	5.2	5.1	5.7	9.8
69633-08	3.5	5.5	3.8	5.5	3.6	8.7	3.4	5.0	5.1	5.8	7.6	4.2
69635-02	4.7	3.4	7.8	5.2	6.3	4.4	5.9	7.1	7.2	5.4	13.1	0.6
69636-10	5.8	2.3	7.8	3.7	5.4	6.4	5.4	6.7	4.0	6.7	7.8	5.3
69637-08	2.9	3.3	6.4	3.9	4.8	5.7	5.8	4.0	3.9	5.8	8.2	4.7
MEAN	4.8	4.7	5.5	4.9	5.5	6.3	5.5	5.6	5.4	5.6	6.1	6.2
S.D.	1.06	1.27	1.38	0.89	1.30	1.24	0.95	1.26	1.49	1.75	2.83	2.73
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: [redacted]250									
69627-08	9.2	4.7	9.1	6.7	4.4	3.6	2.0	7.1	117.9
69628-02	6.0	7.6	5.3	6.3	1.0	7.0	0.0	5.0	102.6
69628-08	6.4	5.9	2.9	0.4	3.7	6.7	2.9	4.0	89.5
69629-02	6.6	5.8	5.6	5.2	3.9	0.1	5.2	4.5	98.9
69629-04	8.8	4.6	5.8	3.3	6.3	6.6	5.0	3.5	99.9
69629-06	9.9	8.9	3.7	3.6	3.9	7.5	8.6	-5.2	112.1
69629-08	9.7	-0.4	17.1	-0.2	5.9	9.0	-1.9	6.4	113.9
69631-02	2.4	2.6	4.9	3.6	4.4	-0.7	1.5	7.1	103.2
69631-07	0.5	6.3	6.2	8.1	3.7	-0.6	5.6	2.2	96.1
69632-01	2.3	13.9	0.7	6.1	0.0	2.5	3.4	4.6	105.0
69633-07	5.5	3.4	8.7	0.3	6.3	-2.7	5.4	-2.3	94.7
69633-08	5.7	4.2	3.0	6.3	3.3	4.2	1.5	4.8	94.7
69635-02	8.9	10.8	7.5	0.8	6.7	-5.4	12.6	6.3	119.3
69636-10	8.4	5.8	3.0	6.2	6.7	0.2	6.9	3.9	108.4
69637-08	7.2	5.4	6.3	3.1	5.5	3.6	3.0	5.8	99.3
MEAN	6.5	6.0	6.0	4.0	4.4	2.8	4.1	3.8	103.7
S.D.	2.89	3.41	3.83	2.69	1.98	4.20	3.59	3.41	8.96
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: [redacted]1000												
69626-01	5.3	4.9	5.6	4.3	4.7	6.3	6.3	3.8	4.4	5.0	3.0	5.6
69626-05	5.3	4.3	5.3	6.0	2.7	5.4	6.0	4.9	4.7	5.5	4.1	5.3
69626-06	5.1	2.0	3.9	6.6	3.6	5.8	5.4	2.4	7.3	5.4	7.0	6.1
69627-03	4.0	4.8	8.0	5.3	4.4	5.6	6.2	5.7	4.9	6.4	5.8	6.2
69628-07	2.7	2.6	5.0	6.5	4.9	5.7	5.4	6.3	5.6	3.6	6.2	3.9
69628-10	2.8	3.7	5.6	4.5	4.9	4.1	5.9	6.4	4.4	6.5	3.5	7.1
69630-07	7.1	2.4	5.4	1.5	6.5	3.5	5.1	4.6	3.3	4.5	5.7	4.5
69631-09	8.4	4.7	4.4	5.6	5.3	8.6	5.3	5.6	7.6	6.4	5.3	7.7
69632-06	4.0	4.8	1.5	4.8	6.0	7.7	3.7	5.4	6.0	4.1	5.5	5.5
69633-02	3.9	0.3	5.6	7.7	5.2	6.6	3.3	-8.2	-5.3	-5.4	-4.0	0.7
69633-10	5.2	4.5	5.0	5.8	6.1	6.8	4.2	7.8	4.7	0.1	6.9	5.5
69634-05	4.5	1.3	4.5	5.7	5.1	3.3	5.1	6.2	2.7	4.7	4.4	8.2
69637-10	2.0	3.5	6.4	6.5	4.0	6.1	5.9	4.5	4.1	2.6	6.6	3.6
69638-01	2.8	4.0	5.3	5.4	5.4	2.7	4.2	4.3	1.8	4.0	4.8	5.3
69638-07	3.1	5.6	4.0	1.9	8.2	2.9	8.4	3.2	5.8	5.9	6.7	9.2
MEAN	4.4	3.6	5.0	5.2	5.1	5.4	5.4	4.2	4.1	4.0	4.8	5.6
S.D.	1.73	1.52	1.40	1.67	1.29	1.77	1.24	3.69	3.04	3.08	2.72	2.06
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: [redacted]1000									
69626-01	7.0	4.4	4.9	4.3	5.3	2.9	4.2	4.1	96.3
69626-05	5.9	5.9	4.3	4.1	4.6	4.8	5.8	0.9	95.8
69626-06	9.7	3.8	7.7	4.1	8.5	5.4	2.2	8.0	110.0
69627-03	11.9	4.7	7.8	3.7	2.2	5.7	5.3	-0.2	108.4
69628-07	10.7	4.4	4.5	6.5	2.5	2.7	7.6	-0.8	96.5
69628-10	7.5	6.5	7.4	5.8	2.1	8.4	3.7	4.0	104.8
69630-07	5.1	5.6	5.8	5.7	6.5	5.6	4.0	3.4	95.8
69631-09	9.1	5.1	8.1	8.1	6.4	4.0	10.6	-2.2	124.1
69632-06	7.9	3.7	1.8	8.0	6.0	2.1	3.6	6.4	98.5
69633-02	5.2	9.2	7.3	3.6	6.0	7.0	6.4	5.1	60.2
69633-10	5.6	4.9	5.5	5.1	4.2	4.2	0.3	4.3	96.7
69634-05	0.6	5.4	4.8	6.2	2.9	3.5	5.9	4.2	89.2
69637-10	4.5	4.3	3.7	5.7	-2.2	7.5	2.8	2.0	84.1
69638-01	1.1	4.5	5.7	3.3	1.8	4.9	5.2	1.3	77.8
69638-07	4.9	6.6	2.5	-21.4	7.0	-6.6			
MEAN	6.4	5.3	5.5	3.5	4.3	4.1	4.8	2.9	95.6
S.D.	3.19	1.40	1.95	7.05	2.73	3.47	2.50	2.86	15.25
N	15	15	15	15	15	15	14	14	14

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: [redacted]60												
69627-01	4.5	5.7	3.4	6.3	5.7	7.5	4.5	5.4	8.4	6.6	7.1	7.8
69627-02	5.1	5.1	5.0	6.3	6.5	6.3	4.6	5.1	7.8	6.1	4.0	6.9
69627-06	5.4	6.6	4.8	5.8	6.5	7.5	6.8	5.4	7.2	8.1	7.2	8.5
69627-10	4.8	4.9	4.2	3.9	4.1	3.7	5.3	5.3	3.7	7.3	5.4	4.6
69628-01	4.8	6.4	4.9	6.0	6.0	7.6	6.2	9.7	3.5	7.1	4.2	3.6
69630-08	4.7	4.1	3.9	2.9	4.0	4.2	4.4	4.9	5.0	4.8	6.7	1.2
69630-09	6.9	6.2	3.3	6.2	4.3	2.2	5.5	4.1	7.3	7.0	3.0	6.4
69631-06	5.7	4.0	4.8	5.9	3.3	6.9	6.0	6.3	4.7	6.1	7.2	7.8
69631-08	5.3	5.6	6.1	5.7	5.0	8.3	7.2	5.7	6.8	6.7	8.1	8.1
69632-08	5.3	5.9	4.4	6.5	12.7	-0.8	8.8	5.0	9.3	4.8	8.7	5.6
69634-02	4.8	5.6	6.5	5.5	5.1	5.6	6.5	6.8	4.9	6.6	7.3	6.8
69634-08	6.5	6.4	7.1	7.8	-2.4	14.1	6.9	8.3	10.1	3.7	6.7	7.5
69635-09	3.1	7.8	5.8	5.0	3.8	6.5	4.1	4.5	5.6	7.1	6.0	8.3
69637-04	5.2	3.8	7.3	4.5	4.6	8.3	4.1	3.2	5.0	7.3	8.6	3.8
69638-04	4.1	4.0	5.9	5.9	6.0	4.9	5.5	7.7	3.1	6.9	4.6	10.7
MEAN	5.1	5.5	5.2	5.6	5.0	6.2	5.8	5.8	6.2	6.4	6.3	6.5
S.D.	0.91	1.16	1.25	1.17	3.02	3.32	1.34	1.69	2.16	1.16	1.74	2.39
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: [redacted]60									
69627-01	5.7	7.8	6.4	5.2	4.3	7.2	6.2	5.5	121.2
69627-02	10.2	7.3	4.2	5.6	4.3	4.7	7.4	0.6	113.1
69627-06	7.3	9.3	7.4	7.7	0.0	6.9	5.2	5.5	129.1
69627-10	7.4	7.1	3.4	4.7	8.9	2.8	6.6	7.8	105.9
69628-01	11.0	6.5	6.8	0.8	1.9	7.4	7.6	1.6	113.6
69630-08	10.1	6.2	5.1	2.2	9.1	2.9	6.4	1.4	94.2
69630-09	7.8	7.0	5.3	2.5	9.9	3.9	4.7	4.6	108.1
69631-06	4.4	5.7	5.0	6.8	3.8	8.7	1.6	-0.6	104.1
69631-08	7.6	-2.3	9.3	7.6	4.3	6.1	-3.3	8.0	115.9
69632-08	4.7	8.0	8.7	3.1	0.3	0.3	10.6	2.0	113.9
69634-02	8.1	5.8	3.0	8.3	4.8	3.9	5.9	1.4	113.2
69634-08	10.6	8.5	6.9	-2.6	8.4	9.0	-5.0	2.2	120.7
69635-09	6.2	6.2	7.9	5.8	6.2	6.0	-1.0	5.3	110.2
69637-04	8.2	3.2	2.6	4.1	6.8	-0.3	9.2	5.5	105.0
69638-04	8.1	-2.5	5.1	7.3	4.6	4.7	-0.1	9.9	106.4
MEAN	7.8	5.6	5.8	4.6	5.2	4.9	4.1	4.0	111.6
S.D.	2.04	3.54	2.04	3.00	3.07	2.78	4.63	3.09	8.41
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 11

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 6: [redacted]250												
69626-02	4.7	5.7	5.1	4.1	3.7	4.8	7.9	7.0	3.3	8.6	1.6	9.0
69626-04	4.8	5.8	4.1	4.5	3.8	5.7	4.6	4.2	9.9	3.0	6.2	4.8
69626-10	5.5	7.4	4.1	4.9	5.5	6.7	4.7	5.9	4.7	2.2	8.4	2.6
69628-05	5.3	5.5	4.8	4.7	6.9	4.9	5.7	4.3	10.5	6.7	8.3	7.5
69628-09	5.5	3.7	4.6	4.2	3.9	6.8	7.2	3.0	7.5	8.0	3.7	7.6
69629-01	6.5	6.7	3.3	6.7	4.4	6.5	7.0	6.2	8.1	9.2	3.9	4.8
69630-05	5.2	6.4	3.3	5.2	5.4	4.2	5.3	4.4	7.0	6.2	3.9	5.5
69632-04	6.0	6.7	4.9	6.7	5.8	4.8	5.7	4.7	8.4	8.2	5.7	8.9
69632-10	7.5	2.9	5.9	5.5	4.8	0.7	10.7	1.6	1.9	8.5	4.2	4.6
69633-03	5.0	5.8	6.6	5.9	3.6	7.7	6.6	6.7	9.1	1.9	9.7	5.0
69633-04	6.2	4.4	6.2	7.8	6.1	6.6	7.3	5.4	7.7	6.6	5.0	6.8
69634-10	4.4	6.8	3.1	6.8	5.9	5.2	5.2	5.1	7.1	9.2	3.2	7.4
69635-10	4.9	3.5	5.3	3.9	4.2	5.6	1.8	9.1	4.2	7.0	7.4	5.5
69637-02	4.7	4.3	4.9	3.9	4.5	5.5	3.2	6.6	6.2	4.3	7.7	4.7
69638-08	5.1	5.0	5.9	5.9	5.1	6.6	5.4	6.7	7.7	6.0	7.3	5.7
MEAN	5.4	5.4	4.8	5.4	4.9	5.5	5.9	5.4	6.9	6.4	5.7	6.0
S.D.	0.82	1.36	1.08	1.22	1.01	1.64	2.08	1.82	2.43	2.47	2.33	1.78
N	15	15	15	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 12

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 6: [redacted]250									
69626-02	8.9	5.6	9.0	3.2	2.1	4.7	5.4	4.3	108.7
69626-04	11.6	5.4	5.9	2.4	4.6	5.4	2.7	1.7	101.1
69626-10	7.7	8.8	-0.6	3.8	4.6	2.5	1.0	6.6	97.0
69628-05	6.2	8.1	9.1	2.6	9.5	5.6	5.4	5.2	126.8
69628-09	6.7	7.7	7.8	4.8	7.1	9.3	2.0	0.5	111.6
69629-01	7.5	10.2	7.2	5.6	9.1	2.7	-3.0	11.8	124.4
69630-05	8.7	4.6	6.4	5.2	4.8	5.1	3.1	3.1	103.0
69632-04	0.3	11.9	1.9	8.5	5.1	-2.3	5.6	8.5	116.0
69632-10	6.5	-0.1	7.6	0.4	7.2	3.1	-2.3	10.2	91.4
69633-03	5.8	11.5	0.3	2.7	6.4	5.5	4.1	-1.7	108.2
69633-04	9.0	8.1	4.2	3.6	4.3	5.3	4.9	-2.3	113.2
69634-10	8.7	6.9	6.5	4.7	1.4	9.1	5.3	5.2	117.2
69635-10	8.4	2.7	4.0	3.3	8.0	2.3	2.1	9.2	102.4
69637-02	9.4	6.2	5.5	0.9	4.8	3.7	4.8	6.8	102.6
69638-08	7.5	8.7	0.4	5.7	7.2	5.4	-0.2	12.8	119.9
MEAN	7.5	7.1	5.0	3.8	5.7	4.5	2.7	5.5	109.6
S.D.	2.48	3.20	3.20	2.03	2.33	2.80	2.81	4.63	10.16
N	15	15	15	15	15	15	15	15	15

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 7: [redacted]1000												
69626-07	5.7	4.0	4.3	6.2	6.3	4.3	6.3	7.9	6.8	5.3	6.9	6.9
69628-03	5.5	4.8	5.3	6.0	6.5	5.1	8.1	6.4	7.7	8.3	6.6	6.7
69628-04	5.5	5.5	4.3	4.4	5.3	6.2	5.6	4.3	4.6	9.9	4.4	4.2
69629-03	5.3	5.4	5.3	4.9	5.8	3.4	6.4	5.7				
69629-05	5.5	6.8	4.8	7.2	5.2	4.7	6.6	6.3	4.5	9.2	7.3	3.7
69630-01	3.3	7.0	5.4	4.6	5.1	5.2	5.7	8.7	3.4	7.3	7.6	6.0
69630-02	4.7	4.5	4.7	4.2	4.7	4.2	2.9	4.3	3.8	6.1	3.5	5.1
69631-01	5.6	5.1	2.7	6.2	5.0	5.5	5.0	5.6	6.2	7.0	7.2	4.7
69631-10	5.3	6.1	6.0	6.7	5.6	9.5	4.2	6.1	5.3	10.1	6.2	9.5
69632-05	4.6	6.0	4.1	5.3	6.6	2.6	4.0	6.6	2.8	3.2	6.4	6.6
69634-01	5.3	6.3	6.1	6.0	5.6	6.5	2.7	9.9	6.0	4.0	7.7	8.0
69634-03	4.8	6.1	5.6	4.3	6.1	6.8	7.5	6.1	5.5	6.1	6.7	5.2
69637-03	4.0	5.6	5.9	4.8	4.8	4.8	5.2	7.6	6.3	6.3	4.1	5.6
69638-02	5.0	4.2	4.5	6.0	5.5	4.9	7.1	8.0	5.0	4.8	6.8	8.3
69638-10	4.5	5.5	5.9	7.2	6.0	7.0	6.5	9.3	7.2	7.5	11.1	4.9
MEAN	5.0	5.5	5.0	5.6	5.6	5.4	5.6	6.9	5.4	6.8	6.6	6.1
S.D.	0.67	0.89	0.93	1.03	0.60	1.67	1.60	1.68	1.45	2.10	1.85	1.67
N	15	15	15	15	15	15	15	15	14	14	14	14

TABLE 17

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 7: [redacted]1000									
69626-07	10.1	4.6	7.3	5.6	5.2	6.0	5.8	2.2	117.7
69628-03	9.2	4.3	9.4	4.2	5.5	1.9	8.3	3.7	123.5
69628-04	9.8	7.2	5.6	6.8	3.3	-1.6	10.8	3.1	109.2
69629-05	7.4	6.7	6.4	5.0	6.4	4.8	5.9	1.7	116.1
69630-01	6.7	7.8	4.8	6.5	3.0	6.6	6.2	5.5	116.4
69630-02	4.8	3.3	7.5	4.3	3.2	2.6	5.1	6.2	89.7
69631-01	5.8	6.1	4.5	4.1	7.5	5.1	3.8	-0.1	102.6
69631-10	2.8	7.3	7.3	4.0	3.5	-2.3	5.9	7.4	116.5
69632-05	5.6	5.1	6.3	3.9	1.6	6.6	-3.9	11.1	95.1
69634-01	7.2	2.1	2.6	9.5	6.4	0.6	-4.2	11.8	110.1
69634-03	7.3	1.5	5.0	2.6	1.1	6.4	-1.0	11.7	105.4
69637-03	7.4	6.3	4.0	4.4	6.4	2.5	8.2	4.9	109.1
69638-02	6.9	1.3	7.0	3.3	4.9	2.8	0.6	11.6	108.5
69638-10	11.7	10.0	5.2	6.7	4.6	0.0	10.5	5.6	136.9
MEAN	7.3	5.3	5.9	5.1	4.5	3.0	4.4	6.2	111.2
S.D.	2.31	2.57	1.74	1.80	1.92	3.04	4.84	4.02	11.70
N	14	14	14	14	14	14	14	14	14

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01/20/2005

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

GROUP: CORN OIL SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69626-09	34	122.8	N	N	N	N	N	N	N	N	N	Y					
69627-04	34	122.3	N	N	N	N	N	N	N	N	N	Y					
69627-05	33	107.9	N	N	N	N	N	N	N	N	Y						
69629-07	35	122.8	N	N	N	N	N	N	N	N	N	N	Y				
69629-09	32	132.6	N	N	N	N	N	N	N	Y							
69630-03	33	103.8	N	N	N	N	N	N	N	N	Y						
69630-04	33	103.1	N	N	N	N	N	N	N	N	Y						
69631-03	32	115.4	N	N	N	N	N	N	N	Y							
69631-04	30	100.9	N	N	N	N	N	Y									
69632-02	29	103.2	N	N	N	N	Y										
69633-05	29	107.7	N	N	N	N	Y										
69634-09	31	113.8	N	N	N	N	N	N	Y								
69636-06	28	104.3	N	N	N	Y											
69636-09	32	125.3	N	N	N	N	N	N	N	Y							
69638-09	32	105.9	N	N	N	N	N	N	N	Y							
MEAN	31.8	112.8															
S.D.	2.04	10.09															
N	15	15															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:04-027

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69626-03	31	102.6	N	N	N	N	N	N	Y								
69626-08	31	97.0	N	N	N	N	N	N	Y								
69627-07	35	147.8	N	N	N	N	N	N	N	N	N	N	Y				
69628-06	35	101.8	N	N	N	N	N	N	N	N	N	N	Y				
69629-10	34	119.8	N	N	N	N	N	N	N	N	N	Y					
69630-06	30	119.9	N	N	N	N	N	Y									
69630-10	33	115.5	N	N	N	N	N	N	N	N	Y						
69631-05	27	77.4	N	N	Y												
69632-03	30	116.2	N	N	N	N	N	Y									
69632-07	28	88.1	N	N	N	Y											
69632-09	32	115.7	N	N	N	N	N	N	N	Y							
69634-07	27	101.7	N	N	Y												
69635-01	28	88.7	N	N	N	Y											
69637-01	33	102.8	N	N	N	N	N	N	N	N	Y						
69637-09	32	110.8	N	N	N	N	N	N	N	Y							
MEAN	31.1	107.1															
S.D.	2.71	16.91															
N	15	15															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

SPONSOR NO.:04-027

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69627-08	27	88.0	N	N	Y												
69628-02	27	78.7	N	N	Y												
69628-08	26	77.0	N	Y													
69629-02	27	89.5	N	N	Y												
69629-04	29	86.7	N	N	N	N	Y										
69629-06	29	104.5	N	N	N	N	Y										
69629-08	26	75.3	N	Y													
69631-02	27	91.5	N	N	Y												
69631-07	28	81.5	N	N	N	Y											
69632-01	26	77.9	N	Y													
69633-07	26	85.9	N	Y													
69633-08	27	91.5	N	N	Y												
69635-02	27	85.7	N	N	Y												
69636-10	26	74.7	N	Y													
69637-08	27	75.1	N	N	Y												
MEAN	27.0	84.2															
S.D.	1.00	8.25															
N	15	15															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

PND= POSTNATAL DAY

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

SPONSOR NO.:04-027

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69626-01	28	89.6	N	N	N	Y											
69626-05	26	83.2	N	Y													
69626-06	27	80.8	N	N	Y												
69627-03	26	79.4	N	Y													
69628-07	26	72.7	N	Y													
69628-10	26	65.6	N	Y													
69630-07	26	73.7	N	Y													
69631-09	26	84.2	N	Y													
69632-06	25	70.2	Y														
69633-02	26	81.6	N	Y													
69633-10	26	87.1	N	Y													
69634-05	26	68.8	N	Y													
69637-10	27	75.6	N	N	Y												
69638-01	26	77.1	N	Y													
69638-07	25	66.7	Y														
MEAN	26.1	77.1															
S.D.	0.74	7.43															
N	15	15															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

PND= POSTNATAL DAY

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

SPONSOR NO.:04-027

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69627-01	34	137.8	N	N	N	N	N	N	N	N	N	Y					
69627-02	37	150.5	N	N	N	N	N	N	N	N	N	N	N	N	Y		
69627-06	34	141.9	N	N	N	N	N	N	N	N	N	Y					
69627-10	32	100.3	N	N	N	N	N	N	N	Y							
69628-01	31	114.0	N	N	N	N	N	N	Y								
69630-08	37	122.1	N	N	N	N	N	N	N	N	N	N	N	N	Y		
69630-09	34	115.1	N	N	N	N	N	N	N	N	N	Y					
69631-06	32	111.8	N	N	N	N	N	N	N	Y							
69631-08	34	135.0	N	N	N	N	N	N	N	N	N	Y					
69632-08	30	110.8	N	N	N	N	N	Y									
69634-02	33	127.6	N	N	N	N	N	N	N	N	Y						
69634-08	30	121.0	N	N	N	N	N	Y									
69635-09	31	103.3	N	N	N	N	N	N	Y								
69637-04	39	141.9	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
69638-04	36	135.7	N	N	N	N	N	N	N	N	N	N	N	Y			
MEAN	33.6	124.6															
S.D.	2.72	15.36															
N	15	15															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

PND= POSTNATAL DAY

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:04-027

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69626-02	34	127.9	N	N	N	N	N	N	N	N	N	Y					
69626-04	34	122.2	N	N	N	N	N	N	N	N	N	Y					
69626-10	34	121.8	N	N	N	N	N	N	N	N	N	Y					
69628-05	33	117.6	N	N	N	N	N	N	N	N	Y						
69628-09	33	114.1	N	N	N	N	N	N	N	N	Y						
69629-01	31	116.8	N	N	N	N	N	N	Y								
69630-05	32	109.0	N	N	N	N	N	N	N	Y							
69632-04	33	127.8	N	N	N	N	N	N	N	N	Y						
69632-10	31	98.7	N	N	N	N	N	N	Y								
69633-03	33	132.6	N	N	N	N	N	N	N	N	Y						
69633-04	29	112.2	N	N	N	N	Y										
69634-10	34	122.3	N	N	N	N	N	N	N	N	N	Y					
69635-10	35	127.6	N	N	N	N	N	N	N	N	N	N	Y				
69637-02	33	109.2	N	N	N	N	N	N	N	N	Y						
69638-08	33	125.2	N	N	N	N	N	N	N	N	Y						
MEAN	32.8	119.0															
S.D.	1.52	9.13															
N	15	15															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

TABLE 18

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:04-027

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
69626-07	36	149.2	N	N	N	N	N	N	N	N	N	N	N	Y			
69628-03	34	130.7	N	N	N	N	N	N	N	N	N	Y					
69628-04	34	117.6	N	N	N	N	N	N	N	N	N	Y					
69629-03	RESPONSE NOT EXHIBITED BY DAY 30																
69629-05	35	141.0	N	N	N	N	N	N	N	N	N	N	Y				
69630-01	34	127.9	N	N	N	N	N	N	N	N	N	Y					
69630-02	34	107.2	N	N	N	N	N	N	N	N	N	Y					
69631-01	32	109.9	N	N	N	N	N	N	N	Y							
69631-10	30	109.7	N	N	N	N	N	Y									
69632-05	35	122.5	N	N	N	N	N	N	N	N	N	N	Y				
69634-01	32	124.6	N	N	N	N	N	N	N	Y							
69634-03	31	118.3	N	N	N	N	N	N	Y								
69637-03	33	113.8	N	N	N	N	N	N	N	N	Y						
69638-02	33	122.1	N	N	N	N	N	N	N	N	Y						
69638-10	34	136.4	N	N	N	N	N	N	N	N	N	Y					
MEAN	33.4	123.6															
S.D.	1.65	12.42															
N	14	14															

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

PJTBBv1.11
01/20/2005
R:01/26/2005

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA

SPONSOR NO.:04-027

FEMALES FROM GROUP 1: CORN OIL

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9	1 0	1 1	1 2	1 3	1 4	1 5	1 6	1 7	1 8	1 9	2 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69626-09	N N N N N N N N N	D	D	D	D	E	D	D	D	P			A
69627-04	N N N N N N N N N	E	D	D	D	D	D	E	D	D			6.0
69627-05	N N N N N N N N E	D	D	D	P	E	D	D	D	E			5.0
69629-07	N N N N N N N N N	D	D	D	E	E	D	D	D	D			A
69629-09	N N N N N N N D D	D	P	E	D	D	D	D	E	D			5.0
69630-03	N N N N N N N N E	D	D	D	D	E	E	D	D	D			6.0
69630-04	N N N N N N N N N	D	D	D	D	D	D	D	D	D			A
69631-03	N N N N N N N N N	D	D	D	D	E	D	D	D	E	E	D	5.0
69631-04	N N N N N N D D D	D	D	P	E	D	D	D	D	E	D		5.0
69632-02	N N N N N E D D D	D	E	E	D	D	D	D	E	D	D		5.5
69633-05	N N N N N D D P E	D	D	D	D	E	D	D	D	D	E		5.0
69634-09	N N N N N N N E D	D	D	P	E	D	D	D	E	E	D		5.0
69636-06	N N N N N D D D E	D	D	D	D	D	E	D	D	D	E	D	5.0
69636-09	N N N N N N N N N	D	D	D	D	D	D	D	D	D	D	D	A
69638-09	N N N N N N N N N	D	D	D	D	E	D	D	D	E	E	D	5.0

MEAN	5.2
S.D.	0.41
N	11

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

INDIVIDUAL ESTROUS CYCLE DATA

SPONSOR NO.:04-027

FEMALES FROM GROUP 2: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9	1 0	1 1 2 3 4 5 6 7 8 9 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69626-03	N N N N N N P E D	D D D D E	D D D P	6.0
69626-08	N N N N N N E D D	D P E	D D D P E D	5.0
69627-07	N N N N N N N N N	N D D	E D D D E	A
69628-06	N N N N N N N N N	N E E	D D D D E E	A
69629-10	N N N N N N N N N	E D D	D D D D D D	A
69630-06	N N N N N D D D P	E D D	D E E D D D	5.0
69630-10	N N N N N N N N D	E D D	D D P E D D	6.0
69631-05	N N N D D D D D E	D D D	D D D P E D D D	7.0
69632-03	N N N N N N D D E	D D D	D D D E D D D D	6.0
69632-07	N N N N D D D E D	D D D	D D E D D E E D	5.0
69632-09	N N N N N N N N E	D D D	D D D E D D D P	6.0
69634-07	N N N D D D D D E	D D D	D E E D D D E D	4.5
69635-01	N N N N N D D E D	D D D	D E D D D E D D	5.0
69637-01	N N N N N N N N N	N E D	D D D D E E D D	7.0
69637-09	N N N N N N N N N	D E D	D D D D D E D D	6.0
			MEAN	5.7
			S.D.	0.81
			N	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:04-027

FEMALES FROM GROUP 3: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69627-08	N N D D D D D D D D P E D D D D E D	5.0
69628-02	N N D D D D D D D D E D D D D D E D	6.0
69628-08	N D D D E D D D P E D D D D E D D D	5.0
69629-02	N N D D P E D D D D E D D D D E E D	5.5
69629-04	N N N N D D D E D D D D D D D D D E	A
69629-06	N N N N D D D E D D D D D D D D E E	A
69629-08	N D D D D D E D D D D E D D D D E D	5.0
69631-02	N N N D D D E D D D D D D D D D E E D	11.0
69631-07	N N N N D D D D D D D D D E D D D D	A
69632-01	N N D D D D E D D D D D E D D D D E D D	5.0
69633-07	N N D D D D D D D D D D D E D D D E E	A
69633-08	N N N D P D D D P M D D D D E D D D E	5.0
69635-02	N N N N D D D D D E D D D D D E D D D D	6.0
69636-10	N N N D D D D D D E E E D D D E D D D D	4.0
69637-08	N N N N D D D D E D D D D D D D D D E	A
	MEAN	5.8
	S.D.	1.93
	N	10

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

INDIVIDUAL ESTROUS CYCLE DATA

SPONSOR NO.:04-027

FEMALES FROM GROUP 4: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69626-01	N N N E D D D D E D D E D E D D E E	3.3
69626-05	N E E D D D D D D D D D D D D E E	A
69626-06	N N D D D D D D D D D D D E E E	A
69627-03	N D D D D D D D E D D D D E D D D	5.0
69628-07	N D D D D D D D D D D D D D D E D	A
69628-10	N D D D D D D D D D D D D D D D	A
69630-07	N D D D D D D D D D D D D D D E	A
69631-09	N N D D D D D D D D D D D D P D D	A
69632-06	N E E D D D D E D D D D D D D D P	5.0
69633-02	N N D D D D E D E D D E D D D E E E	2.5
69633-10	N N D D D D D D D D D D D D P D D	A
69634-05	N N D D D D D D D D D D D D D D D	A
69637-10	N N N N D D D D D D D D D D E E E E E	A
69638-01	N N N E D D D D D D D E D D D E E E D	7.5
69638-07	N N D E E D D D D D D D D D D E D	12.0
	MEAN	5.9
	S.D.	3.45
	N	6

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:04-027

FEMALES FROM GROUP 5: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69627-01	N N N N N N N N N D D D D D E D D D	A
69627-02	N N N N N N N N N N N N D D D D E E	A
69627-06	N N N N N N N N N D E D D D E D D D	4.0
69627-10	N N N N N N N D D D D D D E D D D D	A
69628-01	N N N N N N D D D E D D D E E D D D	5.0
69630-08	N N N N N N N N N N N N E D D D D E	A
69630-09	N N N N N N N N N D D D P E D D D D	A
69631-06	N N N N N N N N N D D D D E M D D D D E	A
69631-08	N N N N N N N N N N D E E D D D E E D	5.0
69632-08	N N N N N N P D D D D D E D D D E E D D	5.0
69634-02	N N N N N N N N N D D D D E D D D D E	A
69634-08	N N N N N N E D D D E D D D E D D D D E	4.0
69635-09	N N N N N N N N E D D D D E D D D E E D	5.0
69637-04	N N N N N N N N N N N N N N N N D E E D	A
69638-04	N N N N N N N N N N N N N D D D D D E E	A
	MEAN	4.7
	S.D.	0.52
	N	6

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 6: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69626-02	N N N N N N N N N D D D D E E D D D	A
69626-04	N N N N N N N N N D D D E D D D E E	A
69626-10	N N N N N N N N N D D D E D D D E E	A
69628-05	N N N N N N N N E D D D D E D D D D	5.0
69628-09	N N N N N N N N E D D D D E D D D E	5.0
69629-01	N N N N N N E D D D D E D D D D E D	5.0
69630-05	N N N N N N N N D D D D D D E D D D	A
69632-04	N N N N N N N N N D D E D D D D E D D	5.0
69632-10	N N N N N N N E D D D D E D D D E E D	5.0
69633-03	N N N N N N N N N D D D D D E D D D D	A
69633-04	N N N N N D D D D E D D D D E D D D E	5.0
69634-10	N N N N N N N N N N D D D D P E D D D	A
69635-10	N N N N N N N N N N N N D D D D P E E D	A
69637-02	N N N N N N N N N N D D D D P E D D D D	A
69638-08	N N N N N N N N N N E D D D D D D D D E	A
	MEAN	5.0
	S.D.	0.00
	N	6

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

N = NOT ENTERED

TABLE 19

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 7: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
69626-07	N N N N N N N N N N E D D D D E D	5.0
69628-03	N N N N N N N N N D E E D D D E D D	4.0
69628-04	N N N N N N N N N D D D D D D E D D	A
69629-03	N N N N N N	A
69629-05	N N N N N N N N N N D D E E D D D E	A
69630-01	N N N N N N N N N E D D D D D E D D	6.0
69630-02	N N N N N N N N N D D D D D E E D D	A
69631-01	N N N N N N N N N D D D D D P E D D D D	A
69631-10	N N N N N N E D D D D E D D D D E D D	5.0
69632-05	N N N N N N N N N N E D D D D P E E	A
69634-01	N N N N N N N N N D D D D D D E D D P E D	4.0
69634-03	N N N N N N N E D D D D E D D D D E D	5.0
69637-03	N N N N N N N N N N E D D D D D D E E E D	8.0
69638-02	N N N N N N N N N N D D D E D D D D D D	A
69638-10	N N N N N N N N N N N E D D D D D E D D	6.0
	MEAN	5.4
	S.D.	1.30
	N	8

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

PCYCv5.22
01/20/2005
R:07/15/2005

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP:	CORN OIL	FEMALES
69626-09	5.30	10.7
69627-04	4.90	12.6
69627-05	7.80	12.2
69629-07	5.70	8.8
69629-09	3.80	7.0
69630-03	3.20	14.2
69630-04	5.10	22.7
69631-03	4.30	10.7
69631-04	4.00	8.7
69632-02	4.10	12.3
69633-05	4.70	8.2
69634-09	3.80	14.0
69636-06	2.60	8.9
69636-09	4.50	10.3
69638-09	3.80	9.1
MEAN	4.51	11.4
S.D.	1.217	3.80
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]60		FEMALES
69626-03	7.50	16.4
69626-08	4.20	8.8
69627-07	5.40	22.9
69628-06	3.60	12.9
69629-10	5.30	7.2
69630-06	5.90	22.6
69630-10	4.70	7.6
69631-05	4.20	10.7
69632-03	5.50	7.8
69632-07	4.60	12.8
69632-09	5.40	12.9
69634-07	3.70	9.1
69635-01	5.60	9.4
69637-01	5.00	9.8
69637-09	4.70	9.5
MEAN	5.02	12.0
S.D.	0.976	5.01
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]250		FEMALES
69627-08	5.30	18.0
69628-02	4.90	8.9
69628-08	5.10	6.3
69629-02	4.70	9.0
69629-04	6.20	8.9
69629-06	5.90	10.6
69629-08	4.00	9.0
69631-02	5.50	7.8
69631-07	4.60	9.9
69632-01	5.00	10.9
69633-07	4.80	9.0
69633-08	6.30	13.5
69635-02	5.90	11.1
69636-10	4.70	8.6
69637-08	6.40	9.1
MEAN	5.29	10.0
S.D.	0.718	2.74
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]1000	FEMALES	
69626-01	6.60	10.1
69626-05	6.30	8.7
69626-06	6.30	8.6
69627-03	6.90	12.5
69628-07	7.20	6.9
69628-10	5.60	8.8
69630-07	6.60	19.6
69631-09	4.10	15.0
69632-06	5.50	18.3
69633-02	1.90	11.1
69633-10	5.30	9.2
69634-05	5.80	13.2
69637-10	5.30	9.4
69638-01	4.90	13.5
69638-07	1.60	5.8
MEAN	5.33	11.4
S.D.	1.664	3.97
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42

SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]60	FEMALES	
69627-01	5.40	7.9
69627-02	6.50	4.9
69627-06	5.10	19.5
69627-10	2.30	17.2
69628-01	5.90	6.0
69630-08	5.20	8.1
69630-09	4.70	9.5
69631-06	4.40	13.8
69631-08	2.70	9.4
69632-08	5.30	12.3
69634-02	3.90	11.6
69634-08	6.50	9.8
69635-09	3.30	7.9
69637-04	3.40	10.6
69638-04	5.80	9.3
MEAN	4.69	10.5
S.D.	1.324	3.93
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42

SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]250	FEMALES	
69626-02	3.80	8.1
69626-04	5.60	9.9
69626-10	5.20	7.1
69628-05	5.90	7.7
69628-09	6.40	10.4
69629-01	4.00	5.6
69630-05	5.80	9.9
69632-04	4.00	23.4
69632-10	3.60	9.1
69633-03	4.70	12.8
69633-04	3.90	21.7
69634-10	5.50	11.6
69635-10	4.00	6.5
69637-02	6.30	9.2
69638-08	4.80	8.0
MEAN	4.90	10.7
S.D.	0.976	5.16
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

TABLE 20

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted] INDIVIDUAL SPECIAL CHEMISTRY VALUES DAY 42
SPONSOR NO.:04-027

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]1000	FEMALES	
69626-07	4.60	6.6
69628-03	3.80	22.8
69628-04	3.60	6.8
69629-05	6.10	11.5
69630-01	4.70	12.0
69630-02	5.20	7.8
69631-01	3.80	10.7
69631-10	3.30	14.6
69632-05	5.50	16.9
69634-01	3.20	10.1
69634-03	4.20	6.7
69637-03	5.50	8.6
69638-02	4.90	10.2
69638-10	5.40	10.3
MEAN	4.56	11.1
S.D.	0.921	4.49
N	14	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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02/25/2005

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.69638-07 GROUP 4: [redacted]1000 FEMALE EUTH IN EXTREMIS 12/16/04 DATE OF DEATH: 12/16/04

			GRADE
SKIN	GROSS: MATTING, RED OCULAR, BILATERAL; NASAL; BUCCAL		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPINAL CORD
SAL. GLAND MAND	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.69629-03 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 12/04/04 DATE OF DEATH: 12/04/04

		GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED RIGHT ACCESSORY LOBE	P

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.52
01/20/2005

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-09	162.	0.5868	0.3511	0.2357	7.2589	1.5521	0.0631	0.0350	0.0085	0.0179
69627-04	168.	0.2146	0.1962	0.0184	7.5687	1.4785	0.0888	0.0365	0.0088	0.0196
69627-05	152.	0.7503	0.3568	0.3935	7.2796	1.4955	0.0734	0.0462	0.0095	0.0212
69629-07	161.	0.4015	0.3750	0.0265	7.6348	1.5507	0.0773	0.0336	0.0073	0.0206
69629-09	191.	0.3167	0.2969	0.0198	8.4661	1.9762	0.1293	0.0493	0.0104	0.0208
69630-03	153.	0.2912	0.2597	0.0315	7.3757	1.3603	0.0715	0.0414	0.0078	0.0266
69630-04	154.	0.2439	0.2321	0.0118	6.5913	1.4882	0.0713	0.0325	0.0082	0.0168
69631-03	165.	0.2570	0.2399	0.0171	8.1251	1.6934	0.0995	0.0490	0.0096	0.0104
69631-04	154.	0.2300	0.2119	0.0181	7.4773	1.6024	0.0856	0.0380	0.0081	0.0226
69632-02	174.	0.2579	0.2409	0.0170	8.6821	1.6670	0.0832	0.0431	0.0100	0.0206
69633-05	167.	0.3169	0.3027	0.0142	7.7868	1.7537	0.1456	0.0532	0.0118	0.0279
69634-09	172.	0.2196	0.1770	0.0426	7.9126	1.6184	0.0726	0.0404	0.0078	0.0165
69636-06	192.	0.3277	0.3152	0.0125	9.2141	1.8762	0.1421	0.0479	0.0119	0.0233
69636-09	208.	0.4663	0.4268	0.0395	10.8659	2.1381	0.0820	0.0512	0.0108	A
69638-09	157.	0.2502	0.2327	0.0175	7.4316	1.5606	0.1252	0.0444	0.0095	0.0334
MEAN	169.	0.3420	0.2810	0.0610	7.9780	1.6541	0.0940	0.0428	0.0093	0.0213
S.D.	16.6	0.15255	0.07266	0.10757	1.02781	0.20746	0.02767	0.00666	0.00144	0.00556
N	15	15	15	15	15	15	15	15	15	14

FBW = FINAL BODY WEIGHT

A = LOST AT NECROPSY; WEIGHT NOT RECORDED

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:04-027 INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-03	164.	0.6318	0.3906	0.2412	7.0495	1.5736	0.0790	0.0400	0.0086	0.0177
69626-08	135.	0.2055	0.1887	0.0168	5.6652	1.3707	0.0718	0.0372	0.0071	A
69627-07	187.	0.8172	0.4138	0.4034	9.2877	1.8674	0.0701	0.0416	0.0087	0.0222
69628-06	133.	0.2739	0.2545	0.0194	6.5732	1.1870	0.0708	0.0363	0.0080	0.0163
69629-10	177.	0.2016	0.1850	0.0166	7.5122	1.5986	0.0773	0.0335	0.0074	0.0197
69630-06	188.	0.6332	0.4549	0.1783	9.8185	1.9422	0.0998	0.0260	0.0099	0.0160
69630-10	169.	0.1957	0.1781	0.0176	6.9437	1.3895	0.0676	0.0381	0.0074	0.0142
69631-05	141.	0.1748	0.1603	0.0145	6.6891	1.3905	0.0528	0.0320	0.0054	0.0170
69632-03	185.	0.2754	0.2578	0.0176	8.9708	1.7543	0.1027	0.0465	0.0089	0.0178
69632-07	157.	0.2775	0.2587	0.0188	7.9366	1.4927	0.0891	0.0340	0.0101	0.0151
69632-09	167.	0.5874	0.3480	0.2394	8.6380	1.7272	0.0665	0.0442	0.0099	0.0197
69634-07	196.	0.3130	0.2988	0.0142	10.1678	1.9961	0.1538	0.0670	0.0122	0.0196
69635-01	172.	0.2380	0.2176	0.0204	7.8314	1.5330	0.0960	0.0426	0.0097	0.0206
69637-01	144.	0.2148	0.2026	0.0122	7.2250	1.4675	0.0924	0.0364	0.0071	0.0179
69637-09	171.	0.2759	0.2569	0.0190	9.2200	1.5515	0.0807	0.0383	0.0078	0.0177
MEAN	166.	0.3544	0.2711	0.0833	7.9686	1.5895	0.0847	0.0396	0.0085	0.0180
S.D.	20.0	0.20453	0.09204	0.12224	1.32512	0.22863	0.02368	0.00916	0.00166	0.00221
N	15	15	15	15	15	15	15	15	15	14

FBW = FINAL BODY WEIGHT

A = LOST AT NECROPSY; WEIGHT NOT RECORDED

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69627-08	179.	0.2346	0.2210	0.0136	8.7799	1.7541	0.1043	0.0435	0.0101	0.0188
69628-02	155.	0.2050	0.1955	0.0095	7.6919	1.6341	0.0803	0.0462	0.0085	0.0215
69628-08	147.	0.4946	0.3562	0.1384	6.7948	1.4897	0.0867	0.0452	0.0088	0.0197
69629-02	161.	0.2289	0.2165	0.0124	7.5470	1.5567	0.0924	0.0418	0.0081	0.0172
69629-04	155.	0.5986	0.3414	0.2572	6.8675	1.4450	0.0721	0.0431	0.0081	0.0182
69629-06	175.	0.2873	0.2697	0.0176	8.8958	1.8232	0.0945	0.0511	0.0075	0.0199
69629-08	168.	0.2738	0.2588	0.0150	7.4142	1.5711	0.1147	0.0530	0.0100	0.0200
69631-02	165.	0.2194	0.1982	0.0212	8.2546	1.7057	0.0826	0.0500	0.0080	0.0126
69631-07	150.	0.3620	0.2832	0.0788	7.8658	1.4953	0.0940	0.0477	0.0087	0.0150
69632-01	163.	0.2616	0.2408	0.0208	8.7875	1.5501	0.0883	0.0472	0.0085	0.0167
69633-07	161.	0.2535	0.2421	0.0114	8.0422	1.7720	0.1001	0.0507	0.0108	0.0218
69633-08	165.	0.6112	0.3616	0.2496	7.4897	1.6098	0.1014	0.0472	0.0092	0.0171
69635-02	179.	0.3857	0.2961	0.0896	8.8784	1.6966	0.0804	0.0476	0.0084	0.0125
69636-10	164.	0.2065	0.1949	0.0116	7.8833	1.5624	0.0759	0.0419	0.0092	0.0140
69637-08	154.	0.2829	0.2634	0.0195	7.2245	1.6066	0.0874	0.0391	0.0103	0.0136
MEAN	163.	0.3270	0.2626	0.0644	7.8945	1.6182	0.0903	0.0464	0.0089	0.0172
S.D.	9.8	0.13692	0.05630	0.08540	0.70578	0.11141	0.01155	0.00394	0.00097	0.00312
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:04-027 INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-01	154.	0.1508	0.1383	0.0125	9.0637	1.5916	0.0290	0.0318	0.0059	0.0188
69626-05	159.	0.1705	0.1620	0.0085	8.9757	1.4303	0.0494	0.0402	0.0067	0.0231
69626-06	170.	0.1691	0.1605	0.0086	9.6927	1.7321	0.0776	0.0545	0.0085	0.0257
69627-03	166.	0.2255	0.2116	0.0139	10.0642	1.6824	0.0940	0.0552	0.0080	0.0213
69628-07	152.	0.2027	0.1893	0.0134	9.5213	1.6615	0.0517	0.0543	0.0071	0.0238
69628-10	155.	0.1716	0.1566	0.0150	10.0835	1.6875	0.0636	0.0445	0.0081	0.0217
69630-07	152.	0.1639	0.1548	0.0091	10.5469	1.4490	0.0484	0.0397	0.0062	0.0239
69631-09	184.	0.2662	0.2367	0.0295	11.9356	1.8045	0.0917	0.0445	0 0089	0.0156
69632-06	158.	0.2586	0.2442	0.0144	9.9005	1.5390	0.0894	0.0496	0.0081	0.0115
69633-02	125.	0.1729	0.1589	0.0140	9.0919	1.4013	0.0454	0.0305	0.0060	0.0129
69633-10	164.	0.1741	0.1650	0.0091	9.6638	1.5870	0.0804	0.0517	0.0077	0.0199
69634-05	144.	0.1542	0.1395	0.0147	9.0963	1.3174	0.0467	0.0331	0.0056	0.0148
69637-10	139.	0.2140	0.1994	0.0146	7.8928	1.4792	0.0466	0.0430	0.0079	0.0182
69638-01	138.	0.1512	0.1430	0.0082	8.3035	1.4058	0.0621	0.0508	0.0077	0.0129
MEAN	154.	0.1890	0.1757	0.0133	9.5595	1.5549	0.0626	0.0445	0.0073	0.0189
S.D.	14.9	0.03843	0.03491	0.00539	0.98729	0.14577	0.02061	0.00859	0.00106	0.00466
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69627-01	186.	0.4336	0.4088	0.0248	7.9759	1.7878	0.1099	0.0466	0.0096	0.0188
69627-02	173.	0.2796	0.2629	0.0167	8.6120	1.8867	0.0877	0.0509	0.0102	0.0224
69627-06	192.	0.6586	0.4234	0.2352	9.0889	1.9655	0.1066	0.0570	0.0107	0.0275
69627-10	159.	0.3515	0.3192	0.0323	8.4322	1.3776	0.0875	0.0345	0.0090	0.0191
69628-01	173.	0.5127	0.4185	0.0942	9.1595	1.7768	0.0747	0.0376	0.0097	0.0197
69630-08	143.	0.6795	0.3528	0.3267	6.4131	1.4868	0.0682	0.0354	0.0073	0.0200
69630-09	161.	0.2568	0.2358	0.0210	7.2360	1.4338	0.0818	0.0359	0.0074	0.0222
69631-06	163.	0.4283	0.3849	0.0434	7.0036	1.6948	0.1108	0.0524	0.0091	0.0133
69631-08	174.	0.2573	0.2447	0.0126	8.3397	1.6596	0.1035	0.0460	0.0089	0.0135
69632-08	178.	0.2824	0.2602	0.0222	8.8036	1.7207	0.0961	0.0405	0.0096	0.0184
69634-02	176.	0.3453	0.3297	0.0156	9.1275	1.6887	0.0988	0.0483	0.0088	0.0131
69634-08	188.	0.4293	0.4120	0.0173	9.8412	1.8607	0.1652	0.0559	0.0121	0.0145
69635-09	167.	0.2412	0.2275	0.0137	7.6628	1.6803	0.1158	0.0471	0.0098	0.0146
69637-04	159.	0.2133	0.1955	0.0178	8.3063	1.6195	0.1099	0.0426	0.0064	0.0210
69638-04	166.	0.3363	0.3142	0.0221	8.0814	1.6166	0.0803	0.0433	0.0081	0.0139
MEAN	171.	0.3804	0.3193	0.0610	8.2722	1.6837	0.0998	0.0449	0.0091	0.0181
S.D.	12.9	0.14476	0.07829	0.09315	0.91463	0.16412	0.02324	0.00727	0.00143	0.00424
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-02	171.	0.4355	0.3728	0.0627	7.2450	1.7356	0.1024	0.0464	0.0083	0.0198
69626-04	162.	0.3814	0.3668	0.0146	7.7995	1.6769	0.1201	0.0488	0.0099	0.0205
69626-10	155.	0.3157	0.2925	0.0232	6.9190	1.5751	0.0865	0.0369	0.0084	0.0172
69628-05	177.	0.4315	0.4022	0.0293	8.6275	1.6785	0.0923	0.0414	0.0106	0.0190
69628-09	167.	0.3926	0.3687	0.0239	7.8012	1.6754	0.0946	0.0460	0.0084	0.0214
69629-01	187.	0.2541	0.2333	0.0208	8.6154	1.8394	0.1250	0.0503	0.0087	0.0167
69630-05	160.	0.4760	0.4390	0.0370	6.9732	1.5521	0.1068	0.0469	0.0085	0.0223
69632-04	176.	0.2760	0.2536	0.0224	9.1934	1.6936	0.0906	0.0407	0.0091	0.0189
69632-10	149.	0.2637	0.2420	0.0217	7.1997	1.4456	0.0829	0.0345	0.0085	0.0180
69633-03	173.	0.3968	0.3526	0.0442	9.0417	1.8702	0.0856	0.0416	0.0104	0.0211
69633-04	183.	0.3644	0.3483	0.0161	9.6408	1.9413	0.1443	0.0619	0.0120	0.0241
69634-10	172.	0.2674	0.2449	0.0225	8.1057	1.6851	0.1034	0.0470	0.0080	0.0253
69635-10	157.	0.2426	0.2201	0.0225	7.1110	1.4810	0.0861	0.0369	0.0077	0.0181
69637-02	156.	0.4840	0.4476	0.0364	7.7758	1.5809	0.0703	0.0403	0.0083	0.0212
69638-08	179.	0.3188	0.2885	0.0303	9.4935	1.6044	0.0924	0.0441	0.0109	0.0191
MEAN	168.	0.3534	0.3249	0.0285	8.1028	1.6690	0.0989	0.0442	0.0092	0.0202
S.D.	11.3	0.08257	0.07627	0.01244	0.94154	0.13857	0.01895	0.00675	0.00127	0.00245
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 22

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-07	182.	0.2254	0.2054	0.0200	9.1182	2.0103	0.0852	0.0399	0.0085	0.0169
69628-03	177.	0.2595	0.2329	0.0266	10.6027	1.9185	0.0701	0.0411	0.0096	0.0258
69628-04	162.	0.2702	0.2492	0.0210	7.3981	1.7115	0.0882	0.0371	0.0076	0.0217
69629-05	177.	0.6046	0.4271	0.1775	9.1322	1.7912	0.1033	0.0455	0.0094	0.0242
69630-01	174.	0.2201	0.2023	0.0178	8.9601	1.7088	0.0639	0.0314	0.0088	0.0226
69630-02	144.	0.2205	0.2012	0.0193	6.4330	1.4794	0.0753	0.0291	0.0081	0.0214
69631-01	158.	0.4100	0.3381	0.0719	7.6077	1.6600	0.0615	0.0435	0.0093	0.0207
69631-10	178.	0.2868	0.2700	0.0168	8.7561	1.7445	0.0910	0.0522	0.0100	0.0231
69632-05	152.	0.4774	0.3128	0.1646	7.6456	1.4052	0.0592	0.0340	0.0080	0.0202
69634-01	177.	0.2313	0.2167	0.0146	8.5909	1.7006	0.1014	0.0436	0.0088	0.0179
69634-03	170.	0.2502	0.2371	0.0131	8.7518	1.7662	0.1337	0.0533	0.0105	0.0214
69637-03	164.	0.2623	0.2358	0.0265	7.6053	1.7948	0.0656	0.0410	0.0080	0.0207
69638-02	168.	0.2393	0.2170	0.0223	8.5589	1.7497	0.1523	0.0597	0.0106	0.0187
69638-10	191.	0.2659	0.2464	0.0195	9.6217	1.8914	0.0904	0.0391	0.0105	0.0191
MEAN	170.	0.3017	0.2566	0.0451	8.4845	1.7380	0.0887	0.0422	0.0091	0.0210
S.D.	12.6	0.11461	0.06348	0.05531	1.06062	0.15786	0.02739	0.00852	0.00102	0.00244
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

POFBWv4.14
01/20/2005
R:02/25/2005

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS- WET	UTERUS- BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-09	162.	0.362	0.217	4.481	0.958	0.039	0.022	0.005	0.011
69627-04	168.	0.128	0.117	4.505	0.880	0.053	0.022	0.005	0.012
69627-05	152.	0.494	0.235	4.789	0.984	0.048	0.030	0.006	0.014
69629-07	161.	0.249	0.233	4.742	0.963	0.048	0.021	0.005	0.013
69629-09	191.	0.166	0.155	4.433	1.035	0.068	0.026	0.005	0.011
69630-03	153.	0.190	0.170	4.821	0.889	0.047	0.027	0.005	0.017
69630-04	154.	0.158	0.151	4.280	0.966	0.046	0.021	0.005	0.011
69631-03	165.	0.156	0.145	4.924	1.026	0.060	0.030	0.006	0.006
69631-04	154.	0.149	0.138	4.855	1.041	0.056	0.025	0.005	0.015
69632-02	174.	0.148	0.138	4.990	0.958	0.048	0.025	0.006	0.012
69633-05	167.	0.190	0.181	4.663	1.050	0.087	0.032	0.007	0.017
69634-09	172.	0.128	0.103	4.600	0.941	0.042	0.023	0.005	0.010
69636-06	192.	0.171	0.164	4.799	0.977	0.074	0.025	0.006	0.012
69636-09	208.	0.224	0.205	5.224	1.028	0.039	0.025	0.005	A
69638-09	157.	0.159	0.148	4.734	0.994	0.080	0.028	0.006	0.021
MEAN	169.	0.205	0.167	4.723	0.979	0.056	0.025	0.005	0.013
S.D.	16.6	0.0995	0.0402	0.2399	0.0518	0.0151	0.0034	0.0006	0.0037
N	15	15	15	15	15	15	15	15	14

FBW = FINAL BODY WEIGHT

A = LOST AT NECROPSY, WEIGHT NOT RECORDED

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:04-027 INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-03	164.	0.385	0.238	4.298	0.960	0.048	0.024	0.005	0.011
69626-08	135.	0.152	0.140	4.196	1.015	0.053	0.028	0.005	A
69627-07	187.	0.437	0.221	4.967	0.999	0.037	0.022	0.005	0.012
69628-06	133.	0.206	0.191	4.942	0.892	0.053	0.027	0.006	0.012
69629-10	177.	0.114	0.105	4.244	0.903	0.044	0.019	0.004	0.011
69630-06	188.	0.337	0.242	5.223	1.033	0.053	0.014	0.005	0.009
69630-10	169.	0.116	0.105	4.109	0.822	0.040	0.023	0.004	0.008
69631-05	141.	0.124	0.114	4.744	0.986	0.037	0.023	0.004	0.012
69632-03	185.	0.149	0.139	4.849	0.948	0.056	0.025	0.005	0.010
69632-07	157.	0.177	0.165	5.055	0.951	0.057	0.022	0.006	0.010
69632-09	167.	0.352	0.208	5.172	1.034	0.040	0.026	0.006	0.012
69634-07	196.	0.160	0.152	5.188	1.018	0.078	0.034	0.006	0.010
69635-01	172.	0.138	0.127	4.553	0.891	0.056	0.025	0.006	0.012
69637-01	144.	0.149	0.141	5.017	1.019	0.064	0.025	0.005	0.012
69637-09	171.	0.161	0.150	5.392	0.907	0.047	0.022	0.005	0.010
MEAN	166.	0.210	0.163	4.797	0.959	0.051	0.024	0.005	0.011
S.D.	20.0	0.1089	0.0466	0.4182	0.0641	0.0110	0.0044	0.0007	0.0013
N	15	15	15	15	15	15	15	15	14

FBW = FINAL BODY WEIGHT

A = LOST AT NECROPSY, WEIGHT NOT RECORDED

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:04-027 INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69627-08	179.	0.131	0.123	4.905	0.980	0.058	0.024	0.006	0.011
69628-02	155.	0.132	0.126	4.963	1.054	0.052	0.030	0.005	0.014
69628-08	147.	0.336	0.242	4.622	1.013	0.059	0.031	0.006	0.013
69629-02	161.	0.142	0.134	4.688	0.967	0.057	0.026	0.005	0.011
69629-04	155.	0.386	0.220	4.431	0.932	0.047	0.028	0.005	0.012
69629-06	175.	0.164	0.154	5.083	1.042	0.054	0.029	0.004	0.011
69629-08	168.	0.163	0.154	4.413	0.935	0.068	0.032	0.006	0.012
69631-02	165.	0.133	0.120	5.003	1.034	0.050	0.030	0.005	0.008
69631-07	150.	0.241	0.189	5.244	0.997	0.063	0.032	0.006	0.010
69632-01	163.	0.160	0.148	5.391	0.951	0.054	0.029	0.005	0.010
69633-07	161.	0.157	0.150	4.995	1.101	0.062	0.031	0.007	0.014
69633-08	165.	0.370	0.219	4.539	0.976	0.061	0.029	0.006	0.010
69635-02	179.	0.215	0.165	4.960	0.948	0.045	0.027	0.005	0.007
69636-10	164.	0.126	0.119	4.807	0.953	0.046	0.026	0.006	0.009
69637-08	154.	0.184	0.171	4.691	1.043	0.057	0.025	0.007	0.009
MEAN	163.	0.203	0.162	4.849	0.995	0.056	0.029	0.006	0.011
S.D.	9.8	0.0898	0.0392	0.2857	0.0507	0.0067	0.0025	0.0008	0.0021
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:04-027
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-01	154.	0.098	0.090	5.886	1.034	0.019	0.021	0.004	0.012
69626-05	159.	0.107	0.102	5.645	0.900	0.031	0.025	0.004	0.015
69626-06	170.	0.099	0.094	5.702	1.019	0.046	0.032	0.005	0.015
69627-03	166.	0.136	0.127	6.063	1.013	0.057	0.033	0.005	0.013
69628-07	152.	0.133	0.125	6.264	1.093	0.034	0.036	0.005	0.016
69628-10	155.	0.111	0.101	6.505	1.089	0.041	0.029	0.005	0.014
69630-07	152.	0.108	0.102	6.939	0.953	0.032	0.026	0.004	0.016
69631-09	184.	0.145	0.129	6.487	0.981	0.050	0.024	0.005	0.008
69632-06	158.	0.164	0.155	6.266	0.974	0.057	0.031	0.005	0.007
69633-02	125.	0.138	0.127	7.274	1.121	0.036	0.024	0.005	0.010
69633-10	164.	0.106	0.101	5.893	0.968	0.049	0.032	0.005	0.012
69634-05	144.	0.107	0.097	6.317	0.915	0.032	0.023	0.004	0.010
69637-10	139.	0.154	0.143	5.678	1.064	0.034	0.031	0.006	0.013
69638-01	138.	0.110	0.104	6.017	1.019	0.045	0.037	0.006	0.009
MEAN	154.	0.123	0.114	6.210	1.010	0.040	0.029	0.005	0.012
S.D.	14.9	0.0218	0.0200	0.4779	0.0664	0.0109	0.0050	0.0007	0.0030
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:04-027 INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69627-01	186.	0.233	0.220	4.288	0.961	0.059	0.025	0.005	0.010
69627-02	173.	0.162	0.152	4.978	1.091	0.051	0.029	0.006	0.013
69627-06	192.	0.343	0.221	4.734	1.024	0.056	0.030	0.006	0.014
69627-10	159.	0.221	0.201	5.303	0.866	0.055	0.022	0.006	0.012
69628-01	173.	0.296	0.242	5.295	1.027	0.043	0.022	0.006	0.011
69630-08	143.	0.475	0.247	4.485	1.040	0.048	0.025	0.005	0.014
69630-09	161.	0.160	0.146	4.494	0.891	0.051	0.022	0.005	0.014
69631-06	163.	0.263	0.236	4.297	1.040	0.068	0.032	0.006	0.008
69631-08	174.	0.148	0.141	4.793	0.954	0.059	0.026	0.005	0.008
69632-08	178.	0.159	0.146	4.946	0.967	0.054	0.023	0.005	0.010
69634-02	176.	0.196	0.187	5.186	0.959	0.056	0.027	0.005	0.007
69634-08	188.	0.228	0.219	5.235	0.990	0.088	0.030	0.006	0.008
69635-09	167.	0.144	0.136	4.589	1.006	0.069	0.028	0.006	0.009
69637-04	159.	0.134	0.123	5.224	1.019	0.069	0.027	0.004	0.013
69638-04	166.	0.203	0.189	4.868	0.974	0.048	0.026	0.005	0.008
MEAN	171.	0.224	0.187	4.848	0.987	0.058	0.026	0.005	0.011
S.D.	12.9	0.0917	0.0430	0.3582	0.0584	0.0113	0.0032	0.0006	0.0026
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:04-027

INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-02	171.	0.255	0.218	4.237	1.015	0.060	0.027	0.005	0.012
69626-04	162.	0.235	0.226	4.815	1.035	0.074	0.030	0.006	0.013
69626-10	155.	0.204	0.189	4.464	1.016	0.056	0.024	0.005	0.011
69628-05	177.	0.244	0.227	4.874	0.948	0.052	0.023	0.006	0.011
69628-09	167.	0.235	0.221	4.671	1.003	0.057	0.028	0.005	0.013
69629-01	187.	0.136	0.125	4.607	0.984	0.067	0.027	0.005	0.009
69630-05	160.	0.298	0.274	4.358	0.970	0.067	0.029	0.005	0.014
69632-04	176.	0.157	0.144	5.224	0.962	0.051	0.023	0.005	0.011
69632-10	149.	0.177	0.162	4.832	0.970	0.056	0.023	0.006	0.012
69633-03	173.	0.229	0.204	5.226	1.081	0.049	0.024	0.006	0.012
69633-04	183.	0.199	0.190	5.268	1.061	0.079	0.034	0.007	0.013
69634-10	172.	0.155	0.142	4.713	0.980	0.060	0.027	0.005	0.015
69635-10	157.	0.155	0.140	4.529	0.943	0.055	0.024	0.005	0.012
69637-02	156.	0.310	0.287	4.984	1.013	0.045	0.026	0.005	0.014
69638-08	179.	0.178	0.161	5.304	0.896	0.052	0.025	0.006	0.011
MEAN	168.	0.211	0.194	4.807	0.992	0.059	0.026	0.005	0.012
S.D.	11.3	0.0529	0.0490	0.3417	0.0477	0.0094	0.0031	0.0006	0.0015
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

TABLE 23

PROJECT NO.:WIL-187042 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

SPONSOR NO.:04-027

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
69626-07	182.	0.124	0.113	5.010	1.105	0.047	0.022	0.005	0.009
69628-03	177.	0.147	0.132	5.990	1.084	0.040	0.023	0.005	0.015
69628-04	162.	0.167	0.154	4.567	1.056	0.054	0.023	0.005	0.013
69629-05	177.	0.342	0.241	5.159	1.012	0.058	0.026	0.005	0.014
69630-01	174.	0.126	0.116	5.149	0.982	0.037	0.018	0.005	0.013
69630-02	144.	0.153	0.140	4.467	1.027	0.052	0.020	0.006	0.015
69631-01	158.	0.259	0.214	4.815	1.051	0.039	0.028	0.006	0.013
69631-10	178.	0.161	0.152	4.919	0.980	0.051	0.029	0.006	0.013
69632-05	152.	0.314	0.206	5.030	0.924	0.039	0.022	0.005	0.013
69634-01	177.	0.131	0.122	4.854	0.961	0.057	0.025	0.005	0.010
69634-03	170.	0.147	0.139	5.148	1.039	0.079	0.031	0.006	0.013
69637-03	164.	0.160	0.144	4.637	1.094	0.040	0.025	0.005	0.013
69638-02	168.	0.142	0.129	5.095	1.041	0.091	0.036	0.006	0.011
69638-10	191.	0.139	0.129	5.038	0.990	0.047	0.020	0.005	0.010
MEAN	170.	0.179	0.152	4.991	1.025	0.052	0.025	0.005	0.013
S.D.	12.6	0.0712	0.0395	0.3643	0.0528	0.0157	0.0049	0.0005	0.0018
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

POFBWv4.14
01/20/2005
R:02/25/2005

APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

[redacted]

[redacted]

[redacted]

Test Substance Certificate

[redacted]

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Brown viscous liquid

Storage Conditions
Ambient, store under nitrogen blanket

Expiration Date
1 July 2005

Additional Comments
None

[redacted]

25 October 2004
Date

[redacted]

[redacted]

[redacted]

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Black viscous liquid

Storage Conditions
Ambient, store under nitrogen blanket

Expiration Date
1 July 2005

Additional Comments
None

[redacted]

25 October 2004
Date

[redacted]

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

[redacted]

TITLE

The Analytical Report in Support of a Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

SUBMITTED TO SUPPORT THE TESTING OF:

[redacted]

WIL Research Study #WIL-187042

ETC Reference #04-027

AUTHOR

[redacted], Principal Investigator

STUDY INITIATION DATE

4 November 2004

ANALYTICAL START DATE

11 November 2004

ANALYTICAL END DATE

30 December 2004

ANALYTICAL STUDY COMPLETION DATE

4 November 2005

PERFORMING LABORATORY

[redacted]

TOTAL PAGES

13

[redacted]

[redacted]

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[redacted]

[redacted]

ANALYTICAL STUDY GLP COMPLIANCE STATEMENT

[redacted]

All analytical tests performed by [redacted] for WIL Research Study #WIL-187042 ([redacted] Reference #04-027) were conducted in compliance with current EPA Good Laboratory Practice (GLP) standards as described by the Toxic Substances Control Act (TSCA) 40 CFR Part 792.

[redacted]

Principal Investigator [redacted] Date: 4 Nov 2005

[redacted]

[redacted]

[redacted]

ANALYTICAL STUDY QUALITY ASSURANCE UNIT STATEMENT

[redacted]

The analytical raw data and final report for the [redacted] study have been reviewed by the [redacted] Quality Assurance Team.

The report appears to accurately describe the methods and Standard Operating Procedures (SOPs) used in the study The reported results accurately reflect the raw data of the study.

[redacted]

Study #
WIL Research Study #WIL-187042
[redacted] Reference #04-027

Study Title
The Analytical Report in Support of a Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

[redacted]

	Study Director	*Dates Reported to* WIL Research Mgmt	[redacted] Mgmt
Study In-progress Inspection December 10, 2004	November 4, 2005	November 4, 2005	November 4, 2005
Analytical Draft Report Review May 11-13 and 16-19, 2005	November 4, 2005	November 4, 2005	November 4, 2005
Analytical Final Report Review November 3-4, 2005	November 4, 2005	November 4, 2005	November 4, 2005

[redacted]

Date: Nov 1, 2005

[redacted]

[redacted]

ABSTRACT

Samples of suspensions ([redacted]4 and [redacted]5 in corn oil) used in a female pubertal assay in rats, WIL Research Study #WIL-187042 ([redacted]; Reference #04-027), were analyzed at [redacted]n [redacted]y to verify their homogeneity, stability, and nominal concentrations. A direct dilution procedure was employed to prepare the samples for elemental analysis by Inductively Coupled Plasma-Atomic Emission Spectroscopy (ICP-AES). Homogeneity and stability of [redacted]4 and [redacted]5 in corn oil were established. The nominal concentrations of all dosing suspensions were verified by the analytical data.

TEST SUBSTANCES

The test substances used in the preparation of the dosing suspensions are identified as [redacted] and [redacted]. The CAS numbers are confidential; contac[redacted]for further information. The test substances were characterized and their stabilities were established prior to the initiation of the study.

INTRODUCTION

The purpose of this analytical study was the determination and verification of test substance homogeneity, stability, and concentration in corn oil. The concentration study samples were aliquots taken from mixtures prepared as dosing suspensions for a female pubertal assay in rats as outlined in the protocol for WIL Research Study #WIL-187042.

The analytical portion of the study was performed by the High Volume Services team located in the [redacted]es [redacted]group at [redacted]y [redacted]. The analytical start and end dates were 11 November 2004 and 30 December 2004 respectively.

EXPERIMENTAL

SAMPLES
Samples were shipped from WIL Research to [redacted]; Principal Investigator. Samples were stored at room temperature and in the dark prior to analysis.

The first batch of samples was transferred to the laboratory and analyzed on 11 November 2004. The analysis of the last set of samples was completed on 21 December 2004. Test substance and corn oil densities were determined on 30 December 2004.

STANDARDS
Calibration standards for the ICP-AES were made from certified commercially prepared elemental concentrates (Conostan Division of Conoco, Inc.). Standard preparation data is archived by [redacted]

[redacted]

[redacted]

ANALYTICAL METHOD
Samples were prepared as stated in [redacted] Test Code 30176, SOP ME-125 "Elemental Analysis of Additives or Additive Mixtures by Direct Dilution and ICP Analysis." The procedures outlined in SOP EQ-130, "IRIS Intrepid XDL II Radial Inductively Coupled Plasma Spectrometer," were followed during the instrumental analysis of the samples.

The approach employed in this method was to verify concentration based on the known elemental composition of [redacted]. Aliquots of the dosing suspensions were diluted in an o-xylene diluent and the elemental composition was determined by ICP-AES. The calcium concentration of the samples was then used to ascertain the concentration of the test substance in the dosing suspensions.

DISCUSSION

METHOD VALIDATION
Method validation was performed following the recommendations outlined in the International Conference on Harmonisation's Q2B document: Guideline on the Validation of Analytical Procedures: Methodology. The limit of detection (LOD) and limit of quantitation (LOQ) were calculated to be 0.063 and 0.192 wt ppm calcium respectively. A reporting limit of 2 wt ppm calcium was determined to be appropriate for vehicle results.

SAMPLE ANALYSIS
The analytical results for the suspensions of [redacted] in corn oil are summarized in the tables located on pages 8 through 13. Seven calibration standards were analyzed to generate a linear calibration curve with inverse concentration weighting. All instrument control checks and quality control samples were within acceptable limits. Known amounts of calcium were spiked into 31 samples throughout the duration of the study and gave acceptable percent recoveries of 96 to 106%.

The dosing suspensions were analyzed for calcium, an element present in known concentrations in the test substances. Dosing suspension estimates of weight percent calcium were derived by the following formula:

$$Wt\%\ Ca = \left[\frac{x}{x + \left(D_2 - \frac{xD_2}{D_1}\right)}\right] \%\ Ca\ in\ [redacted]$$

where x is the solute test substance concentration in mg/µL; D_1 is the test substance density (0.9397 g/mL for [redacted] and 0.9103 g/mL for [redacted]); and D_2 is the vehicle or solvent density (corn oil, 0.9193 g/mL). The concentration of calcium in [redacted] is 4.004 wt% and 2.585 wt% in [redacted]. The measured results of calcium were obtained by ICP-AES, converted to wt% from ppm by multiplying by 10^{-4}, and then compared against the estimated values.

Homogeneity was confirmed if the percent differences between the overall dose level mean and individual strata means were 10% or less. Stability and concentration data were evaluated using percent difference. The acceptable tolerance was 15%.

[redacted]

[redacted]

RESULTS AND CONCLUSIONS

The confirmation of dosing suspension homogeneity is supported by the data presented on pages 8 and 9. The percent difference of all strata means with their respective overall mean is well below the 10% tolerance

The stabilities of [redacted] in corn oil over a 12-day period are established on pages 10 and 11. The percent difference between the estimated and measured concentrations is less than 15% for all dosing levels.

The analytical result summaries for the concentration studies are found on pages 12 and 13. The nominal concentrations of all dosing suspensions were verified by the analytical data. The percent difference between the estimated and measured concentrations is less than 15% for all dosing levels.

ARCHIVES

SAMPLES
The unused portion of all samples shall be stored in room [redacted] for a minimum of one year after the final analytical report is issued.

RAW DATA
Calibration data; and instrument, chemical, and standard logbook documentation shall be archived by [redacted] as facility records [redacted]. All other raw data shall be archived in the Analytical Study File in [redacted]; Analytical Study Archives.

FINAL REPORT
A copy of the final report shall be archived with the Analytical Study File in [redacted]

PROTOCOL AND SOP DEVIATIONS

Due to laboratory scheduling conflicts, the stability of the test substances in corn oil was evaluated over a 12-day period instead of 10 days as specified in the protocol. This did not affect the outcome of the analytical study.

SOP ME-125 states a duplicate sample shall be prepared for every batch of 20 samples. Only one duplicate was prepared over the course of the study instead of the expected 12. All QCs and instrument control samples were within acceptable limits. This did not affect the outcome of the analytical results.

STUDY PERSONNEL

PRINCIPAL INVESTIGATOR [redacted]

ANALYSTS [redacted]

SUPERVISORY PERSONNEL [redacted]

[redacted]

SUMMARY OF ANALYTICAL RESULTS

[redacted]

CONCENTRATION OF CALCIUM IN [redacted] PENSIONS
WIL Research #WIL-187042
[redacted] Reference #04-027

Homogeneity Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted] wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
439930002	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0001	1	1	Middle	0 000	<2 wt ppm			
439930003	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0011	1	1	Middle	0 000	<2 wt ppm	<2 wt ppm	<2 wt ppm	0 0
439930004	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0002	1	2	Top	12	0 052	0.052		
439930005	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0012	1	2	Top	12	0 052	0 052		0 0
439930006	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0003	1	2	Middle	12	0 052	0.052	0 052	
439930007	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0013	1	2	Middle	12	0.052	0 052		0 0
439930008	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0004	1	2	Bottom	12	0.052	0 052		
439930009	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0014	1	2	Bottom	12	0 052	0 052		0 0
439930010	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0005	1	3	Top	50	0 218	0.213		
439930011	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0015	1	3	Top	50	0.218	0.213		0.5
439930012	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0006	1	3	Middle	50	0.218	0.212	0.212	
439930013	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0016	1	3	Middle	50	0 218	0 211		0 0
439930014	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0007	1	3	Bottom	50	0 218	0.211		
439930015	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0017	1	3	Bottom	50	0 218	0.211		0 5
439930016	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0008	1	4	Top	200	0.867	0 840		
439930017	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0018	1	4	Top	200	0 867	0 858		0 6
439930018	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0009	1	4	Middle	200	0.867	0 864	0 854	
439930019	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0019	1	4	Middle	200	0 867	0.848		0 2
439930020	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0010	1	4	Bottom	200	0 867	0.855		
439930021	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0020	1	4	Bottom	200	0 867	0.858		0.4

[redacted]

8

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

[redacted]

[redacted]

SUMMARY OF ANALYTICAL RESULTS

[redacted]

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187042
[redacted] Reference #04-027

Homogeneity Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated [redacted] mg/mL	Concentration wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
439930022	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0031	1	5	Top	[redacted]	0 034	0.033			
439930023	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0040	1	5	Top	[redacted]	0 034	0 033	0 033		0 0
439930024	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0032	1	5	Middle	12	0.034	0 034		0 033	
439930025	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0041	1	5	Middle	12	0 034	0 033	0.034		3 0
439930026	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0033	1	5	Bottom	12	0 034	0 033			
439930027	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0042	1	5	Bottom	12	0 034	0 033	0 033		0 0
439930028	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0034	1	6	Top	50	0.141	0.140			
439930029	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0043	1	6	Top	50	0.141	0 139	0 140		0.0
439930030	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0035	1	6	Middle	50	0.141	0 140		0 140	
439930031	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0044	1	6	Middle	50	0 141	0 139	0 140		0.0
439930032	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0036	1	6	Bottom	50	0 141	0 140			
439930033	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0045	1	6	Bottom	50	0 141	0 140	0.140		0 0
439930034	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0037	1	7	Top	200	0.564	0 574			
439930035	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0046	1	7	Top	200	0.564	0.553	0 564		1.2
439930036	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0038	1	7	Middle	200	0.564	0 573		0 571	
439930037	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0047	1	7	Middle	200	0 564	0 576	0.575		0 7
439930038	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0039	1	7	Bottom	200	0 564	0 576			
439930039	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0048	1	7	Bottom	200	0 564	0 576	0.576		0.9

[redacted]

6

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

[redacted]

[redacted]

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187042
[redacted]: Reference #04-027

12-Day Stability Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted], mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
439930004	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0002	1	2	Top	12	0 052	0 052	0 0
439930004	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0002	1	2	Top	12	0 052	0 056	7 7
439930005	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0012	1	2	Top	12	0.052	0 052	0 0
439930005	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0012	1	2	Top	12	0 052	0.046	11.5
439930006	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0003	1	2	Middle	12	0 052	0 052	0 0
439930006	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0003	1	2	Middle	12	0.052	0 059	13.5
439930007	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0013	1	2	Middle	12	0.052	0 052	0 0
439930007	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0013	1	2	Middle	12	0 052	0 051	1.9
439930008	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0004	1	2	Bottom	12	0 052	0.052	0.0
439930008	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0004	1	2	Bottom	12	0 052	0 051	1.9
439930009	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0014	1	2	Bottom	12	0.052	0.052	0.0
439930009	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0014	1	2	Bottom	12	0.052	0.050	3 8
439930010	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0005	1	3	Top	50	0 218	0.213	2 3
439930010	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0005	1	3	Top	50	0 218	0.208	4 6
439930011	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0015	1	3	Top	50	0.218	0 213	2 3
439930011	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0015	1	3	Top	50	0.218	0.211	3.2
439930012	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0006	1	3	Middle	50	0 218	0 212	2.8
439930012	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0006	1	3	Middle	50	0.218	0 211	3 2
439930013	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0016	1	3	Middle	50	0 218	0 211	3.2
439930013	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0016	1	3	Middle	50	0.218	0 211	3 2
439930014	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0007	1	3	Bottom	50	0 218	0 211	3 2
439930014	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0007	1	3	Bottom	50	0.218	0.211	3 2
439930015	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0017	1	3	Bottom	50	0.218	0.211	3 2
439930015	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0017	1	3	Bottom	50	0 218	0 212	2 8
439930016	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0008	1	4	Top	200	0.867	0 840	3 1
439930016	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0008	1	4	Top	200	0 867	0 844	2 7
439930017	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0018	1	4	Top	200	0 867	0 858	1 0
439930017	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0018	1	4	Top	200	0.867	0 848	2 2
439930018	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0009	1	4	Middle	200	0 867	0 864	0 3
439930018	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0009	1	4	Middle	200	0 867	0 853	1 6
439930019	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0019	1	4	Middle	200	0 867	0 848	2 2
439930019	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0019	1	4	Middle	200	0.867	0 849	2 1
439930020	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0010	1	4	Bottom	200	0 867	0 855	1.4
439930020	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0010	1	4	Bottom	200	0.867	0 804	7 3
439930021	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0020	1	4	Bottom	200	0.867	0 858	1 0
439930021	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0020	1	4	Bottom	200	0 867	0.852	1.7

PERCENT DIFFERENCE CALCULATION

Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

[redacted]

[redacted]

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187042
[redacted]: Reference #04-027

12-Day Stability Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted], mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
439930022	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0031	1	5	Top	12	0 034	0 033	2 9
439930022	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0031	1	5	Top	12	0 034	0 033	2 9
439930023	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0040	1	5	Top	12	0 034	0 033	2.9
439930023	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0040	1	5	Top	12	0.034	0.033	2.9
439930024	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0032	1	5	Middle	12	0 034	0 034	0.0
439930024	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0032	1	5	Middle	12	0 034	0 032	5 9
439930025	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0041	1	5	Middle	12	0 034	0 033	2.9
439930025	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0041	1	5	Middle	12	0.034	0 032	5 9
439930026	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0033	1	5	Bottom	12	0 034	0 033	2 9
439930026	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0033	1	5	Bottom	12	0 034	0 033	2 9
439930027	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0042	1	5	Bottom	12	0 034	0.033	2 9
439930027	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0042	1	5	Bottom	12	0.034	0 033	2 9
439930028	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0034	1	6	Top	50	0.141	0 140	0 7
439930028	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0034	1	6	Top	50	0.141	0 137	2.8
439930029	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0043	1	6	Top	50	0.141	0 139	1.4
439930029	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0043	1	6	Top	50	0 141	0 136	3 5
439930030	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0035	1	6	Middle	50	0 141	0 140	0 7
439930030	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0035	1	6	Middle	50	0 141	0.137	2 8
439930031	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0044	1	6	Middle	50	0 141	0.139	1 4
439930031	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0044	1	6	Middle	50	0 141	0 136	3.5
439930032	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0036	1	6	Bottom	50	0 141	0 140	0 7
439930032	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0036	1	6	Bottom	50	0 141	0 137	2 8
439930033	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0045	1	6	Bottom	50	0 141	0 140	0 7
439930033	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0045	1	6	Bottom	50	0 141	0 137	2 8
439930034	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0037	1	7	Top	200	0 564	0 574	1 8
439930034	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0037	1	7	Top	200	0.564	0.563	0 2
439930035	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0046	1	7	Top	200	0 564	0 553	2 0
439930035	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0046	1	7	Top	200	0 564	0.549	2.7
439930036	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0038	1	7	Middle	200	0 564	0 573	1 6
439930036	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0038	1	7	Middle	200	0.564	0.569	0 9
439930037	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0047	1	7	Middle	200	0 564	0 576	2 1
439930037	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0047	1	7	Middle	200	0.564	0 565	0 2
439930038	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0039	1	7	Bottom	200	0 564	0 576	2 1
439930038	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0039	1	7	Bottom	200	0 564	0 566	0 4
439930039	08-Nov-04	08-Nov-04	11-Nov-04	RX-187042L-0048	1	7	Bottom	200	0 564	0.576	2.1
439930039	08-Nov-04	08-Nov-04	23-Nov-04	RX-187042L-0048	1	7	Bottom	200	0 564	0 562	0.4

PERCENT DIFFERENCE CALCULATION

Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

[redacted]

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187042
[redacted] Reference #04-027

Concentration Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted], mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
441944008	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0058	2	1	Middle	0	0 000	<2 wt ppm	*
441944009	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0059	2	2	Middle	12	0.052	0.050	3.8
441944010	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0060	2	3	Middle	50	0.218	0.208	4.6
441944011	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0061	2	4	Middle	200	0.867	0.803	7 4
443586001	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0076	3	1	Middle	0	0.000	<2 wt ppm	*
443586002	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0077	3	2	Middle	12	0 052	0.051	1.9
443586003	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0078	3	3	Middle	50	0.218	0.212	2.8
443586004	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0079	3	4	Middle	200	0.867	0.843	2 8
443586008	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0086	4	1	Middle	0	0 000	<2 wt ppm	*
443586009	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0087	4	2	Middle	12	0.052	0.050	3.8
443586010	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0088	4	3	Middle	50	0.218	0.207	5 0
443586011	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0089	4	4	Middle	200	0.867	0.800	7.7
444085001	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0100	5	1	Middle	0	0 000	<2 wt ppm	*
444085002	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0101	5	2	Middle	12	0.052	0.054	3.8
444085003	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0102	5	3	Middle	50	0 218	0 220	0.9
444085004	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0103	5	4	Middle	200	0.867	0.876	1.0
444085008	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0114	6	1	Middle	0	0.000	<2 wt ppm	*
444085009	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0115	6	2	Middle	12	0.052	0.052	0 0
444085010	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0116	6	3	Middle	50	0.218	0.218, Dup 0.218	0 0
444085011	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0117	6	4	Middle	200	0.867	0.876	1.0
445215001	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0128	7	1	Middle	0	0.000	<2 wt ppm	*
445215002	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0129	7	2	Middle	12	0 052	0.052	0.0
445215003	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0130	7	3	Middle	50	0.218	0.215	1.4
445215004	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0131	7	4	Middle	200	0.867	0.881	1.6

PERCENT DIFFERENCE CALCULATION
Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

* Not a significant difference

[redacted]

SUMMARY OF ANALYTICAL RESULTS

[redacted]

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS

WIL Research #WIL-187042

[redacted] Reference #04-027

Concentration Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted], mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
441944012	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0066	2	5	Middle	12	0.034	0 033	2 9
441944013	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0067	2	6	Middle	50	0 141	0 139	1.4
441944014	23-Nov-04	23-Nov-04	26-Nov-04	RX-187042L-0068	2	7	Middle	200	0 564	0 549	2 7
443586005	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0083	3	5	Middle	12	0 034	0 033	2.9
443586006	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0084	3	6	Middle	50	0.141	0 138	2 1
443586007	01-Dec-04	01-Dec-04	10-Dec-04	RX-187042L-0085	3	7	Middle	200	0 564	0 549	2 7
443586012	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0094	4	5	Middle	12	0 034	0 033	2 9
443586013	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0095	4	6	Middle	50	0 141	0 154	9 2
443586014	23-Nov-04	02-Dec-04	10-Dec-04	RX-187042L-0096	4	7	Middle	200	0 564	0.543	3.7
444085005	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0108	5	5	Middle	12	0 034	0 034	0.0
444085006	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0109	5	6	Middle	50	0 141	0 142	0.7
444085007	01-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0110	5	7	Middle	200	0.564	0 570	1.1
444085012	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0122	6	5	Middle	12	0 034	0 035	2 9
444085013	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0123	6	6	Middle	50	0 141	0.147	4 3
444085014	09-Dec-04	09-Dec-04	14-Dec-04	RX-187042L-0124	6	7	Middle	200	0.564	0 586	3 9
445215005	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0136	7	5	Middle	12	0.034	0.035	2.9
445215006	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0137	7	6	Middle	50	0 141	0.143	1 4
445215007	09-Dec-04	17-Dec-04	21-Dec-04	RX-187042L-0138	7	7	Middle	200	0 564	0 545	3.4

[redacted]

PERCENT DIFFERENCE CALCULATION

Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

* Not a significant difference

[redacted]

APPENDIX C

Animal Room Environmental Conditions

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO.:WIL- 187042 TEMPERATURE/HUMIDITY - DAILY SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187042 DATE IN: 11/09/04 TIME IN: 11:00
DATE OUT: 12/18/04 TIME OUT: 11:00

ROOM SPECIFICATIONS: B ROOM 23 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
09-Nov-04	70.6	21.5	36.0
10-Nov-04	70.6	21.4	36.3
11-Nov-04	70.5	21.4	37.2
12-Nov-04	70.6	21.4	37.3
13-Nov-04	70.5	21.4	36.8
14-Nov-04	70.4	21.4	37.0
15-Nov-04	70.4	21.3	38.0
16-Nov-04	70.6	21.4	39.5
17-Nov-04	70.4	21.3	42.0
18-Nov-04	70.7	21.5	44.6
19-Nov-04	70.6	21.5	44.7
20-Nov-04	70.6	21.4	42.4
21-Nov-04	70.7	21.5	40.6
22-Nov-04	70.6	21.4	39.2
23-Nov-04	70.6	21.5	41.9
24-Nov-04	70.8	21.6	45.6
25-Nov-04	70.5	21.4	38.1
26-Nov-04	70.5	21.4	38.1
27-Nov-04	70.4	21.3	38.1
28-Nov-04	70.6	21.4	37.6
29-Nov-04	70.7	21.5	38.0
30-Nov-04	70.5	21.4	39.9
01-Dec-04	70.7	21.5	39.5

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.08
1/21/05 15:16

STUDY SPECIFICATIONS: 187042 DATE IN: 11/09/04 TIME IN: 11:00
DATE OUT: 12/18/04 TIME OUT: 11:00

ROOM SPECIFICATIONS: B ROOM 23 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
02-Dec-04	70.4	21.3	39.0
03-Dec-04	70.7	21.5	37.6
04-Dec-04	70.6	21.4	37.8
05-Dec-04	70.7	21.5	38.4
06-Dec-04	70.5	21.4	41.8
07-Dec-04	70.7	21.5	46.6
08-Dec-04	70.5	21.4	38.7
09-Dec-04	70.6	21.5	38.8
10-Dec-04	70.5	21.4	40.9
11-Dec-04	70.6	21.5	37.8
12-Dec-04	70.6	21.4	37.3
13-Dec-04	70.6	21.4	36.9
14-Dec-04	70.6	21.4	37.1
15-Dec-04	70.5	21.4	37.6
16-Dec-04	70.8	21.5	38.8
17-Dec-04	70.7	21.5	38.2
18-Dec-04	70.4	21.4	37.8

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

STUDY SPECIFICATIONS: 187042

DATE IN: 11/09/04 TIME IN: 11:00
DATE OUT: 12/18/04 TIME OUT: 11:00

ROOM SPECIFICATIONS: B ROOM 23
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.6	70.4	70.8
TEMPERATURE °C	21.4	21.3	21.6
HUMIDITY (%RH)	39.2	36.0	46.6
N DAYS	40		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

ROOM SPECIFICATIONS:	B ROOM 23		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	11/09/04
HIGH TEMPERATURE:	76.0	TIME IN:	11:00
LOW HUMIDITY:	30.0	DATE OUT:	12/18/04
HIGH HUMIDITY:	70.0	TIME OUT:	11:00

ROOM B ROOM 23 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.6	39.3
MIN	68.4	33.4
MAX	72.8	58.3
SD	1.29	3.30
N SAMPLES	936	936
FIRST DAY	11/09/04	
LAST DAY	12/18/04	
N DAYS	40	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

STUDY 187042 SUMMARY

MEAN	70.6	39.3
MIN	68.4	33.4
MAX	72.8	58.3
SD	1.29	3.30
N SAMPLES	936	936
FIRST DAY	11/09/04	
LAST DAY	12/18/04	
N DAYS	40	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

APPENDIX D

Clinical Pathology Methods, Procedures And References

CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Immunoassay- DPC Immulite®

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

Immunoassay-GAMMA-C12 Gamma Counter

Rat Thyroid Stimulating Hormone (rTSH) - ^{125}I assay system with magnetic separation for the quantitative measurement of (rTSH). DPC GAMMA C-12 gamma counter. Biotrak™ rat thyroid stimulating hormone ^{125}I assay system. Amersham Pharmacia Biotech. Package insert.

References:

Immulite®. Diagnostics Products Corporation. Package Insert.

APPENDIX E

WIL Reproductive Historical Control Data [Crl:CD®(SD) Rats]

WIL Reproductive Historical Control Data
Crl:CD(SD) Rat*

Grand Mean Summary
Parental and Neonatal Observations

ENDPOINT	TOTAL	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
TOTAL NUMBER OF DATASETS	107							
NO. MALES IN CONTROL GROUP	2141	27.1	3.95	79	15	40	25	30
MALE MATING INDEX (%)		96.3	4.72	77	72.0	100.0	95.7	100.0
MALE FERTILITY INDEX (%)		89.6	8.10	79	56.7	100.0	86.5	95.7
NO. FEMALES IN CONTROL GROUP	2815	26.6	3.57	106	15	40	25	30
FEMALE MATING INDEX (%)		97.5	3.60	83	84.0	100.0	96.0	100.0
FEMALE FERTILITY INDEX (%)		92.0	7.47	105	56.7	100.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	1755	27.0	3.10	65	22	40	25	30
NO. THAT DELIVERED	1583	24.4	3.22	65	17	38	23	26
NO. THAT DID NOT DELIVER	172	2.6	2.44	65	0	13	1	3
NO. THAT DIED	13	0.1	0.36	106	0	2	0	0
NO. WITH TOTAL LITTER LOSS	13	0.2	0.44	65	0	2	0	0
NO. WITH DYSTOCIA	6	0.1	0.29	65	0	1	0	0
MEAN PRE-COITAL INTERVAL (DAYS)		3.0	0.56	81	1.8	4.7	2.6	3.3
MEAN GESTATION LENGTH (DAYS)		21.8	0.15	65	21.6	22.3	21.7	21.9
MEAN NO. PUPS BORN		14.5	0.94	65	12.0	16.5	13.7	15.0
MEAN VIABLE LITTER SIZE ON PND 0		14.2	0.94	65	11.6	16.0	13.4	14.9
PUP SEX RATIO								
MEAN % MALE		49.7	2.83	65	42.7	56.6	47.7	51.8
MEAN % FEMALE		50.3	2.86	65	43.4	57.3	48.2	52.3
MEAN NO. OF FORMER IMPLANTATION SITES AT WEANING		15.3	0.83	58	13.7	17.1	14.7	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING		0.8	0.21	58	0.3	1.3	0.7	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY		15.5	0.90	40	13.8	16.8	15.1	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)		4.5	0.41	59	4.0	5.8	4.2	4.6
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM		96.4	23.11	13	50.4	132.9	87.8	107.8

EXPERIMENTAL START DATE OF OLDEST DATASET 6/17/96
DATE OF LAST NECROPSY OF MOST RECENT DATASET 2/3/04

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN NO. PUPS BORN	14.5	0.94	65	12.0	16.5	13.7	15.0
PUP SURVIVAL INDICES (% PER LITTER)							
PND 0 (RELATIVE TO NO. BORN)	98.0	1.42	65	92.3	100.0	97.4	99.0
PND 0 TO PND 1	99.0	1.24	65	94.3	100.0	98.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	1.08	64	93.5	100.0	98.8	99.6
PND 4 (AFTER SELECTION) TO PND 7	99.5	0.94	57	95.8	100.0	99.5	100.0
PND 7 TO PND 14	99.4	1.38	53	93.5	100.0	99.5	100.0
PND 14 TO PND 21	99.7	0.97	54	94.7	100.0	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.1	2.01	62	91.3	99.3	95.0	97.5
PND 4 (AFTER SELECTION) TO PND 21	98.7	1.96	53	91.1	100.0	98.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)							
PND 1	7.1	0.25	65	6.5	7.6	6.9	7.2
PND 4 (BEFORE SELECTION)	9.9	0.59	64	8.6	11.4	9.5	10.4
PND 7	15.4	1.34	57	11.7	17.8	15.1	16.4
PND 14	31.0	3.50	53	22.5	36.5	29.2	33.1
PND 21	48.7	5.47	54	34.9	58.0	45.4	52.1
PND 28	81.5	8.23	18	65.4	94.0	74.6	87.6
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)							
PND 1	6.7	0.25	65	6.1	7.2	6.5	6.8
PND 4 (BEFORE SELECTION)	9.4	0.57	64	8.1	10.9	8.9	9.7
PND 7	14.6	1.32	57	11.0	17.1	14.1	15.5
PND 14	29.8	3.41	53	21.2	35.1	27.6	32.1
PND 21	46.6	5.07	54	33.3	55.6	43.9	49.7
PND 28	75.3	7.25	18	59.8	86.2	69.0	79.5
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.4365	0.0509	21	1.3451	1.5175	1.4000	1.4775
SPLEEN	0.1938	0.0343	21	0.1189	0.2480	0.1755	0.2211
THYMUS GLAND	0.1933	0.0269	21	0.1392	0.2446	0.1723	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.3886	0.0459	21	1.2903	1.4597	1.3623	1.4242
SPLEEN	0.1923	0.0321	21	0.1182	0.2408	0.1722	0.2200
THYMUS GLAND	0.1969	0.0281	21	0.1338	0.2479	0.1778	0.2113

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

Grand Mean Summary
Parental and Neonatal Observations

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)							
MALE	4.6	0.92	10	2.5	5.7	4.3	5.3
FEMALE	2.7	0.70	10	1.3	3.9	2.4	3.2
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.8	1.83	41	41.6	49.0	44.0	45.8
MEAN BODY WEIGHT AT ACQUISITION (G)	228.4	10.21	38	210.5	248.6	221.9	235.5
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	1.39	41	31.7	38.8	32.7	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	112.4	7.79	38	99.0	133.0	107.0	117.6
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)							
MALE	5.1	0.08	7	5.0	5.2	5.0	5.1
FEMALE	5.2	0.10	7	5.0	5.3	5.1	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)							
MALE	4.0	0.08	6	4.0	4.2	4.0	4.0
FEMALE	4.0	0.08	6	4.0	4.2	4.0	4.0
MEAN DAY OF EYE OPENING (PND)							
MALE	16.1	1.35	6	15.1	18.7	15.3	16.0
FEMALE	16.0	1.37	6	14.8	18.6	15.2	16.0
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)							
MALE	14.9	NA	1	14.9	14.9	14.9	14.9
FEMALE	14.9	NA	1	14.9	14.9	14.9	14.9
MEAN DAY OF HAIR GROWTH (PND)							
MALE	12.4	0.99	2	11.7	13.1	12.1	12.8
FEMALE	12.4	0.85	2	11.8	13.0	12.1	12.7
MEAN DAY OF INCISOR ERUPTION (PND)							
MALE	9.8	0.44	3	9.3	10.1	9.7	10.1
FEMALE	9.7	0.38	3	9.3	10.0	9.6	10.0

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHT (G)	2.20	0.295	37	1.76	2.80	1.95	2.30
MEAN RIGHT TESTIS WEIGHT (G)	1.79	0.067	55	1.65	1.93	1.73	1.84
MEAN LEFT TESTIS WEIGHT (G)	1.79	0.065	55	1.67	1.92	1.74	1.84
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.73	0.039	55	0.64	0.81	0.71	0.75
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.040	55	0.62	0.80	0.70	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3249	0.0227	55	0.2629	0.3693	0.3159	0.3366
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3282	0.0206	55	0.2714	0.3712	0.3183	0.3413
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)							
LEFT TESTIS	86.8	9.3	49	69.6	106.9	79.2	93.2
LEFT EPIDIDYMIS	460.7	54.6	49	343.6	640.1	421.3	477.0
LEFT CAUDA EPIDIDYMIS	677.5	50.3	4	618.7	738.9	651.8	701.9
MEAN SPERM PRODUCTION RATE							
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	1.5	49	11.4	17.5	13.0	15.3
% MOTILE SPERM	84.6	4.4	53	71.3	91.9	82.0	87.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)							
NORMAL	98.9	1.3	50	91.9	99.9	98.8	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.6	50	0.0	3.4	0.2	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.7	50	0.0	4.7	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)							
NORMAL	198.0	2.6	50	183.8	200.0	197.9	199.3
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.3	1.7	50	0.0	10.0	0.4	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	1.5	50	0.0	9.4	0.2	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	1	2	3	4	5
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
MALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
FEMALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	30
NO. THAT DELIVERED	25	17	28	27	28
NO. THAT DID NOT DELIVER	5	13	2	3	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	0
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	3.0	2.3	2.4	2.2
MEAN GESTATION LENGTH (DAYS)	22.3	22.0	21.8	21.8	21.8
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
MEAN VIABLE LITTER SIZE ON PND 0	11.6	12.5	13.5	13.4	13.0
PUP SEX RATIO					
MEAN % MALE	49.7	52.1	51.1	51.8	52.1
MEAN % FEMALE	50.3	47.9	48.9	48.2	47.9
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.5	14.2	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.9	0.7	1.2
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	4.2	4.1	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	11/19/97	2/23/98	11/3/98	2/3/99	9/24/98
DATE OF LAST NECROPSY	4/7/98	8/18/98	3/16/99	7/23/99	2/5/99
ROUTE	Diet	Diet	Diet	Diet	Inhalation
VEHICLE	Basal Feed	Basal Feed	Basal Feed	Basal Feed	Filtered Air

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DATASET NO.	6	7	8	9	10
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	29	30	30
NO. THAT DELIVERED	29	24	26	28	28
NO. THAT DID NOT DELIVER	1	6	3	2	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	1	1	0	0	0
NO. WITH DYSTOCIA	0	1	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.5	2.6	2.7	2.7	2.8
MEAN GESTATION LENGTH (DAYS)	21.7	22.0	21.8	22.1	21.8
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
MEAN VIABLE LITTER SIZE ON PND 0	13.1	14.5	12.9	12.9	13.1
PUP SEX RATIO					
MEAN % MALE	48.6	49.2	48.6	44.0	45.0
MEAN % FEMALE	51.4	50.8	51.4	56.0	55.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	15.7	14.0	13.7	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	0.8	0.6	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.1	4.2	4.3	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	96.7	54.4	98.1	---	85.5
EXPERIMENTAL START DATE	12/24/98	2/9/99	5/27/99	11/23/98	2/25/99
DATE OF LAST NECROPSY	6/11/99	7/9/99	11/12/99	4/7/99	8/19/99
ROUTE	Inhalation	Gavage	Gavage	Diet	Diet
VEHICLE	Filtered Air	DI Water	DI Water	Basal Feed	Basal Feed

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DATASET NO.	11	12	13	14	15
NO. MALES IN CONTROL GROUP	30	30	30	30	---
MALE MATING INDEX (%)	96.6	96.7	93.3	100.0	---
MALE FERTILITY INDEX (%)	89.7	96.7	86.7	100.0	---
NO. FEMALES IN CONTROL GROUP	30	30	30	30	25
FEMALE MATING INDEX (%)	96.7	96.7	93.3	100.0	---
FEMALE FERTILITY INDEX (%)	90.0	96.7	86.7	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	25
NO. THAT DELIVERED	27	29	26	30	25
NO. THAT DID NOT DELIVER	3	1	4	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	1
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.7	3.3	2.6	2.0	---
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	21.8	21.6	21.8
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
MEAN VIABLE LITTER SIZE ON PND 0	13.3	13.1	13.2	14.4	14.4
PUP SEX RATIO					
MEAN % MALE	56.4	50.6	51.3	50.0	49.0
MEAN % FEMALE	43.6	49.4	48.7	50.0	51.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	---	15.6	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	---	0.8	0.8
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	87.8	96.9	---	---	---
EXPERIMENTAL START DATE	1/14/97	4/15/97	4/15/97	11/4/97	8/31/98
DATE OF LAST NECROPSY	6/3/97	11/29/97	11/29/97	11/25/97	10/9/98
ROUTE	Inhalation	Inhalation	Inhalation	Inhalation	Gavage
VEHICLE	Filtered Air	Filtered Air	Filtered Air	Filtered Air	0.4% MC

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DATASET NO.	16	17	18	19	20
NO. MALES IN CONTROL GROUP	25	24	---	25	25
MALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	92.0	95.8	---	100.0	96.0
NO. FEMALES IN CONTROL GROUP	25	24	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	95.8	92.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	24	25	---	---
NO. THAT DELIVERED	23	23	23	---	---
NO. THAT DID NOT DELIVER	2	1	2	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	---
NO. WITH DYSTOCIA	0	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	2.4	---	2.8	2.7
MEAN GESTATION LENGTH (DAYS)	21.8	21.6	21.8	---	---
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
MEAN VIABLE LITTER SIZE ON PND 0	13.9	15.0	14.7	---	---
PUP SEX RATIO					
MEAN % MALE	52.1	49.7	51.9	---	---
MEAN % FEMALE	47.9	50.3	48.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.1	15.9	15.7	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	0.9	1.0	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	16.4	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/14/98	7/7/98	9/23/98	10/27/98	3/29/99
DATE OF LAST NECROPSY	2/1/99	10/1/98	11/23/98	3/1/99	5/4/99
ROUTE	Gavage	Diet	Gavage	Gavage	Gavage
VEHICLE	0.4% MC	Basal Feed	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80

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DATASET NO.	21	22	23	24	25
NO. MALES IN CONTROL GROUP	---	25	---	25	---
MALE MATING INDEX (%)	---	96.0	---	72.0	---
MALE FERTILITY INDEX (%)	---	88.0	---	72.0	---
NO. FEMALES IN CONTROL GROUP	25	25	22	25	25
FEMALE MATING INDEX (%)	---	96.0	---	84.0	---
FEMALE FERTILITY INDEX (%)	100.0	88.0	95.5	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25	22	---	25
NO. THAT DELIVERED	25	22	21	---	25
NO. THAT DID NOT DELIVER	0	3	1	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	0
NO. WITH DYSTOCIA	0	0	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	2.2	---	3.5	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.8	21.8	---	22.0
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	13.8	14.9	14.6	---	14.7
PUP SEX RATIO					
MEAN % MALE	47.7	49.8	47.7	---	47.7
MEAN % FEMALE	52.3	50.2	52.3	---	52.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.9	15.4	---	15.7
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.8	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	13.9	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.2	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	10/26/98	11/17/98	1/12/99	2/3/99	7/27/98
DATE OF LAST NECROPSY	12/13/98	4/13/99	3/1/99	6/15/99	9/12/98
ROUTE	SubQ	SubQ	SubQ	SubQ	Gavage
VEHICLE	20 mM Na Phosphate	21 mM Na Phosphate	Sponsor-Supplied	Sponsor-Supplied	0.75% MC

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DATASET NO.	26	27	28	29	30
NO. MALES IN CONTROL GROUP	25	---	---	25	---
MALE MATING INDEX (%)	96.0	---	---	96.0	---
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	96.0	---
FEMALE FERTILITY INDEX (%)	92.0	88.0	96.0	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	25	25	25
NO. THAT DELIVERED	---	22	23	24	25
NO. THAT DID NOT DELIVER	---	3	2	1	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	0	0
NO. WITH DYSTOCIA	---	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	---	---	2.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.7	21.7	21.7	21.7
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	15.9	14.7	15.0
PUP SEX RATIO					
MEAN % MALE	---	50.8	54.0	50.8	48.5
MEAN % FEMALE	---	49.2	46.0	49.2	51.5
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.8	16.7	---	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.6	0.5	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	13.8	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/18/98	9/13/99	8/2/99	8/17/99	8/9/99
DATE OF LAST NECROPSY	12/29/98	10/31/99	9/12/99	1/10/00	9/25/99
ROUTE	Gavage	Gavage	Gavage	Gavage	Intranasal
VEHICLE	0.75% MC	0.1 M Na Phosphate	0.4% MC	0.4% MC	MC

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DATASET NO.	31	32	33	34	35
NO. MALES IN CONTROL GROUP	25	40	---	---	40
MALE MATING INDEX (%)	82.6	97.5	---	---	---
MALE FERTILITY INDEX (%)	73.9	95.0	---	---	75.0
NO. FEMALES IN CONTROL GROUP	25	40	25	25	40
FEMALE MATING INDEX (%)	95.8	97.5	100.0	100.0	---
FEMALE FERTILITY INDEX (%)	87.5	95.0	92.0	96.0	---
NO. FEMALES SELECTED TO DELIVER	---	40	---	---	---
NO. THAT DELIVERED	---	38	---	---	---
NO. THAT DID NOT DELIVER	---	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	---	---	---
NO. WITH DYSTOCIA	---	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	2.8	2.6	3.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.6	---	---	---
MEAN NO. PUPS BORN	---	15.4	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	---	48.8	---	---	---
MEAN % FEMALE	---	51.2	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.9	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.1	---	15.4	15.6	16.5
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/31/99	6/17/96	9/29/98	11/6/98	3/4/99
DATE OF LAST NECROPSY	1/11/00	11/15/96	11/24/98	12/31/98	4/14/99
ROUTE	Intranasal	Inhalation	Gavage	Gavage	Dermal
VEHICLE	MC	Filtered Air	1% Avicel-5% Tween 80 50mM Sodium Acetate	0.5% Aqueous MC	Fire Pond Water

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DATASET NO.	36	37	38	39	40
NO. MALES IN CONTROL GROUP	20	25	---	25	25
MALE MATING INDEX (%)	---	96.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	95.0	88.0	---	92.0	100.0
NO. FEMALES IN CONTROL GROUP	20	25	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	92.0	96.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	---	25	25	---
NO. THAT DELIVERED	---	---	24	23	---
NO. THAT DID NOT DELIVER	---	---	1	2	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	1	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.2	---	2.6	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	21.6	21.7	---
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	14.8	14.4	---
PUP SEX RATIO					
MEAN % MALE	---	---	55.2	50.9	---
MEAN % FEMALE	---	---	44.8	49.1	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	15.4	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.9	15.3	---	---	15.8
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/15/99	4/9/99	6/15/99	6/17/96	11/18/99
DATE OF LAST NECROPSY	6/24/99	6/17/99	7/31/99	11/17/99	1/28/00
ROUTE	Dermal	Gavage	Gavage	Untreated	Untreated
VEHICLE	Fire Pond Water	10mM Lactic Acid in DI Water	5% Acacia	Not Applicable	Not Applicable

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DATASET NO.	41	42	43	44	45
NO. MALES IN CONTROL GROUP	---	24	35	15	30
MALE MATING INDEX (%)	---	95.7	97.1	100.0	100.0
MALE FERTILITY INDEX (%)	---	91.3	91.4	86.7	96.7
NO. FEMALES IN CONTROL GROUP	25	24	35	15	30
FEMALE MATING INDEX (%)	---	100.0	97.1	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	95.7	94.3	86.7	96.7
NO. FEMALES SELECTED TO DELIVER	25	23	---	---	30
NO. THAT DELIVERED	24	21	---	---	28
NO. THAT DID NOT DELIVER	1	2	---	---	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	1
NO. WITH TOTAL LITTER LOSS	0	0	---	---	0
NO. WITH DYSTOCIA	0	0	---	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.3	2.2	2.2	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	21.8	---	---	21.7
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	15.5	15.0	---	---	14.7
PUP SEX RATIO					
MEAN % MALE	53.1	47.3	---	---	46.7
MEAN % FEMALE	46.9	52.7	---	---	53.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.3	16.0	---	---	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	---	---	0.6
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	15.4	16.6	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.3	---	---	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/21/99	11/3/99	10/1/99	1/12/00	10/1/99
DATE OF LAST NECROPSY	11/7/99	3/9/00	1/17/00	8/17/00	2/11/00
ROUTE	Gavage	Untreated	Dermal	Untreated Recovery	Gavage
VEHICLE	10% Aqueous Acacia	Not Applicable	Sponsor-Supplied Placebo	Not Applicable	Citric Acid Solution

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DATASET NO.	46	47	48	49	50
NO. MALES IN CONTROL GROUP	29	25	25	24	25
MALE MATING INDEX (%)	93.1	100.0	96.0	100.0	96.0
MALE FERTILITY INDEX (%)	79.3	84.0	92.0	87.5	92.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	93.1	100.0	96.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	79.3	84.0	92.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	29	---	25	25	---
NO. THAT DELIVERED	23	---	23	22	---
NO. THAT DID NOT DELIVER	6	---	2	3	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	---
NO. WITH DYSTOCIA	0	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	4.3	2.6	3.4	3.8	2.9
MEAN GESTATION LENGTH (DAYS)	21.8	---	22.0	22.0	---
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
MEAN VIABLE LITTER SIZE ON PND 0	14.7	---	14.4	14.5	---
PUP SEX RATIO					
MEAN % MALE	48.3	---	53.7	44.7	---
MEAN % FEMALE	51.7	---	46.3	56.3	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.7	---	15.3	15.5	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.3	0.5	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.2	---	---	16.3
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.4	4.1	4.2	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	107.8	105.6	---
EXPERIMENTAL START DATE	1/25/00	10/25/99	11/3/99	2/29/00	11/19/99
DATE OF LAST NECROPSY	6/22/00	12/30/99	3/20/00	7/25/00	1/21/00
ROUTE	Gavage	SubQ	Inhalation	Inhalation	Intranasal
VEHICLE	Citric Acid Solution	Sponsor-Supplied Placebo	Filtered Air	Filtered Air	Sponsor-Supplied Placebo

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	51	52	53	54	55
NO. MALES IN CONTROL GROUP	25	25	30	30	25
MALE MATING INDEX (%)	96.0	92.0	93.3	93.3	96.0
MALE FERTILITY INDEX (%)	88.0	92.0	83.3	80.0	92.0
NO. FEMALES IN CONTROL GROUP	25	25	30	30	25
FEMALE MATING INDEX (%)	100.0	100.0	93.3	93.3	96.0
FEMALE FERTILITY INDEX (%)	92.0	100.0	83.3	80.0	92.0
NO. FEMALES SELECTED TO DELIVER	---	---	30	30	---
NO. THAT DELIVERED	---	---	25	24	---
NO. THAT DID NOT DELIVER	---	---	5	6	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	0	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.6	3.6	3.5	3.7	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	22.0	21.6	---
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	13.0	13.9	---
PUP SEX RATIO					---
MEAN % MALE	---	---	49.7	50.3	---
MEAN % FEMALE	---	---	50.3	49.7	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.0	15.3	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.8	1.0	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.2	16.7	---	---	15.9
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.3	---	4.4	4.9	4.5
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	114.9	---
EXPERIMENTAL START DATE	1/14/00	1/25/00	2/4/00	5/30/00	2/7/00
DATE OF LAST NECROPSY	3/20/00	3/8/00	6/16/00	10/23/00	3/19/00
ROUTE	Gavage	Dermal	Diet	Diet	Gavage
VEHICLE	0.5% CMC	Sponsor-Supplied Placebo	Basal Feed	Basal Feed	0.5% MC-0.10% Tween 80

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DATASET NO.	56	57	58	59	60
NO. MALES IN CONTROL GROUP	25	---	25	25	---
MALE MATING INDEX (%)	95.8	---	100.0	84.0	---
MALE FERTILITY INDEX (%)	95.8	---	96.0	84.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	95.8	---	100.0	84.0	---
FEMALE FERTILITY INDEX (%)	95.8	92.0	96.0	84.0	96.0
NO. FEMALES SELECTED TO DELIVER	---	25	---	---	25
NO. THAT DELIVERED	---	23	---	---	24
NO. THAT DID NOT DELIVER	---	2	---	---	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	---	---	0
NO. WITH DYSTOCIA	---	0	---	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.6	---	2.9	2.4	---
MEAN GESTATION LENGTH (DAYS)	---	21.8	---	---	21.8
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	---	---	16.0
PUP SEX RATIO					
MEAN % MALE	---	50.4	---	---	52.0
MEAN % FEMALE	---	49.6	---	---	48.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	16.0	---	---	17.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.9	---	---	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.3	---	13.9	16.1	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.0	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/7/00	2/8/00	2/7/00	3/31/00	5/15/00
DATE OF LAST NECROPSY	6/6/00	3/26/00	7/11/00	6/12/00	7/4/00
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.5% MC-0.10% Tween 80	0.5% CMC	0.5% CMC	0.5% CMC	0.5% Aqueous CMC

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DATASET NO.	61	62	63	64	65
NO. MALES IN CONTROL GROUP	25	----	23	25	25
MALE MATING INDEX (%)	100.0	----	95.7	100.0	100.0
MALE FERTILITY INDEX (%)	100.0	----	91.3	84.0	100.0
NO. FEMALES IN CONTROL GROUP	25	25	23	25	25
FEMALE MATING INDEX (%)	100.0	---	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	96.0	91.3	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	23	---	---
NO. THAT DELIVERED	---	24	20	---	---
NO. THAT DID NOT DELIVER	---	1	3	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	---	---
NO. WITH DYSTOCIA	---	1	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	----	3.1	---	2.1
MEAN GESTATION LENGTH (DAYS)	---	21.8	21.9	---	---
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.0	13.1	---	---
PUP SEX RATIO					
MEAN % MALE	---	50.5	51.8	---	---
MEAN % FEMALE	---	49.5	48.2	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.7	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.0	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.0	---	---	15.4	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.3	4.1	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	6/28/00	7/4/00	8/15/00	8/25/00	9/25/00
DATE OF LAST NECROPSY	10/12/00	8/21/00	12/21/00	10/6/00	11/10/00
ROUTE	Untreated	Gavage	Untreated	Diet	Diet
VEHICLE	Not Applicable	10% Aqueous Acacia	Not Applicable	Basal Feed	Basal Feed

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DATASET NO.	66	67	68	69	70
NO. MALES IN CONTROL GROUP	---	25	25	25	---
MALE MATING INDEX (%)	----	100.0	92.0	96.0	---
MALE FERTILITY INDEX (%)	----	87.5	80.0	92.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	---	100.0	92.0	96.0	---
FEMALE FERTILITY INDEX (%)	76.0	88.0	80.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	23
NO. THAT DELIVERED	19	---	20	---	23
NO. THAT DID NOT DELIVER	6	---	5	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	2
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	----	3.8	2.7	2.2	---
MEAN GESTATION LENGTH (DAYS)	21.9	---	22.0	---	22.0
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
MEAN VIABLE LITTER SIZE ON PND 0	14.0	---	14.6	---	14.3
PUP SEX RATIO					
MEAN % MALE	46.9	---	51.9	---	51.2
MEAN % FEMALE	53.1	---	48.1	---	48.8
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.3	---	15.4	---	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.7	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.6	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.2	4.8	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/22/00	10/4/00	10/27/00	12/5/00	1/19/01
DATE OF LAST NECROPSY	10/8/00	1/23/01	3/3/01	1/31/01	3/6/01
ROUTE	Gavage	Untreated	Gavage	IV	Gavage
VEHICLE	Aqueous 10% Lactic Acid	Not Applicable	Sesame Oil	Saline	DI Water

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DATASET NO.	71	72	73	74	75
NO. MALES IN CONTROL GROUP	23	---	25	25	40
MALE MATING INDEX (%)	95.5	---	88.0	96.0	97.5
MALE FERTILITY INDEX (%)	90.9	---	84.0	87.5	90.0
NO. FEMALES IN CONTROL GROUP	23	25	25	25	40
FEMALE MATING INDEX (%)	95.7	---	92.0	100.0	97.5
FEMALE FERTILITY INDEX (%)	91.3	100.0	88.0	92.0	90.0
NO. FEMALES SELECTED TO DELIVER	23	25	---	---	---
NO. THAT DELIVERED	21	25	---	---	---
NO. THAT DID NOT DELIVER	2	0	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	---	---	---
NO. WITH DYSTOCIA	0	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.3	---	3.1	3.1	2.7
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	---	---	---
MEAN NO. PUPS BORN	12.6	15.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	12.6	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	47.6	50.5	---	---	---
MEAN % FEMALE	52.4	49.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	16.2	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.3	0.7	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.3	16.6	16.6
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.4	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/3/01	2/19/01	3/28/01	2/20/01	3/20/01
DATE OF LAST NECROPSY	7/2/01	4/2/01	7/10/01	4/26/01	7/5/01
ROUTE	Untreated	Gavage	Untreated	Gavage	Gavage
VEHICLE	Not Applicable	Reverse Osmosis-Purified Water	Not Applicable	Reverse Osmosis-Purified Water	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water

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DATASET NO.	76	77	78	79	80
NO. MALES IN CONTROL GROUP	---	30	29	---	30
MALE MATING INDEX (%)	---	100.0	96.6	---	100.0
MALE FERTILITY INDEX (%)	---	96.7	86.2	---	93.3
NO. FEMALES IN CONTROL GROUP	25	30	30	25	30
FEMALE MATING INDEX (%)	96.0	100.0	96.6	92.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	96.7	86.2	92.0	93.3
NO. FEMALES SELECTED TO DELIVER	---	30	29	---	---
NO. THAT DELIVERED	---	29	25	---	---
NO. THAT DID NOT DELIVER	---	1	4	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	---	2	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.1	2.7	2.6	3.4	2.8
MEAN GESTATION LENGTH (DAYS)	---	21.6	21.8	---	---
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.2	13.9	---	---
PUP SEX RATIO					
MEAN % MALE	---	51.2	49.2	---	---
MEAN % FEMALE	---	48.8	50.8	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.6	15.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	0.9	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.6	---	---	14.9	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.5	4.9	5.5	5.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	132.9	---	---
EXPERIMENTAL START DATE	4/20/01	6/12/01	10/4/01	6/15/01	7/12/01
DATE OF LAST NECROPSY	6/11/01	10/22/01	3/8/02	7/30/01	10/5/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water	0.5% MC

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DATASET NO.	81	82	83	84	85
NO. MALES IN CONTROL GROUP	25	25	25	25	25
MALE MATING INDEX (%)	92.0	92.0	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	84.0	92.0	100.0	91.7	100.0
NO. FEMALES IN CONTROL GROUP	25	25	25	24	25
FEMALE MATING INDEX (%)	100.0	96.0	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	88.0	92.0	100.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	25	---	---	---
NO. THAT DELIVERED	20	23	---	---	---
NO. THAT DID NOT DELIVER	5	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	1	0	0	0
NO. WITH TOTAL LITTER LOSS	1	1	---	---	---
NO. WITH DYSTOCIA	0	1	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.8	4.7	2.8	2.5	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	22.0	---	---	---
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	14.3	12.7	---	---	---
PUP SEX RATIO					
MEAN % MALE	46.6	47.1	---	---	---
MEAN % FEMALE	53.4	52.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	14.3	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.8	15.1	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.8	4.9	5.2	---	5.0
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	50.4	---	---	---
EXPERIMENTAL START DATE	8/6/01	11/28/01	8/6/01	9/7/01	7/17/01
DATE OF LAST NECROPSY	12/10/01	4/27/02	9/18/01	11/21/01	10/16/01
ROUTE	Inhalation/ Gavage	Inhalation/ Gavage	Gavage	Gavage	Gavage
VEHICLE	Filtered Air/ Olive Oil	Filtered Air/ Olive Oil	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	PEG 1000/ Carbowax PEG 400 in DI Water

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	86	87	88	89	90
NO. MALES IN CONTROL GROUP	---	30	30	25	25
MALE MATING INDEX (%)	---	86.7	96.7	100.0	100.0
MALE FERTILITY INDEX (%)	---	73.3	73.3	96.0	100.0
NO. FEMALES IN CONTROL GROUP	25	30	30	25	25
FEMALE MATING INDEX (%)	100.0	86.7	96.7	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	73.3	73.3	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	30	30	---	---
NO. THAT DELIVERED	---	22	22	---	---
NO. THAT DID NOT DELIVER	---	8	8	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	2.8	4.0	2.5	2.6
MEAN GESTATION LENGTH (DAYS)	---	22.0	22.0	---	---
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	13.6	13.0	---	---
PUP SEX RATIO					
MEAN % MALE	---	49.6	46.9	---	---
MEAN % FEMALE	---	50.4	53.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.1	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	1.2	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.7	---	---	16.8	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	5.3	4.7	4.6	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	114.6	---	---
EXPERIMENTAL START DATE	8/26/01	9/2/01	1/2/02	10/12/01	10/19/01
DATE OF LAST NECROPSY	10/21/01	1/15/02	5/31/02	12/14/01	12/27/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	DI Water	2.5%HPMC in 50mM Sodium Acetate

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	91	92	93	94	95
NO. MALES IN CONTROL GROUP	---	25	30	30	30
MALE MATING INDEX (%)	---	95.5	96.7	96.7	100.0
MALE FERTILITY INDEX (%)	---	95.5	93.3	80.0	93.3
NO. FEMALES IN CONTROL GROUP	25	25	30	30	30
FEMALE MATING INDEX (%)	---	95.8	96.7	96.7	100.0
FEMALE FERTILITY INDEX (%)	100.0	95.8	93.3	80.0	93.3
NO. FEMALES SELECTED TO DELIVER	25	---	30	30	30
NO. THAT DELIVERED	25	---	28	24	27
NO. THAT DID NOT DELIVER	0	---	2	6	3
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	0
NO. WITH DYSTOCIA	0	---	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.0	3.5	3.1	1.8
MEAN GESTATION LENGTH (DAYS)	21.7	---	21.9	22.1	21.7
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
MEAN VIABLE LITTER SIZE ON PND 0	14.9	---	14.7	13.0	14.8
PUP SEX RATIO					
MEAN % MALE	49.1	---	42.7	56.6	45.9
MEAN % FEMALE	50.9	---	57.3	43.4	54.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.0	---	15.7	13.9	15.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	---	0.8	0.8	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	13.9	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.0	4.5	4.5	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	107.0	---
EXPERIMENTAL START DATE	12/3/01	1/8/02	2/15/02	6/21/02	12/26/01
DATE OF LAST NECROPSY	1/14/02	4/24/02	7/11/02	11/6/02	5/7/02
ROUTE	Gavage	Untreated	Diet	Diet	Drinking Water
VEHICLE	DI Water	Not Applicable	Basal Feed	Basal Feed	Drinking Water

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	96	97	98	99	100
NO. MALES IN CONTROL GROUP	30	---	25	---	25
MALE MATING INDEX (%)	96.7	---	96.0	---	96.0
MALE FERTILITY INDEX (%)	86.7	---	92.0	---	96.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	96.7	---	100.0	---	100.0
FEMALE FERTILITY INDEX (%)	86.7	96.0	96.0	88.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	25	---	25	25
NO. THAT DELIVERED	26	24	---	22	24
NO. THAT DID NOT DELIVER	4	1	---	3	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	1	0
NO. WITH TOTAL LITTER LOSS	0	0	---	0	0
NO. WITH DYSTOCIA	0	0	---	1	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.9	---	3.1	---	4.0
MEAN GESTATION LENGTH (DAYS)	22.0	21.7	---	21.8	21.8
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
MEAN VIABLE LITTER SIZE ON PND 0	14.3	15.0	---	15.3	14.2
PUP SEX RATIO					
MEAN % MALE	53.5	48.4	---	45.8	48.9
MEAN % FEMALE	46.5	51.6	---	54.2	51.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.7	---	17.1	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.7	---	1.1	1.1
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.5	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.0	---	4.2	---	4.3
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/18/02	10/22/02	2/11/03	11/18/02	3/10/03
DATE OF LAST NECROPSY	9/12/02	12/9/02	3/20/03	12/30/02	5/8/03
ROUTE	Drinking Water	Gavage	Gavage	Gavage	Gavage
VEHICLE	Drinking Water	2.5%HPMC in 50mM Sodium Acetate	2.5%HPMC in 50mM Sodium Acetate	0.5% MC	0.5% MC

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DATASET NO.	101	102	103	104	105
NO. MALES IN CONTROL GROUP	25	---	---	25	25
MALE MATING INDEX (%)	96.0	---	---	96.0	96.0
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	72.0
NO. FEMALES IN CONTROL GROUP	25	---	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	100.0	96.0
FEMALE FERTILITY INDEX (%)	92.0	---	96.0	100.0	72.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	25
NO. THAT DELIVERED	23	---	24	---	18
NO. THAT DID NOT DELIVER	2	---	1	---	7
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	---	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	---	---	3.5	3.4
MEAN GESTATION LENGTH (DAYS)	22.0	---	21.9	---	21.9
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
MEAN VIABLE LITTER SIZE ON PND 0	13.9	---	15.3	---	13.4
PUP SEX RATIO					
MEAN % MALE	52.6	---	47.9	---	53.7
MEAN % FEMALE	47.4	---	52.1	---	46.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.5	---	16.1	---	14.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	---	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	15.4	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	4.2	4.7
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	1/7/03	1/7/03	7/22/03	11/10/03	6/10/03
DATE OF LAST NECROPSY	5/30/03	6/20/03	10/28/03	12/16/03	10/12/03
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.10% Sodium Phosphate Buffer	0.10% Sodium Phosphate Buffer	DI Water	DI Water	1.0% MC

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DATASET NO.	106	107
NO. MALES IN CONTROL GROUP	---	---
MALE MATING INDEX (%)	---	---
MALE FERTILITY INDEX (%)	---	---
NO. FEMALES IN CONTROL GROUP	25	25
FEMALE MATING INDEX (%)	---	---
FEMALE FERTILITY INDEX (%)	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25
NO. THAT DELIVERED	25	25
NO. THAT DID NOT DELIVER	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0
NO. WITH TOTAL LITTER LOSS	0	0
NO. WITH DYSTOCIA	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.7
MEAN NO. PUPS BORN	15.9	15.5
MEAN VIABLE LITTER SIZE ON PND 0	15.7	15.3
PUP SEX RATIO		
MEAN % MALE	49.4	46.3
MEAN % FEMALE	50.6	53.7
MEAN NO. OF IMPLANTATION SITES AT WEANING	17.0	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---
EXPERIMENTAL START DATE	10/27/03	10/28/03
DATE OF LAST NECROPSY	2/2/04	2/3/04
ROUTE	Gavage	Gavage
VEHICLE	1.0% MC	1.0% MC

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DATASET NO.	1	2	3	4	5
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	92.3	97.5	99.3	99.2	99.4
PND 0 TO PND 1	100.0	99.6	99.2	99.4	99.2
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	98.6	99.3	100.0	99.3
PND 4 (AFTER SELECTION) TO PND 7	99.5	100.0	100.0	99.1	100.0
PND 7 TO PND 14	100.0	100.0	100.0	100.0	100.0
PND 14 TO PND 21	100.0	98.5	100.0	100.0	99.6
BIRTH TO PND 4 (BEFORE SELECTION)	92.3	95.9	97.8	98.7	97.9
PND 4 (AFTER SELECTION) TO PND 21	99.5	98.5	100.0	99.1	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.4	7.1	7.2	7.0	7.2
PND 4 (BEFORE SELECTION)	10.6	10.6	10.1	10.2	10.4
PND 7	17.2	17.2	16.4	16.8	15.1
PND 14	33.7	35.8	29.9	35.0	27.8
PND 21	53.8	58.0	45.4	53.1	44.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.8	6.8	6.6	6.7
PND 4 (BEFORE SELECTION)	10.0	10.0	9.5	9.7	9.7
PND 7	16.1	16.3	15.5	16.2	14.1
PND 14	32.1	34.3	28.9	33.9	26.3
PND 21	51.6	54.8	44.1	51.0	42.2
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3915
SPLEEN	---	---	---	---	0.1698
THYMUS GLAND	---	---	---	---	0.1690
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3530
SPLEEN	---	---	---	---	0.1722
THYMUS GLAND	---	---	---	---	0.1743

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DATASET NO.	6	7	8	9	10
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.3	96.6	97.7	98.2	97.7
PND 0 TO PND 1	99.8	94.5	99.4	99.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	97.8	99.4	97.8	99.7	100.0
PND 4 (AFTER SELECTION) TO PND 7	100.0	100.0	99.5	100.0	100.0
PND 7 TO PND 14	96.6	100.0	100.0	100.0	96.9
PND 14 TO PND 21	99.6	100.0	100.0	100.0	97.8
BIRTH TO PND 4 (BEFORE SELECTION)	96.0	91.3	95.2	97.7	97.4
PND 4 (AFTER SELECTION) TO PND 21	96.1	100.0	99.5	100.0	96.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	6.8	6.8	7.3	7.1
PND 4 (BEFORE SELECTION)	10.2	9.6	9.6	10.5	10.4
PND 7	15.3	15.3	15.4	16.4	16.6
PND 14	28.5	31.1	31.8	33.1	33.4
PND 21	45.3	51.0	49.5	50.6	52.1
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.5	6.3	6.9	6.7
PND 4 (BEFORE SELECTION)	9.5	9.1	9.0	10.0	9.7
PND 7	14.3	14.5	14.6	15.7	15.6
PND 14	27.5	29.7	30.8	32.2	31.2
PND 21	43.5	47.9	47.7	49.2	49.0
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4000	1.4926	1.4660	---	---
SPLEEN	0.1805	0.2106	0.1901	---	---
THYMUS GLAND	0.1790	0.2155	0.2076	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3682	1.4242	1.4214	---	---
SPLEEN	0.1846	0.1975	0.1929	---	---
THYMUS GLAND	0.1853	0.2113	0.2099	---	---

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DATASET NO.	11	12	13	14	15
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.4	97.6	97.8	97.0	95.7
PND 0 TO PND 1	99.3	98.9	99.4	99.6	95.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	99.6	99.2	98.8	100.0
PND 4 (AFTER SELECTION) TO PND 7	97.2	99.6	---	---	100.0
PND 7 TO PND 14	96.3	---	---	---	99.5
PND 14 TO PND 21	100.0	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.5	96.2	96.4	95.4	94.0
PND 4 (AFTER SELECTION) TO PND 21	95.4	98.5	---	---	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.6	7.0	6.9	7.1
PND 4 (BEFORE SELECTION)	9.1	8.9	9.3	9.5	10.0
PND 7	11.7	12.3	---	---	16.2
PND 14	22.5	24.6	---	---	32.5
PND 21	34.9	38.2	---	---	51.4
PND 28	65.4	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	6.2	6.5	6.4	6.7
PND 4 (BEFORE SELECTION)	8.5	8.4	8.8	9.0	9.5
PND 7	11.0	11.5	---	---	15.4
PND 14	21.2	23.4	---	---	31.7
PND 21	33.3	37.0	---	---	49.1
PND 28	59.8	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3616	1.4033	---	---	---
SPLEEN	0.1189	0.1544	---	---	---
THYMUS GLAND	0.1392	0.1640	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.2903	1.3390	---	---	---
SPLEEN	0.1182	0.1539	---	---	---
THYMUS GLAND	0.1338	0.1612	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.5	97.3	99.0	---	---
PND 0 TO PND 1	100.0	98.5	98.8	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.4	99.0	99.6	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	94.9	97.5	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	100.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	6.7	7.1	---	---
PND 4 (BEFORE SELECTION)	10.3	9.2	10.2	---	---
PND 7	---	13.1	16.5	---	---
PND 14	---	25.1	34.9	---	---
PND 21	---	39.5	54.7	---	---
PND 28	---	70.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.3	6.7	---	---
PND 4 (BEFORE SELECTION)	9.8	8.7	9.7	---	---
PND 7	---	12.6	15.9	---	---
PND 14	---	24.1	33.7	---	---
PND 21	---	38.0	52.4	---	---
PND 28	---	66.8	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.6	98.7	99.0	---	99.8
PND 0 TO PND 1	99.7	99.1	100.0	---	100.0
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	99.8	98.8	---	99.5
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	---	100.0
PND 7 TO PND 14	99.5	---	100.0	---	100.0
PND 14 TO PND 21	100.0	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.4	97.5	97.8	---	99.3
PND 4 (AFTER SELECTION) TO PND 21	99.5	---	100.0	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.1	7.4	---	6.8
PND 4 (BEFORE SELECTION)	10.2	10.4	10.7	---	9.6
PND 7	16.7	---	17.8	---	15.7
PND 14	34.8	---	36.5	---	32.4
PND 21	53.3	---	55.3	---	52.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.7	6.9	---	6.5
PND 4 (BEFORE SELECTION)	9.7	9.7	10.0	---	9.1
PND 7	16.1	---	16.8	---	14.9
PND 14	33.5	---	34.7	---	31.2
PND 21	50.9	---	53.1	---	50.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.9	97.7	98.9	99.5
PND 0 TO PND 1	---	94.3	96.7	98.2	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.6	98.8	98.8	99.4
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	99.5
PND 7 TO PND 14	---	99.3	100.0	---	98.5
PND 14 TO PND 21	---	100.0	100.0	---	98.8
BIRTH TO PND 4 (BEFORE SELECTION)	---	92.1	93.8	96.0	98.0
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	100.0	---	97.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	6.7	7.1	6.5
PND 4 (BEFORE SELECTION)	---	9.4	9.4	9.8	8.6
PND 7	---	15.1	15.1	---	13.0
PND 14	---	31.3	32.9	---	27.1
PND 21	---	48.1	50.9	---	41.3
PND 28	---	86.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.4	6.4	6.6	6.1
PND 4 (BEFORE SELECTION)	---	8.9	8.8	9.1	8.1
PND 7	---	14.1	14.3	---	12.2
PND 14	---	29.4	31.2	---	25.7
PND 21	---	45.0	48.0	---	39.4
PND 28	---	79.4	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN NO. PUPS BORN	---	15.4	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.3	---	---	---
PND 0 TO PND 1	---	99.3	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	99.7	---	---	---
PND 7 TO PND 14	---	99.7	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	97.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	---	---	---
PND 4 (BEFORE SELECTION)	---	10.1	---	---	---
PND 7	---	14.8	---	---	---
PND 14	---	27.2	---	---	---
PND 21	---	45.5	---	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	---	---	---
PND 4 (BEFORE SELECTION)	---	9.6	---	---	---
PND 7	---	14.0	---	---	---
PND 14	---	26.3	---	---	---
PND 21	---	43.8	---	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	36	37	38	39	40
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	95.8	97.7	---
PND 0 TO PND 1	---	---	98.7	98.9	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	97.7	98.1	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	---	---
PND 7 TO PND 14	---	---	99.5	---	---
PND 14 TO PND 21	---	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	92.4	94.8	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.8	6.8	---
PND 4 (BEFORE SELECTION)	---	---	9.5	9.2	---
PND 7	---	---	15.0	---	---
PND 14	---	---	31.8	---	---
PND 21	---	---	48.9	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.4	6.3	---
PND 4 (BEFORE SELECTION)	---	---	8.9	8.8	---
PND 7	---	---	14.1	---	---
PND 14	---	---	30.5	---	---
PND 21	---	---	46.7	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.5	98.6	---	---	99.1
PND 0 TO PND 1	99.7	99.6	---	---	98.6
PND 1 TO PND 4 (BEFORE SELECTION)	99.1	98.4	---	---	99.8
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.7	---	---	99.6
PND 7 TO PND 14	100.0	---	---	---	100.0
PND 14 TO PND 21	100.0	---	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	---	---	97.5
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	---	---	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	7.4	---	---	6.6
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	9.0
PND 7	15.3	15.2	---	---	14.9
PND 14	32.5	---	---	---	31.1
PND 21	51.4	---	---	---	45.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.9	---	---	6.2
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	8.5
PND 7	14.5	14.4	---	---	14.2
PND 14	31.3	---	---	---	30.0
PND 21	49.5	---	---	---	44.5
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.4163
SPLEEN	---	---	---	---	0.1822
THYMUS GLAND	---	---	---	---	0.1758
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3876
SPLEEN	---	---	---	---	0.1915
THYMUS GLAND	---	---	---	---	0.1852

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DATASET NO.	46	47	48	49	50
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.5	---	96.6	97.3	---
PND 0 TO PND 1	100.0	---	100.0	99.7	---
PND 1 TO PND 4 (BEFORE SELECTION)	98.4	---	99.5	99.7	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	100.0	---
PND 7 TO PND 14	100.0	---	99.5	100.0	---
PND 14 TO PND 21	100.0	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	---	96.1	96.8	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	99.5	100.0	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	---	7.3	7.1	---
PND 4 (BEFORE SELECTION)	9.3	---	10.7	10.3	---
PND 7	15.1	---	15.4	15.5	---
PND 14	32.1	---	28.8	29.2	---
PND 21	51.1	---	48.4	49.5	---
PND 28	---	---	88.1	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.2	---	6.9	6.7	---
PND 4 (BEFORE SELECTION)	8.7	---	10.1	9.6	---
PND 7	14.0	---	14.5	14.5	---
PND 14	30.4	---	27.4	27.6	---
PND 21	47.5	---	45.9	46.6	---
PND 28	---	---	79.5	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4763	---	1.4897	1.4728	---
SPLEEN	0.2176	---	0.2063	0.2189	---
THYMUS GLAND	0.1990	---	0.1951	0.1958	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4261	---	1.4332	1.3957	---
SPLEEN	0.2042	---	0.1977	0.2087	---
THYMUS GLAND	0.1986	---	0.2001	0.1895	---

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DATASET NO.	51	52	53	54	55
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	98.7	97.6	---
PND 0 TO PND 1	---	---	100.0	99.5	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	99.3	99.2	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	99.5	---
PND 7 TO PND 14	---	---	100.0	100.0	---
PND 14 TO PND 21	---	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	98.0	96.3	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	100.0	99.5	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.6	7.2	---
PND 4 (BEFORE SELECTION)	---	---	11.2	10.2	---
PND 7	---	---	17.7	16.9	---
PND 14	---	---	35.1	35.2	---
PND 21	---	---	57.6	55.2	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.2	6.8	---
PND 4 (BEFORE SELECTION)	---	---	10.7	9.7	---
PND 7	---	---	17.1	16.2	---
PND 14	---	---	35.1	33.7	---
PND 21	---	---	55.6	52.2	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.5175	1.4836	---
SPLEEN	---	---	0.2476	0.2227	---
THYMUS GLAND	---	---	0.2372	0.2446	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4597	1.4341	---
SPLEEN	---	---	0.2302	0.2200	---
THYMUS GLAND	---	---	0.2479	0.2407	---

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DATASET NO.	56	57	58	59	60
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.9	---	---	97.3
PND 0 TO PND 1	---	98.6	---	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	---	93.5	---	---	100.0
PND 4 (AFTER SELECTION) TO PND 7	---	99.4	---	---	100.0
PND 7 TO PND 14	---	100.0	---	---	100.0
PND 14 TO PND 21	---	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	---	91.6	---	---	95.9
PND 4 (AFTER SELECTION) TO PND 21	---	99.4	---	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.0	---	---	7.1
PND 4 (BEFORE SELECTION)	---	9.6	---	---	9.7
PND 7	---	16.1	---	---	16.1
PND 14	---	33.9	---	---	34.4
PND 21	---	52.4		---	54.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.6	---	---	6.7
PND 4 (BEFORE SELECTION)	---	9.2	---	---	9.2
PND 7	---	15.1	---	---	15.2
PND 14	---	32.5	---	---	32.8
PND 21	---	49.2	---	---	52.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	95.6	95.8	---	---
PND 0 TO PND 1	---	95.4	98.1	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	98.9	99.3	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	93.1	93.3	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	7.1	---	---
PND 4 (BEFORE SELECTION)	---	9.9	10.7	---	---
PND 7	---	15.7	---	---	---
PND 14	---	30.0	---	---	---
PND 21	---	48.4	---	---	---
PND 28	---	88.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	6.8	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.1	---	---
PND 7	---	14.9	---	---	---
PND 14	---	28.9	---	---	---
PND 21	---	46.6	---	---	---
PND 28	---	80.5	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.0	---	98.8	---	97.8
PND 0 TO PND 1	99.0	---	98.1	---	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	95.7	---	99.7	---	99.3
PND 4 (AFTER SELECTION) TO PND 7	95.8	---	100.0	---	98.4
PND 7 TO PND 14	100.0	---	100.0	---	99.4
PND 14 TO PND 21	99.2	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	91.9	---	96.6	---	96.7
PND 4 (AFTER SELECTION) TO PND 21	95.2	---	100.0	---	97.8
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	---	7.1	---	7.2
PND 4 (BEFORE SELECTION)	10.3	---	9.8	---	10.1
PND 7	16.3	---	15.3	---	15.1
PND 14	32.5	---	32.3	---	30.9
PND 21	49.4	---	52.1	---	48.2
PND 28	89.8	---	---	---	83.2
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	---	6.6	---	6.8
PND 4 (BEFORE SELECTION)	9.7	---	9.1	---	9.4
PND 7	15.8	---	14.5	---	14.1
PND 14	32.8	---	31.1	---	29.5
PND 21	50.2	---	49.7	---	46.3
PND 28	86.2	---	---	---	77.9
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	71	72	73	74	75
MEAN NO. PUPS BORN	12.6	15.5	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.6	97.4	---	---	---
PND 0 TO PND 1	98.5	99.8	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	99.0	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.4	99.5	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.1	96.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	7.0	---	---	---
PND 4 (BEFORE SELECTION)	10.8	9.7	---	---	---
PND 7	17.4	15.4	---	---	---
PND 14	---	32.4	---	---	---
PND 21	---	50.0	---	---	---
PND 28	---	87.8	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.6	---	---	---
PND 4 (BEFORE SELECTION)	10.4	9.1	---	---	---
PND 7	16.5	14.4	---	---	---
PND 14	---	30.9	---	---	---
PND 21	---	47.3	---	---	---
PND 28	---	82.1	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.3	97.5	---	---
PND 0 TO PND 1	---	98.0	99.5	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	98.8	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	96.6	100.0	---	---
PND 7 TO PND 14	---	94.4	99.0	---	---
PND 14 TO PND 21	---	95.9	99.5	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	94.9	95.7	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	92.2	98.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	7.2	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.5	---	---
PND 7	---	12.8	15.0	---	---
PND 14	---	24.8	29.7	---	---
PND 21	---	39.1	45.1	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	8.9	9.9	---	---
PND 7	---	11.8	14.3	---	---
PND 14	---	23.6	28.3	---	---
PND 21	---	39.1	42.9	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3553	1.4080	---	---
SPLEEN	---	0.1471	0.1755	---	---
THYMUS GLAND	---	0.1723	0.1901	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3241	1.3683	---	---
SPLEEN	---	0.1471	0.1850	---	---
THYMUS GLAND	---	0.1710	0.2032	---	---

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DATASET NO.	81	82	83	84	85
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.0	93.3	---	---	---
PND 0 TO PND 1	100.0	100.0	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.6	99.3	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.0	100.0	---	---	---
PND 7 TO PND 14	93.5	100.0	---	---	---
PND 14 TO PND 21	94.7	99.5	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.7	92.7	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	91.1	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.4	---	---	---
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	---
PND 7	12.8	15.2	---	---	---
PND 14	23.3	---	---	---	---
PND 21	38.4	42.6	---	---	---
PND 28	74.0	79.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	7.1	---	---	---
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	---
PND 7	12.2	14.3	---	---	---
PND 14	22.7	---	---	---	---
PND 21	37.6	40.5	---	---	---
PND 28	69.3	73.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3451	1.4458	---	---	---
SPLEEN	0.1503	0.1817	---	---	---
THYMUS GLAND	0.1617	0.1971	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3142	1.3833	---	---	---
SPLEEN	0.1515	0.1686	---	---	---
THYMUS GLAND	0.1669	0.1948	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.8	98.8	---	---
PND 0 TO PND 1	---	100.0	99.4	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.7	99.7	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	99.4	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	95.5	97.9	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.4	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.9	7.3	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.4	---	---
PND 7	---	12.9	14.6	---	---
PND 14	---	24.0	27.3	---	---
PND 21	---	38.5	43.9	---	---
PND 28	---	72.0	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	9.0	9.8	---	---
PND 7	---	12.5	13.9	---	---
PND 14	---	23.3	26.2	---	---
PND 21	---	36.9	41.9	---	---
PND 28	---	66.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3987	---	---
SPLEEN	---	---	0.1815	---	---
THYMUS GLAND	---	---	0.1678	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3623	---	---
SPLEEN	---	---	0.1905	---	---
THYMUS GLAND	---	---	0.1778	---	---

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DATASET NO.	91	92	93	94	95
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	96.8	---	99.1	98.7	98.7
PND 0 TO PND 1	100.0	---	98.9	97.0	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	99.8	---	99.0	99.2	99.8
PND 4 (AFTER SELECTION) TO PND 7	99.0	---	99.6	99.5	100.0
PND 7 TO PND 14	98.0	---	100.0	100.0	100.0
PND 14 TO PND 21	99.0	---	99.6	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.5	---	97.1	94.9	97.6
PND 4 (AFTER SELECTION) TO PND 21	96.0	---	99.1	99.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	7.1	7.5	6.9
PND 4 (BEFORE SELECTION)	9.2	---	9.9	10.8	9.5
PND 7	14.0	---	15.7	17.3	15.5
PND 14	24.6	---	32.2	35.3	32.6
PND 21	37.8	---	50.5	56.7	51.3
PND 28	69.8	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	---	6.7	7.0	6.4
PND 4 (BEFORE SELECTION)	8.8	---	9.4	10.1	8.9
PND 7	13.3	---	15.0	16.3	14.6
PND 14	24.2	---	31.3	33.9	31.2
PND 21	36.9	---	48.9	53.5	49.3
PND 28	67.4	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4143	1.4899	1.4775
SPLEEN	---	---	0.2232	0.2480	0.2220
THYMUS GLAND	---	---	0.1943	0.2330	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3958	1.4378	1.4216
SPLEEN	---	---	0.2335	0.2408	0.2229
THYMUS GLAND	---	---	0.2120	0.2363	0.2265

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DATASET NO.	96	97	98	99	100
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.9	100.0	---	96.1	99.0
PND 0 TO PND 1	99.5	99.5	---	99.7	98.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	97.4	---	96.8	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	97.3	---	96.9	---
PND 7 TO PND 14	100.0	99.4	---	99.3	---
PND 14 TO PND 21	100.0	100.0	---	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.2	96.9	---	92.4	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	96.8	---	96.3	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.9	---	7.0	7.3
PND 4 (BEFORE SELECTION)	9.9	9.3	---	9.5	---
PND 7	16.2	14.5	---	15.4	---
PND 14	33.0	30.7	---	32.7	---
PND 21	50.0	49.7	---	51.6	---
PND 28	---	83.5	---	87.1	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.6	---	6.6	6.9
PND 4 (BEFORE SELECTION)	9.4	8.9	---	9.0	---
PND 7	15.5	13.9	---	14.4	---
PND 14	31.9	29.5	---	30.7	---
PND 21	48.5	47.6	---	48.6	---
PND 28	---	77.7	---	78.4	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4605	---	---	---	---
SPLEEN	0.2211	---	---	---	---
THYMUS GLAND	0.2123	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4199	---	---	---	---
SPLEEN	0.2261	---	---	---	---
THYMUS GLAND	0.2078	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.7	---	99.2	---	98.3
PND 0 TO PND 1	99.4	---	99.4	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	99.2	---	99.2	---	99.2
PND 4 (AFTER SELECTION) TO PND 7	99.6	---	99.5	---	100.0
PND 7 TO PND 14	99.6	---	99.5	---	---
PND 14 TO PND 21	100.0	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	97.8	---	---
PND 4 (AFTER SELECTION) TO PND 21	99.1	---	99.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	---	7.3	---	7.6
PND 4 (BEFORE SELECTION)	10.5	---	10.1	---	11.4
PND 7	16.1	---	16.4	---	16.4
PND 14	31.1	---	34.0	---	---
PND 21	49.0	---	53.8	---	---
PND 28	76.4	---	94.0	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	6.9	---	7.2
PND 4 (BEFORE SELECTION)	9.9	---	9.6	---	10.9
PND 7	15.4	---	15.5	---	15.7
PND 14	29.9	---	32.8	---	---
PND 21	47.0	---	51.6	---	---
PND 28	68.9	---	85.3	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	106	107
MEAN NO. PUPS BORN	15.9	15.5
PUP SURVIVAL INDICES (% PER LITTER)		
PND 0 (RELATIVE TO NO. BORN)	98.6	98.6
PND 0 TO PND 1	99.2	99.5
PND 1 TO PND 4 (BEFORE SELECTION)	99.5	98.7
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.5
PND 7 TO PND 14	100.0	100.0
PND 14 TO PND 21	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.3	96.8
PND 4 (AFTER SELECTION) TO PND 21	100.0	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)		
PND 1	7.0	6.8
PND 4 (BEFORE SELECTION)	9.5	9.4
PND 7	15.1	15.3
PND 14	31.8	31.6
PND 21	50.5	50.2
PND 28	86.6	85.3
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)		
PND 1	6.5	6.3
PND 4 (BEFORE SELECTION)	8.9	8.8
PND 7	14.0	14.4
PND 14	30.0	30.4
PND 21	48.0	47.7
PND 28	79.1	77.0
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---

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DATASET NO.	1	2	3	4	5
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	43.3	---	46.7	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	230.4	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.2	---	33.1	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	106.9	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	6	7	8	9	10
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	5.3	5.7	---	---
FEMALE	---	3.2	3.9	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.0	---	44.6	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	217.9	---	223.0	---	232.0
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	---	34.4	---	32.6
MEAN BODY WEIGHT AT ACQUISITION (G)	105.1	---	118.9	---	112.2
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	11	12	13	14	15
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	5.3	5.3	---	---	---
FEMALE	3.3	3.1	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	47.0	47.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	38.8	32.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	5.2
FEMALE	---	---	---	---	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	4.8	---	---	---
FEMALE	---	2.7	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	41.6	---	41.8	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	210.5	---	212.2	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	32.5	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	107.4	---	117.7	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	4.0	---	---
FEMALE	---	---	4.0	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	16.1	---	---
FEMALE	---	---	16.1	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.0	---	42.4	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	227.1	---	229.0	---	226.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.4	---	31.9	---	33.2
MEAN BODY WEIGHT AT ACQUISITION (G)	115.2	---	109.9	---	119.1
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.0	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.2	---	---	---	---
FEMALE	14.8	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.1	---	43.8	49.0
MEAN BODY WEIGHT AT ACQUISITION (G)	---	247.9	---	229.2	248.0
MEAN DAY OF VAGINAL PATENCY (PND)	---	31.9	---	33.2	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	103.8	---	119.5	102.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	49.0	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	248.0	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	33.7	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	102.8	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	36	37	38	39	40
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.7	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	235.1	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	112.1	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.1	---	---	---	46.3
MEAN BODY WEIGHT AT ACQUISITION (G)	240.3	---	---	---	231.0
MEAN DAY OF VAGINAL PATENCY (PND)	32.7	---	---	---	31.7
MEAN BODY WEIGHT AT ACQUISITION (G)	114.7	---	---	---	99.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.1	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	18.7	---	---	---	---
FEMALE	18.6	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	46	47	48	49	50
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.2	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	228.9	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	36.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	130.3	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	51	52	53	54	55
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	42.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	227.0	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	34.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	133.0	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	56	57	58	59	60
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	42.0	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	---	215.7	---	---	248.6
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.9	---	---	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	112.6	---	---	125.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.7	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	238.3	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	107.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	5.1	---	---	---
FEMALE	---	5.2	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	4.2	---	---	---
FEMALE	---	4.2	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	15.5	---	---	---
FEMALE	---	15.5	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.7	---	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	224.7	---	---	---	220.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.1	---	---	---	33.1
MEAN BODY WEIGHT AT ACQUISITION (G)	114.4	---	---	---	107.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	14.9
FEMALE	---	---	---	---	14.9
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	10.1
FEMALE	---	---	---	---	10.0

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DATASET NO.	71	72	73	74	75
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.4	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	231.8	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.2	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	117.2	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	2.45	4.41	---	---
FEMALE	---	1.34	2.57	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	219.5	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	37.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	119.8	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	81	82	83	84	85
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.6	45.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	223.2	222.2	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	35.1	33.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	114.0	109.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.2	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	4.0	---	---	---
FEMALE	4.0	4.0	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.7	15.1	---	---	---
FEMALE	15.7	15.1	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	13.1	11.7	---	---	---
FEMALE	13.0	11.8	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	10.0	9.3	---	---	---
FEMALE	9.9	9.3	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	49.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	236.1	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	35.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	109.0	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	91	92	93	94	95
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	4.34	4.32	---
FEMALE	---	---	2.41	2.37	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.8	---	46.1	---	44.4
MEAN BODY WEIGHT AT ACQUISITION (G)	213.8	---	236.6	---	212.8
MEAN DAY OF VAGINAL PATENCY (PND)	33.8	---	34.2	---	33.0
MEAN BODY WEIGHT AT ACQUISITION (G)	99.5	---	121.9	---	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	96	97	98	99	100
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	4.36	---	---	---	---
FEMALE	2.28	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.0	---	44.8	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	220.2	---	235.6	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.9	---	33.5	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	115.1	---	111.5	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.7	---	42.3	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	221.8	---	223.8	---	225.2
MEAN DAY OF VAGINAL PATENCY (PND)	33.0	---	33.0	---	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	103.4	---	119.0	---	109.7
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	106	107
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.4	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	238.2	228.2
MEAN DAY OF VAGINAL PATENCY (PND)	32.9	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	112.1	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)		
MALE	5.1	5.0
FEMALE	5.3	5.1
MEAN DAY OF PINNAL DETACHMENT (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF EYE OPENING (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF HAIR GROWTH (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF INCISOR ERUPTION (PND)		
MALE	---	---
FEMALE	---	---

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DATASET NO.	1	2	3	4	5
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.55	2.64	2.73	1.95	2.70
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.85	1.72	1.84	1.71
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.88	1.74	1.85	1.71
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.71	0.75	0.74	0.74	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.76	0.72	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3266	0.3293	0.3185	0.3164	0.3022
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3197	0.3423	0.3280	0.3295	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	85.2	89.1	99.3	87.0	87.3
LEFT EPIDIDYMIS	449.0	407.9	436.1	413.4	343.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.0	14.6	16.3	14.3	14.3
% MOTILE SPERM	84.9	82.4	85.5	87.6	80.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.6	99.4	99.9	99.6	99.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	0.5	0.0	0.3	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.1	0.0	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.2	198.8	199.9	199.1	198.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.4	0.9	0.1	0.6	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	1.3	0.3	0.1	0.3	0.9
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	6	7	8	9	10
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.05	1.88	1.82	2.80	1.76
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.72	1.72	1.73	1.79
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.73	1.75	1.75	1.81
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.75	0.68	0.71	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.70	0.69	0.74	0.76
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3269	0.3364	0.2812	0.3157	0.3210
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3225	0.3242	0.3057	0.3280	0.3271
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.6	81.7	104.8	90.8	95.8
LEFT EPIDIDYMIS	517.5	410.6	534.3	452.1	416.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	13.4	17.2	14.9	15.7
% MOTILE SPERM	80.8	85.3	82.3	87.6	85.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.7	99.8	99.0	99.8	96.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.8	0.1	0.7	0.2	2.0
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.1	0.3	0.1	1.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.4	199.6	198.0	199.5	192.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.6	0.3	1.5	0.3	4.0
HEAD ABSENT WITH NORMAL FLAGELLUM	1.0	0.1	0.5	0.2	3.2
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	11	12	13	14	15
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.64	2.73	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.76	1.73	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.76	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	0.72	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.70	0.70	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3262	0.3174	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3064	0.2950	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	72.9	94.1	---	---	---
LEFT EPIDIDYMIS	456.0	467.9	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	11.9	15.4	---	---	---
% MOTILE SPERM	80.2	75.4	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.5	99.6	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.9	0.1	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.3	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.0	199.2	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.9	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	1.1	0.6	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.1	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.65	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.67	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2807	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2943	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	96.6	---	---	---
LEFT EPIDIDYMIS	---	438.8	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.8	---	---	---
% MOTILE SPERM	---	80.9	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.8	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.0	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.9	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.		22	23	24	25
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.45	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.73	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3160	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3293	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	91.7	---	---	---
LEFT EPIDIDYMIS	---	478.5	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.0	---	---	---
% MOTILE SPERM	---	86.2	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.1	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.3	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	1.77
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.68
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3092
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	106.7
LEFT EPIDIDYMIS	---	---	---	---	442.7
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	17.5
% MOTILE SPERM	---	---	---	---	81.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0

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DATASET NO.	36	37	38	39	40
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.80	1.76	---	---	1.93
MEAN LEFT TESTIS WEIGHT (G)	1.88	1.75	---	---	1.90
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.78	0.67	---	---	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.80	0.67	---	---	0.77
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3402	0.2857	---	---	0.3552
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3712	0.3061	---	---	0.3380
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.0	95.5	---	---	83.8
LEFT EPIDIDYMIS	393.1	556.7	---	---	418.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.1	15.7	---	---	13.7
% MOTILE SPERM	77.3	79.3	---	---	86.4
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.8	---	---	---	98.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.4	---	---	---	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.5	---	---	---	197.6
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	---	---	---	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	1.8	---	---	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0

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DATASET NO.	41	42	43	44	45
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	1.79	1.87	1.83	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.90	1.82	1.76	1.79
MEAN LEFT TESTIS WEIGHT (G)	---	1.89	1.84	1.82	1.80
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.81	0.78	0.78	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.77	0.77	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3586	0.3495	0.3272	0.3338
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3374	0.3555	0.3487	0.3149
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	95.5	76.7	74.1	---
LEFT EPIDIDYMIS	---	476.1	421.3	407.1	477.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.7	12.6	12.1	---
% MOTILE SPERM	---	85.9	87.1	75.9	89.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.8	99.4	99.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.3	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.5	198.8	199.4	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	0.7	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.6	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---

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DATASET NO.	46	47	48	49	50
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.15	2.14	---
MEAN RIGHT TESTIS WEIGHT (G)	1.83	1.70	1.79	1.84	1.69
MEAN LEFT TESTIS WEIGHT (G)	1.84	1.71	1.79	1.80	1.72
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.75	0.67	0.72	0.74	0.67
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.68	0.74	0.72	0.66
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3291	0.2817	0.3327	0.3178	0.3080
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3298	0.2967	0.3252	0.3304	0.3025
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	94.7	84.8	106.9	82.4
LEFT EPIDIDYMIS	539.2	500.8	471.9	640.1	503.2
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.5	13.9	17.5	13.5
% MOTILE SPERM	88.1	89.2	86.8	88.9	79.2
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.5	99.7	99.5	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.3	0.2	0.2	0.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.3	0.1	0.2	0.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	198.9	199.4	199.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.5	0.4	0.0	0.9
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.6	0.1	0.0	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	51	52	53	54	55
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.24	2.28
MEAN RIGHT TESTIS WEIGHT (G)	1.73	---	1.82	1.89	1.77
MEAN LEFT TESTIS WEIGHT (G)	1.69	---	1.80	1.92	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	---	0.81	0.75	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.69	---	0.76	0.78	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3121	---	0.3548	0.3431	0.3396
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3084	---	0.3387	0.3504	0.3475
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	90.5	---	105.4	83.8	---
LEFT EPIDIDYMIS	462.7	---	454.6	412.9	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.8	---	17.3	13.7	
% MOTILE SPERM	91.6	---	91.1	85.3	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.8	---	99.8	99.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.1	---	0.2	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	199.6	199.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	---	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---

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DATASET NO.	56	57	58	59	60
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---		---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.73	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.69	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.2962	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3168	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	91.0	---
LEFT EPIDIDYMIS	447.6	---	---	585.8	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	14.9	---
% MOTILE SPERM	86.3	---	---	84.2	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.3	---	---	99.5	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	---	---	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	198.6	---	---	199.1	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.1	---	---	0.4	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.3	---	---	0.5	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---

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DATASET NO.	61	62	63	64	65
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	----	1.92	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	----	1.80	---	1.80
MEAN LEFT TESTIS WEIGHT (G)	---	----	1.79	---	1.75
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.67
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3189	---	0.3368
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3449	---	0.3239
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	----	79.8	---	77.8
LEFT EPIDIDYMIS	---	----	506.2	---	417.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	----	13.1	---	12.8
% MOTILE SPERM	---	----	91.9	---	71.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	----	99.4	---	91.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.4	---	3.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.2	---	4.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	----	198.8	---	183.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.8	---	6.7
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.4	---	9.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0

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DATASET NO.	66	67	68	69	70
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	----	----	1.95	1.82	---
MEAN RIGHT TESTIS WEIGHT (G)	----	----	1.85	1.71	---
MEAN LEFT TESTIS WEIGHT (G)	----	----	1.83	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	----	----	0.71	0.64	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	----	----	0.70	0.62	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.2972	0.2629	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.3065	0.2714	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	----	----	81.0	---	---
LEFT EPIDIDYMIS	----	----	443.9	480.0	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	----	----	13.3	---	---
% MOTILE SPERM	----	----	87.3	82.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	----	----	98.9	97.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	0.7	1.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.4	0.9	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	----	----	197.9	195.8	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	1.4	1.7	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.8	2.4	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.1	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---

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DATASET NO.	71	72	73	74	75
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.68	1.90
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.69	1.91
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.68	0.78
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3057	0.3564
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3143	0.3693
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	75.0	69.6
LEFT EPIDIDYMIS	---	---	---	458.8	466.3
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	12.3	11.4
% MOTILE SPERM	---	---	---	82.0	83.1
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	99.0	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	0.5	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	0.5	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	198.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	1.0	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	1.0	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0

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DATASET NO.	76	77	78	79	80
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.26	2.29	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.84	---	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	1.84	1.87	---	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.74	---	0.74
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.76	---	0.74
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3354	0.3364	---	0.3397
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3460	0.3498	---	0.3377
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	77.7	90.8	---	74.3
LEFT EPIDIDYMIS	---	454.3	436.0	---	353.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	12.6	14.9	---	12.2
% MOTILE SPERM	---	87.5	87.0	---	84.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	96.1	99.2	---	98.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.6	0.4	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	2.3	0.5	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	192.2	198.3	---	197.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	3.1	0.7	---	1.2
HEAD ABSENT WITH NORMAL FLAGELLUM	---	4.6	0.9	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0

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DATASET NO.	81	82	83	84	85
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.13	2.15	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.84	1.80	---	1.76	1.75
MEAN LEFT TESTIS WEIGHT (G)	1.81	1.80	---	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.80	0.73	---	0.79	0.70
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.76	0.73	---	0.78	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3686	0.3270	---	0.3682	0.3326
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3595	0.3243	---	0.3706	0.3286
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	79.1	96.6	---	79.2	84.6
LEFT EPIDIDYMIS	---	---	---	469.0	452.3
LEFT CAUDA EPIDIDYMIS	738.9	618.7	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	13.0	15.8	---	13.0	13.9
% MOTILE SPERM	88.6	84.3	---	89.7	78.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.5	99.3	---	99.3	97.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	0.4	---	0.5	1.8
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	0.2	---	0.3	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	199.0	198.7	---	198.6	195.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.9	---	0.9	3.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.4	0.4	---	0.5	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0

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DATASET NO.	86	87	88	89	90
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	2.30		---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.79	1.76	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	1.83	1.80	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.69	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.71	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3055	0.3194	0.3257	0.3352
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3306	0.3226	0.3384	0.3310
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	88.8	81.6	86.7	87.4
LEFT EPIDIDYMIS	---	476.2	434.0	475.8	461.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	14.5	13.4	14.2	14.3
% MOTILE SPERM	---	83.0	87.0	83.4	81.7
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.9	97.3	99.7	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.3	0.4	0.1	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.8	0.3	0.2	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.8	198.6	199.4	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.6	0.8	0.3	10.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.6	0.6	0.3	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	91	92	93	94	95
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.22	2.09
MEAN RIGHT TESTIS WEIGHT (G)	---	---	1.85	1.90	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	---	1.82	1.91	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.76	0.72
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.77	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3234	0.3424	0.3162
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3421	0.3460	0.3212
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	75.9	93.2	78.1
LEFT EPIDIDYMIS	---	---	---	---	406.0
LEFT CAUDA EPIDIDYMIS	---	---	689.5	662.8	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	12.4	15.3	12.8
% MOTILE SPERM	---	---	91.0	82.0	88.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	99.4	99.7	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.4	0.2	0.3
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.2	0.1	0.1
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	198.9	199.4	199.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.8	0.4	1.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.3	0.2	0.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0

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DATASET NO.	96	97	98	99	100
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	1.98	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.86	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.82	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.63	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3264	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3232	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	76.2	---	---	---	---
LEFT EPIDIDYMIS	548.6	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	12.5	---	---	---	---
% MOTILE SPERM	89.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.7	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.2	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.23	2.04	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.87	1.92	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.73	1.85	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.78	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.68	0.74	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3336	0.3693	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.2858	0.3405	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

DATASET NO.	106	107
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)		
LEFT TESTIS	---	---
LEFT EPIDIDYMIS	---	---
LEFT CAUDA EPIDIDYMIS	---	---
MEAN SPERM PRODUCTION RATE		
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---
% MOTILE SPERM	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

APPENDIX F

Study Protocol

[redacted]

Study Number: WIL-187042

PROTOCOL AMENDMENT II

Sponsor: [redacted]

Sponsor Study No.: 04-027

A. Title of Study:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Additions:

1) **9.1** **Macroscopic Examination:**

Change cervix and uterine body (two sections) to cervix and uterine body (one longitudinal section)

2) **9.3** **Microscopic Examination:**

Change cervix and uterine body (two sections) to cervix and uterine body (one longitudinal section)

C. Reasons for Protocol Modifications:

1 & 2) The procedure for sectioning the cervix and uterine body has been revised.

Approved By:

[redacted]

Sponsor Representative — 3 January 2005 Date

Prepared By:

WIL Research Laboratories, LLC

[redacted]

Study Director — 12/21/2004 Date

[redacted]

Director, Developmental and Reproductive Toxicology — 12-21-04 Date

Study Number: WIL-187042

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor Study No.: 04-027

A. Title of Study:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Addition:

1) **3. STUDY SCHEDULE:**

Proposed Experimental Start Date:	November 26, 2004
Proposed Experimental Termination/Completion Date:	December 18, 2004
Proposed Audited Report Date:	February 25, 2005

2) **5.4 Number on Study:**

The second sentence is replaced as follows:

The immature females were 3-5 days old upon receipt.

C. Reasons for Protocol Modifications:

1) The Proposed Experimental Start Date and Proposed Experimental Termination/Completion Date have been revised and the Proposed Audited Report Date has been added.

2) The age of the immature females upon receipt has been corrected.

Approved By:

[redacted]

Sponsor Representative

23 Nov. 2004
Date

Prepared By:
WIL Research Laboratories, LLC

[redacted]

Study Director

11/22/2004
Date

[redacted]

Director, Developmental and Reproductive Toxicology

11/22/2004
Date

PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 04-027

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]

2.2 WIL Study Director:

[redacted]

2.3 WIL Deputy Director:

[redacted]

2.4 WIL Departmental Responsibilities:

[redacted]
President, Director

[redacted]
Director, Developmental and
Reproductive Toxicology

[redacted]
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology

[redacted]
Operations Manager, Developmental,
Reproductive and Neurotoxicology

[redacted]
Director, Informational Systems

[redacted]
Director, Regulatory Affairs and Services

[redacted]
Manager, Gross Pathology and
Developmental Toxicology Laboratory

[redacted]
Manager, Quality Assurance

[redacted]
Director, Metabolism and Analytical Chemistry

[redacted]
Clinical Veterinarian

[redacted]
Assistant Director, Anatomic Pathology

3 STUDY SCHEDULE:

Proposed Animal Receipt Date: (Experimental Starting Date)	November 9, 2004
Proposed Experimental Start Date:	November 25, 2004
Proposed Experimental Termination/Completion Date:	December 17, 2004
Proposed Audited Report Date:	To be determined.

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

4.1.1 Lot Number:

[redacted]

4.1.2 Purity:

100%

4.1.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.1.4 Physical Description:

Brown, viscous liquid.

4.1.5 Storage Conditions:

Store at ambient conditions under nitrogen.

4.1.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.1.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) should accompany the test article upon arrival at the laboratory.

4.2 Identification:

[redacted]

4.2.1 Lot Number:

[redacted]

4.2.2 Purity:

100%

4.2.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.2.4 Physical Description:

Black, viscous liquid.

4.2.5 Storage Conditions:

Store at ambient conditions under nitrogen.

4.2.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.2.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) should accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Sprague-Dawley Crl:CD®(SD)IGS BR

5.3 Source:

Charles River Laboratories
Portage, Michigan

5.4 Number on Study:

105 Females (maximum of 130 immature females and 13 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 4-6 days old upon

receipt. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and discarded.

5.5 Body Weight Range:

At randomization: 30-50 g. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal eartag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed-O'Cobs®). Following randomization, the juvenile female animals will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL Standard Operating Procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol-specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals approximately 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Each of 7 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, disposable plastic dosing cannulae will be used for the oral administration by gavage. Any losses or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[redacted]	60	12	5	15
3	[redacted]	250	50	5	15
4	[redacted]	1000	200	5	15
5	[redacted]	60	12	5	15
6	[redacted]	250	50	5	15
7	[redacted]	1000	200	5	15

7.4.2 Vehicle Control Article:

Corn oil

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 of age and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Article Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity will be collected prior to the initiation of test article administration. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Two of the three samples will be sent to [redacted] c/o [redacted] for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control

group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. The methods employed will be one or more of the following:

[redacted] SOP #ME-125

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted] shall be notified in advance of shipping by telefax at [redacted] phone at [redacted] or by email [redacted]. This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will be observed also approximately one hour following dosing and the observations will be recorded. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded.

7.6.2 Body Weights:

Daily body weights will be recorded individually (to the nearest 0.1 gram PND 22-42, with the exception of the weight collected the day prior to dosing and the final body weight) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized as described above.

8 HOROMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH) Thyroxine (T_4)

9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized *in extremis*. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. The following tissues will be collected and placed in 10% neutral-buffered formalin:

Cervix and Uterine Body (two sections)	Thyroid
Ovaries	Uterine horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized *in extremis*.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in the same sequence as which dosing occurred. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper

(ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

9.2.2 Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Ovaries and oviducts
Kidneys	Pituitary gland
Liver	Thyroid

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 Microscopic Examination:

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination. The vagina, ovaries, and thyroid from each animal will be similarly preserved with the uterus.

Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

Ovaries	Thyroid
Cervix and Uterine Body (two sections)	Uterine Horns (four sections per horn)

10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age of first estrous and estrous cycle length will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of EPA/TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Good Laboratory Practice Regulations [C (97) 186/Final]. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

Dosing formulation and test article concentration analyses will be conducted following the Standard Operating Procedures of the performing laboratory and in accordance with GLPs. Quality Assurance monitoring of these analyses for SOP and GLP compliance is the responsibility of the performing laboratory. Inspection reports will be supplied to the Study Director. Upon completion of the prescribed activities and submission of the results to the Sponsor and Study Director, the performing laboratory will provide a signed Quality Assurance Statement to the Sponsor (copy to the Study Director). The results will be included in the report.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional paper copies of the final report may result in additional charges.

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory Standard Operating Procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via email on 10/29/2004.
Date

[redacted]

5 November 2004
Date

Team Leader, Toxicology Testing

WIL Research Laboratories, LLC

[redacted]

11/4/2004
Date

Study Director

[redacted]

11/4/2004
Date

Director, Developmental and
Reproductive Toxicology

ABBREVIATED FINAL REPORT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [ ] AND [ ]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187043

COMPANY SANITIZED

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

14 April 2005

STUDY COMPLETION DATE

1 August 2007

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

05-002

SPONSOR

[ ]
[ ]

COMPLIANCE STATEMENT

This study, designated WIL-187043, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 160), 16 October 1989; the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor. Stability of the test article in the dosing formulations was not tested. However, in the professional judgment of the sponsor, the formulations were stable under the conditions of this study because the test article is intended for use at high temperatures under oxidative conditions.

_____ _____

[ ]
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Date

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] or [ ], in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to 3 groups each of 15 Crl:CD®(SD) immature female rats. Dosage levels for each test article were 60, 250 and 1000 mg/kg/day, and the dose volume was 5 mL/kg for all groups. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director.

Dosing procedures were performed from 26 May through 16 June 2005, when the animals were 22-41 days of age; the study start was staggered, based on age. At the initiation of dose administration, body weights ranged from 32.1 g to 54.6 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[ ]	60	12	5	15
3	[ ]	250	50	5	15
4	[ ]	1000	200	5	15
5	[ ]	60	12	5	15
6	[ ]	250	50	5	15
7	[ ]	1000	200	5	15

Due to spacing constraints, the dose group names for the vehicle control and the 60, 250 and 1000 mg/kg/day [ ] and [ ] groups are presented on the tables and

WIL-187043 [ ] and [ ]
[ ] 05-002

figures as corn oil, [ ]/60, [ ]/250, [ ]/1000, [ ]/60, [ ]/250 and [ ]/1000.

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (100% pure corn oil, exp. date: 6 April 2006) was dispensed into a storage container and stirred throughout use. The [ ] and [ ] dosing formulations were prepared as follows. [ ] was heated to 35°C to 45°C for approximately 15-30 minutes prior to preparation of the dosing formulations. Both test articles were inverted or shaken prior to use. An appropriate amount of test article for each group was weighed into a tared, calibrated glass container. A stir bar and approximately 80% of the vehicle were added to each container, and the mixture was stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The [ ] and [ ] dosing formulations were prepared weekly, divided into aliquots for daily dispensation and stored at room temperature under nitrogen. Three samples from the control group and 3 sets each of samples from the top, middle and bottom strata were collected from representative (bulk) batches of the test article formulations prior to the initiation of dose administration. Two sets of samples for concentration verification were collected from the dosing formulations on each day of preparation and 2 sets were collected on the last day of use of each preparation. Two full sets of homogeneity/stability samples and 6 full sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC, for possible future analysis. The back-up sample for the 60 mg/kg/day [ ]group pre-initiation formulation was also shipped to the sponsor. The test article formulations were determined to be homogeneous and contained the amount of test article specified in the protocol (as determined by calcium content).

Thirteen dams with 10 female pups each (130 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on 10 May 2005. The pups were 4 to 6 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam) during the acclimation period (16 to 18 days) until randomization of the pups on postnatal day (PND) 21. Following randomization, the female pups were weaned, identified by metal eartag and housed 3 per cage in plastic maternity cages. Environmental controls were set to maintain an average daily temperature of 71°F ± 5°F (22°C ± 3°C) and an average daily relative humidity of 50% ± 20%. Actual mean daily temperatures ranged from 70.4°F to 70.6°F (21.3°C to 21.4°C) and mean daily relative humidity ranged from 38.0% to 51.1%. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse osmosis-purified water were offered ad libitum.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on PND 25 (Adams et al., 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (i.e., the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia). In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A

gross necropsy was performed only on animals that were found dead. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum thyroxine (T_4) and thyroid stimulating hormone (TSH) levels. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, adrenal glands, pituitary gland and thyroid glands were weighed. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The ovaries, uterus (horns and body), cervix, vagina, pituitary gland, thyroid glands and gross lesions were retained from all females, including those found dead.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. Mean body weights, body weight changes, day of acquisition of vaginal patency, estrous cycle lengths, age at the first occurrence of estrus, serum hormone levels, luminal fluid weight and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
10 May 2005	Experimental starting date (animal receipt)
26 May 2005	Experimental start date (first day of dose administration)
26 May - 16 June 2005	Test article administration
28 June 2005	Experimental termination/completion date (last analysis of thyroid stimulating hormone)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS - [ ]

All females in the [ ]-treated groups survived to the scheduled euthanasia. There were no test article-related clinical findings at the daily examinations. At the time of dose administration, evidence of salivation (including clear material around the mouth) was noted in 1, 3 and 9 females in the 60, 250 and 1000 mg/kg/day [ ] groups, respectively; the incidence of this finding was greatest in the 1000 mg/kg/day [ ] group. One hour following dose administration, evidence of salivation (including clear material around the nose and/or mouth, ventral neck, ventral abdomen) was observed in the 1000 mg/kg/day [ ] group. These findings were not suggestive of systemic toxicity because none persisted to the daily observations on the following day. Therefore, although these findings were considered test article-related, they were not considered adverse.

No test article-related effects on mean body weights or body weight gains were noted in the 60, 250 and 1000 mg/kg/day [ ] groups. The only statistically significant ($p<0.05$) differences from the control group values were increases in mean body weight gain during PND 26-27 (250 mg/kg/day [ ] group) and PND 35-36 (60 mg/kg/day [ ] group).

Vaginal patency in the 250 and 1000 mg/kg/day [ ] groups was achieved earlier than in the control group; the differences were significant ($p<0.01$). Mean ages of attainment were 33.5, 32.8, 29.9 and 27.2 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. The values in the 250 and 1000 mg/kg/day [ ] groups were below the minimum mean value in the WIL historical control data (31.7 days). Because the females were younger on the day vaginal patency was observed, mean body weights at the age of attainment of vaginal patency in the 250 and 1000 mg/kg/day [ ] groups were lower (statistically significant, $p<0.01$) than the control group value. The changes in these parameters were consistent with an interpretation of estrogenic effects resulting from the test article.

No differences in mean estrous cycle length were observed when the [ ]-treated groups were compared to the control group. Estrous cycle length could not be determined for 2, 5, 1 and 3 females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively, due to incomplete estrous cycles; estrous cycle lengths in females of this age are highly variable. The ages of the first occurrence of estrus in the 60, 250 and 1000 mg/kg/day [ ] groups (33.5, 33.1 and 35.8 days of age, respectively) were similar to that in the control group (35.5 days of age); the differences were not statistically significant. While vaginal patency was observed in all females in the 1000 mg/kg/day [ ] group by 29 days of age (the mean age at attainment was 6 days earlier than that observed in the control group), the age at the first occurrence of estrus in this group was PND 38 or later for 6 females (compared to 3 females in the control group). In addition, 2 females in the 1000 mg/kg/day [ ] group had no occurrence of estrus prior to euthanasia (compared to none in the control group), and 1 of these 2 females was in persistent diestrus for 16 days.

Mean total T_4 levels in the 60, 250 and 1000 mg/kg/day [ ] groups were increased by approximately 31%, 29% and 44%, respectively, compared to the control group value. The differences were statistically significant ($p<0.05$ or $p<0.01$). There was no dose-response relationship between the 60 and 250 mg/kg/day groups. The mean TSH

level in the 1000 mg/kg/day [ ] group was also 36% increased ($p<0.05$) compared to the control group value. These increases were considered test article-related; however, no effects on mean absolute and relative (to final body weight) thyroid gland weights were noted in this group. Mean TSH levels in the 60 and 250 mg/kg/day [ ] groups were similar to the control group value.

Test article-related reductions in mean absolute and relative (to final body weight) uterus (wet and blotted) weights and mean absolute ovary/oviduct weight were observed in the 1000 mg/kg/day [ ] group when compared to the control group values. The differences in mean absolute and relative blotted uterus and absolute ovary/oviduct weights were statistically significant ($p<0.05$ or $p<0.01$). The mean absolute weights for the wet and blotted uterus and ovary/oviducts were 26%, 30% and 14%, respectively, lower than the control group values. The mean relative ovary/oviduct weight in the 1000 mg/kg/day [ ] group was similar to that in the control group. Mean relative liver weight in the 1000 mg/kg/day [ ] group was increased compared to the control group value. The difference was statistically significant ($p<0.01$); however, no statistically significant differences or dose-related trends were evident when the absolute liver weights were evaluated. No test article-related or statistically significant differences in organ weights were observed in the 60 and 250 mg/kg/day [ ] groups. Luminal fluid weights in the [ ]-treated groups were highly variable; no statistically significant differences from the control group were observed for these data, and no dose-related trends were evident.

1.6. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in estrogenic effects in the 250 and 1000 mg/kg/day groups, as evidenced by early attainment of vaginal patency. However, a delay in the first occurrence of estrus was noted in the 1000 mg/kg/day [ ] group. The decreased mean ovary/oviduct and uterus (wet and blotted) weights at 1000 mg/kg/day [ ] were also attributed to test article administration. Mean total T_4 levels were increased in

the 60, 250 and 1000 mg/kg/day [ ] groups, and mean TSH level in the 1000 mg/kg/day [ ] group was increased. However, no effects on thyroid gland weights were noted at any dosage level.

1.7. RESULTS - [ ]

Female nos. 83683-10 (34 days of age) and 83680-06 (26 days of age) in the 1000 mg/kg/day [ ] group were found dead approximately 45 minutes following administration of the 13th and 5th doses, respectively. Clinical findings prior to death, consisting of salivation prior to dose administration and clear material around the mouth 1 hour following dose administration (30-33 days of age), were noted only for female no. 83683-10; these findings were also observed in surviving females in all [ ]-treated groups and were not considered related to the death. These females had no internal findings at necropsy. However, because these deaths occurred at the highest dosage level and survival was unaffected in the control group, the mortality at 1000 mg/kg/day [ ] was attributed to the test article. Female no. 83689-09 in the 60 mg/kg/day [ ] group was found dead at 31 days of age 1 hour and 15 minutes following administration of the 10th dose. This animal had no clinical findings prior to death; at necropsy, dark red discoloration of the lungs was noted. Because no deaths were noted in the 250 mg/kg/day [ ] group, the death at 60 mg/kg/day [ ] was not considered test article-related. All other animals survived to the scheduled euthanasia.

Salivation was observed prior to dose administration in 1, 4 and 11 females in the 60, 250 and 1000 mg/kg/day [ ] groups, respectively. Evidence of salivation (clear material on the ventral neck and/or around the nose and/or mouth) was also observed in the 250 and 1000 mg/kg/day [ ] groups 1 hour following test article administration; the incidence was markedly increased in the 1000 mg/kg/day [ ] group. These findings were not suggestive of systemic toxicity because they generally did not persist to the daily examinations on the following day. Therefore, the salivation-related findings were attributed to the test article but were not considered adverse. At the daily examinations, 3 females in the 1000 mg/kg/day [ ] group were noted with masses on the head, neck and/or thorax, beginning at 32-36 days of age. Because the

affected females survived to the scheduled euthanasia, macroscopic evaluation of the masses was not conducted; the relationship to test article administration is unclear.

No test article-related effects on mean body weights or body weight gains were noted in the 60, 250 and 1000 mg/kg/day [ ] groups. The only statistically significant ($p<0.05$) difference from the control group was an increase in mean body weight gain during PND 26-27 in the 60 mg/kg/day [ ] group.

Vaginal patency was achieved slightly later in the 1000 mg/kg/day [ ] group than in the control group. Female no. 83687-04 in this group did not achieve patency before the scheduled euthanasia at 42 days of age. Mean ages of acquisition were 33.5, 33.6, 34.3 and 35.5 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. None of the differences from the control group were statistically significant. Since females in the 1000 mg/kg/day [ ] group were slightly older on the day vaginal patency was observed, mean body weight on the day of attainment of vaginal patency was also higher (statistically significant, $p<0.01$) than the control group value. The delay in attainment of vaginal patency in the 1000 mg/kg/day [ ] group was considered to be test article-related. The mean ages of attainment of vaginal patency in the 60 and 250 mg/kg/day [ ] groups were similar to the control group value.

Because animals were older on the day of attainment of vaginal patency in the 1000 mg/kg/day [ ] group, the first occurrence of estrus in this group was also later (37.2 days of age) than that of the control group (35.5 days of age). The difference was not statistically significant. Mean estrous cycle length in the 1000 mg/kg/day [ ] group (6.3 days) was increased compared to the control group value (4.8 days); the difference was statistically significant ($p<0.01$). However, only 4/15 females in this group had at least 1 complete cycle. One female in this group was in diestrus for 10 consecutive days. The delay in the first occurrence of estrus and the increase in mean estrous cycle length in the 1000 mg/kg/day [ ] group were considered to be test

article-related. Mean estrous cycle length and the age of first occurrence of estrus were unaffected by test article administration in the 60 and 250 mg/kg/day [ ] groups.

Mean T_4 and TSH levels in the 60, 250 and 1000 mg/kg/day [ ] groups were similar to the control group values. No statistically significant differences or dose-related trends were evident.

Mean absolute and relative (to final body weight) liver weights in the 1000 mg/kg/day [ ] group were increased (statistically significant, $p<0.01$) compared to the control group values. These increases were considered test article-related. No other test article-related differences in organ weights (absolute or relative to final body weight) were observed in the [ ]-treated groups. Luminal fluid weights were highly variable; however, no statistically significant differences in mean luminal fluid weights were observed in the [ ]-treated groups, and no dose-related trends were evident.

1.8. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in mortality and delays in the age of attainment of vaginal patency and the first occurrence of estrus, as well as an increase in mean estrous cycle length at 1000 mg/kg/day. Because of the delay in vaginal patency at 1000 mg/kg/day [ ], only 4/15 females had at least 1 complete estrous cycle prior to the scheduled euthanasia at 42 days of age. Increases in mean absolute and relative liver weights were also observed in this group.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____
[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____
[ ] Date
Senior Study Analyst

Report Reviewed By:

_____ _____
[ ] Date
Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

[ ]	Manager, Clinical Pathology
[ ]	Senior Operations Manager, Vivarium
[ ]	Manager, Gross Pathology and Developmental Toxicology Laboratory
[ ]	Group Manager, Formulations Laboratory
[ ]	Director, Metabolism and Analytical Chemistry
[ ]	Operations Manager, Developmental, Reproductive and Neurotoxicology and the Formulations Laboratory
[ ]	Manager, Reporting and Regulatory Technical Services

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
01-Jun-2005	Vaginal Perforation	01-Jun-2005	25-Jul-2005	[ ] [ ]
13-Jul-2005, 14-Jul-2005, 15-Jul-2005, 18-Jul-2005	Study Records (I-1)	18-Jul-2005	25-Aug-2005	[ ]
13-Jul-2005, 14-Jul-2005, 15-Jul-2005, 18-Jul-2005	Study Records (I-2)	18-Jul-2005	25-Aug-2005	[ ]
13-Jul-2005, 14-Jul-2005, 15-Jul-2005, 18-Jul-2005	Study Records (I-3)	18-Jul-2005	25-Aug-2005	[ ]
14-Jul-2005, 15-Jul-2005, 18-Jul-2005	Study Records (N-1)	18-Jul-2005	25-Aug-2005	[ ]
27-Jul-2005, 28-Jul-2005	Study Records (Rx-1)	28-Jul-2005	25-Aug-2005	[ ]
01-Aug-2005, 02-Aug-2005	Study Records (C-1)	02-Aug-2005	22-Sep-2005	[ ]
01-Aug-2005, 02-Aug-2005	Study Records (C-2)	02-Aug-2005	22-Sep-2005	[ ]
06-Aug-2005, 07-Aug-2005, 08-Aug-2005, 09-Aug-2005, 11-Aug-2005	Draft Report	11-Aug-2005	22-Sep-2005	[ ]

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Parts 160 and 792), the OECD Principles of Good Laboratory Practice, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol with the following exceptions. The data located in Appendices A

(Certificates of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

[ ] Associate Compliance Specialist

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

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5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 5.3** states that animals would be supplied by Charles River Laboratories, Portage, Michigan. Animals were supplied by the Raleigh, North Carolina facility of Charles River Laboratories.
- **Protocol Section 5.7** states that the pups would be identified by tail tattoo. At the time of randomization, each pup was identified by a unique Monel® eartag in addition to the tail tattoo that was applied following receipt.
- **Protocol Section 6.1** states that following weaning, the juvenile females would be housed 3 per cage in plastic maternity cages. Documentation of triple-housing was not recorded.
- **Protocol Section 6.4** states that animals would be offered food ad libitum during the study. On the morning of 16 May 2005 (during the acclimation period, when pups were 10-12 days old), all animals, with the exception of 1 female, were without food. It could not be determined how long the animals were without food; all animals were given 2 food jars on 16 May 2005. The dams and pups were examined by a veterinarian, and no abnormalities were noted.
- **Protocol Section 7.5.1** states that any special procedures required for formulation would be documented. The sponsor-supplied instructions required that the dosing aliquots would be purged with nitrogen. No documentation of purging could be located for the aliquots dispensed on 2 and 8 June 2005 (used for dose administration on 2-8 June and 9-16 June 2005, respectively).
- **Protocol Section 7.6.2** states that individual daily body weights would be recorded (to the nearest 0.1 gram, with the exception of the weight collected on the day prior to dose administration and the final body weight) beginning 1 day prior to initiation of test article administration. However, individual body weights were recorded to the nearest 0.1 gram on the day prior to test article administration.
- **Protocol Section 7.6.4** states daily vaginal lavages were to be performed to determine the stage of the estrous cycle, starting on the day vaginal perforation was observed and continuing through the day of euthanasia. Vaginal lavages were not performed on female no. 83689-04 (60 mg/kg/day [ ] group) at 39 days of age and on female nos. 83687-09, 83689-01, 83682-01 and 83685-07 (250 mg/kg/day [ ] group) at 31, 31, 32 and 32 days of age, respectively.

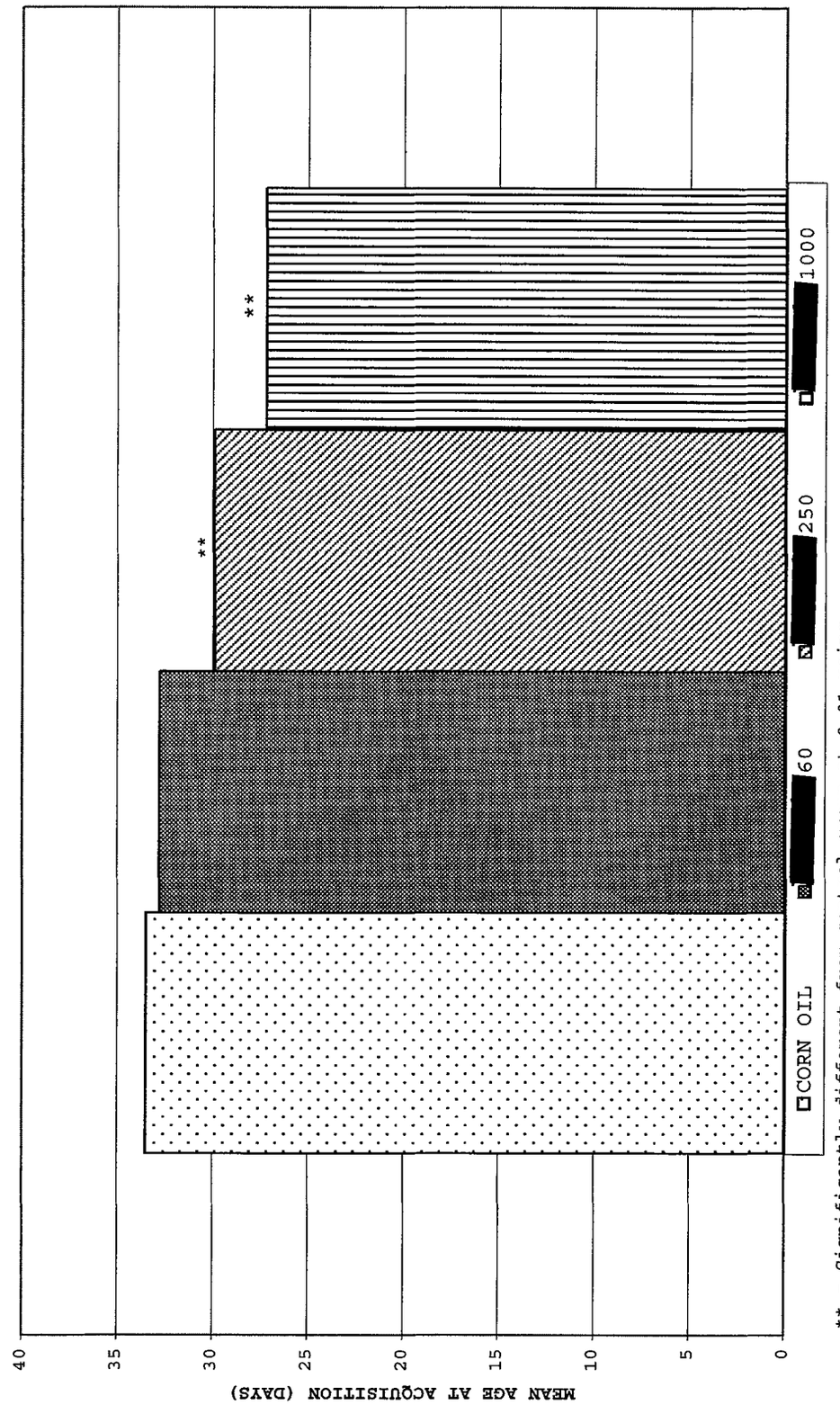
These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1-12

Draft Final Report

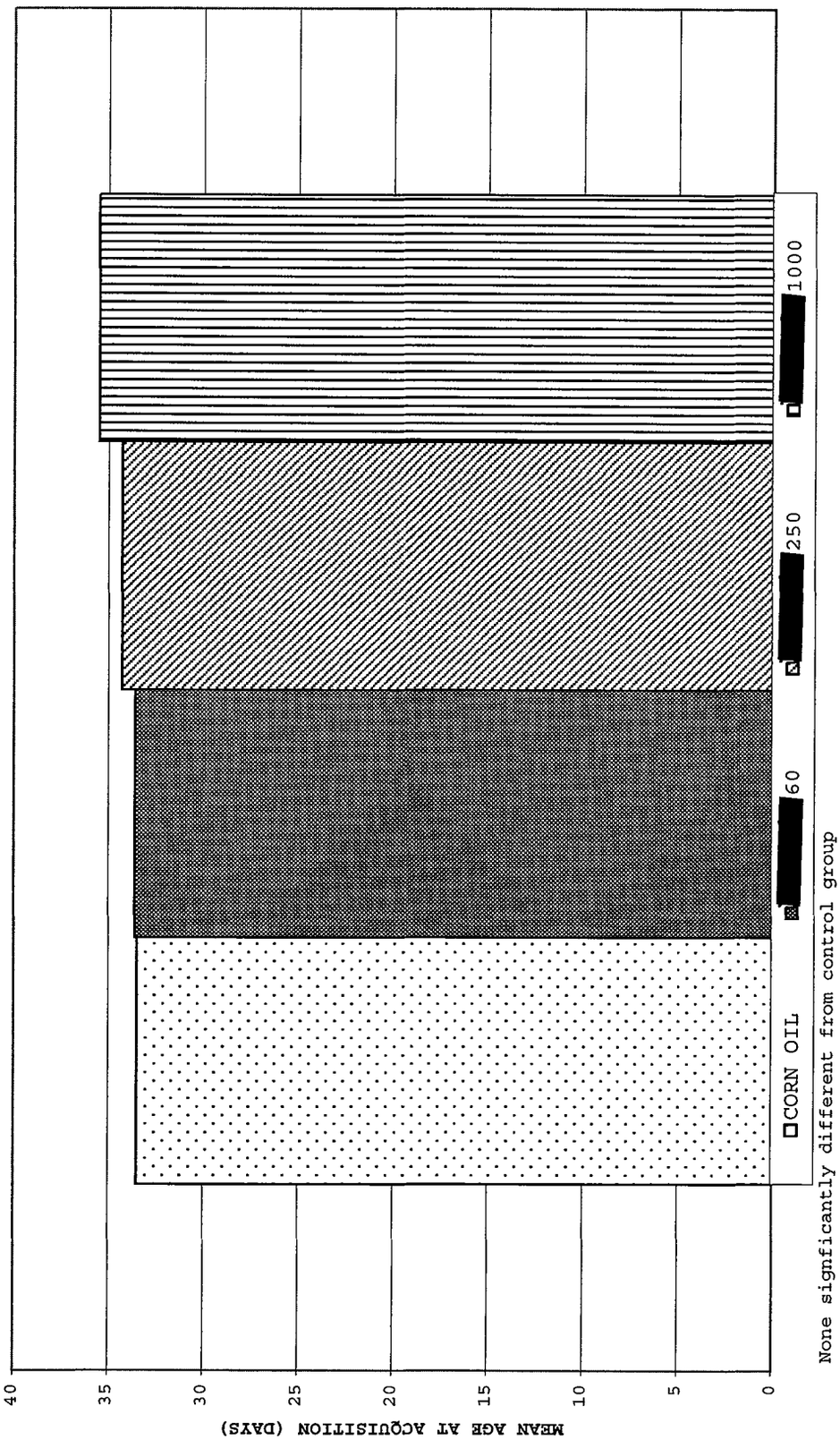
PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

FIGURE 1 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



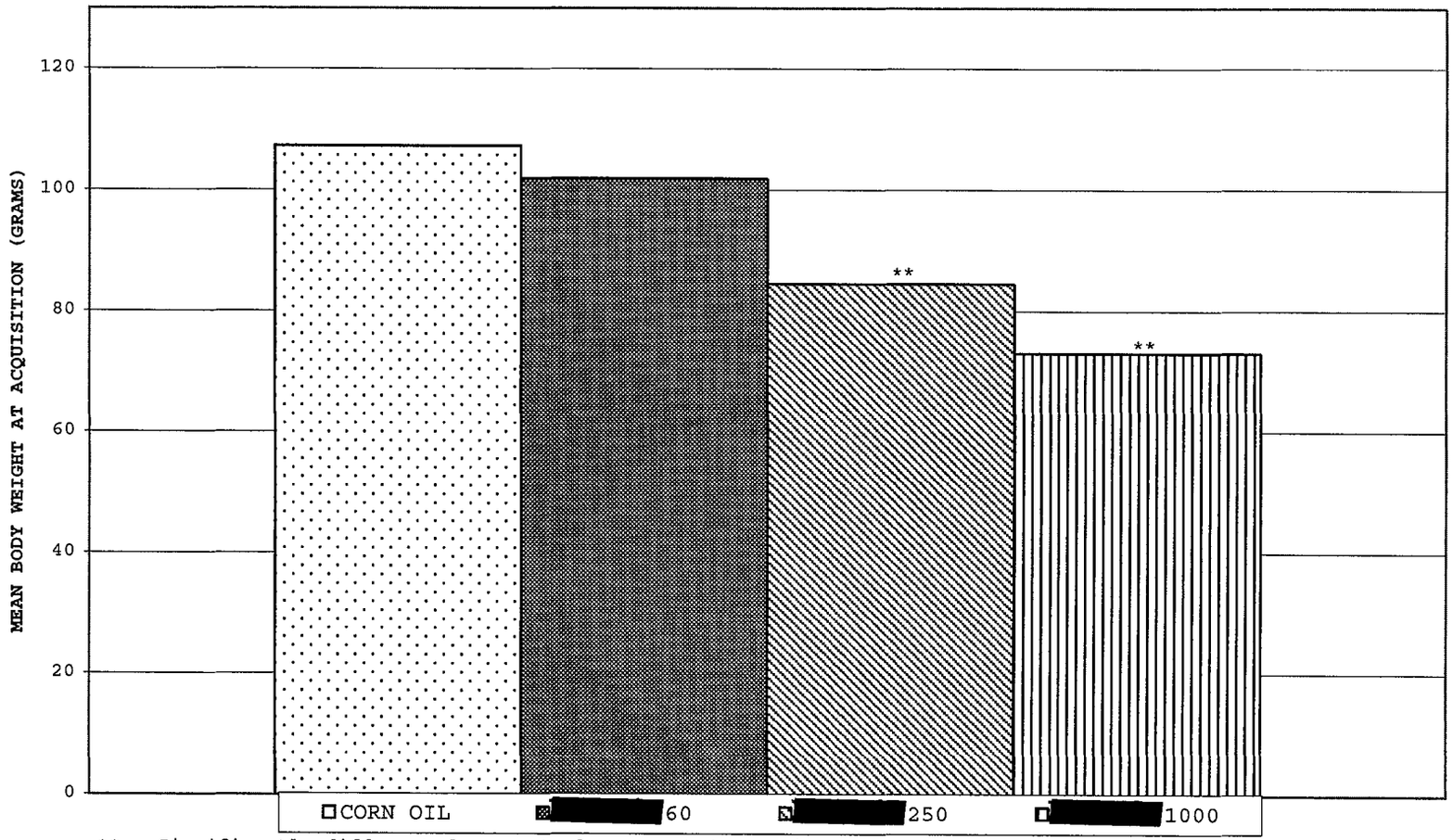
PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

FIGURE 2
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

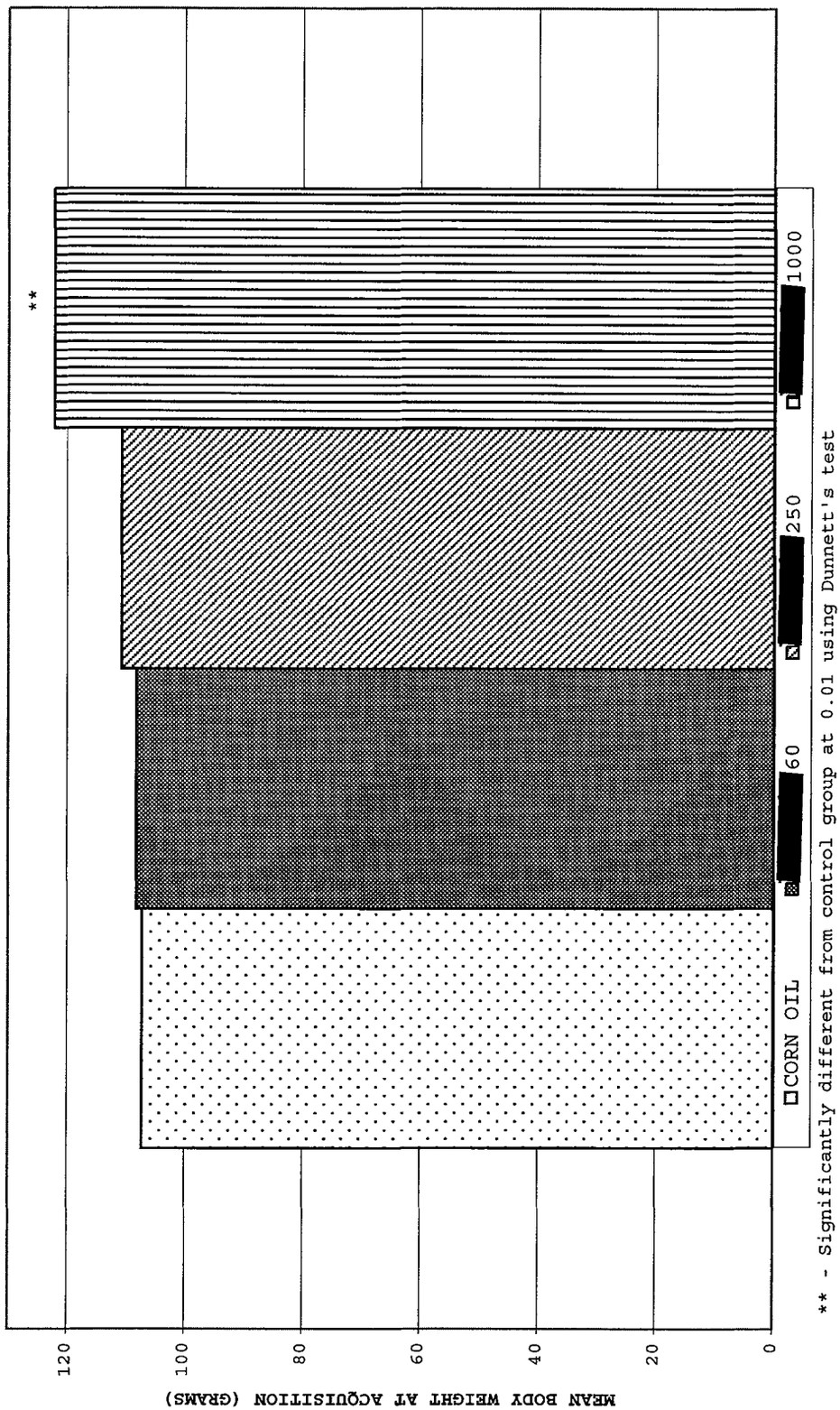
FIGURE 3 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN BODY WEIGHT (GRAMS) AT ACQUISITION OF VAGINAL PATENCY



** = Significantly different from control group at 0.01 using Dunnett's test

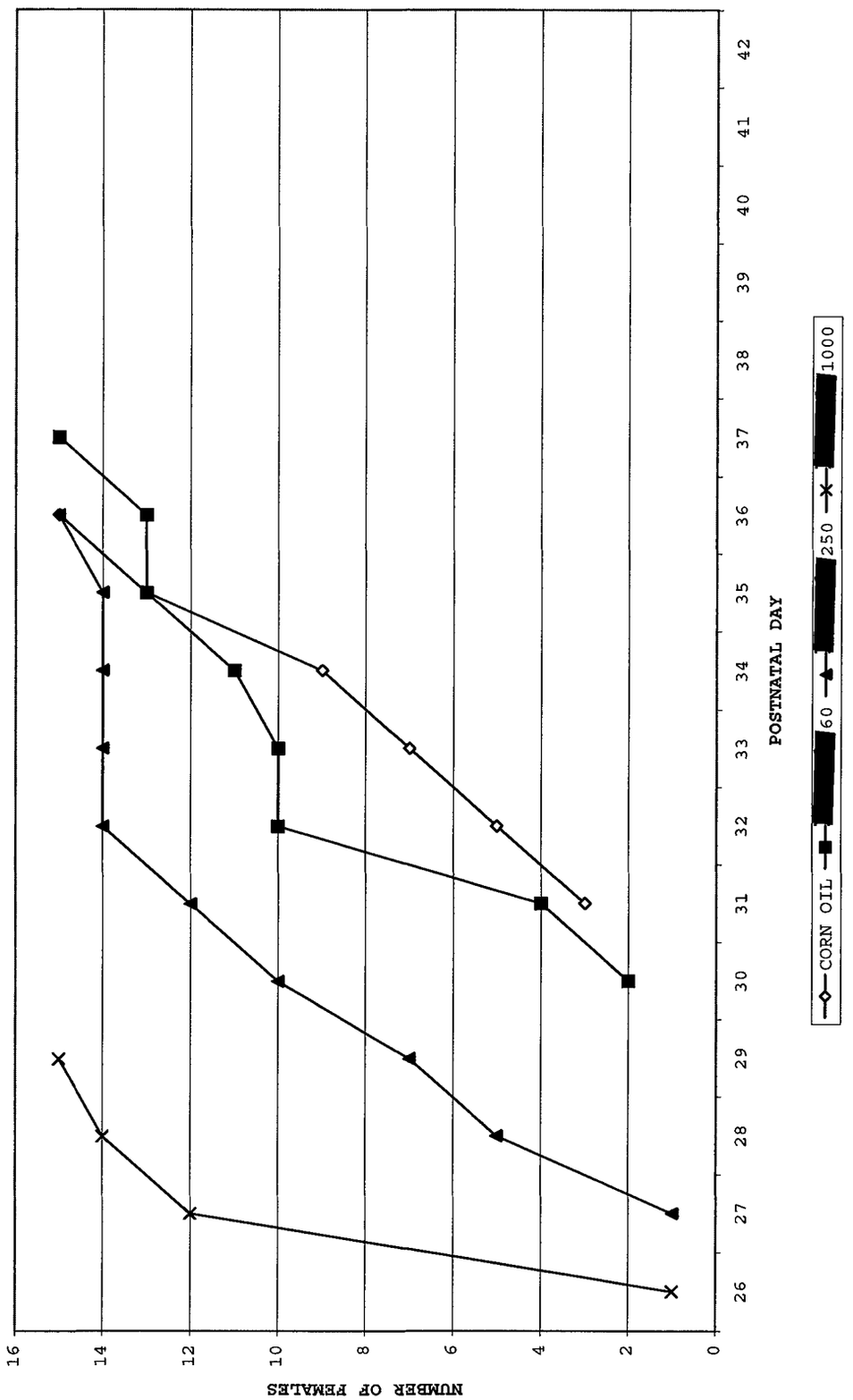
PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

FIGURE 4 [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
PUBERTAL ASSAY OF
MEAN BODY WEIGHT (GRAMS) AT ACQUISITION OF VAGINAL PATENCY



PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

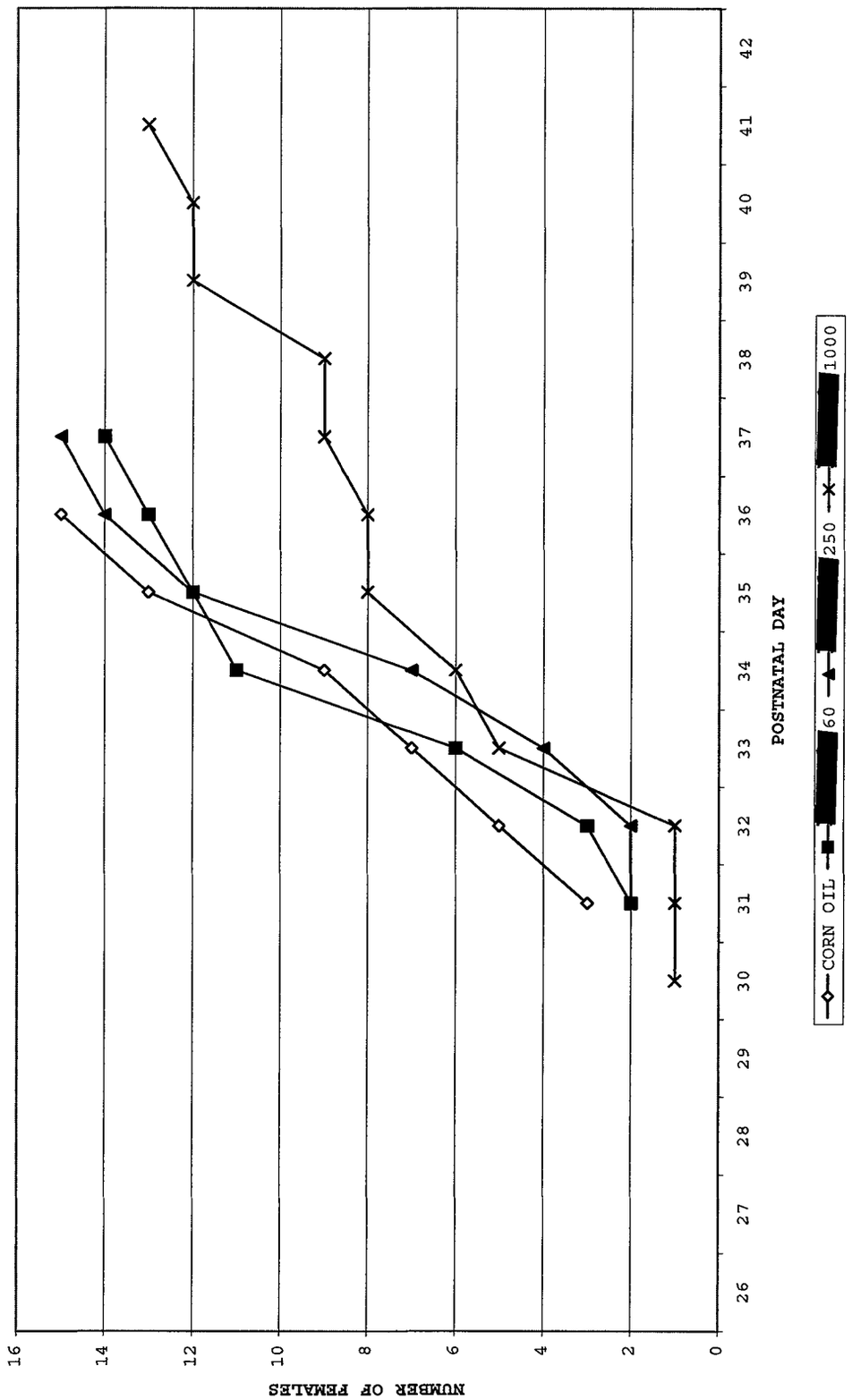
FIGURE 5 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY



PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

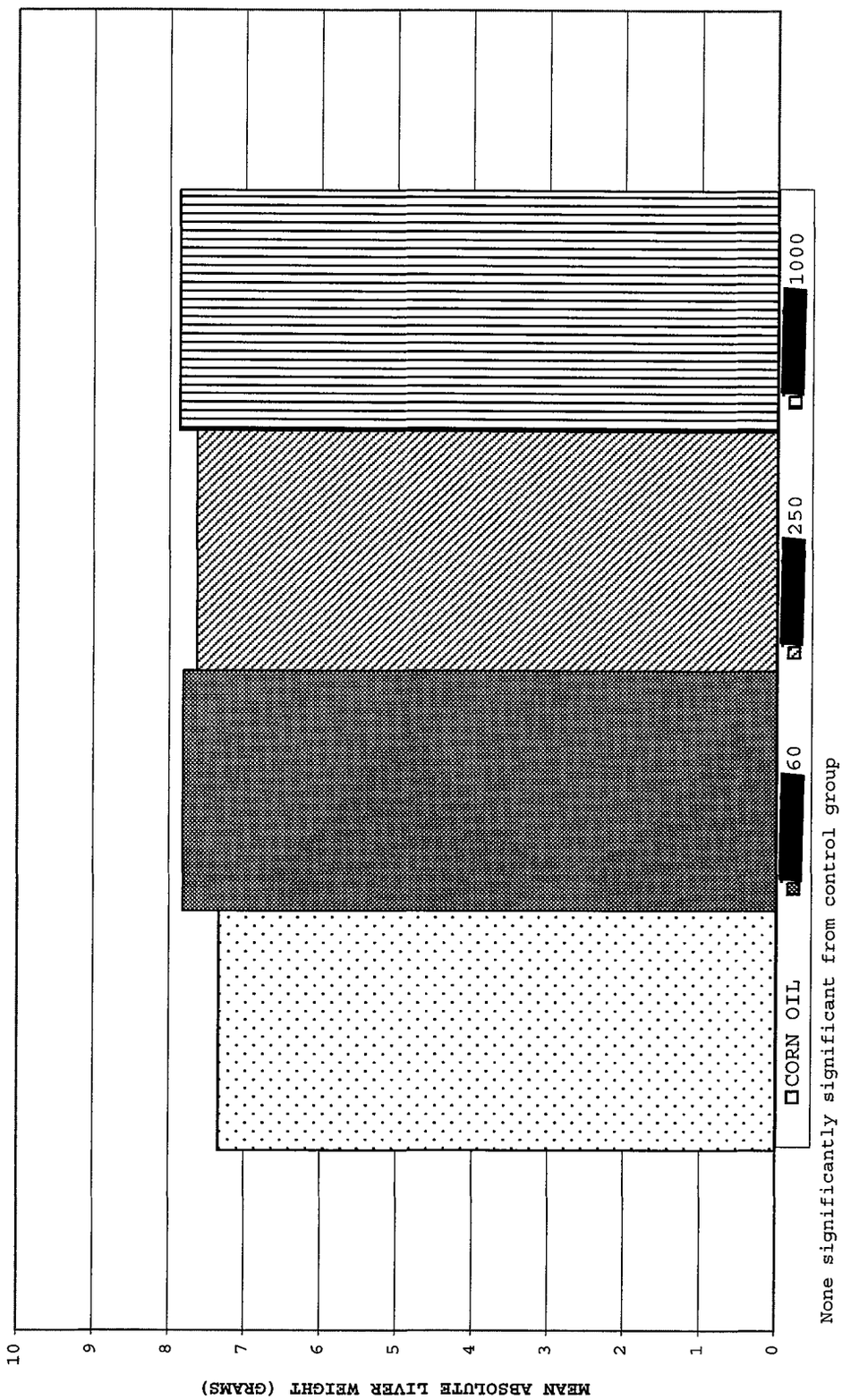
FIGURE 6 [redacted]

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY



PROJECT NO.:WIL-187043
SPONSOR:[redacted]
SPONSOR NO.:05-002

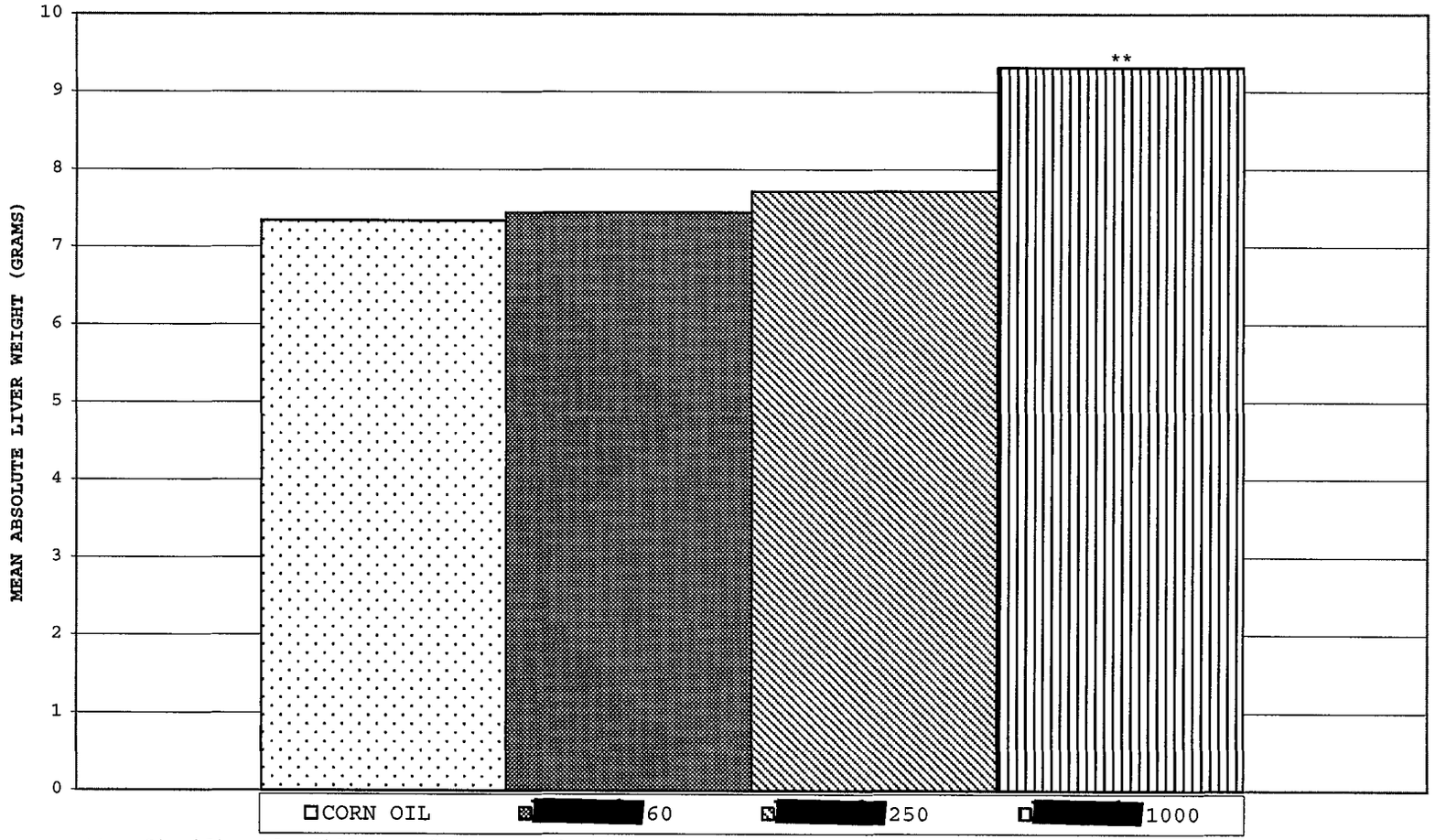
FIGURE 7
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABSOLUTE LIVER WEIGHT (GRAMS)



None significantly significant from control group

PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

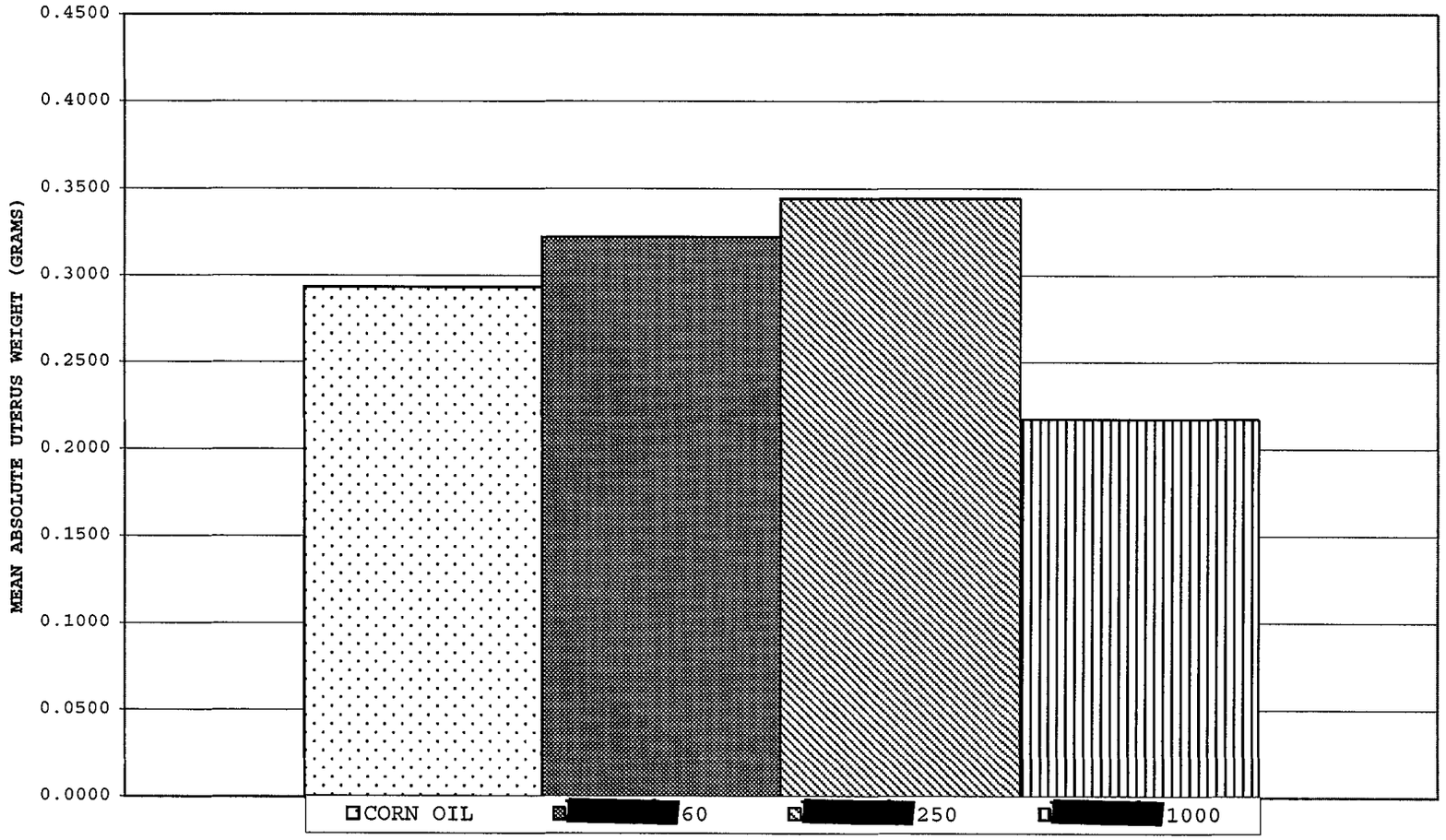
FIGURE 8 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABSOLUTE LIVER WEIGHT (GRAMS)



** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT NO.:WIL-187043
SPONSOR:[redacted]
SPONSOR NO.:05-002

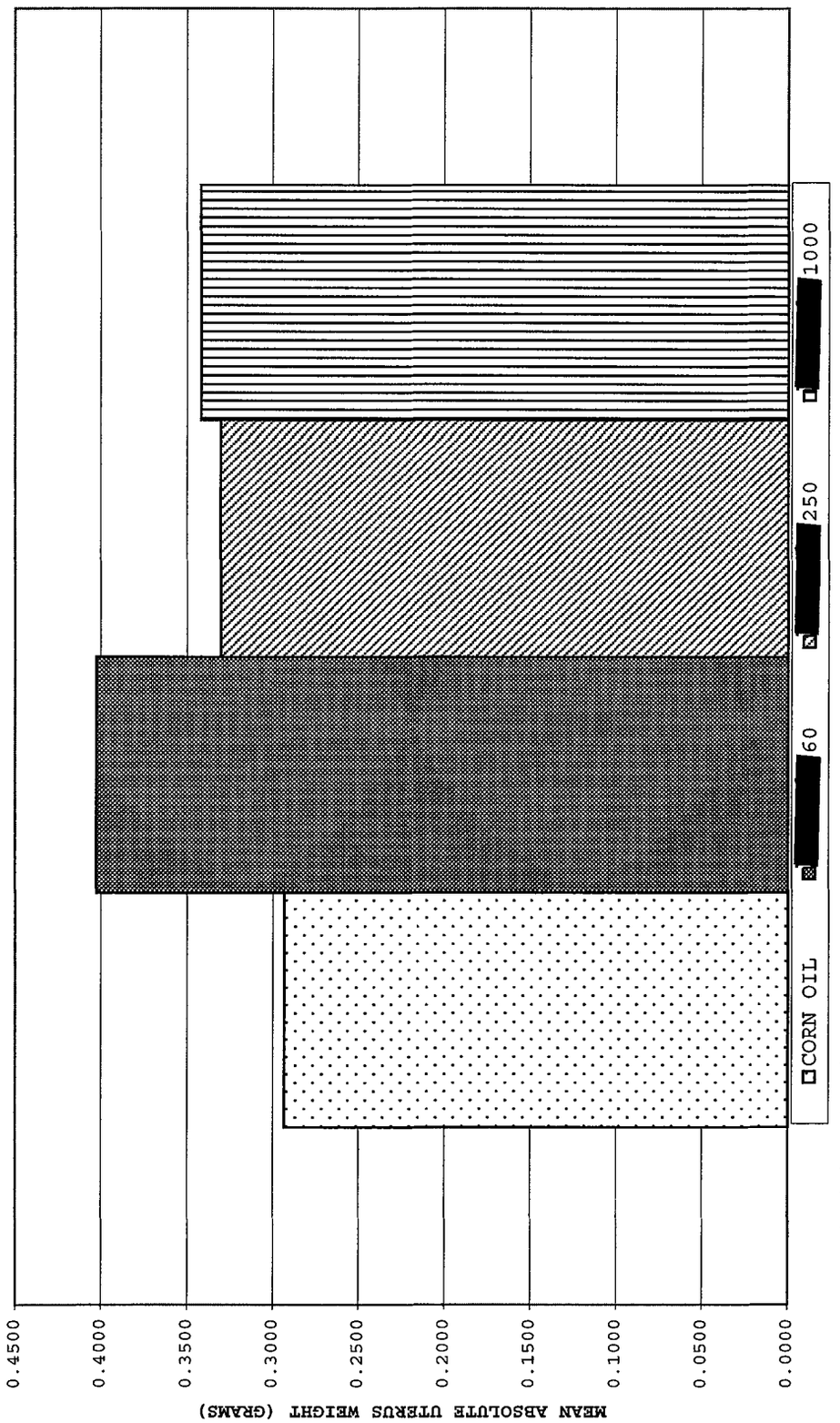
FIGURE 9 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABSOLUTE UTERUS (WET) WEIGHT (GRAMS)



None significantly different from control group

PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

FIGURE 10 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABSOLUTE UTERUS (WET) WEIGHT (GRAMS)

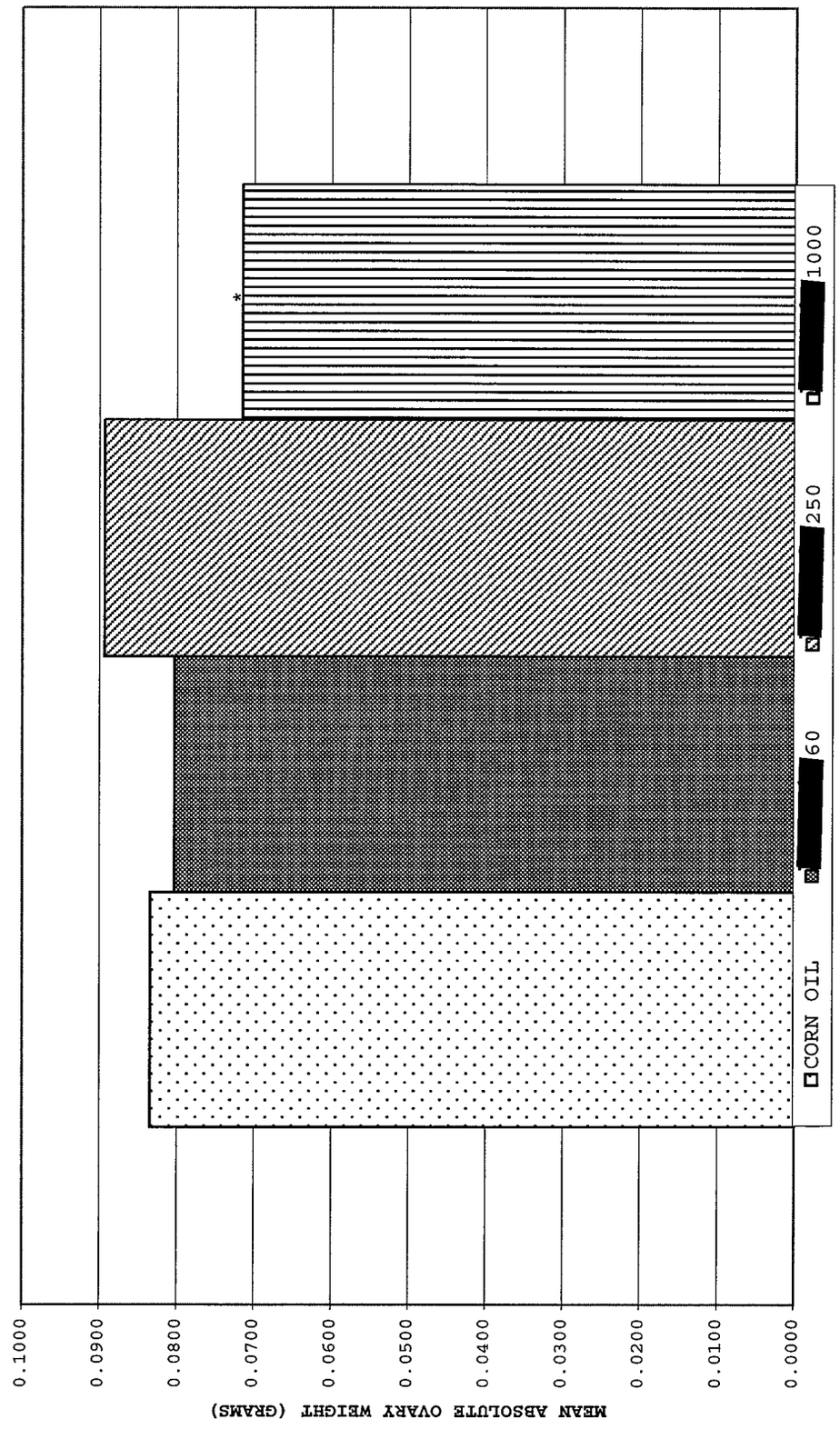


None significantly different from control group

PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

FIGURE 11 [redacted]

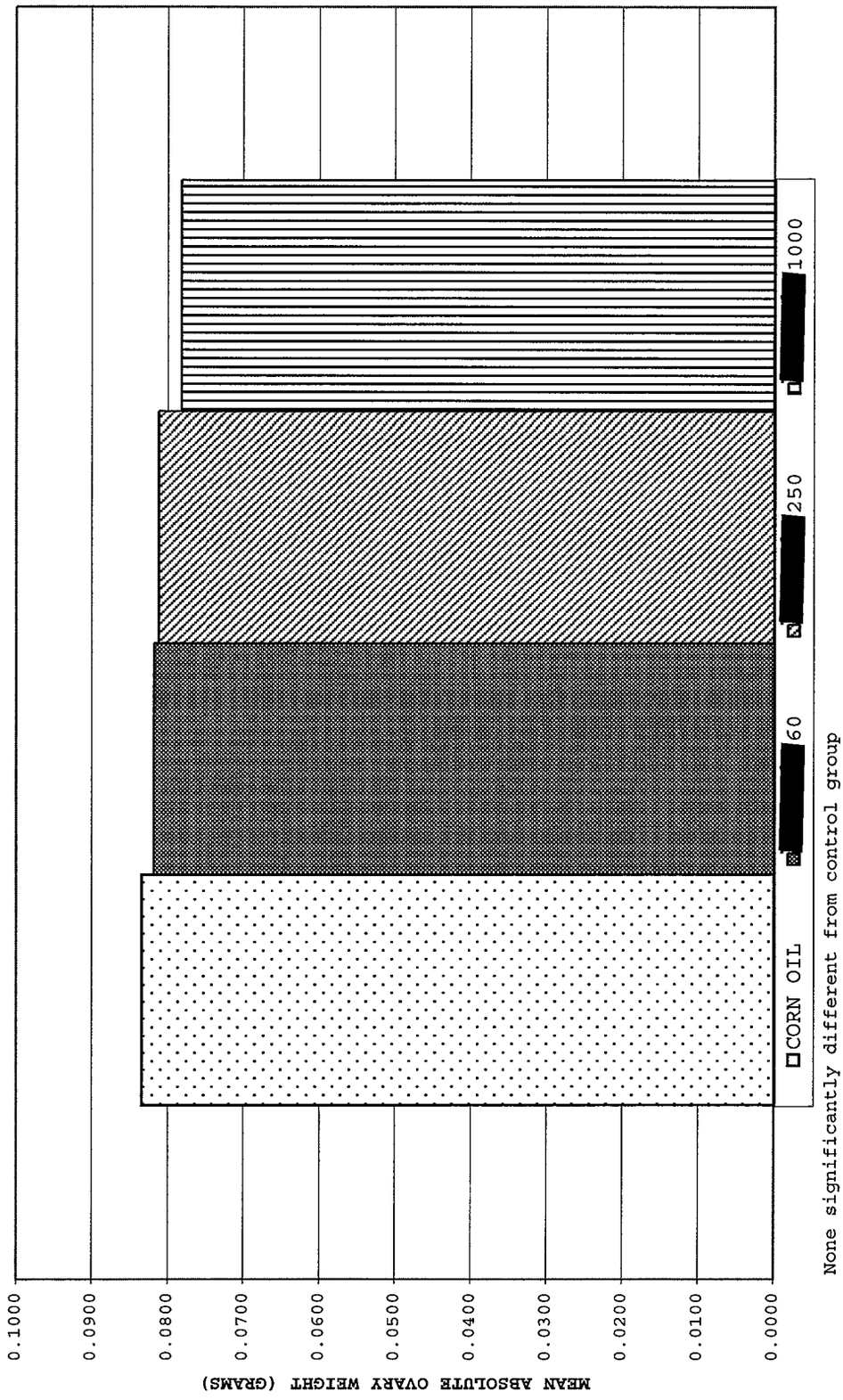
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



* = Significantly different from control group at 0.05 using Dunnett's test

PROJECT NO.:WIL-187043
SPONSOR: [redacted]
SPONSOR NO.:05-002

FIGURE 12 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



None significantly different from control group

TABLES 1-23

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TABLE 1

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SUMMARY OF SURVIVAL AND DISPOSITION
SPONSOR NO.:05-002

FEMALES

GROUP :	1				2				3				4			
PND	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
30	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
31	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
32	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
33	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
34	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
35	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
36	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
37	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
38	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
39	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
40	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
41	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15

PND = POSTNATAL DAY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000

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TABLE 1

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	5				6				7			
PND	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0
26	15	0	0	0	15	0	0	0	14	1	0	0
27	15	0	0	0	15	0	0	0	14	0	0	0
28	15	0	0	0	15	0	0	0	14	0	0	0
29	15	0	0	0	15	0	0	0	14	0	0	0
30	15	0	0	0	15	0	0	0	14	0	0	0
31	14	1	0	0	15	0	0	0	14	0	0	0
32	14	0	0	0	15	0	0	0	14	0	0	0
33	14	0	0	0	15	0	0	0	14	0	0	0
34	14	0	0	0	15	0	0	0	13	1	0	0
35	14	0	0	0	15	0	0	0	13	0	0	0
36	14	0	0	0	15	0	0	0	13	0	0	0
37	14	0	0	0	15	0	0	0	13	0	0	0
38	14	0	0	0	15	0	0	0	13	0	0	0
39	14	0	0	0	15	0	0	0	13	0	0	0
40	14	0	0	0	15	0	0	0	13	0	0	0
41	14	0	0	0	15	0	0	0	13	0	0	0
42	0	0	0	14	0	0	0	15	0	0	0	13

PND = POSTNATAL DAY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

5- [redacted]60 6- [redacted]250 7- [redacted]1000

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07/13/2005
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TABLE 2 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	05-26-05 TO 06-17-05						
GROUP:	1	2	3	4	5	6	7
NORMAL							
-NO SIGNIFICANT CLINICAL OBSERVATIONS	315/15	315/15	315/15	315/15	294/15	315/15	264/15
DISPOSITION							
-FOUND DEAD	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	2/ 2
-SCHEDULED EUTHANASIA	15/15	15/15	15/15	15/15	14/14	15/15	13/13
BODY/INTEGUMENT							
-TAIL SHEATH MISSING	0/ 0	0/ 0	0/ 0	0/ 0	10/ 1	0/ 0	0/ 0
-SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	7/ 1
-HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	8/ 1
-HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	9/ 2
-SOFT MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 20 MM	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	8/ 1
-HARD MOVEABLE MASS RIGHT LATERAL HEAD 20 MM X 20 MM X 10 MM	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	4/ 1
ORAL/DENTAL							
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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07/13/2005

TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	05-26-05 TO 06-16-05						
GROUP:	1	2	3	4	5	6	7
ORAL/DENTAL							
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
-SALIVATION PRIOR TO DOSING	0/ 0	6/ 1	4/ 3	31/ 9	1/ 1	6/ 4	23/11

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.06
07/13/2005
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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	05-26-05 TO 06-16-05						
GROUP:	1	2	3	4	5	6	7
BODY/INTEGUMENT							
-WET CLEAR MATERIAL VENTRAL NECK	0/ 0	0/ 0	0/ 0	6/ 4	0/ 0	1/ 1	20/ 5
-WET CLEAR MATERIAL VENTRAL ABDOMINAL AREA	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
EYES/EARS/NOSE							
-WET CLEAR MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	13/ 5	0/ 0	0/ 0	10/ 5
-LACRIMATION RIGHT EYE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
-LACRIMATION LEFT EYE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
-WET RED MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	1/ 1
ORAL/DENTAL							
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	1/ 1	1/ 1	88/13	0/ 0	7/ 3	118/13
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	19/10	0/ 0	6/ 5	6/ 4
-SALIVATION	0/ 0	0/ 0	0/ 0	6/ 5	0/ 0	1/ 1	1/ 1
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	3/ 2
-WET RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	2/ 2	0/ 0	0/ 0	1/ 1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
07/19/2005
R:07/19/2005

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Modified: 5/22/2006

TABLE 5

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22								
	MEAN	46.4	44.7	44.8	47.3	45.2	45.6	46.6
	S.D.	4.31	5.28	4.32	3.91	3.88	4.53	4.28
	N	15	15	15	15	15	15	15
PND 23								
	MEAN	51.8	50.2	50.0	51.7	51.1	51.5	51.1
	S.D.	4.81	6.39	4.89	4.39	4.57	4.69	4.24
	N	15	15	15	15	15	15	15
PND 24								
	MEAN	57.2	55.9	53.7	57.8	56.7	56.6	56.7
	S.D.	5.37	6.19	7.10	3.71	4.27	5.09	4.56
	N	15	15	15	15	15	15	15
PND 25								
	MEAN	62.2	60.3	56.9	62.5	61.5	61.4	61.4
	S.D.	5.42	6.30	9.51	4.00	4.06	5.37	4.59
	N	15	15	15	15	15	15	15
PND 26								
	MEAN	66.7	64.6	62.8	67.2	66.2	65.6	66.1
	S.D.	6.18	6.64	7.62	4.68	4.32	5.74	4.45
	N	15	15	15	15	15	15	15
PND 27								
	MEAN	71.3	69.7	68.3	71.4	71.9	70.7	71.7
	S.D.	6.47	7.30	7.31	4.58	4.50	6.30	4.49
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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Modified: 5/22/2006

TABLE 5

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28								
	MEAN	76.7	74.7	72.9	76.2	77.3	75.7	76.8
	S.D.	7.24	7.55	7.35	4.96	4.37	6.40	5.09
	N	15	15	15	15	15	15	14
PND 29								
	MEAN	81.9	80.1	78.4	80.9	82.4	81.0	82.5
	S.D.	7.62	7.61	7.79	5.13	4.56	6.87	4.95
	N	15	15	15	15	15	15	14
PND 30								
	MEAN	87.9	85.6	84.1	86.6	87.7	86.0	88.6
	S.D.	8.56	8.00	8.51	6.05	5.15	7.47	5.30
	N	15	15	15	15	15	15	14
PND 31								
	MEAN	93.2	91.5	89.9	91.5	93.4	92.3	94.8
	S.D.	9.08	8.30	9.30	6.06	5.84	8.26	6.05
	N	15	15	15	15	15	15	14
PND 32								
	MEAN	98.9	97.0	95.1	97.2	98.8	98.0	100.8
	S.D.	9.73	8.21	9.72	6.33	5.25	8.99	6.14
	N	15	15	15	15	14	15	14
PND 33								
	MEAN	104.4	102.4	101.2	102.5	104.2	103.6	106.9
	S.D.	10.47	8.75	9.71	6.91	5.06	9.20	5.78
	N	15	15	15	15	14	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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Modified: 5/22/2006

TABLE 5

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34								
	MEAN	109.6	108.9	106.9	107.5	109.3	109.6	112.8
	S.D.	10.44	9.26	9.92	7.43	5.26	10.46	6.00
	N	15	15	15	15	14	15	14
PND 35								
	MEAN	115.4	114.3	113.3	112.6	114.8	114.8	118.3
	S.D.	11.13	9.73	10.88	8.13	5.23	11.20	5.63
	N	15	15	15	15	14	15	13
PND 36								
	MEAN	120.3	121.3	118.2	117.8	120.6	121.5	124.1
	S.D.	11.70	10.14	11.54	8.85	5.63	12.61	5.55
	N	15	15	15	15	14	15	13
PND 37								
	MEAN	126.7	126.8	124.7	123.3	126.8	127.5	130.6
	S.D.	12.92	10.27	12.98	8.49	4.81	12.47	7.21
	N	15	15	15	15	14	15	13
PND 38								
	MEAN	131.8	132.5	130.8	127.8	130.9	132.4	135.8
	S.D.	12.82	11.73	13.42	9.43	4.93	13.11	6.70
	N	15	15	15	15	14	15	13
PND 39								
	MEAN	135.9	138.0	135.8	131.9	134.9	137.2	140.7
	S.D.	12.53	11.88	14.08	9.73	4.77	14.18	7.17
	N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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TABLE 5

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40								
	MEAN	139.5	142.1	139.9	135.7	140.4	141.7	145.5
	S.D.	13.58	12.34	13.92	10.97	6.16	14.92	7.64
	N	15	15	15	15	14	15	13
PND 41								
	MEAN	143.0	145.8	144.3	139.1	145.3	145.6	149.9
	S.D.	14.27	13.04	15.48	10.59	5.74	15.92	8.18
	N	15	15	15	15	14	15	13
PND 42								
	MEAN	148.4	150.6	149.2	142.7	149.8	150.3	153.5
	S.D.	14.45	13.61	16.00	11.20	5.53	16.10	9.28
	N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PJTBWSUv5.13
07/13/2005

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TABLE 6

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22- 23								
	MEAN	5.4	5.5	5.1	4.3	5.9	5.8	4.5
	S.D.	1.35	1.75	1.15	1.41	1.39	1.27	1.01
	N	15	15	15	15	15	15	15
PND 23- 24								
	MEAN	5.5	5.7	3.8	6.1	5.6	5.1	5.6
	S.D.	1.66	0.89	3.11	1.42	1.02	1.08	0.82
	N	15	15	15	15	15	15	15
PND 24- 25								
	MEAN	5.0	4.4	3.2	4.7	4.8	4.9	4.7
	S.D.	0.87	0.80	3.46	0.91	1.06	1.03	1.03
	N	15	15	15	15	15	15	15
PND 25- 26								
	MEAN	4.5	4.3	5.9	4.8	4.7	4.2	4.7
	S.D.	1.06	1.03	3.10	1.10	1.22	0.97	0.96
	N	15	15	15	15	15	15	15
PND 26- 27								
	MEAN	4.6	5.1	5.5a	4.1	5.7c	5.1	5.5
	S.D.	0.83	1.22	0.78	1.17	0.94	1.26	1.33
	N	15	15	15	15	15	15	14
PND 27- 28								
	MEAN	5.4	5.1	4.6	4.8	5.4	5.0	5.0
	S.D.	1.28	1.09	1.11	1.03	0.62	0.84	1.16
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
c = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28- 29	MEAN	5.2	5.4	5.5	4.7	5.1	5.3	5.7
	S.D.	1.23	0.83	1.06	1.04	1.31	1.20	1.03
	N	15	15	15	15	15	15	14
PND 29- 30	MEAN	6.0	5.5	5.8	5.6	5.3	5.0	6.1
	S.D.	1.96	1.17	1.12	1.53	1.22	1.25	1.02
	N	15	15	15	15	15	15	14
PND 30- 31	MEAN	5.3	5.9	5.8	4.9	5.7	6.2	6.2
	S.D.	1.35	0.98	1.35	0.90	1.80	1.29	1.54
	N	15	15	15	15	15	15	14
PND 31- 32	MEAN	5.7	5.4	5.2	5.7	6.3	5.7	6.1
	S.D.	1.84	0.96	1.20	1.16	1.94	1.44	1.31
	N	15	15	15	15	14	15	14
PND 32- 33	MEAN	5.5	5.5	6.0	5.3	5.4	5.7	6.1
	S.D.	1.54	1.68	1.89	1.33	0.85	1.34	1.67
	N	15	15	15	15	14	15	14
PND 33- 34	MEAN	5.2	6.5	5.7	4.9	5.1	6.0	5.9
	S.D.	2.13	1.71	1.80	1.66	1.42	1.84	1.06
	N	15	15	15	15	14	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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Modified: 5/22/2006

TABLE 6

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34- 35	MEAN	5.8	5.4	6.4	5.1	5.5	5.2	6.2
	S.D.	2.76	2.16	2.58	1.41	1.36	1.82	1.26
	N	15	15	15	15	14	15	13
PND 35- 36	MEAN	4.9	7.0a	4.9	5.3	5.9	6.7	5.8
	S.D.	2.32	1.78	1.71	2.34	2.32	1.99	2.38
	N	15	15	15	15	14	15	13
PND 36- 37	MEAN	6.5	5.5	6.5	5.4	6.2	6.0	6.5
	S.D.	2.99	1.32	2.39	2.10	1.24	1.71	2.32
	N	15	15	15	15	14	15	13
PND 37- 38	MEAN	5.1	5.7	6.1	4.5	4.1	4.9	5.2
	S.D.	1.91	2.34	1.76	1.65	2.14	1.87	2.70
	N	15	15	15	15	14	15	13
PND 38- 39	MEAN	4.1	5.4	5.0	4.1	4.0	4.8	4.9
	S.D.	1.96	1.83	1.77	2.22	2.30	2.62	2.22
	N	15	15	15	15	14	15	13
PND 39- 40	MEAN	3.7	4.1	4.1	3.9	5.5	4.5	4.8
	S.D.	2.90	2.27	2.05	2.46	2.16	2.29	1.62
	N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40- 41								
	MEAN	3.5	3.8	4.4	3.4	4.9	3.9	4.5
	S.D.	2.82	2.47	2.56	3.28	2.28	2.39	1.84
	N	15	15	15	15	14	15	13
PND 41- 42								
	MEAN	5.3	4.8	4.9	3.6	4.6	4.7	3.6
	S.D.	2.40	1.95	2.35	3.51	1.94	2.83	2.03
	N	15	15	15	15	14	15	13
PND 22- 42								
	MEAN	101.9	105.9	104.4	95.4	104.9	104.7	106.9
	S.D.	12.90	11.70	13.45	11.37	6.88	14.17	9.38
	N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.13
07/13/2005

TABLE 7

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
VAGINAL PATENCY (PND)							
MEAN	33.5	32.8	29.9b	27.2b	33.6	34.3	35.5
S.D.	1.81	2.27	2.28	0.68	1.69	1.71	3.26
N	15	15	15	15	14	15	13
BODY WEIGHT (GRAMS)							
MEAN	107.2	101.9	84.5b	73.0b	108.2	110.7	122.2d
S.D.	10.93	12.34	13.54	4.77	10.62	7.90	16.11
N	15	15	15	15	14	15	13

PND= POSTNATAL DAY
MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group at 0.01 using Dunnett's test
d = Significantly different from control group at 0.01 using Dunnett's test

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TABLE 8

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF ESTROUS CYCLE DATA

	FEMALES						
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ESTROUS CYCLE LENGTH (DAYS)							
MEAN	4.8	5.4	5.2	4.7	5.0	5.0	6.3d
S.D.	0.63	1.41	0.91	0.50	0.45	0.47	1.50
N	13	10	14	12	12	10	4
MEAN AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)							
MEAN	35.5	33.5	33.1	35.8	33.9	35.3	37.2
S.D.	2.50	2.97	2.71	4.99	1.85	2.35	3.94
N	15	15	15	13	13	15	10

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
d = Significantly different from control group 1 at 0.01 using Dunnett's test

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07/13/2005
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TABLE 9

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF SERUM HORMONE VALUES

ANALYSIS	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
				FEMALES				
TOTAL T4 (uG/dL)								
DAY 42	MEAN	3.89	5.10a	5.02a	5.61b	4.60	4.68	4.49
	S.D.	1.270	0.855	0.972	1.467	1.105	1.005	0.800
	N	15	15	15	15	14	15	13
TSH (ng/ml)								
DAY 42	MEAN	7.8	9.0	7.2	10.6a	8.7	8.2	9.0
	S.D.	1.88	2.93	2.03	3.81	2.05	1.94	3.92
	N	15	15	15	15	14	15	13

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

PCPSv5.21
07/13/2005
R:07/28/2005

TABLE 10 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:05-002

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS EXAMINED	0	0	0	0	1	0	2
LUNGS							
-DISCOLORATION, DARK RED	0	0	0	0	1	0	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	0	0	0	0	0	0	2

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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07/13/2005
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TABLE 11

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS [G]

	FEMALES						
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
UTERUS- WET (G)							
MEAN	0.2932	0.3219	0.3442	0.2173	0.4025	0.3302	0.3419
S.D.	0.07476	0.14030	0.15577	0.09582	0.16780	0.17014	0.15420
N	15	15	15	15	14	15	13
UTERUS- BLOTTED (G)							
MEAN	0.2625	0.2720	0.2863	0.1832b	0.3128	0.2760	0.2771
S.D.	0.06174	0.07330	0.07182	0.04835	0.08865	0.10380	0.09076
N	15	15	15	15	14	15	13
LUMINAL FLUID (G)							
MEAN	0.0306	0.0500	0.0579	0.0341	0.0897	0.0542	0.0648
S.D.	0.01860	0.08706	0.10278	0.05780	0.09091	0.07557	0.08067
N	15	15	15	15	14	15	13
LIVER (G)							
MEAN	7.3330	7.8122	7.6346	7.8663	7.4434	7.7157	9.3133d
S.D.	1.01308	1.05826	1.02319	0.92281	0.80657	1.08002	0.94452
N	15	15	15	15	14	15	13
KIDNEYS (G)							
MEAN	1.5682	1.5521	1.5251	1.5048	1.5772	1.6049	1.6736
S.D.	0.18232	0.18688	0.18998	0.14201	0.10218	0.16587	0.18186
N	15	15	15	15	14	15	13
OVARIES/OVIDUCTS (G)							
MEAN	0.0834	0.0803	0.0893	0.0715a	0.0818	0.0812	0.0782
S.D.	0.00977	0.00913	0.01319	0.01196	0.00848	0.01324	0.01548
N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test

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TABLE 11

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS [G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ADRENAL GLANDS (G)							
MEAN	0.0377	0.0362	0.0416	0.0385	0.0371	0.0366	0.0414
S.D.	0.00698	0.00706	0.00526	0.00641	0.00369	0.00687	0.00504
N	15	15	15	15	14	15	13
PITUITARY (G)							
MEAN	0.0079	0.0080	0.0085	0.0070	0.0082	0.0079	0.0078
S.D.	0.00178	0.00118	0.00145	0.00170	0.00123	0.00165	0.00131
N	15	15	15	15	14	15	13
THYROID GLANDS (G)							
MEAN	0.0179	0.0172	0.0154	0.0160	0.0161	0.0164	0.0166
S.D.	0.00361	0.00279	0.00390	0.00299	0.00203	0.00308	0.00343
N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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07/13/2005
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TABLE 12

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
FINAL BODY WT (G)							
MEAN	148.	151.	149.	143.	150.	150.	153.
S.D.	14.5	13.7	16.0	11.2	5.6	16.0	9.2
N	15	15	15	15	14	15	13
UTERUS- WET							
MEAN	0.197	0.217	0.228	0.152	0.268	0.215	0.222
S.D.	0.0442	0.1105	0.0873	0.0645	0.1125	0.0916	0.0960
N	15	15	15	15	14	15	13
UTERUS- BLOTTED							
MEAN	0.177	0.182	0.191	0.129b	0.209	0.181	0.180
S.D.	0.0377	0.0528	0.0406	0.0338	0.0582	0.0547	0.0553
N	15	15	15	15	14	15	13
LIVER							
MEAN	4.935	5.175	5.114	5.503b	4.959	5.125	6.066d
S.D.	0.3760	0.3865	0.3251	0.2904	0.4357	0.3578	0.3831
N	15	15	15	15	14	15	13
KIDNEYS							
MEAN	1.058	1.029	1.023	1.055	1.051	1.071	1.091
S.D.	0.0712	0.0650	0.0717	0.0582	0.0443	0.0776	0.0938
N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test

TABLE 12

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

	FEMALES						
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
OVARIES/OVIDUCTS							
MEAN	0.056	0.054	0.060	0.050	0.055	0.054	0.051
S.D.	0.0049	0.0075	0.0088	0.0081	0.0052	0.0075	0.0111
N	15	15	15	15	14	15	13
ADRENAL GLANDS							
MEAN	0.025	0.024	0.028	0.027	0.025	0.024	0.027
S.D.	0.0044	0.0040	0.0024	0.0046	0.0024	0.0033	0.0042
N	15	15	15	15	14	15	13
PITUITARY							
MEAN	0.005	0.005	0.006	0.005	0.005	0.005	0.005
S.D.	0.0012	0.0007	0.0008	0.0013	0.0008	0.0008	0.0009
N	15	15	15	15	14	15	13
THYROID GLANDS							
MEAN	0.012	0.011	0.010	0.011	0.011	0.011	0.011
S.D.	0.0027	0.0022	0.0022	0.0026	0.0013	0.0021	0.0022
N	15	15	15	15	14	15	13

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:05-002

TABLE RANGE: 05-26-05 TO 06-17-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83681-01	F	CORN OIL	DISPOSITION	06-15-05	8:07	P	SCHEDULED EUTHANASIA
83680-04	F	CORN OIL	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83677-01	F	CORN OIL	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83679-06	F	CORN OIL	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83678-08	F	CORN OIL	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83677-08	F	CORN OIL	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83679-09	F	CORN OIL	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83683-01	F	CORN OIL	DISPOSITION	06-16-05	7:58	P	SCHEDULED EUTHANASIA
83685-02	F	CORN OIL	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83682-04	F	CORN OIL	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83684-06	F	CORN OIL	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83684-10	F	CORN OIL	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83686-01	F	CORN OIL	DISPOSITION	06-17-05	7:18	P	SCHEDULED EUTHANASIA
83689-05	F	CORN OIL	DISPOSITION	06-17-05	7:18	P	SCHEDULED EUTHANASIA
83687-06	F	CORN OIL	DISPOSITION	06-17-05	7:18	P	SCHEDULED EUTHANASIA
83680-02	F	[redacted]60	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83678-06	F	[redacted]60	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83679-10	F	[redacted]60	DISPOSITION	06-15-05	8:08	P	SCHEDULED EUTHANASIA
83681-07	F	[redacted]60	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83677-02	F	[redacted]60	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83679-01	F	[redacted]60	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83681-03	F	[redacted]60	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83685-06	F	[redacted]60	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83683-07	F	[redacted]60	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83684-08	F	[redacted]60	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83682-03	F	[redacted]60	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83683-05	F	[redacted]60	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83685-10	F	[redacted]60	DISPOSITION	06-16-05	7:59	P	SCHEDULED EUTHANASIA
83687-08	F	[redacted]60	DISPOSITION	06-17-05	7:18	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:05-002

TABLE RANGE: 05-26-05 TO 06-17-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83689-04	F	[redacted]60	DISPOSITION	06-17-05	7:18	P	SCHEDULED EUTHANASIA
83678-04	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83680-05	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83677-10	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83681-09	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83679-04	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83677-04	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83680-01	F	[redacted]250	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83684-02	F	[redacted]250	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83683-02	F	[redacted]250	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83685-03	F	[redacted]250	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83682-09	F	[redacted]250	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83682-01	F	[redacted]250	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83685-07	F	[redacted]250	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83687-09	F	[redacted]250	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83689-01	F	[redacted]250	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83678-03	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83679-05	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83677-03	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83680-03	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83681-06	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83679-08	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83678-01	F	[redacted]1000	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83685-04	F	[redacted]1000	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83683-08	F	[redacted]1000	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83682-08	F	[redacted]1000	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83684-03	F	[redacted]1000	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83684-04	F	[redacted]1000	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83686-05	F	[redacted]1000	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:05-002

TABLE RANGE: 05-26-05 TO 06-17-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83687-02	F	[redacted]1000	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83689-08	F	[redacted]1000	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83678-07	F	[redacted]60	DISPOSITION	06-15-05	8:09	P	SCHEDULED EUTHANASIA
83681-08	F	[redacted]60	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83680-10	F	[redacted]60	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83679-02	F	[redacted]60	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83677-05	F	[redacted]60	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83681-10	F	[redacted]60	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83678-09	F	[redacted]60	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83685-01	F	[redacted]60	DISPOSITION	06-16-05	8:00	P	SCHEDULED EUTHANASIA
83683-03	F	[redacted]60	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83684-09	F	[redacted]60	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83682-02	F	[redacted]60	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83682-06	F	[redacted]60	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83682-06	F	[redacted]60	BODY/INTEGUMENT	06-07-05	12:28	P	TAIL SHEATH MISSING
				06-08-05	9:25	P	TAIL SHEATH MISSING
				06-10-05	7:11	P	TAIL SHEATH MISSING
				06-11-05	7:32	P	TAIL SHEATH MISSING
				06-13-05	8:28	P	TAIL SHEATH MISSING
				06-14-05	8:35	P	TAIL SHEATH MISSING
				06-16-05	7:27	P	TAIL SHEATH MISSING
				06-09-05	8:52	P	TAIL SHEATH MISSING
				06-12-05	7:18	P	TAIL SHEATH MISSING
				06-15-05	7:37	P	TAIL SHEATH MISSING
83683-06	F	[redacted]60	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83686-09	F	[redacted]60	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83689-09	F	[redacted]60	DISPOSITION	06-06-05	12:26	P	FOUND DEAD
83681-05	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83678-10	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:05-002

TABLE RANGE: 05-26-05 TO 06-17-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83680-07	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83677-07	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83679-03	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83680-09	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83681-02	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83678-02	F	[redacted]250	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83685-09	F	[redacted]250	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83684-07	F	[redacted]250	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83683-09	F	[redacted]250	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83682-10	F	[redacted]250	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83682-05	F	[redacted]250	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83688-04	F	[redacted]250	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83687-05	F	[redacted]250	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83678-05	F	[redacted]1000	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83681-04	F	[redacted]1000	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83679-07	F	[redacted]1000	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83680-06	F	[redacted]1000	DISPOSITION	05-30-05	11:23	P	FOUND DEAD
83677-09	F	[redacted]1000	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83677-09	F	[redacted]1000	ORAL/DENTAL	06-13-05	8:33	1	WET CLEAR MATERIAL AROUND MOUTH
83677-06	F	[redacted]1000	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83677-06	F	[redacted]1000	BODY/INTEGUMENT	06-09-05	8:59	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-10-05	7:18	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-11-05	7:37	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-12-05	7:23	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-13-05	8:34	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-14-05	8:40	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-15-05	7:44	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
83680-08	F	[redacted]1000	DISPOSITION	06-15-05	8:10	P	SCHEDULED EUTHANASIA
83685-08	F	[redacted]1000	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:05-002

TABLE RANGE: 05-26-05 TO 06-17-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83682-07	F	[redacted]1000	DISPOSITION	06-16-05	8:01	P	SCHEDULED EUTHANASIA
83682-07	F	[redacted]1000	BODY/INTEGUMENT	06-09-05	9:03	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-13-05	8:35	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-14-05	8:41	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-15-05	7:47	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-16-05	7:32	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-08-05	9:31	P	SOFT MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 20 MM
				06-11-05	7:39	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-12-05	7:24	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
				06-10-05	7:21	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 20 MM X 20 MM X 15 MM
83683-04	F	[redacted]1000	DISPOSITION	06-16-05	8:02	P	SCHEDULED EUTHANASIA
83684-01	F	[redacted]1000	DISPOSITION	06-16-05	8:02	P	SCHEDULED EUTHANASIA
83683-10	F	[redacted]1000	DISPOSITION	06-08-05	12:28	P	FOUND DEAD
83685-05	F	[redacted]1000	DISPOSITION	06-16-05	8:02	P	SCHEDULED EUTHANASIA
83686-02	F	[redacted]1000	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83687-04	F	[redacted]1000	DISPOSITION	06-17-05	7:19	P	SCHEDULED EUTHANASIA
83687-04	F	[redacted]1000	BODY/INTEGUMENT	06-07-05	12:33	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM
				06-07-05	12:35	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-08-05	9:36	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:05-002

TABLE RANGE: 05-26-05 TO 06-17-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83687-04	F	[redacted]1000	BODY/INTEGUMENT	06-08-05	9:37	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-09-05	9:05	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM
				06-09-05	9:05	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-11-05	7:44	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM
				06-11-05	7:44	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-12-05	7:26	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM
				06-12-05	7:26	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-13-05	8:37	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM
				06-13-05	8:37	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-14-05	8:42	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-14-05	8:47	P	HARD MOVEABLE MASS RIGHT LATERAL HEAD 20 MM X 20 MM X 10 MM
				06-15-05	7:53	P	HARD MOVEABLE MASS RIGHT LATERAL HEAD 20 MM X 20 MM X 10 MM
				06-16-05	7:34	P	HARD MOVEABLE MASS RIGHT LATERAL HEAD 20 MM X 20 MM X 10 MM
				06-16-05	7:37	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM
				06-10-05	7:24	P	SOFT MOVEABLE MASS VENTRAL NECK 20 MM X 15 MM X 12 MM
				06-10-05	7:26	P	HARD MOVEABLE MASS VENTRAL THORACIC AREA 8 MM X 5 MM X 5 MM
				06-17-05	6:44	P	HARD MOVEABLE MASS RIGHT LATERAL HEAD 20 MM X 20 MM X 10 MM
				06-17-05	6:46	P	HARD MOVEABLE MASS VENTRAL NECK 5 MM X 5 MM X 5 MM

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83683-05	F	[redacted]60	ORAL/DENTAL	06-07-05	10:50	1	SALIVATION PRIOR TO DOSING
				06-09-05	10:54	1	SALIVATION PRIOR TO DOSING
				06-12-05	10:31	3	SALIVATION PRIOR TO DOSING
				06-13-05	10:14	1	SALIVATION PRIOR TO DOSING
				06-14-05	10:17	2	SALIVATION PRIOR TO DOSING
				06-15-05	10:34	1	SALIVATION PRIOR TO DOSING
83678-04	F	[redacted]250	ORAL/DENTAL	06-04-05	11:09	2	SALIVATION PRIOR TO DOSING
				06-05-05	10:52	2	SALIVATION PRIOR TO DOSING
83677-10	F	[redacted]250	ORAL/DENTAL	06-13-05	10:16	1	SALIVATION PRIOR TO DOSING
83683-02	F	[redacted]250	ORAL/DENTAL	06-13-05	10:18	1	SALIVATION PRIOR TO DOSING
83678-03	F	[redacted]1000	ORAL/DENTAL	06-04-05	11:15	1	SALIVATION PRIOR TO DOSING
				06-05-05	10:59	2	SALIVATION PRIOR TO DOSING
				06-08-05	11:11	1	SALIVATION PRIOR TO DOSING
83679-05	F	[redacted]1000	ORAL/DENTAL	06-05-05	10:59	1	SALIVATION PRIOR TO DOSING
				06-08-05	11:12	1	SALIVATION PRIOR TO DOSING
				06-12-05	10:38	1	SALIVATION PRIOR TO DOSING
83680-03	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:00	1	SALIVATION PRIOR TO DOSING
				06-14-05	10:25	1	SALIVATION PRIOR TO DOSING
83681-06	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:01	2	SALIVATION PRIOR TO DOSING
				06-08-05	11:13	1	SALIVATION PRIOR TO DOSING
83678-01	F	[redacted]1000	ORAL/DENTAL	06-04-05	11:18	3	SALIVATION PRIOR TO DOSING
				06-04-05	11:18	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:01	1	SALIVATION PRIOR TO DOSING
				06-08-05	11:14	1	SALIVATION PRIOR TO DOSING
				06-12-05	10:40	1	SALIVATION PRIOR TO DOSING
83683-08	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:02	2	SALIVATION PRIOR TO DOSING
				06-08-05	11:15	1	SALIVATION PRIOR TO DOSING
				06-11-05	10:26	1	SALIVATION PRIOR TO DOSING
				06-14-05	10:27	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83682-08	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:04	1	SALIVATION PRIOR TO DOSING
83684-03	F	[redacted]1000	ORAL/DENTAL	06-04-05	11:20	2	SALIVATION PRIOR TO DOSING
				06-05-05	11:03	1	SALIVATION PRIOR TO DOSING
				06-12-05	10:42	2	SALIVATION PRIOR TO DOSING
				06-13-05	10:25	1	SALIVATION PRIOR TO DOSING
				06-14-05	10:28	1	SALIVATION PRIOR TO DOSING
83687-02	F	[redacted]1000	ORAL/DENTAL	06-04-05	11:21	1	SALIVATION PRIOR TO DOSING
				06-05-05	11:05	1	SALIVATION PRIOR TO DOSING
				06-07-05	11:05	1	SALIVATION PRIOR TO DOSING
				06-09-05	11:08	2	SALIVATION PRIOR TO DOSING
				06-11-05	10:28	1	SALIVATION PRIOR TO DOSING
				06-12-05	10:43	1	SALIVATION PRIOR TO DOSING
				06-15-05	10:42	1	SALIVATION PRIOR TO DOSING
83683-03	F	[redacted]60	ORAL/DENTAL	06-11-05	10:31	1	SALIVATION PRIOR TO DOSING
83681-05	F	[redacted]250	ORAL/DENTAL	06-04-05	11:31	2	SALIVATION PRIOR TO DOSING
83678-02	F	[redacted]250	ORAL/DENTAL	06-05-05	11:17	1	SALIVATION PRIOR TO DOSING
				06-09-05	11:18	1	SALIVATION PRIOR TO DOSING
				06-14-05	10:38	1	SALIVATION PRIOR TO DOSING
83685-09	F	[redacted]250	ORAL/DENTAL	06-05-05	11:16	1	SALIVATION PRIOR TO DOSING
83682-10	F	[redacted]250	ORAL/DENTAL	06-14-05	10:39	1	SALIVATION PRIOR TO DOSING
83678-05	F	[redacted]1000	ORAL/DENTAL	06-02-05	11:23	2	SALIVATION PRIOR TO DOSING
				06-04-05	11:39	2	SALIVATION PRIOR TO DOSING
				06-05-05	11:21	2	SALIVATION PRIOR TO DOSING
				06-08-05	11:31	1	SALIVATION PRIOR TO DOSING
				06-10-05	10:41	1	SALIVATION PRIOR TO DOSING
				06-12-05	10:56	1	SALIVATION PRIOR TO DOSING
83681-04	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:21	1	SALIVATION PRIOR TO DOSING
				06-07-05	11:23	1	SALIVATION PRIOR TO DOSING
83677-09	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:22	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83677-06	F	[redacted]1000	ORAL/DENTAL	06-07-05	11:25	1	SALIVATION PRIOR TO DOSING
				06-11-05	10:42	1	SALIVATION PRIOR TO DOSING
83685-08	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:25	2	SALIVATION PRIOR TO DOSING
				06-07-05	11:26	1	SALIVATION PRIOR TO DOSING
				06-14-05	10:44	1	SALIVATION PRIOR TO DOSING
83683-04	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:28	1	SALIVATION PRIOR TO DOSING
83684-01	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:26	3	SALIVATION PRIOR TO DOSING
83683-10	F	[redacted]1000	ORAL/DENTAL	06-04-05	11:42	1	SALIVATION PRIOR TO DOSING
				06-05-05	11:26	2	SALIVATION PRIOR TO DOSING
				06-07-05	11:28	1	SALIVATION PRIOR TO DOSING
83685-05	F	[redacted]1000	ORAL/DENTAL	06-02-05	11:29	1	SALIVATION PRIOR TO DOSING
				06-05-05	11:28	2	SALIVATION PRIOR TO DOSING
83686-02	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:29	1	SALIVATION PRIOR TO DOSING
83687-04	F	[redacted]1000	ORAL/DENTAL	06-11-05	10:45	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-002

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83683-05	F	[redacted]60	ORAL/DENTAL	06-14-05	11:10	1	WET CLEAR MATERIAL AROUND MOUTH
83678-04	F	[redacted]250	ORAL/DENTAL	06-12-05	11:36	1	DRIED RED MATERIAL AROUND MOUTH
83683-02	F	[redacted]250	ORAL/DENTAL	06-14-05	11:11	1	WET CLEAR MATERIAL AROUND MOUTH
83678-03	F	[redacted]1000	BODY/INTEGUMENT	06-06-05	11:49	2	WET CLEAR MATERIAL VENTRAL NECK
				06-07-05	11:54	2	WET CLEAR MATERIAL VENTRAL NECK
				06-13-05	11:15	1	WET CLEAR MATERIAL VENTRAL NECK
83678-03	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:07	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	11:51	2	WET CLEAR MATERIAL AROUND NOSE
				06-11-05	11:20	1	WET CLEAR MATERIAL AROUND NOSE
				06-13-05	11:14	1	WET CLEAR MATERIAL AROUND NOSE
				06-14-05	11:12	1	WET RED MATERIAL AROUND NOSE
83678-03	F	[redacted]1000	ORAL/DENTAL	05-31-05	11:50	2	WET CLEAR MATERIAL AROUND MOUTH
				06-01-05	12:00	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-02-05	11:56	2	WET CLEAR MATERIAL AROUND MOUTH
				06-03-05	12:32	2	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:06	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:51	3	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	11:49	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	11:54	2	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:04	3	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	11:55	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:21	2	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:20	3	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:38	2	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:14	2	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:13	1	WET RED MATERIAL AROUND MOUTH
83679-05	F	[redacted]1000	ORAL/DENTAL	06-07-05	11:54	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:04	2	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	11:55	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83679-05	F	[redacted]1000	ORAL/DENTAL	06-10-05	11:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:39	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:13	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:12	1	WET CLEAR MATERIAL AROUND MOUTH
83677-03	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:06	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-09-05	11:54	1	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:20	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:15	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:13	1	WET CLEAR MATERIAL AROUND MOUTH
83680-03	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:07	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	11:52	1	WET CLEAR MATERIAL AROUND NOSE
83680-03	F	[redacted]1000	ORAL/DENTAL	06-02-05	11:57	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:07	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:52	2	DRIED CLEAR MATERIAL AROUND MOUTH
				06-06-05	11:50	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	11:55	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:05	1	SALIVATION
				06-09-05	11:55	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:21	3	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:40	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:16	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:14	1	WET CLEAR MATERIAL AROUND MOUTH
83681-06	F	[redacted]1000	ORAL/DENTAL	06-03-05	12:32	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:07	2	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:52	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-07-05	11:55	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:05	1	SALIVATION
				06-10-05	11:21	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83681-06	F	[redacted]1000	ORAL/DENTAL	06-11-05	11:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:40	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:16	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:14	1	WET CLEAR MATERIAL AROUND MOUTH
83678-01	F	[redacted]1000	BODY/INTEGUMENT	06-05-05	11:53	1	WET CLEAR MATERIAL VENTRAL NECK
83678-01	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:08	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	11:53	2	WET CLEAR MATERIAL AROUND NOSE
				06-13-05	11:17	1	WET CLEAR MATERIAL AROUND NOSE
83678-01	F	[redacted]1000	ORAL/DENTAL	06-02-05	11:58	2	WET CLEAR MATERIAL AROUND MOUTH
				06-03-05	12:33	2	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:08	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:53	3	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	11:50	3	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	11:55	2	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:05	2	SALIVATION
				06-09-05	11:56	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:21	3	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:21	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:41	2	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:17	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:15	1	WET CLEAR MATERIAL AROUND MOUTH
83685-04	F	[redacted]1000	BODY/INTEGUMENT	06-08-05	12:06	2	WET CLEAR MATERIAL VENTRAL NECK
83685-04	F	[redacted]1000	EYES/EARS/NOSE	06-05-05	11:54	1	WET CLEAR MATERIAL AROUND NOSE
				06-13-05	11:18	1	WET CLEAR MATERIAL AROUND NOSE
83685-04	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:53	2	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	11:51	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:06	2	SALIVATION
				06-09-05	11:56	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:22	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:05-002

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83685-04	F	[redacted]1000	ORAL/DENTAL	06-10-05	11:22	2	SALIVATION
				06-11-05	11:22	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:41	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:18	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:15	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:30	1	WET CLEAR MATERIAL AROUND MOUTH
83683-08	F	[redacted]1000	BODY/INTEGUMENT	06-06-05	11:51	2	WET CLEAR MATERIAL VENTRAL ABDOMINAL AREA
				06-13-05	11:17	1	WET CLEAR MATERIAL VENTRAL NECK
83683-08	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:08	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	11:52	1	WET CLEAR MATERIAL AROUND NOSE
83683-08	F	[redacted]1000	ORAL/DENTAL	06-02-05	11:57	1	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:08	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:52	2	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	11:51	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	11:55	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:06	2	SALIVATION
				06-09-05	11:55	1	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:21	2	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:22	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:40	2	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:17	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:16	1	WET RED MATERIAL AROUND MOUTH
				06-15-05	11:30	1	WET CLEAR MATERIAL AROUND MOUTH
83682-08	F	[redacted]1000	ORAL/DENTAL	06-10-05	11:22	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:31	1	DRIED CLEAR MATERIAL AROUND MOUTH
83684-03	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:54	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-06-05	11:52	1	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	11:56	1	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	11:56	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:05-002

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83684-03	F	[redacted]1000	ORAL/DENTAL	06-10-05	11:22	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:22	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:41	2	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:16	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:31	1	WET CLEAR MATERIAL AROUND MOUTH
83684-04	F	[redacted]1000	ORAL/DENTAL	06-05-05	11:54	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:22	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:42	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:18	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:16	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:31	1	DRIED CLEAR MATERIAL AROUND MOUTH
83687-02	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:09	2	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	11:54	1	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	11:56	1	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:23	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:42	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:20	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:17	1	WET CLEAR MATERIAL AROUND MOUTH
83689-08	F	[redacted]1000	ORAL/DENTAL	06-10-05	11:23	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:43	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:20	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:32	1	WET CLEAR MATERIAL AROUND MOUTH
83681-05	F	[redacted]250	ORAL/DENTAL	06-09-05	12:16	1	DRIED CLEAR MATERIAL AROUND MOUTH
83678-02	F	[redacted]250	BODY/INTEGUMENT	06-12-05	11:48	2	WET CLEAR MATERIAL VENTRAL NECK
83678-02	F	[redacted]250	ORAL/DENTAL	06-06-05	12:08	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:29	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:48	2	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:26	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:05-002

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83685-09	F	[redacted]250	ORAL/DENTAL	06-12-05	11:47	1	DRIED CLEAR MATERIAL AROUND MOUTH
83682-10	F	[redacted]250	ORAL/DENTAL	06-09-05	12:17	2	SALIVATION
83688-04	F	[redacted]250	ORAL/DENTAL	06-12-05	11:49	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:27	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:35	1	WET CLEAR MATERIAL AROUND MOUTH
83687-05	F	[redacted]250	ORAL/DENTAL	06-11-05	11:30	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:27	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:42	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:35	1	WET CLEAR MATERIAL AROUND MOUTH
83678-05	F	[redacted]1000	BODY/INTEGUMENT	06-06-05	12:18	2	WET CLEAR MATERIAL VENTRAL NECK
				06-07-05	12:19	1	WET CLEAR MATERIAL VENTRAL NECK
				06-08-05	12:24	2	WET CLEAR MATERIAL VENTRAL NECK
				06-11-05	11:31	1	WET CLEAR MATERIAL VENTRAL NECK
83678-05	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:31	2	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	12:17	1	WET CLEAR MATERIAL AROUND NOSE
				06-09-05	12:18	1	LACRIMATION RIGHT EYE
				06-09-05	12:18	1	LACRIMATION LEFT EYE
				06-13-05	11:29	1	WET CLEAR MATERIAL AROUND NOSE
83678-05	F	[redacted]1000	ORAL/DENTAL	06-03-05	12:42	2	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:31	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:17	3	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:18	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:19	2	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:24	3	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:17	3	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:32	3	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:30	3	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:30	2	SALIVATION
				06-12-05	11:50	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83678-05	F	[redacted]1000	ORAL/DENTAL	06-13-05	11:29	2	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:43	2	WET CLEAR MATERIAL AROUND MOUTH
83681-04	F	[redacted]1000	ORAL/DENTAL	06-09-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:50	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:28	1	WET CLEAR MATERIAL AROUND MOUTH
83679-07	F	[redacted]1000	ORAL/DENTAL	06-06-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:50	1	DRIED RED MATERIAL AROUND MOUTH
				06-13-05	11:28	1	DRIED RED MATERIAL AROUND MOUTH
				06-14-05	11:43	1	WET CLEAR MATERIAL AROUND MOUTH
83677-09	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:32	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	12:18	1	WET CLEAR MATERIAL AROUND NOSE
83677-09	F	[redacted]1000	ORAL/DENTAL	06-01-05	12:18	2	WET CLEAR MATERIAL AROUND MOUTH
				06-03-05	12:42	1	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:32	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:18	2	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:19	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:24	1	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:19	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:33	2	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:31	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:51	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:30	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:44	1	WET CLEAR MATERIAL AROUND MOUTH
83677-06	F	[redacted]1000	BODY/INTEGUMENT	06-06-05	12:19	2	WET CLEAR MATERIAL VENTRAL NECK
				06-07-05	12:20	3	WET CLEAR MATERIAL VENTRAL NECK
				06-11-05	11:31	2	WET CLEAR MATERIAL VENTRAL NECK
				06-13-05	11:30	1	WET CLEAR MATERIAL VENTRAL NECK

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83677-06	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:32	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	12:17	1	WET CLEAR MATERIAL AROUND NOSE
83677-06	F	[redacted]1000	ORAL/DENTAL	06-01-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-03-05	12:43	1	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:32	3	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:17	2	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:19	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:20	3	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:19	3	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:31	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:51	3	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:30	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:44	1	WET CLEAR MATERIAL AROUND MOUTH
83680-08	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:32	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:18	1	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:20	1	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:20	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:24	1	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:20	1	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:34	1	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:32	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:52	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:31	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:45	1	WET CLEAR MATERIAL AROUND MOUTH
83685-08	F	[redacted]1000	BODY/INTEGUMENT	06-06-05	12:20	2	WET CLEAR MATERIAL VENTRAL NECK
83685-08	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:33	1	WET CLEAR MATERIAL AROUND NOSE
				06-05-05	12:18	1	WET CLEAR MATERIAL AROUND NOSE
83685-08	F	[redacted]1000	ORAL/DENTAL	06-03-05	12:43	1	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:33	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83685-08	F	[redacted]1000	ORAL/DENTAL	06-05-05	12:18	2	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:33	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:32	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:52	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:32	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:45	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:39	1	DRIED CLEAR MATERIAL AROUND MOUTH
83682-07	F	[redacted]1000	ORAL/DENTAL	06-13-05	11:31	1	DRIED RED MATERIAL AROUND MOUTH
				06-15-05	11:39	1	WET RED MATERIAL AROUND MOUTH
83683-04	F	[redacted]1000	BODY/INTEGUMENT	06-15-05	11:40	1	WET CLEAR MATERIAL VENTRAL NECK
83683-04	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:34	3	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:25	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:34	1	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:32	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:53	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:33	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:45	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:40	1	WET CLEAR MATERIAL AROUND MOUTH
83684-01	F	[redacted]1000	ORAL/DENTAL	06-01-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-02-05	12:19	1	WET CLEAR MATERIAL AROUND MOUTH
				06-03-05	12:44	1	WET CLEAR MATERIAL AROUND MOUTH
				06-04-05	12:34	2	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:19	2	WET CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83684-01	F	[redacted]1000	ORAL/DENTAL	06-07-05	12:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:25	2	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:34	1	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:33	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:53	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:33	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:45	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:41	1	WET CLEAR MATERIAL AROUND MOUTH
83683-10	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:33	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:19	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:21	2	WET CLEAR MATERIAL AROUND MOUTH
83685-05	F	[redacted]1000	EYES/EARS/NOSE	06-10-05	11:35	1	LACRIMATION RIGHT EYE
				06-10-05	11:35	1	LACRIMATION LEFT EYE
83685-05	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:34	1	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:22	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:25	2	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:20	2	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:34	2	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:34	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:54	2	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:33	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:46	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:42	1	WET CLEAR MATERIAL AROUND MOUTH
83686-02	F	[redacted]1000	ORAL/DENTAL	06-07-05	12:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:26	1	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:21	1	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:54	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 11
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-26-05 TO 06-16-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
83686-02	F	[redacted]1000	ORAL/DENTAL	06-13-05	11:35	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:47	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:42	1	WET CLEAR MATERIAL AROUND MOUTH
83687-04	F	[redacted]1000	BODY/INTEGUMENT	06-06-05	12:22	2	WET CLEAR MATERIAL VENTRAL NECK
				06-07-05	12:22	3	WET CLEAR MATERIAL VENTRAL NECK
				06-08-05	12:26	2	WET CLEAR MATERIAL VENTRAL NECK
				06-09-05	12:21	2	WET CLEAR MATERIAL VENTRAL NECK
				06-10-05	11:35	3	WET CLEAR MATERIAL VENTRAL NECK
				06-11-05	11:34	2	WET CLEAR MATERIAL VENTRAL NECK
				06-12-05	11:55	2	WET CLEAR MATERIAL VENTRAL NECK
				06-13-05	11:34	1	WET CLEAR MATERIAL VENTRAL NECK
				06-14-05	11:46	1	WET CLEAR MATERIAL VENTRAL NECK
				06-15-05	11:41	1	WET CLEAR MATERIAL VENTRAL NECK
83687-04	F	[redacted]1000	EYES/EARS/NOSE	06-04-05	12:35	1	WET CLEAR MATERIAL AROUND NOSE
				06-11-05	11:33	1	WET RED MATERIAL AROUND NOSE
83687-04	F	[redacted]1000	ORAL/DENTAL	06-04-05	12:35	1	WET CLEAR MATERIAL AROUND MOUTH
				06-05-05	12:19	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-06-05	12:22	2	WET CLEAR MATERIAL AROUND MOUTH
				06-07-05	12:22	2	WET CLEAR MATERIAL AROUND MOUTH
				06-08-05	12:26	2	WET CLEAR MATERIAL AROUND MOUTH
				06-09-05	12:21	3	WET CLEAR MATERIAL AROUND MOUTH
				06-10-05	11:35	2	WET CLEAR MATERIAL AROUND MOUTH
				06-11-05	11:33	2	WET CLEAR MATERIAL AROUND MOUTH
				06-12-05	11:55	3	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	11:34	2	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	11:46	2	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	11:41	1	WET CLEAR MATERIAL AROUND MOUTH
				06-16-05	11:37	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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07/19/2005

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: CORN OIL												
83681-01	53.7	58.8	65.7	71.7	78.1	82.9	89.9	95.8	101.5	108.3	117.2	122.5
83680-04	45.5	52.6	60.2	64.3	68.5	74.5	79.1	85.8	92.9	99.9	108.2	114.1
83677-01	44.1	45.8	53.7	59.5	62.9	67.5	72.1	78.1	81.8	88.5	92.6	98.7
83679-06	43.3	48.1	54.5	59.8	64.5	68.9	74.8	79.7	85.2	91.2	96.9	102.0
83678-08	36.0	42.1	44.5	49.6	51.7	56.0	59.4	62.9	66.5	70.3	74.4	77.8
83677-08	43.2	47.5	53.3	59.4	63.6	66.7	72.7	76.7	81.1	85.6	93.6	98.0
83679-09	47.0	53.3	59.5	65.2	68.9	74.0	81.0	84.8	92.0	96.5	102.5	109.1
83683-01	42.9	46.6	50.7	55.1	59.1	62.7	66.4	72.2	77.2	82.5	89.0	92.2
83685-02	47.5	53.2	58.2	61.9	67.9	73.5	79.0	83.9	88.8	93.1	99.4	103.9
83682-04	48.5	54.8	62.4	66.9	70.8	76.2	80.4	83.2	94.0	101.4	107.6	114.0
83684-06	50.7	56.0	59.7	65.9	71.4	76.1	81.1	86.8	93.1	96.3	102.0	106.8
83684-10	48.7	54.1	59.7	63.3	68.0	73.3	78.5	85.6	89.6	95.6	101.3	105.0
83686-01	50.8	57.3	61.4	66.4	71.3	74.9	82.9	88.1	95.5	101.1	103.7	111.8
83689-05	49.5	55.9	60.6	65.3	70.1	73.8	79.0	85.2	90.9	94.5	97.8	105.3
83687-06	44.9	50.5	54.3	58.6	63.6	68.3	74.5	80.2	88.6	92.9	96.8	104.3
MEAN	46.4	51.8	57.2	62.2	66.7	71.3	76.7	81.9	87.9	93.2	98.9	104.4
S.D.	4.31	4.81	5.37	5.42	6.18	6.47	7.24	7.62	8.56	9.08	9.73	10.47
N	15	15	15	15	15	15	15	15	15	15	15	15

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Modified: 5/22/2006

TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: CORN OIL									
83681-01	127.5	131.9	132.9	144.7	144.4	145.7	145.9	151.6	152.6
83680-04	122.1	130.3	135.2	147.0	154.6	158.5	163.9	169.8	178.9
83677-01	104.0	106.7	112.0	121.3	126.8	131.3	128.5	137.1	141.7
83679-06	106.2	114.1	116.5	123.4	126.8	132.4	134.9	134.1	140.9
83678-08	82.9	87.2	89.2	94.6	99.3	103.6	105.1	109.0	114.4
83677-08	105.1	114.0	118.4	123.5	129.7	137.0	143.3	150.4	153.2
83679-09	114.5	119.4	125.1	131.5	137.3	142.3	147.9	151.1	156.4
83683-01	99.0	102.8	109.2	113.5	119.9	126.6	128.4	129.1	136.7
83685-02	109.7	112.7	117.4	121.4	126.6	131.0	133.2	133.5	141.4
83682-04	120.7	126.5	137.1	142.3	148.1	153.3	157.9	160.8	166.0
83684-06	112.8	115.0	121.7	122.0	128.1	132.3	137.2	137.9	139.3
83684-10	110.8	115.8	120.6	128.3	132.3	132.2	141.2	143.8	147.3
83686-01	110.5	122.5	126.8	131.3	136.7	140.1	143.0	144.0	152.0
83689-05	108.9	113.8	120.6	128.0	131.2	132.9	139.1	144.3	150.4
83687-06	109.5	118.1	121.5	128.2	135.0	138.6	143.1	149.2	154.3
MEAN	109.6	115.4	120.3	126.7	131.8	135.9	139.5	143.0	148.4
S.D.	10.44	11.13	11.70	12.92	12.82	12.53	13.58	14.27	14.45
N	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: [redacted]60												
83680-02	51.2	57.2	62.0	66.9	70.2	74.0	79.5	84.2	88.4	93.2	97.9	103.5
83678-06	44.9	52.0	57.4	61.6	64.5	70.9	73.0	79.2	82.4	88.8	93.1	95.0
83679-10	47.5	52.7	59.2	64.5	67.8	74.4	80.1	85.4	90.2	95.8	101.7	106.4
83681-07	40.9	46.0	51.3	55.9	60.4	64.7	69.0	73.8	79.8	85.6	92.3	95.9
83677-02	32.1	32.3	39.2	43.3	46.8	49.4	54.4	60.1	63.8	70.0	75.1	81.8
83679-01	45.2	51.7	56.9	61.4	67.5	71.1	76.8	82.1	89.0	95.6	100.9	104.7
83681-03	46.1	50.8	58.0	64.6	69.7	74.3	79.2	85.3	90.3	96.2	101.5	108.6
83685-06	40.9	45.4	51.4	56.2	60.1	65.2	69.7	74.4	79.7	85.2	91.2	95.9
83683-07	40.1	47.9	53.7	57.7	61.8	67.1	72.8	78.7	84.1	91.5	97.3	103.0
83684-08	48.0	53.4	58.4	62.1	67.6	72.3	79.2	85.0	91.6	97.3	104.7	111.8
83682-03	50.2	56.5	62.7	66.5	72.1	79.1	85.1	90.7	97.4	105.1	108.4	117.1
83683-05	48.4	55.3	62.2	65.7	69.6	76.0	80.4	84.7	90.1	96.0	101.4	106.8
83685-10	40.4	46.9	52.1	56.4	59.2	64.3	69.8	73.5	80.8	84.5	89.4	94.6
83687-08	51.9	57.5	62.0	66.3	71.2	76.1	81.4	87.4	93.0	99.6	104.9	110.2
83689-04	42.8	48.0	52.5	56.0	60.7	66.4	70.7	77.6	83.5	88.8	94.5	101.3
MEAN	44.7	50.2	55.9	60.3	64.6	69.7	74.7	80.1	85.6	91.5	97.0	102.4
S.D.	5.28	6.39	6.19	6.30	6.64	7.30	7.55	7.61	8.00	8.30	8.21	8.75
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: [redacted]60									
83680-02	108.6	112.5	118.8	124.2	128.6	135.4	139.7	141.3	144.8
83678-06	100.1	101.0	105.5	110.7	111.9	119.2	123.9	125.3	130.0
83679-10	112.5	117.1	123.0	128.7	135.4	141.6	145.2	148.8	153.6
83681-07	102.5	108.3	115.2	118.5	124.2	131.5	133.1	136.8	144.0
83677-02	88.6	93.3	102.5	109.1	114.6	118.6	126.2	133.1	137.6
83679-01	110.8	117.0	121.7	126.8	131.1	136.7	145.1	146.3	149.7
83681-03	111.9	119.0	125.9	129.3	137.1	140.4	145.1	145.7	152.1
83685-06	104.4	109.9	116.9	121.6	126.3	128.5	128.7	134.3	140.2
83683-07	108.8	117.1	127.5	132.4	141.0	147.0	150.8	157.7	158.4
83684-08	121.4	128.0	137.8	145.7	157.0	161.4	167.0	174.1	182.6
83682-03	126.8	128.7	135.7	140.1	143.5	150.0	155.0	155.3	160.6
83683-05	113.9	119.8	128.4	135.0	140.6	149.7	153.7	158.6	165.0
83685-10	100.6	107.0	112.9	120.0	124.6	128.5	128.7	130.6	134.3
83687-08	115.9	124.9	130.7	136.8	142.3	146.6	150.2	156.7	161.4
83689-04	106.8	110.8	116.6	123.4	129.5	134.2	138.7	142.9	145.4
MEAN	108.9	114.3	121.3	126.8	132.5	138.0	142.1	145.8	150.6
S.D.	9.26	9.73	10.14	10.27	11.73	11.88	12.34	13.04	13.61
N	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: [redacted]250												
83678-04	52.0	57.6	63.8	69.0	74.7	79.6	85.0	90.4	96.1	103.7	110.5	113.0
83680-05	43.1	47.4	53.4	59.9	62.9	67.5	71.1	74.5	79.9	87.1	92.8	96.9
83677-10	45.2	50.4	53.8	59.0	62.8	67.7	73.0	78.1	83.4	88.4	94.7	102.2
83681-09	44.9	48.5	47.3	43.0	54.3	60.3	65.1	70.4	75.7	79.5	85.4	93.3
83679-04	40.6	44.7	41.8	37.9	48.5	54.9	61.9	67.5	73.5	78.0	82.8	87.4
83677-04	41.5	46.2	45.0	43.5	56.1	62.9	67.4	71.8	76.9	83.0	87.0	94.3
83680-01	45.5	50.8	57.4	61.5	67.9	74.3	78.4	83.3	90.6	96.8	102.2	109.1
83684-02	34.9	39.5	41.6	46.8	50.3	55.7	58.6	63.9	66.7	72.0	75.1	81.4
83683-02	41.9	46.6	52.2	57.9	64.1	69.9	75.0	81.9	88.1	95.0	102.3	107.7
83685-03	44.0	49.3	54.4	58.8	63.0	69.3	74.4	79.5	87.0	92.4	97.7	105.3
83682-09	48.6	57.0	62.7	66.5	70.7	75.7	79.2	86.2	93.3	98.2	103.0	108.4
83682-01	45.7	50.3	55.1	59.1	64.1	68.5	71.4	77.3	82.5	88.0	92.1	97.8
83685-07	44.4	50.7	56.6	60.5	63.2	68.2	72.0	76.4	82.4	86.0	92.3	96.2
83687-09	49.7	55.6	60.5	66.0	70.9	75.5	81.1	87.4	93.3	100.4	104.9	110.5
83689-01	50.4	54.7	60.4	64.1	68.7	74.7	79.4	86.7	92.6	100.6	104.3	114.3
MEAN	44.8	50.0	53.7	56.9	62.8	68.3	72.9	78.4	84.1	89.9	95.1	101.2
S.D.	4.32	4.89	7.10	9.51	7.62	7.31	7.35	7.79	8.51	9.30	9.72	9.71
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: [redacted]250									
83678-04	116.3	127.6	130.4	139.1	143.2	147.0	154.9	157.7	162.3
83680-05	105.1	109.8	116.0	125.6	129.7	135.0	140.3	147.4	154.0
83677-10	106.7	113.4	116.3	120.5	128.6	133.6	137.9	137.8	146.9
83681-09	96.8	106.4	109.1	114.5	119.9	126.1	131.9	134.5	136.3
83679-04	91.8	98.0	103.0	109.0	114.8	118.7	119.7	123.3	128.8
83677-04	99.0	106.6	111.2	116.9	124.5	127.3	133.4	135.7	140.5
83680-01	113.3	122.2	128.4	131.6	141.1	147.9	150.4	158.5	162.1
83684-02	88.2	91.2	95.4	99.7	105.1	108.7	113.4	114.3	120.2
83683-02	117.5	120.7	127.0	136.2	142.0	151.8	155.8	162.2	167.6
83685-03	110.6	117.8	123.3	130.6	136.6	140.9	145.1	150.9	156.3
83682-09	115.9	120.9	129.0	135.7	142.1	147.9	149.0	154.4	160.2
83682-01	103.1	107.2	111.6	114.2	118.6	122.1	124.4	130.5	129.3
83685-07	102.6	105.6	109.1	114.8	120.9	125.6	132.3	134.7	138.9
83687-09	116.0	125.0	128.8	136.6	140.7	146.4	150.4	155.2	162.4
83689-01	120.3	126.7	134.4	145.0	154.2	157.5	159.5	167.6	172.3
MEAN	106.9	113.3	118.2	124.7	130.8	135.8	139.9	144.3	149.2
S.D.	9.92	10.88	11.54	12.98	13.42	14.08	13.92	15.48	16.00
N	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: [redacted]1000												
83678-03	51.6	57.2	62.0	67.1	72.0	76.3	82.2	85.5	92.0	96.6	103.5	108.1
83679-05	45.2	48.9	56.6	61.5	64.8	67.2	71.5	75.8	78.4	82.7	89.0	92.0
83677-03	45.3	48.8	54.3	57.8	61.3	65.7	68.7	74.3	77.5	82.2	86.8	91.1
83680-03	42.3	44.1	52.9	57.3	60.5	66.0	70.0	73.9	79.6	84.5	90.6	95.9
83681-06	45.2	49.6	55.3	61.1	64.2	67.0	72.4	76.7	81.1	86.4	92.0	96.4
83679-08	45.6	50.7	56.1	61.1	66.8	70.9	77.3	82.2	89.3	95.0	99.6	103.4
83678-01	45.4	49.1	56.6	61.6	67.2	72.1	76.7	83.5	91.1	94.3	103.0	108.8
83685-04	44.4	46.7	53.5	58.0	62.7	68.7	72.2	76.5	81.0	86.9	92.0	99.3
83683-08	40.4	47.0	52.6	56.0	60.8	65.8	71.1	76.7	82.8	87.3	93.4	99.8
83682-08	49.0	53.4	61.7	66.0	71.3	73.5	79.3	82.5	90.3	95.6	101.6	108.7
83684-03	54.6	57.7	63.8	68.1	72.9	77.0	82.7	88.4	93.8	97.3	102.3	108.4
83684-04	48.8	54.8	59.8	63.8	68.8	72.4	78.4	82.7	87.2	93.8	98.9	103.7
83686-05	51.4	56.7	61.5	65.2	71.0	74.8	78.7	83.7	89.7	94.3	98.9	102.9
83687-02	51.3	57.3	61.1	67.7	74.7	80.4	84.6	90.7	96.8	102.7	109.2	116.0
83689-08	49.2	52.8	59.0	64.9	69.5	72.7	77.1	81.0	87.8	92.9	97.1	103.6
MEAN	47.3	51.7	57.8	62.5	67.2	71.4	76.2	80.9	86.6	91.5	97.2	102.5
S.D.	3.91	4.39	3.71	4.00	4.68	4.58	4.96	5.13	6.05	6.06	6.33	6.91
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: [redacted]1000									
83678-03	111.8	117.6	118.7	124.9	131.3	134.1	138.6	137.6	139.2
83679-05	95.5	99.2	102.9	108.9	112.3	118.1	119.9	125.3	126.7
83677-03	93.1	98.6	102.9	108.5	110.6	112.4	115.7	119.7	122.4
83680-03	102.4	108.9	113.8	121.0	126.7	134.3	140.1	145.9	151.9
83681-06	102.2	107.0	112.0	119.6	121.7	126.8	133.7	136.3	143.3
83679-08	107.0	110.3	112.2	119.0	121.5	126.8	127.2	130.9	137.9
83678-01	117.1	122.6	126.7	131.7	136.7	143.4	149.2	152.6	150.6
83685-04	104.6	108.2	116.9	121.7	127.7	132.2	137.7	140.0	146.7
83683-08	107.2	109.8	116.3	124.0	130.0	132.9	134.6	138.8	144.4
83682-08	114.1	119.7	127.4	131.9	135.1	138.4	142.9	151.0	147.9
83684-03	113.6	118.4	126.9	128.7	132.2	139.4	142.4	141.6	145.6
83684-04	109.0	114.2	122.5	123.0	128.1	129.1	133.6	134.3	134.1
83686-05	106.2	111.2	116.1	119.9	125.7	125.9	130.2	130.9	135.1
83687-02	120.3	128.6	134.8	142.1	149.2	152.3	159.9	160.4	169.4
83689-08	108.1	114.1	117.6	124.0	128.2	131.9	130.5	141.4	145.3
MEAN	107.5	112.6	117.8	123.3	127.8	131.9	135.7	139.1	142.7
S.D.	7.43	8.13	8.85	8.49	9.43	9.73	10.97	10.59	11.20
N	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: [redacted]60												
83678-07	48.9	54.3	59.1	62.3	66.9	72.6	78.5	85.7	90.3	94.3	102.8	106.9
83681-08	47.1	52.7	58.0	61.5	67.0	72.8	77.9	84.0	89.1	95.8	100.5	106.3
83680-10	44.1	49.6	56.7	61.9	65.5	73.0	77.8	84.3	89.9	93.0	103.4	109.1
83679-02	45.8	50.3	56.7	61.5	65.5	70.7	76.0	80.0	84.1	89.7	93.5	98.5
83677-05	40.2	44.6	51.1	56.2	61.1	66.4	72.1	76.2	81.4	86.4	93.5	99.6
83681-10	46.4	50.4	56.8	61.5	64.4	69.6	75.2	80.3	84.3	88.2	96.6	100.5
83678-09	40.2	48.4	55.4	59.2	65.9	69.6	75.2	80.5	87.4	90.9	96.6	102.6
83685-01	42.7	48.4	53.7	59.7	65.5	71.4	77.0	83.2	87.3	93.9	99.7	105.9
83683-03	44.6	50.2	53.6	59.8	63.5	68.6	73.3	77.8	81.4	85.8	89.6	95.7
83684-09	49.3	55.6	60.1	64.8	68.5	76.0	80.8	84.5	91.4	97.7	103.8	107.6
83682-02	48.4	55.0	60.4	66.0	70.3	76.4	83.2	89.3	96.0	101.5	108.7	114.1
83682-06	45.4	53.2	58.7	61.4	65.1	70.6	75.4	78.5	85.0	91.9	98.6	104.3
83683-06	36.6	40.2	46.1	51.9	56.8	62.8	69.2	75.4	79.4	87.0	93.5	99.3
83686-09	49.8	57.2	61.8	67.1	72.2	77.2	82.5	85.5	92.4	98.7	102.7	108.5
83689-09	48.6	55.8	62.0	67.5	74.8	80.7	85.6	91.0	96.2	106.1		
MEAN	45.2	51.1	56.7	61.5	66.2	71.9	77.3	82.4	87.7	93.4	98.8	104.2
S.D.	3.88	4.57	4.27	4.06	4.32	4.50	4.37	4.56	5.15	5.84	5.25	5.06
N	15	15	15	15	15	15	15	15	15	15	14	14

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: [redacted]60									
83678-07	113.2	119.2	120.6	125.9	131.9	137.6	142.3	144.6	149.8
83681-08	110.1	115.0	119.6	126.4	128.8	134.5	139.8	143.6	148.7
83680-10	114.0	122.3	127.6	132.6	140.4	141.9	148.4	157.0	161.0
83679-02	101.9	106.9	111.6	119.4	123.9	127.1	128.1	134.8	140.4
83677-05	104.8	110.7	116.5	125.3	130.7	131.9	140.9	145.9	150.3
83681-10	104.8	109.9	114.9	121.6	127.5	128.8	133.2	137.7	142.5
83678-09	107.6	113.5	116.0	123.1	130.4	133.8	138.5	144.5	149.1
83685-01	112.2	117.7	122.7	128.5	130.6	133.5	138.0	143.4	145.0
83683-03	102.0	106.5	115.2	120.6	123.5	130.6	134.5	141.0	146.5
83684-09	114.4	119.4	129.2	134.7	136.2	143.5	150.3	154.1	157.5
83682-02	118.6	122.7	129.5	133.6	136.9	139.2	143.9	148.7	153.8
83682-06	106.2	113.2	120.2	127.0	128.5	132.6	138.4	146.0	149.8
83683-06	105.9	112.4	119.9	125.5	127.7	135.5	141.2	144.7	154.1
83686-09	114.6	117.2	125.4	130.9	135.8	138.5	148.3	147.9	149.1
MEAN	109.3	114.8	120.6	126.8	130.9	134.9	140.4	145.3	149.8
S.D.	5.26	5.23	5.63	4.81	4.93	4.77	6.16	5.74	5.53
N	14	14	14	14	14	14	14	14	14

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 11
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 6: [redacted]250												
83681-05	47.9	54.0	58.9	64.5	68.0	72.6	77.4	82.3	86.2	91.1	96.2	100.2
83678-10	44.3	51.7	54.1	60.3	62.2	66.5	70.6	74.4	77.8	81.1	85.9	89.9
83680-07	41.7	49.7	54.5	60.7	64.5	68.8	73.6	78.2	84.1	90.4	98.7	104.2
83677-07	41.6	47.1	52.9	57.7	62.8	67.0	72.6	76.4	82.2	87.4	93.3	97.3
83679-03	43.8	49.1	54.0	57.8	62.2	65.4	70.4	75.6	80.5	85.2	89.1	96.2
83680-09	42.2	47.4	52.5	56.8	59.6	63.8	69.0	73.1	76.2	82.5	87.3	92.4
83681-02	46.3	50.7	56.4	62.2	67.3	71.6	76.7	83.0	89.1	95.0	99.4	104.3
83678-02	51.9	59.1	64.4	69.3	73.9	78.6	84.5	89.6	93.0	99.5	104.4	111.0
83685-09	36.5	42.2	47.0	50.1	54.3	58.2	62.9	68.4	73.2	79.5	84.3	91.4
83684-07	44.6	48.2	52.8	57.0	60.4	67.5	71.8	77.7	81.8	88.9	94.0	100.7
83683-09	42.4	49.3	55.2	59.0	63.9	70.6	76.0	83.9	88.5	95.4	102.8	107.7
83682-10	49.5	56.3	63.1	67.5	71.7	77.7	83.4	90.4	96.1	103.5	111.6	117.7
83682-05	52.4	58.8	65.7	69.7	75.3	81.2	85.6	91.8	98.5	105.7	112.8	117.3
83688-04	51.4	55.8	60.4	65.7	70.4	77.0	80.0	85.6	92.3	99.7	103.8	109.8
83687-05	47.8	52.5	56.8	63.3	67.4	74.2	80.7	84.7	91.1	99.4	105.7	114.1
MEAN	45.6	51.5	56.6	61.4	65.6	70.7	75.7	81.0	86.0	92.3	98.0	103.6
S.D.	4.53	4.69	5.09	5.37	5.74	6.30	6.40	6.87	7.47	8.26	8.99	9.20
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 6: [redacted]250									
83681-05	106.4	108.1	113.3	118.8	123.9	124.6	125.1	129.2	131.5
83678-10	93.7	95.3	99.1	105.7	106.4	108.8	111.7	114.3	118.4
83680-07	109.8	115.6	123.7	131.8	138.8	144.6	152.8	155.3	154.1
83677-07	103.5	109.7	115.2	123.5	128.7	136.6	137.8	141.6	150.1
83679-03	100.4	105.4	110.0	116.6	122.7	126.7	131.6	131.8	137.6
83680-09	97.0	103.8	108.4	115.0	119.7	125.9	129.6	134.5	141.0
83681-02	110.8	118.9	126.1	133.6	138.9	144.0	151.6	155.2	159.4
83678-02	117.8	123.1	127.5	135.5	141.1	143.3	148.7	154.1	158.3
83685-09	97.2	101.7	108.8	112.6	117.3	121.0	126.8	131.8	133.7
83684-07	105.7	109.7	118.3	122.1	129.0	136.3	140.4	144.0	149.3
83683-09	113.7	118.9	126.6	130.8	132.4	135.8	142.2	145.6	149.2
83682-10	129.4	133.7	144.0	149.0	154.0	164.6	169.2	176.9	180.7
83682-05	124.4	131.2	140.6	144.5	151.4	153.4	154.8	163.0	166.4
83688-04	115.8	121.9	127.8	132.0	138.0	142.3	147.1	146.0	155.9
83687-05	118.8	125.7	133.5	141.0	143.8	150.2	156.7	160.9	169.2
MEAN	109.6	114.8	121.5	127.5	132.4	137.2	141.7	145.6	150.3
S.D.	10.46	11.20	12.61	12.47	13.11	14.18	14.92	15.92	16.10
N	15	15	15	15	15	15	15	15	15

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 7: [redacted]1000												
83678-05	51.2	55.8	62.2	68.1	72.2	77.7	83.5	88.8	95.9	104.0	110.5	113.3
83681-04	47.2	52.5	58.4	64.0	67.9	73.2	80.2	84.8	92.3	99.3	107.1	111.9
83679-07	46.5	52.6	58.7	64.9	69.1	73.5	79.5	85.7	92.8	99.7	105.9	112.7
83680-06	44.2	47.8	53.6	58.3	63.9							
83677-09	43.6	47.7	52.0	57.4	63.0	69.5	75.6	80.8	85.8	89.8	97.5	102.2
83677-06	39.7	43.5	48.4	53.7	59.2	65.1	69.7	76.7	82.2	88.0	95.5	102.0
83680-08	49.4	52.5	58.3	64.1	67.9	71.9	78.3	83.3	88.6	97.7	103.6	109.1
83685-08	40.2	45.6	49.7	53.9	58.6	64.1	67.5	73.4	80.6	85.9	90.0	99.2
83682-07	43.0	48.7	55.8	59.7	62.8	68.3	71.4	79.3	83.5	89.6	96.9	102.5
83683-04	47.4	51.8	57.6	61.1	66.7	73.5	78.4	83.4	88.5	95.3	101.0	106.8
83684-01	53.4	57.6	63.4	67.2	71.6	77.8	83.0	89.1	96.1	101.3	104.8	111.6
83683-10	48.3	52.8	59.1	64.6	68.6	76.5	80.5	87.7	93.5	101.5	107.7	116.5
83685-05	42.7	47.1	52.5	57.1	61.8	68.5	72.4	77.0	83.7	88.4	93.0	100.0
83686-02	52.1	57.6	62.2	65.6	72.4	76.0	81.1	86.4	92.7	96.8	102.5	108.5
83687-04	50.6	53.0	58.2	61.2	65.3	68.5	73.5	78.5	84.1	89.5	95.8	100.5
MEAN	46.6	51.1	56.7	61.4	66.1	71.7	76.8	82.5	88.6	94.8	100.8	106.9
S.D.	4.28	4.24	4.56	4.59	4.45	4.49	5.09	4.95	5.30	6.05	6.14	5.78
N	15	15	15	15	15	14	14	14	14	14	14	14

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TABLE 16

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 7: [redacted]1000									
83678-05	120.6	127.7	132.9	142.0	144.8	150.3	155.9	158.5	161.4
83681-04	116.5	121.5	131.9	141.2	148.0	154.6	160.3	168.0	172.4
83679-07	120.2	124.6	128.3	139.0	140.6	145.1	149.3	153.6	158.2
83677-09	107.6	112.1	117.3	122.6	128.1	130.3	134.6	137.7	136.4
83677-06	107.7	114.2	118.5	122.3	133.1	140.5	144.7	151.9	157.2
83680-08	115.6	122.5	129.8	137.3	143.6	145.4	152.8	157.0	161.3
83685-08	103.4	110.7	117.0	121.4	127.5	132.4	135.9	141.2	144.2
83682-07	108.9	114.6	120.8	127.9	132.1	141.8	144.4	145.7	152.5
83683-04	113.4	118.4	124.8	129.5	137.1	142.5	146.8	152.1	156.2
83684-01	116.4	124.3	124.5	129.9	136.2	139.3	141.0	144.4	146.1
83683-10	121.6								
83685-05	107.2	112.5	120.5	124.9	130.8	133.3	139.5	145.7	148.3
83686-02	114.2	120.9	127.2	131.6	135.0	139.9	146.2	149.4	155.1
83687-04	105.7	113.7	119.7	128.3	128.9	133.5	139.6	143.7	146.8
MEAN	112.8	118.3	124.1	130.6	135.8	140.7	145.5	149.9	153.5
S.D.	6.00	5.63	5.55	7.21	6.70	7.17	7.64	8.18	9.28
N	14	13	13	13	13	13	13	13	13

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: CORN OIL												
83681-01	5.1	6.9	6.0	6.4	4.8	7.0	5.9	5.7	6.8	8.9	5.3	5.0
83680-04	7.1	7.6	4.1	4.2	6.0	4.6	6.7	7.1	7.0	8.3	5.9	8.0
83677-01	1.7	7.9	5.8	3.4	4.6	4.6	6.0	3.7	6.7	4.1	6.1	5.3
83679-06	4.8	6.4	5.3	4.7	4.4	5.9	4.9	5.5	6.0	5.7	5.1	4.2
83678-08	6.1	2.4	5.1	2.1	4.3	3.4	3.5	3.6	3.8	4.1	3.4	5.1
83677-08	4.3	5.8	6.1	4.2	3.1	6.0	4.0	4.4	4.5	8.0	4.4	7.1
83679-09	6.3	6.2	5.7	3.7	5.1	7.0	3.8	7.2	4.5	6.0	6.6	5.4
83683-01	3.7	4.1	4.4	4.0	3.6	3.7	5.8	5.0	5.3	6.5	3.2	6.8
83685-02	5.7	5.0	3.7	6.0	5.6	5.5	4.9	4.9	4.3	6.3	4.5	5.8
83682-04	6.3	7.6	4.5	3.9	5.4	4.2	2.8	10.8	7.4	6.2	6.4	6.7
83684-06	5.3	3.7	6.2	5.5	4.7	5.0	5.7	6.3	3.2	5.7	4.8	6.0
83684-10	5.4	5.6	3.6	4.7	5.3	5.2	7.1	4.0	6.0	5.7	3.7	5.8
83686-01	6.5	4.1	5.0	4.9	3.6	8.0	5.2	7.4	5.6	2.6	8.1	-1.3
83689-05	6.4	4.7	4.7	4.8	3.7	5.2	6.2	5.7	3.6	3.3	7.5	3.6
83687-06	5.6	3.8	4.3	5.0	4.7	6.2	5.7	8.4	4.3	3.9	7.5	5.2
MEAN	5.4	5.5	5.0	4.5	4.6	5.4	5.2	6.0	5.3	5.7	5.5	5.2
S.D.	1.35	1.66	0.87	1.06	0.83	1.28	1.23	1.96	1.35	1.84	1.54	2.13
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: CORN OIL									
83681-01	4.4	1.0	11.8	-0.3	1.3	0.2	5.7	1.0	98.9
83680-04	8.2	4.9	11.8	7.6	3.9	5.4	5.9	9.1	133.4
83677-01	2.7	5.3	9.3	5.5	4.5	-2.8	8.6	4.6	97.6
83679-06	7.9	2.4	6.9	3.4	5.6	2.5	-0.8	6.8	97.6
83678-08	4.3	2.0	5.4	4.7	4.3	1.5	3.9	5.4	78.4
83677-08	8.9	4.4	5.1	6.2	7.3	6.3	7.1	2.8	110.0
83679-09	4.9	5.7	6.4	5.8	5.0	5.6	3.2	5.3	109.4
83683-01	3.8	6.4	4.3	6.4	6.7	1.8	0.7	7.6	93.8
83685-02	3.0	4.7	4.0	5.2	4.4	2.2	0.3	7.9	93.9
83682-04	5.8	10.6	5.2	5.8	5.2	4.6	2.9	5.2	117.5
83684-06	2.2	6.7	0.3	6.1	4.2	4.9	0.7	1.4	88.6
83684-10	5.0	4.8	7.7	4.0	-0.1	9.0	2.6	3.5	98.6
83686-01	12.0	4.3	4.5	5.4	3.4	2.9	1.0	8.0	101.2
83689-05	4.9	6.8	7.4	3.2	1.7	6.2	5.2	6.1	100.9
83687-06	8.6	3.4	6.7	6.8	3.6	4.5	6.1	5.1	109.4
MEAN	5.8	4.9	6.5	5.1	4.1	3.7	3.5	5.3	101.9
S.D.	2.76	2.32	2.99	1.91	1.96	2.90	2.82	2.40	12.90
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: [redacted]60												
83680-02	6.0	4.8	4.9	3.3	3.8	5.5	4.7	4.2	4.8	4.7	5.6	5.1
83678-06	7.1	5.4	4.2	2.9	6.4	2.1	6.2	3.2	6.4	4.3	1.9	5.1
83679-10	5.2	6.5	5.3	3.3	6.6	5.7	5.3	4.8	5.6	5.9	4.7	6.1
83681-07	5.1	5.3	4.6	4.5	4.3	4.3	4.8	6.0	5.8	6.7	3.6	6.6
83677-02	0.2	6.9	4.1	3.5	2.6	5.0	5.7	3.7	6.2	5.1	6.7	6.8
83679-01	6.5	5.2	4.5	6.1	3.6	5.7	5.3	6.9	6.6	5.3	3.8	6.1
83681-03	4.7	7.2	6.6	5.1	4.6	4.9	6.1	5.0	5.9	5.3	7.1	3.3
83685-06	4.5	6.0	4.8	3.9	5.1	4.5	4.7	5.3	5.5	6.0	4.7	8.5
83683-07	7.8	5.8	4.0	4.1	5.3	5.7	5.9	5.4	7.4	5.8	5.7	5.8
83684-08	5.4	5.0	3.7	5.5	4.7	6.9	5.8	6.6	5.7	7.4	7.1	9.6
83682-03	6.3	6.2	3.8	5.6	7.0	6.0	5.6	6.7	7.7	3.3	8.7	9.7
83683-05	6.9	6.9	3.5	3.9	6.4	4.4	4.3	5.4	5.9	5.4	5.4	7.1
83685-10	6.5	5.2	4.3	2.8	5.1	5.5	3.7	7.3	3.7	4.9	5.2	6.0
83687-08	5.6	4.5	4.3	4.9	4.9	5.3	6.0	5.6	6.6	5.3	5.3	5.7
83689-04	5.2	4.5	3.5	4.7	5.7	4.3	6.9	5.9	5.3	5.7	6.8	5.5
MEAN	5.5	5.7	4.4	4.3	5.1	5.1	5.4	5.5	5.9	5.4	5.5	6.5
S.D.	1.75	0.89	0.80	1.03	1.22	1.09	0.83	1.17	0.98	0.96	1.68	1.71
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: [redacted]60									
83680-02	3.9	6.3	5.4	4.4	6.8	4.3	1.6	3.5	93.6
83678-06	0.9	4.5	5.2	1.2	7.3	4.7	1.4	4.7	85.1
83679-10	4.6	5.9	5.7	6.7	6.2	3.6	3.6	4.8	106.1
83681-07	5.8	6.9	3.3	5.7	7.3	1.6	3.7	7.2	103.1
83677-02	4.7	9.2	6.6	5.5	4.0	7.6	6.9	4.5	105.5
83679-01	6.2	4.7	5.1	4.3	5.6	8.4	1.2	3.4	104.5
83681-03	7.1	6.9	3.4	7.8	3.3	4.7	0.6	6.4	106.0
83685-06	5.5	7.0	4.7	4.7	2.2	0.2	5.6	5.9	99.3
83683-07	8.3	10.4	4.9	8.6	6.0	3.8	6.9	0.7	118.3
83684-08	6.6	9.8	7.9	11.3	4.4	5.6	7.1	8.5	134.6
83682-03	1.9	7.0	4.4	3.4	6.5	5.0	0.3	5.3	110.4
83683-05	5.9	8.6	6.6	5.6	9.1	4.0	4.9	6.4	116.6
83685-10	6.4	5.9	7.1	4.6	3.9	0.2	1.9	3.7	93.9
83687-08	9.0	5.8	6.1	5.5	4.3	3.6	6.5	4.7	109.5
83689-04	4.0	5.8	6.8	6.1	4.7	4.5	4.2	2.5	102.6
MEAN	5.4	7.0	5.5	5.7	5.4	4.1	3.8	4.8	105.9
S.D.	2.16	1.78	1.32	2.34	1.83	2.27	2.47	1.95	11.70
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: [redacted]250												
83678-04	5.6	6.2	5.2	5.7	4.9	5.4	5.4	5.7	7.6	6.8	2.5	3.3
83680-05	4.3	6.0	6.5	3.0	4.6	3.6	3.4	5.4	7.2	5.7	4.1	8.2
83677-10	5.2	3.4	5.2	3.8	4.9	5.3	5.1	5.3	5.0	6.3	7.5	4.5
83681-09	3.6	-1.2	-4.3	11.3	6.0	4.8	5.3	5.3	3.8	5.9	7.9	3.5
83679-04	4.1	-2.9	-3.9	10.6	6.4	7.0	5.6	6.0	4.5	4.8	4.6	4.4
83677-04	4.7	-1.2	-1.5	12.6	6.8	4.5	4.4	5.1	6.1	4.0	7.3	4.7
83680-01	5.3	6.6	4.1	6.4	6.4	4.1	4.9	7.3	6.2	5.4	6.9	4.2
83684-02	4.6	2.1	5.2	3.5	5.4	2.9	5.3	2.8	5.3	3.1	6.3	6.8
83683-02	4.7	5.6	5.7	6.2	5.8	5.1	6.9	6.2	6.9	7.3	5.4	9.8
83685-03	5.3	5.1	4.4	4.2	6.3	5.1	5.1	7.5	5.4	5.3	7.6	5.3
83682-09	8.4	5.7	3.8	4.2	5.0	3.5	7.0	7.1	4.9	4.8	5.4	7.5
83682-01	4.6	4.8	4.0	5.0	4.4	2.9	5.9	5.2	5.5	4.1	5.7	5.3
83685-07	6.3	5.9	3.9	2.7	5.0	3.8	4.4	6.0	3.6	6.3	3.9	6.4
83687-09	5.9	4.9	5.5	4.9	4.6	5.6	6.3	5.9	7.1	4.5	5.6	5.5
83689-01	4.3	5.7	3.7	4.6	6.0	4.7	7.3	5.9	8.0	3.7	10.0	6.0
MEAN	5.1	3.8	3.2	5.9	5.5	4.6	5.5	5.8	5.8	5.2	6.0	5.7
S.D.	1.15	3.11	3.46	3.10	0.78	1.11	1.06	1.12	1.35	1.20	1.89	1.80
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: [redacted]250									
83678-04	11.3	2.8	8.7	4.1	3.8	7.9	2.8	4.6	110.3
83680-05	4.7	6.2	9.6	4.1	5.3	5.3	7.1	6.6	110.9
83677-10	6.7	2.9	4.2	8.1	5.0	4.3	-0.1	9.1	101.7
83681-09	9.6	2.7	5.4	5.4	6.2	5.8	2.6	1.8	91.4
83679-04	6.2	5.0	6.0	5.8	3.9	1.0	3.6	5.5	88.2
83677-04	7.6	4.6	5.7	7.6	2.8	6.1	2.3	4.8	99.0
83680-01	8.9	6.2	3.2	9.5	6.8	2.5	8.1	3.6	116.6
83684-02	3.0	4.2	4.3	5.4	3.6	4.7	0.9	5.9	85.3
83683-02	3.2	6.3	9.2	5.8	9.8	4.0	6.4	5.4	125.7
83685-03	7.2	5.5	7.3	6.0	4.3	4.2	5.8	5.4	112.3
83682-09	5.0	8.1	6.7	6.4	5.8	1.1	5.4	5.8	111.6
83682-01	4.1	4.4	2.6	4.4	3.5	2.3	6.1	-1.2	83.6
83685-07	3.0	3.5	5.7	6.1	4.7	6.7	2.4	4.2	94.5
83687-09	9.0	3.8	7.8	4.1	5.7	4.0	4.8	7.2	112.7
83689-01	6.4	7.7	10.6	9.2	3.3	2.0	8.1	4.7	121.9
MEAN	6.4	4.9	6.5	6.1	5.0	4.1	4.4	4.9	104.4
S.D.	2.58	1.71	2.39	1.76	1.77	2.05	2.56	2.35	13.45
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: [redacted]1000												
83678-03	5.6	4.8	5.1	4.9	4.3	5.9	3.3	6.5	4.6	6.9	4.6	3.7
83679-05	3.7	7.7	4.9	3.3	2.4	4.3	4.3	2.6	4.3	6.3	3.0	3.5
83677-03	3.5	5.5	3.5	3.5	4.4	3.0	5.6	3.2	4.7	4.6	4.3	2.0
83680-03	1.8	8.8	4.4	3.2	5.5	4.0	3.9	5.7	4.9	6.1	5.3	6.5
83681-06	4.4	5.7	5.8	3.1	2.8	5.4	4.3	4.4	5.3	5.6	4.4	5.8
83679-08	5.1	5.4	5.0	5.7	4.1	6.4	4.9	7.1	5.7	4.6	3.8	3.6
83678-01	3.7	7.5	5.0	5.6	4.9	4.6	6.8	7.6	3.2	8.7	5.8	8.3
83685-04	2.3	6.8	4.5	4.7	6.0	3.5	4.3	4.5	5.9	5.1	7.3	5.3
83683-08	6.6	5.6	3.4	4.8	5.0	5.3	5.6	6.1	4.5	6.1	6.4	7.4
83682-08	4.4	8.3	4.3	5.3	2.2	5.8	3.2	7.8	5.3	6.0	7.1	5.4
83684-03	3.1	6.1	4.3	4.8	4.1	5.7	5.7	5.4	3.5	5.0	6.1	5.2
83684-04	6.0	5.0	4.0	5.0	3.6	6.0	4.3	4.5	6.6	5.1	4.8	5.3
83686-05	5.3	4.8	3.7	5.8	3.8	3.9	5.0	6.0	4.6	4.6	4.0	3.3
83687-02	6.0	3.8	6.6	7.0	5.7	4.2	6.1	6.1	5.9	6.5	6.8	4.3
83689-08	3.6	6.2	5.9	4.6	3.2	4.4	3.9	6.8	5.1	4.2	6.5	4.5
MEAN	4.3	6.1	4.7	4.8	4.1	4.8	4.7	5.6	4.9	5.7	5.3	4.9
S.D.	1.41	1.42	0.91	1.10	1.17	1.03	1.04	1.53	0.90	1.16	1.33	1.66
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: [redacted]1000									
83678-03	5.8	1.1	6.2	6.4	2.8	4.5	-1.0	1.6	87.6
83679-05	3.7	3.7	6.0	3.4	5.8	1.8	5.4	1.4	81.5
83677-03	5.5	4.3	5.6	2.1	1.8	3.3	4.0	2.7	77.1
83680-03	6.5	4.9	7.2	5.7	7.6	5.8	5.8	6.0	109.6
83681-06	4.8	5.0	7.6	2.1	5.1	6.9	2.6	7.0	98.1
83679-08	3.3	1.9	6.8	2.5	5.3	0.4	3.7	7.0	92.3
83678-01	5.5	4.1	5.0	5.0	6.7	5.8	3.4	-2.0	105.2
83685-04	3.6	8.7	4.8	6.0	4.5	5.5	2.3	6.7	102.3
83683-08	2.6	6.5	7.7	6.0	2.9	1.7	4.2	5.6	104.0
83682-08	5.6	7.7	4.5	3.2	3.3	4.5	8.1	-3.1	98.9
83684-03	4.8	8.5	1.8	3.5	7.2	3.0	-0.8	4.0	91.0
83684-04	5.2	8.3	0.5	5.1	1.0	4.5	0.7	-0.2	85.3
83686-05	5.0	4.9	3.8	5.8	0.2	4.3	0.7	4.2	83.7
83687-02	8.3	6.2	7.3	7.1	3.1	7.6	0.5	9.0	118.1
83689-08	6.0	3.5	6.4	4.2	3.7	-1.4	10.9	3.9	96.1
MEAN	5.1	5.3	5.4	4.5	4.1	3.9	3.4	3.6	95.4
S.D.	1.41	2.34	2.10	1.65	2.22	2.46	3.28	3.51	11.37
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: [redacted]60												
83678-07	5.4	4.8	3.2	4.6	5.7	5.9	7.2	4.6	4.0	8.5	4.1	6.3
83681-08	5.6	5.3	3.5	5.5	5.8	5.1	6.1	5.1	6.7	4.7	5.8	3.8
83680-10	5.5	7.1	5.2	3.6	7.5	4.8	6.5	5.6	3.1	10.4	5.7	4.9
83679-02	4.5	6.4	4.8	4.0	5.2	5.3	4.0	4.1	5.6	3.8	5.0	3.4
83677-05	4.4	6.5	5.1	4.9	5.3	5.7	4.1	5.2	5.0	7.1	6.1	5.2
83681-10	4.0	6.4	4.7	2.9	5.2	5.6	5.1	4.0	3.9	8.4	3.9	4.3
83678-09	8.2	7.0	3.8	6.7	3.7	5.6	5.3	6.9	3.5	5.7	6.0	5.0
83685-01	5.7	5.3	6.0	5.8	5.9	5.6	6.2	4.1	6.6	5.8	6.2	6.3
83683-03	5.6	3.4	6.2	3.7	5.1	4.7	4.5	3.6	4.4	3.8	6.1	6.3
83684-09	6.3	4.5	4.7	3.7	7.5	4.8	3.7	6.9	6.3	6.1	3.8	6.8
83682-02	6.6	5.4	5.6	4.3	6.1	6.8	6.1	6.7	5.5	7.2	5.4	4.5
83682-06	7.8	5.5	2.7	3.7	5.5	4.8	3.1	6.5	6.9	6.7	5.7	1.9
83683-06	3.6	5.9	5.8	4.9	6.0	6.4	6.2	4.0	7.6	6.5	5.8	6.6
83686-09	7.4	4.6	5.3	5.1	5.0	5.3	3.0	6.9	6.3	4.0	5.8	6.1
83689-09	7.2	6.2	5.5	7.3	5.9	4.9	5.4	5.2	9.9			
MEAN	5.9	5.6	4.8	4.7	5.7	5.4	5.1	5.3	5.7	6.3	5.4	5.1
S.D.	1.39	1.02	1.06	1.22	0.94	0.62	1.31	1.22	1.80	1.94	0.85	1.42
N	15	15	15	15	15	15	15	15	15	14	14	14

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 10
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: [redacted]60									
83678-07	6.0	1.4	5.3	6.0	5.7	4.7	2.3	5.2	100.9
83681-08	4.9	4.6	6.8	2.4	5.7	5.3	3.8	5.1	101.6
83680-10	8.3	5.3	5.0	7.8	1.5	6.5	8.6	4.0	116.9
83679-02	5.0	4.7	7.8	4.5	3.2	1.0	6.7	5.6	94.6
83677-05	5.9	5.8	8.8	5.4	1.2	9.0	5.0	4.4	110.1
83681-10	5.1	5.0	6.7	5.9	1.3	4.4	4.5	4.8	96.1
83678-09	5.9	2.5	7.1	7.3	3.4	4.7	6.0	4.6	108.9
83685-01	5.5	5.0	5.8	2.1	2.9	4.5	5.4	1.6	102.3
83683-03	4.5	8.7	5.4	2.9	7.1	3.9	6.5	5.5	101.9
83684-09	5.0	9.8	5.5	1.5	7.3	6.8	3.8	3.4	108.2
83682-02	4.1	6.8	4.1	3.3	2.3	4.7	4.8	5.1	105.4
83682-06	7.0	7.0	6.8	1.5	4.1	5.8	7.6	3.8	104.4
83683-06	6.5	7.5	5.6	2.2	7.8	5.7	3.5	9.4	117.5
83686-09	2.6	8.2	5.5	4.9	2.7	9.8	-0.4	1.2	99.3
MEAN	5.5	5.9	6.2	4.1	4.0	5.5	4.9	4.6	104.9
S.D.	1.36	2.32	1.24	2.14	2.30	2.16	2.28	1.94	6.88
N	14	14	14	14	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 6: [redacted]250												
83681-05	6.1	4.9	5.6	3.5	4.6	4.8	4.9	3.9	4.9	5.1	4.0	6.2
83678-10	7.4	2.4	6.2	1.9	4.3	4.1	3.8	3.4	3.3	4.8	4.0	3.8
83680-07	8.0	4.8	6.2	3.8	4.3	4.8	4.6	5.9	6.3	8.3	5.5	5.6
83677-07	5.5	5.8	4.8	5.1	4.2	5.6	3.8	5.8	5.2	5.9	4.0	6.2
83679-03	5.3	4.9	3.8	4.4	3.2	5.0	5.2	4.9	4.7	3.9	7.1	4.2
83680-09	5.2	5.1	4.3	2.8	4.2	5.2	4.1	3.1	6.3	4.8	5.1	4.6
83681-02	4.4	5.7	5.8	5.1	4.3	5.1	6.3	6.1	5.9	4.4	4.9	6.5
83678-02	7.2	5.3	4.9	4.6	4.7	5.9	5.1	3.4	6.5	4.9	6.6	6.8
83685-09	5.7	4.8	3.1	4.2	3.9	4.7	5.5	4.8	6.3	4.8	7.1	5.8
83684-07	3.6	4.6	4.2	3.4	7.1	4.3	5.9	4.1	7.1	5.1	6.7	5.0
83683-09	6.9	5.9	3.8	4.9	6.7	5.4	7.9	4.6	6.9	7.4	4.9	6.0
83682-10	6.8	6.8	4.4	4.2	6.0	5.7	7.0	5.7	7.4	8.1	6.1	11.7
83682-05	6.4	6.9	4.0	5.6	5.9	4.4	6.2	6.7	7.2	7.1	4.5	7.1
83688-04	4.4	4.6	5.3	4.7	6.6	3.0	5.6	6.7	7.4	4.1	6.0	6.0
83687-05	4.7	4.3	6.5	4.1	6.8	6.5	4.0	6.4	8.3	6.3	8.4	4.7
MEAN	5.8	5.1	4.9	4.2	5.1	5.0	5.3	5.0	6.2	5.7	5.7	6.0
S.D.	1.27	1.08	1.03	0.97	1.26	0.84	1.20	1.25	1.29	1.44	1.34	1.84
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 6: [redacted]250									
83681-05	1.7	5.2	5.5	5.1	0.7	0.5	4.1	2.3	83.6
83678-10	1.6	3.8	6.6	0.7	2.4	2.9	2.6	4.1	74.1
83680-07	5.8	8.1	8.1	7.0	5.8	8.2	2.5	-1.2	112.4
83677-07	6.2	5.5	8.3	5.2	7.9	1.2	3.8	8.5	108.5
83679-03	5.0	4.6	6.6	6.1	4.0	4.9	0.2	5.8	93.8
83680-09	6.8	4.6	6.6	4.7	6.2	3.7	4.9	6.5	98.8
83681-02	8.1	7.2	7.5	5.3	5.1	7.6	3.6	4.2	113.1
83678-02	5.3	4.4	8.0	5.6	2.2	5.4	5.4	4.2	106.4
83685-09	4.5	7.1	3.8	4.7	3.7	5.8	5.0	1.9	97.2
83684-07	4.0	8.6	3.8	6.9	7.3	4.1	3.6	5.3	104.7
83683-09	5.2	7.7	4.2	1.6	3.4	6.4	3.4	3.6	106.8
83682-10	4.3	10.3	5.0	5.0	10.6	4.6	7.7	3.8	131.2
83682-05	6.8	9.4	3.9	6.9	2.0	1.4	8.2	3.4	114.0
83688-04	6.1	5.9	4.2	6.0	4.3	4.8	-1.1	9.9	104.5
83687-05	6.9	7.8	7.5	2.8	6.4	6.5	4.2	8.3	121.4
MEAN	5.2	6.7	6.0	4.9	4.8	4.5	3.9	4.7	104.7
S.D.	1.82	1.99	1.71	1.87	2.62	2.29	2.39	2.83	14.17
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 7: [redacted]1000												
83678-05	4.6	6.4	5.9	4.1	5.5	5.8	5.3	7.1	8.1	6.5	2.8	7.3
83681-04	5.3	5.9	5.6	3.9	5.3	7.0	4.6	7.5	7.0	7.8	4.8	4.6
83679-07	6.1	6.1	6.2	4.2	4.4	6.0	6.2	7.1	6.9	6.2	6.8	7.5
83680-06	3.6	5.8	4.7	5.6								
83677-09	4.1	4.3	5.4	5.6	6.5	6.1	5.2	5.0	4.0	7.7	4.7	5.4
83677-06	3.8	4.9	5.3	5.5	5.9	4.6	7.0	5.5	5.8	7.5	6.5	5.7
83680-08	3.1	5.8	5.8	3.8	4.0	6.4	5.0	5.3	9.1	5.9	5.5	6.5
83685-08	5.4	4.1	4.2	4.7	5.5	3.4	5.9	7.2	5.3	4.1	9.2	4.2
83682-07	5.7	7.1	3.9	3.1	5.5	3.1	7.9	4.2	6.1	7.3	5.6	6.4
83683-04	4.4	5.8	3.5	5.6	6.8	4.9	5.0	5.1	6.8	5.7	5.8	6.6
83684-01	4.2	5.8	3.8	4.4	6.2	5.2	6.1	7.0	5.2	3.5	6.8	4.8
83683-10	4.5	6.3	5.5	4.0	7.9	4.0	7.2	5.8	8.0	6.2	8.8	5.1
83685-05	4.4	5.4	4.6	4.7	6.7	3.9	4.6	6.7	4.7	4.6	7.0	7.2
83686-02	5.5	4.6	3.4	6.8	3.6	5.1	5.3	6.3	4.1	5.7	6.0	5.7
83687-04	2.4	5.2	3.0	4.1	3.2	5.0	5.0	5.6	5.4	6.3	4.7	5.2
MEAN	4.5	5.6	4.7	4.7	5.5	5.0	5.7	6.1	6.2	6.1	6.1	5.9
S.D.	1.01	0.82	1.03	0.96	1.33	1.16	1.03	1.02	1.54	1.31	1.67	1.06
N	15	15	15	15	14	14	14	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-002

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 7: [redacted]1000									
83678-05	7.1	5.2	9.1	2.8	5.5	5.6	2.6	2.9	110.2
83681-04	5.0	10.4	9.3	6.8	6.6	5.7	7.7	4.4	125.2
83679-07	4.4	3.7	10.7	1.6	4.5	4.2	4.3	4.6	111.7
83677-09	4.5	5.2	5.3	5.5	2.2	4.3	3.1	-1.3	92.8
83677-06	6.5	4.3	3.8	10.8	7.4	4.2	7.2	5.3	117.5
83680-08	6.9	7.3	7.5	6.3	1.8	7.4	4.2	4.3	111.9
83685-08	7.3	6.3	4.4	6.1	4.9	3.5	5.3	3.0	104.0
83682-07	5.7	6.2	7.1	4.2	9.7	2.6	1.3	6.8	109.5
83683-04	5.0	6.4	4.7	7.6	5.4	4.3	5.3	4.1	108.8
83684-01	7.9	0.2	5.4	6.3	3.1	1.7	3.4	1.7	92.7
83685-05	5.3	8.0	4.4	5.9	2.5	6.2	6.2	2.6	105.6
83686-02	6.7	6.3	4.4	3.4	4.9	6.3	3.2	5.7	103.0
83687-04	8.0	6.0	8.6	0.6	4.6	6.1	4.1	3.1	96.2
MEAN	6.2	5.8	6.5	5.2	4.9	4.8	4.5	3.6	106.9
S.D.	1.26	2.38	2.32	2.70	2.22	1.62	1.84	2.03	9.38
N	13	13	13	13	13	13	13	13	13

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: CORN OIL SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83681-01	31	108.9	N	N	N	N	N	Y										
83680-04	35	130.0	N	N	N	N	N	N	N	N	N	Y						
83677-01	35	108.6	N	N	N	N	N	N	N	N	N	Y						
83679-06	36	116.3	N	N	N	N	N	N	N	N	N	N	Y					
83678-08	35	86.7	N	N	N	N	N	N	N	N	N	Y						
83677-08	35	112.2	N	N	N	N	N	N	N	N	N	Y						
83679-09	34	114.5	N	N	N	N	N	N	N	N	Y							
83683-01	33	92.4	N	N	N	N	N	N	N	Y								
83685-02	36	117.7	N	N	N	N	N	N	N	N	N	N	Y					
83682-04	33	106.1	N	N	N	N	N	N	N	Y								
83684-06	31	97.0	N	N	N	N	N	Y										
83684-10	32	108.8	N	N	N	N	N	N	Y									
83686-01	31	101.4	N	N	N	N	N	Y										
83689-05	34	109.7	N	N	N	N	N	N	N	N	Y							
83687-06	32	97.7	N	N	N	N	N	N	Y									
MEAN	33.5	107.2																
S.D.	1.81	10.93																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND==> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83680-02	37	125.2	N	N	N	N	N	N	N	N	N	N	N	Y				
83678-06	32	92.1	N	N	N	N	N	N	Y									
83679-10	35	118.3	N	N	N	N	N	N	N	N	N	Y						
83681-07	32	93.0	N	N	N	N	N	N	Y									
83677-02	35	94.9	N	N	N	N	N	N	N	N	N	Y						
83679-01	32	101.4	N	N	N	N	N	N	Y									
83681-03	32	100.9	N	N	N	N	N	N	Y									
83685-06	34	105.5	N	N	N	N	N	N	N	N	Y							
83683-07	30	84.8	N	N	N	N	Y											
83684-08	31	98.5	N	N	N	N	N	Y										
83682-03	32	108.1	N	N	N	N	N	N	Y									
83683-05	30	90.4	N	N	N	N	Y											
83685-10	32	90.0	N	N	N	N	N	N	Y									
83687-08	31	101.7	N	N	N	N	N	Y										
83689-04	37	123.5	N	N	N	N	N	N	N	N	N	N	N	Y				
MEAN	32.8	101.9																
S.D.	2.27	12.34																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83678-04	28	86.5	N	N	Y													
83680-05	30	81.5	N	N	N	N	Y											
83677-10	28	73.5	N	N	Y													
83681-09	28	64.3	N	N	Y													
83679-04	36	103.1	N	N	N	N	N	N	N	N	N	N	Y					
83677-04	31	83.0	N	N	N	N	N	Y										
83680-01	32	102.2	N	N	N	N	N	N	Y									
83684-02	28	59.0	N	N	Y													
83683-02	32	99.6	N	N	N	N	N	N	Y									
83685-03	30	87.7	N	N	N	N	Y											
83682-09	31	99.1	N	N	N	N	N	Y										
83682-01	27	69.1	N	Y														
83685-07	30	83.1	N	N	N	N	Y											
83687-09	29	88.3	N	N	N	Y												
83689-01	29	87.2	N	N	N	Y												
MEAN	29.9	84.5																
S.D.	2.28	13.54																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83678-03	26	73.7	Y															
83679-05	27	70.2	N	Y														
83677-03	27	66.3	N	Y														
83680-03	27	64.8	N	Y														
83681-06	27	67.4	N	Y														
83679-08	28	78.0	N	N	Y													
83678-01	28	76.9	N	N	Y													
83685-04	27	67.5	N	Y														
83683-08	29	76.4	N	N	N	Y												
83682-08	27	74.3	N	Y														
83684-03	27	77.9	N	Y														
83684-04	27	73.3	N	Y														
83686-05	27	74.6	N	Y														
83687-02	27	80.5	N	Y														
83689-08	27	72.6	N	Y														
MEAN	27.2	73.0																
S.D.	0.68	4.77																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83678-07	31	94.5	N	N	N	N	N	Y										
83681-08	32	99.4	N	N	N	N	N	N	Y									
83680-10	34	112.9	N	N	N	N	N	N	N	N	Y							
83679-02	34	102.5	N	N	N	N	N	N	N	N	Y							
83677-05	34	105.5	N	N	N	N	N	N	N	N	Y							
83681-10	35	112.8	N	N	N	N	N	N	N	N	N	Y						
83678-09	31	92.0	N	N	N	N	N	Y										
83685-01	34	111.7	N	N	N	N	N	N	N	N	Y							
83683-03	37	121.4	N	N	N	N	N	N	N	N	N	N	N	Y				
83684-09	36	130.9	N	N	N	N	N	N	N	N	N	N	Y					
83682-02	34	117.1	N	N	N	N	N	N	N	N	Y							
83682-06	33	105.4	N	N	N	N	N	N	N	Y								
83683-06	33	100.1	N	N	N	N	N	N	N	Y								
83686-09	33	108.0	N	N	N	N	N	N	N	Y								
83689-09	RESPONSE NOT EXHIBITED BY DAY 31, DAY OF DEATH																	
MEAN	33.6	108.2																
S.D.	1.69	10.62																
N	14	14																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83681-05	35	109.4	N	N	N	N	N	N	N	N	N	Y						
83678-10	35	98.0	N	N	N	N	N	N	N	N	N	Y						
83680-07	35	117.1	N	N	N	N	N	N	N	N	N	Y						
83677-07	36	114.9	N	N	N	N	N	N	N	N	N	N	Y					
83679-03	35	106.5	N	N	N	N	N	N	N	N	N	Y						
83680-09	37	116.4	N	N	N	N	N	N	N	N	N	N	N	Y				
83681-02	31	95.3	N	N	N	N	N	Y										
83678-02	34	119.2	N	N	N	N	N	N	N	N	Y							
83685-09	35	100.3	N	N	N	N	N	N	N	N	N	Y						
83684-07	36	118.7	N	N	N	N	N	N	N	N	N	N	Y					
83683-09	34	113.5	N	N	N	N	N	N	N	N	Y							
83682-10	33	117.8	N	N	N	N	N	N	N	Y								
83682-05	31	106.4	N	N	N	N	N	Y										
83688-04	33	109.5	N	N	N	N	N	N	N	Y								
83687-05	34	117.2	N	N	N	N	N	N	N	N	Y							
MEAN	34.3	110.7																
S.D.	1.71	7.90																
N	15	15																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-002

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
83678-05	33	113.7	N	N	N	N	N	N	N	Y								
83681-04	33	111.8	N	N	N	N	N	N	N	Y								
83679-07	35	125.8	N	N	N	N	N	N	N	N	N	Y						
83680-06	RESPONSE NOT EXHIBITED BY DAY 26, DAY OF DEATH																	
83677-09	35	112.0	N	N	N	N	N	N	N	N	N	Y						
83677-06	39	141.8	N	N	N	N	N	N	N	N	N	N	N	N	N	Y		
83680-08	33	111.0	N	N	N	N	N	N	N	Y								
83685-08	37	123.9	N	N	N	N	N	N	N	N	N	N	N	Y				
83682-07	33	102.2	N	N	N	N	N	N	N	Y								
83683-04	39	141.1	N	N	N	N	N	N	N	N	N	N	N	N	N	Y		
83684-01	30	96.5	N	N	N	N	Y											
83683-10	34	123.0	N	N	N	N	N	N	N	N	Y							
83685-05	41	145.0	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
83686-02	39	141.3	N	N	N	N	N	N	N	N	N	N	N	N	N	Y		
83687-04	A	A	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
MEAN	35.5	122.2																
S.D.	3.26	16.11																
N	13	13																

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY
A = RESPONSE NOT EXHIBITED BY DAY 42

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 1: CORN OIL

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83681-01	N N N N N P M D D P E D D D E D D	4.5
83680-04	N N N N N N N N N M D D P E D D D	A
83677-01	N N N N N N N N N E D D D P E M D	5.0
83679-06	N N N N N N N N N E D D D P E D	5.0
83678-08	N N N N N N N N N D D D D E E D D	A
83677-08	N N N N N N N N N E D D D P E D D	5.0
83679-09	N N N N N N N N E M D D D E D D D	5.0
83683-01	N N N N N N N N D D D P E D D D E D	4.0
83685-02	N N N N N N N N N N E D D D D E D	5.0
83682-04	N N N N N N N N D E D D E D D D E D	3.5
83684-06	N N N N N N E D D D D E E D D D E E	6.0
83684-10	N N N N N N N D D E D D D P E D D D	5.0
83686-01	N N N N N N N E D D D P E D D D E E D	5.0
83689-05	N N N N N N N N N N P D D D P E D D D	5.0
83687-06	N N N N N N N N M D D P E D D D E D D	4.0
	MEAN	4.8
	S.D.	0.63
	N	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 2: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 1 0	1 1 2	1 3	1 4	1 5	1 6	1 7	1 8	1 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83680-02	N N N N N N N N N N	E	D	D	D	P	E			A
83678-06	N N N N N N E D D D	D	D	E	M	D	D	D		6.0
83679-10	N N N N N N N N N E	D	D	D	P	E	D	D		5.0
83681-07	N N N N N N E M D D	D	E	E	D	D	D	D		6.0
83677-02	N N N N N N N N N E	D	D	D	D	D	D	D		A
83679-01	N N N N N N E M D D	D	E	M	D	D	E	D		4.5
83681-03	N N N N N N E D D D	P	E	D	D	D	E	M		4.5
83685-06	N N N N N N N N N P	E	D	D	D	D	E	D	D	5.0
83683-07	N N N N N D P E D D	D	P	E	D	D	D	E	E	5.0
83684-08	N N N N N N E D D D	D	D	D	D	D	D	D	D	A
83682-03	N N N N N N N P E D	D	D	E	D	D	D	E	D	4.0
83683-05	N N N N N P E D D D	D	D	D	D	D	D	D	D	A
83685-10	N N N N N N N E D D	D	D	D	D	D	D	E	D	9.0
83687-08	N N N N N N N E D D	D	P	E	D	D	D	D	D	5.0
83689-04	N N N N N N N N N N	N	N	D	D	X	D	P	E	A
								MEAN		5.4
								S.D.		1.41
								N		10

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED
X = VAGINAL LAVAGE NOT PERFORMED

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 3: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83678-04	N N P E D D D E E D D D E E D D D	5.0
83680-05	N N N N D D D D E M D D P E D D D	5.0
83677-10	N N D D D D E D D D E E D D D E D	4.5
83681-09	N N D E E D D D D D P E D D D E E	7.0
83679-04	N N N N N N N N N N E M D D P E D	5.0
83677-04	N N N N N D P E D D D E M D D E E	4.0
83680-01	N N N N N N D D D E D D D D E D D	5.0
83684-02	N N N D D D E D D D D P E M D D E D	5.0
83683-02	N N N N N N N E D D D D D E D D D P	6.0
83685-03	N N N N N D E M D D D D P E D D D D	7.0
83682-09	N N N N N N P M D D P E M D D D E D	5.0
83682-01	N N D D D D P X D D D P E D D D D E	A
83685-07	N N N N N D D X D P E D D D P E D D	5.0
83687-09	N N N N N D P X D D D P E D D D E D D	4.0
83689-01	N N N N N D E X D D D E M D D D E M D	5.0
	MEAN	5.2
	S.D.	0.91
	N	14

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED
X = VAGINAL LAVAGE NOT PERFORMED

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 4: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83678-03	E D D D P E D D D P E D D D P E D	5.0
83679-05	N D D D D D E D D D D P D D D P D	4.5
83677-03	N D P D D D D P D P D D D P E D D	4.0
83680-03	N E D D D D D P D D D D P D D D E	5.5
83681-06	N D D D D D D P D D D D D D D D P	A
83679-08	N N D D P D D D D P D D D P E D D	5.0
83678-01	N N D D D D P D D D P E D D D D E	5.0
83685-04	N N D D D D D P D D D D P D D E E D	4.5
83683-08	N N N N D D D E D D D E E D D E D D	4.0
83682-08	N N D D D D D P P D D D P E D D D D	5.0
83684-03	N N D D D D D D D D D E D D D D D D	A
83684-04	N N D D D D D P D D D P E D D D E E	5.0
83686-05	N N N D D D D D D D D D P D D P E D D	4.0
83687-02	N N N D D D D D D D D D P D D D E E D	5.0
83689-08	N N N D D D D D D D D D D D D D D D D	A
	MEAN	4.7
	S.D.	0.50
	N	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 5: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83678-07	N N N N N E D D D D E D D D D E D	5.0
83681-08	N N N N N N P D D D D D D D D D D	A
83680-10	N N N N N N N N E D D D P E D D D	5.0
83679-02	N N N N N N N N E M D D D E E M D	6.0
83677-05	N N N N N N N N E D D D D E D D D	5.0
83681-10	N N N N N N N N N E D D D P E D D	5.0
83678-09	N N N N N E D D D P E D D D E D D	4.5
83685-01	N N N N N N N N N E D D D E D D D P	4.0
83683-03	N N N N N N N N N N N D E D D D D	A
83684-09	N N N N N N N N N N E D D D P E D	5.0
83682-02	N N N N N N N N N E M D D D E D D D	5.0
83682-06	N N N N N N N N P E M D D D E M D D	5.0
83683-06	N N N N N N N N E D D D P E D D D P	5.0
83686-09	N N N N N N N N N E D D D D E D D D D	5.0
83689-09	N N N N N N N N	A
	MEAN	5.0
	S.D.	0.45
	N	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
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N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 6: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83681-05	N N N N N N N N E M D D D E M D	5.0
83678-10	N N N N N N N N M D D D D E E D	A
83680-07	N N N N N N N N E D D D D D D E	A
83677-07	N N N N N N N N N E D D D D E D	5.0
83679-03	N N N N N N N N E D D D D E E D	6.0
83680-09	N N N N N N N N N N D D D E P E	A
83681-02	N N N N N E D D D D D D D D D D	A
83678-02	N N N N N N N E D D D D E D D D	5.0
83685-09	N N N N N N N N N E M D D D D D D	A
83684-07	N N N N N N N N N N E D D D E E D	5.0
83683-09	N N N N N N N N E M D D D E D D D	5.0
83682-10	N N N N N N N N E M D D P E D D D P	5.0
83682-05	N N N N N N D D D D E D D D P E D D	5.0
83688-04	N N N N N N N N M D D P E M D D E M	4.0
83687-05	N N N N N N N N N E M D D D E D D D	5.0
	MEAN	5.0
	S.D.	0.47
	N	10

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-002

FEMALES FROM GROUP 7: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
83678-05	N N N N N N N P D D D D D D D E D	8.0
83681-04	N N N N N N N D D D D D D D D D D	A
83679-07	N N N N N N N N N D D D D E D D D	A
83680-06	N	A
83677-09	N N N N N N N N N P E D D D D D E	A
83677-06	N N N N N N N N N N N N N E D D D	A
83680-08	N N N N N N N P E M D D D E D D D	5.0
83685-08	N N N N N N N N N N N N N E D D D D E	A
83682-07	N N N N N N N N E M D D P E M D D P	5.0
83683-04	N N N N N N N N N N N N N N D P E D	A
83684-01	N N N N N E D D D D D D E M D D D E	7.0
83683-10	N N N N N N N N N D	A
83685-05	N N N N N N N N N N N N N N N N D E	A
83686-02	N N N N N N N N N N N N N N N D D D D	A
83687-04	N N N N N N N N N N N N N N N N N N N	A
	MEAN	6.3
	S.D.	1.50
	N	4

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

PCYCv5.23
07/13/2005
R:08/16/2005

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: CORN OIL		FEMALES
83681-01	3.50	5.2
83680-04	3.00	8.2
83677-01	3.90	6.9
83679-06	3.90	4.7
83678-08	4.30	11.1
83677-08	6.00	9.6
83679-09	5.30	7.4
83683-01	2.50	10.7
83685-02	2.70	5.5
83682-04	3.10	8.1
83684-06	6.40	8.5
83684-10	4.10	9.0
83686-01	2.00	8.0
83689-05	4.60	8.2
83687-06	3.10	6.4
MEAN	3.89	7.8
S.D.	1.270	1.88
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]60	FEMALES	
83680-02	6.70	5.2
83678-06	5.40	15.6
83679-10	4.60	8.5
83681-07	4.80	12.3
83677-02	4.80	5.8
83679-01	3.60	8.0
83681-03	5.50	6.1
83685-06	4.50	6.7
83683-07	5.10	7.6
83684-08	4.00	9.6
83682-03	6.40	11.1
83683-05	5.70	9.9
83685-10	5.90	5.9
83687-08	4.40	11.4
83689-04	5.10	10.9
MEAN	5.10	9.0
S.D.	0.855	2.93
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]250	FEMALES	
83678-04	3.90	9.3
83680-05	4.30	6.9
83677-10	4.20	7.9
83681-09	5.50	7.0
83679-04	4.60	5.6
83677-04	5.20	5.6
83680-01	6.70	5.0
83684-02	3.50	4.6
83683-02	4.50	8.7
83685-03	5.90	12.2
83682-09	4.50	8.9
83682-01	6.90	6.2
83685-07	5.10	5.3
83687-09	4.90	8.3
83689-01	5.60	6.7
MEAN	5.02	7.2
S.D.	0.972	2.03
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]1000	FEMALES	
83678-03	2.90	9.4
83679-05	6.10	19.3
83677-03	5.00	9.5
83680-03	6.70	10.7
83681-06	5.90	9.5
83679-08	6.40	5.5
83678-01	4.70	8.0
83685-04	4.90	9.2
83683-08	5.50	13.7
83682-08	5.40	16.4
83684-03	8.70	7.9
83684-04	7.90	9.7
83686-05	3.70	14.7
83687-02	5.30	6.9
83689-08	5.00	7.9
MEAN	5.61	10.6
S.D.	1.467	3.81
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]60	FEMALES	
83678-07	2.10	6.6
83681-08	3.70	7.9
83680-10	3.80	9.3
83679-02	5.50	5.6
83677-05	4.80	10.4
83681-10	3.50	8.1
83678-09	5.20	6.0
83685-01	5.40	9.8
83683-03	6.40	12.5
83684-09	4.00	8.1
83682-02	4.50	9.8
83682-06	5.30	10.6
83683-06	5.60	6.5
83686-09	4.60	10.5
MEAN	4.60	8.7
S.D.	1.105	2.05
N	14	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]250	FEMALES	
83681-05	3.20	4.0
83678-10	4.60	7.9
83680-07	6.30	6.4
83677-07	5.30	9.0
83679-03	5.10	7.4
83680-09	4.60	7.8
83681-02	5.60	7.8
83678-02	3.90	8.5
83685-09	3.50	7.8
83684-07	3.80	10.0
83683-09	4.50	7.9
83682-10	6.40	11.5
83682-05	5.50	6.4
83688-04	3.50	11.0
83687-05	4.40	10.3
MEAN	4.68	8.2
S.D.	1.005	1.94
N	15	15

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-002

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]1000	FEMALES	
83678-05	3.10	6.3
83681-04	4.50	11.2
83679-07	5.70	9.7
83677-09	4.10	6.6
83677-06	5.20	7.2
83680-08	5.30	8.0
83685-08	5.10	12.0
83682-07	4.00	20.0
83683-04	4.60	7.6
83684-01	5.30	10.0
83685-05	4.30	7.4
83686-02	3.80	5.6
83687-04	3.40	5.2
MEAN	4.49	9.0
S.D.	0.800	3.92
N	13	13

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

PCHEv4.03
07/13/2005
R:07/28/2005

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-002

ANIMAL NO.83689-09 GROUP 5: [redacted]60 FEMALE FOUND DEAD 06/06/05 DATE OF DEATH: 06/06/05

					GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES				P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
		PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
		SKIN	SPLEEN	STOMACH	THYMUS
		THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
		CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.83680-06 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 05/30/05 DATE OF DEATH: 05/30/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-002

ANIMAL NO.83683-10 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.52
07/13/2005

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TABLE 22

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83681-01	153.	0.2647	0.2504	0.0143	8.0994	1.8978	0.0926	0.0427	0.0095	0.0243
83680-04	179.	0.3996	0.3265	0.0731	9.5561	1.7673	0.0823	0.0469	0.0045	0.0142
83677-01	142.	0.2864	0.2575	0.0289	7.3093	1.4706	0.0830	0.0321	0.0092	0.0215
83679-06	141.	0.2443	0.2238	0.0205	6.2702	1.5631	0.0713	0.0400	0.0072	0.0205
83678-08	114.	0.1920	0.1753	0.0167	4.9141	1.1770	0.0579	0.0259	0.0064	0.0188
83677-08	153.	0.2929	0.2714	0.0215	6.8156	1.7517	0.0880	0.0338	0.0078	0.0203
83679-09	156.	0.4145	0.3432	0.0713	6.9451	1.6446	0.0890	0.0324	0.0054	0.0210
83683-01	137.	0.2034	0.1771	0.0263	7.5546	1.4462	0.0858	0.0356	0.0058	0.0128
83685-02	141.	0.2162	0.1952	0.0210	7.1561	1.5350	0.0818	0.0410	0.0087	0.0116
83682-04	166.	0.2243	0.1959	0.0284	8.2291	1.7811	0.0956	0.0439	0.0092	0.0182
83684-06	139.	0.3612	0.3334	0.0278	7.3007	1.4369	0.0793	0.0494	0.0079	0.0184
83684-10	147.	0.4095	0.3676	0.0419	6.8919	1.3858	0.0904	0.0429	0.0079	0.0145
83686-01	152.	0.2710	0.2550	0.0160	7.6118	1.5622	0.0905	0.0399	0.0098	0.0196
83689-05	150.	0.3293	0.2928	0.0365	7.5047	1.5875	0.0739	0.0286	0.0079	0.0145
83687-06	154.	0.2881	0.2728	0.0153	7.8366	1.5156	0.0896	0.0308	0.0109	0.0179
MEAN	148.	0.2932	0.2625	0.0306	7.3330	1.5682	0.0834	0.0377	0.0079	0.0179
S.D.	14.5	0.07476	0.06174	0.01860	1.01308	0.18232	0.00977	0.00698	0.00178	0.00361
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 5/22/2006

TABLE 22

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83680-02	145.	0.3091	0.2836	0.0255	7.0310	1.4704	0.0792	0.0359	0.0072	0.0184
83678-06	130.	0.7289	0.3762	0.3527	6.0419	1.3223	0.0668	0.0317	0.0078	0.0169
83679-10	154.	0.2732	0.2554	0.0178	7.6533	1.6335	0.0751	0.0402	0.0072	0.0186
83681-07	144.	0.5125	0.3994	0.1131	7.5320	1.4464	0.0864	0.0261	0.0084	0.0184
83677-02	138.	0.1841	0.1629	0.0212	7.4919	1.5846	0.0800	0.0251	0.0062	0.0194
83679-01	150.	0.2368	0.2102	0.0266	7.6249	1.5178	0.0952	0.0484	0.0079	0.0197
83681-03	152.	0.2419	0.2274	0.0145	7.1008	1.5214	0.0853	0.0458	0.0098	0.0209
83685-06	140.	0.2166	0.1988	0.0178	7.8586	1.2563	0.0623	0.0266	0.0078	0.0096
83683-07	158.	0.4156	0.3929	0.0227	9.5763	1.8190	0.0909	0.0378	0.0097	0.0150
83684-08	183.	0.3076	0.2847	0.0229	10.2540	1.9553	0.0780	0.0426	0.0093	0.0185
83682-03	161.	0.2450	0.2234	0.0216	7.7680	1.6333	0.0782	0.0331	0.0076	0.0158
83683-05	165.	0.3649	0.3378	0.0271	8.4343	1.5796	0.0732	0.0377	0.0084	0.0153
83685-10	134.	0.2818	0.2555	0.0263	6.6936	1.3340	0.0901	0.0349	0.0056	0.0183
83687-08	161.	0.2457	0.2239	0.0218	8.4773	1.7197	0.0757	0.0428	0.0089	0.0180
83689-04	145.	0.2655	0.2474	0.0181	7.6453	1.4876	0.0880	0.0345	0.0076	0.0145
MEAN	151.	0.3219	0.2720	0.0500	7.8122	1.5521	0.0803	0.0362	0.0080	0.0172
S.D.	13.7	0.14030	0.07330	0.08706	1.05826	0.18688	0.00913	0.00706	0.00118	0.00279
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 22

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-04	162.	0.4597	0.3692	0.0905	8.5392	1.6233	0.0835	0.0439	0.0081	0.0128
83680-05	154.	0.3676	0.3257	0.0419	8.4294	1.6834	0.0885	0.0480	0.0092	0.0171
83677-10	147.	0.2905	0.2594	0.0311	7.7238	1.6429	0.1239	0.0473	0.0107	0.0164
83681-09	136.	0.3798	0.3397	0.0401	6.8023	1.4089	0.0976	0.0375	0.0090	0.0162
83679-04	129.	0.2066	0.1830	0.0236	5.8626	1.3262	0.0852	0.0380	0.0076	0.0137
83677-04	141.	0.3095	0.2933	0.0162	6.8665	1.4514	0.0859	0.0401	0.0085	0.0153
83680-01	162.	0.2691	0.2493	0.0198	7.5048	1.7604	0.0831	0.0426	0.0081	0.0196
83684-02	120.	0.2181	0.1924	0.0257	6.4625	1.2215	0.0681	0.0367	0.0067	0.0110
83683-02	168.	0.8383	0.4149	0.4234	9.1012	1.8058	0.0877	0.0485	0.0092	0.0134
83685-03	156.	0.4287	0.3869	0.0418	8.4375	1.4298	0.0972	0.0451	0.0099	0.0153
83682-09	160.	0.2431	0.2139	0.0292	7.7233	1.4224	0.0855	0.0425	0.0090	0.0115
83682-01	129.	0.2907	0.2660	0.0247	6.8107	1.2052	0.0707	0.0329	0.0058	0.0111
83685-07	139.	0.2690	0.2444	0.0246	6.6141	1.5703	0.0853	0.0331	0.0063	0.0185
83687-09	162.	0.2444	0.2279	0.0165	8.9784	1.5911	0.0989	0.0395	0.0095	0.0128
83689-01	172.	0.3478	0.3290	0.0188	8.6622	1.7337	0.0985	0.0478	0.0104	0.0258
MEAN	149.	0.3442	0.2863	0.0579	7.6346	1.5251	0.0893	0.0416	0.0085	0.0154
S.D.	16.0	0.15577	0.07182	0.10278	1.02319	0.18998	0.01319	0.00526	0.00145	0.00390
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 22

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-03	139.	0.1906	0.1660	0.0246	8.0387	1.5562	0.0755	0.0365	0.0075	0.0162
83679-05	127.	0.1460	0.1301	0.0159	6.6143	1.2397	0.0462	0.0341	0.0055	0.0164
83677-03	122.	0.2208	0.2052	0.0156	6.4690	1.2476	0.0757	0.0362	0.0069	0.0195
83680-03	152.	0.2243	0.2113	0.0130	7.6878	1.5814	0.0740	0.0403	0.0086	0.0150
83681-06	143.	0.1371	0.1221	0.0150	7.6974	1.5039	0.0633	0.0381	0.0073	0.0182
83679-08	138.	0.2086	0.1797	0.0289	7.2097	1.6243	0.0789	0.0406	0.0085	0.0185
83678-01	151.	0.2630	0.2397	0.0233	8.1788	1.6361	0.1009	0.0522	0.0093	0.0157
83685-04	147.	0.1626	0.1458	0.0168	8.6409	1.4320	0.0661	0.0289	0.0060	0.0126
83683-08	144.	0.1818	0.1598	0.0220	7.9484	1.5840	0.0761	0.0429	0.0060	0.0119
83682-08	148.	0.5293	0.2873	0.2420	7.9973	1.5741	0.0682	0.0457	0.0064	0.0116
83684-03	146.	0.2564	0.2246	0.0318	8.2383	1.6400	0.0603	0.0320	0.0064	0.0183
83684-04	134.	0.2349	0.2168	0.0181	7.0528	1.3348	0.0743	0.0464	0.0091	0.0120
83686-05	135.	0.1884	0.1729	0.0155	7.4837	1.4264	0.0662	0.0342	0.0030	0.0213
83687-02	169.	0.1955	0.1794	0.0161	10.2900	1.6948	0.0809	0.0382	0.0087	0.0153
83689-08	145.	0.1206	0.1080	0.0126	8.4481	1.4962	0.0664	0.0305	0.0057	0.0178
MEAN	143.	0.2173	0.1832	0.0341	7.8663	1.5048	0.0715	0.0385	0.0070	0.0160
S.D.	11.2	0.09582	0.04835	0.05780	0.92281	0.14201	0.01196	0.00641	0.00170	0.00299
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 5/22/2006

TABLE 22

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-07	150.	0.2181	0.1915	0.0266	7.9020	1.5306	0.1030	0.0399	0.0079	0.0131
83681-08	149.	0.2657	0.2361	0.0296	8.0362	1.5038	0.0714	0.0340	0.0077	0.0199
83680-10	161.	0.3966	0.3520	0.0446	9.1555	1.7634	0.0891	0.0345	0.0108	0.0147
83679-02	140.	0.2221	0.1897	0.0324	6.5053	1.4625	0.0808	0.0376	0.0081	0.0186
83677-05	150.	0.4180	0.3711	0.0469	7.0404	1.6570	0.0892	0.0393	0.0078	0.0169
83681-10	143.	0.2545	0.2384	0.0161	6.5758	1.5772	0.0715	0.0343	0.0054	0.0124
83678-09	149.	0.2527	0.2336	0.0191	6.3264	1.6026	0.0765	0.0409	0.0088	0.0151
83685-01	145.	0.6801	0.4051	0.2750	8.1158	1.4070	0.0809	0.0370	0.0083	0.0158
83683-03	147.	0.4677	0.3833	0.0844	7.0029	1.5658	0.0750	0.0315	0.0080	0.0156
83684-09	158.	0.2373	0.2135	0.0238	8.3179	1.7617	0.0889	0.0450	0.0092	0.0168
83682-02	154.	0.4439	0.3761	0.0678	7.6480	1.5622	0.0823	0.0369	0.0081	0.0176
83682-06	150.	0.4868	0.3668	0.1200	7.0267	1.5182	0.0804	0.0342	0.0074	0.0171
83683-06	154.	0.6376	0.4100	0.2276	6.9309	1.6408	0.0801	0.0339	0.0072	0.0147
83686-09	149.	0.6544	0.4125	0.2419	7.6231	1.5278	0.0762	0.0407	0.0094	0.0168
MEAN	150.	0.4025	0.3128	0.0897	7.4434	1.5772	0.0818	0.0371	0.0082	0.0161
S.D.	5.6	0.16780	0.08865	0.09091	0.80657	0.10218	0.00848	0.00369	0.00123	0.00203
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

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TABLE 22

SPONSOR: [redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83681-05	132.	0.1808	0.1645	0.0163	6.8287	1.5499	0.0664	0.0336	0.0072	0.0120
83678-10	118.	0.1931	0.1781	0.0150	5.4731	1.3897	0.0769	0.0291	0.0056	0.0117
83680-07	154.	0.3542	0.3373	0.0169	8.3754	1.7469	0.1070	0.0474	0.0099	0.0191
83677-07	150.	0.2169	0.1966	0.0203	7.7624	1.6119	0.0851	0.0356	0.0087	0.0141
83679-03	138.	0.2224	0.2072	0.0152	6.7391	1.4339	0.0565	0.0305	0.0063	0.0238
83680-09	141.	0.2549	0.2287	0.0262	6.1964	1.5278	0.0854	0.0328	0.0064	0.0176
83681-02	159.	0.6421	0.4487	0.1934	8.4230	1.5649	0.0948	0.0454	0.0085	0.0170
83678-02	158.	0.4536	0.3927	0.0609	7.5884	1.9236	0.0742	0.0346	0.0077	0.0137
83685-09	134.	0.1954	0.1774	0.0180	7.6017	1.4263	0.0665	0.0363	0.0066	0.0161
83684-07	149.	0.2258	0.2096	0.0162	7.7827	1.3966	0.0746	0.0316	0.0073	0.0182
83683-09	149.	0.4130	0.3458	0.0672	7.6799	1.6088	0.0747	0.0307	0.0069	0.0144
83682-10	181.	0.7342	0.4628	0.2714	9.6465	1.8703	0.0941	0.0523	0.0094	0.0164
83682-05	166.	0.2258	0.2056	0.0202	7.9810	1.7517	0.0806	0.0393	0.0070	0.0154
83688-04	156.	0.2473	0.2257	0.0216	8.7893	1.5716	0.0940	0.0313	0.0104	0.0180
83687-05	169.	0.3937	0.3594	0.0343	8.8683	1.6992	0.0877	0.0383	0.0111	0.0184
MEAN	150.	0.3302	0.2760	0.0542	7.7157	1.6049	0.0812	0.0366	0.0079	0.0164
S.D.	16.0	0.17014	0.10380	0.07557	1.08002	0.16587	0.01324	0.00687	0.00165	0.00308
N	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 22

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-05	161.	0.1906	0.1607	0.0299	10.4538	1.6697	0.0894	0.0400	0.0073	0.0090
83681-04	172.	0.5000	0.4314	0.0686	11.6992	1.8110	0.0917	0.0472	0.0095	0.0179
83679-07	158.	0.5386	0.3839	0.1547	9.7344	1.8605	0.0809	0.0394	0.0095	0.0132
83677-09	136.	0.2806	0.2531	0.0275	7.9355	1.6219	0.1072	0.0498	0.0083	0.0148
83677-06	157.	0.2245	0.1987	0.0258	8.3757	1.7344	0.0748	0.0364	0.0070	0.0217
83680-08	161.	0.4810	0.3598	0.1212	9.3739	1.9988	0.0801	0.0452	0.0081	0.0171
83685-08	144.	0.3264	0.3009	0.0255	9.2224	1.5316	0.0798	0.0434	0.0078	0.0160
83682-07	153.	0.6614	0.3712	0.2902	8.6482	1.5285	0.0723	0.0386	0.0078	0.0139
83683-04	156.	0.2296	0.2128	0.0168	9.3864	1.8574	0.0870	0.0389	0.0093	0.0162
83684-01	146.	0.3487	0.3270	0.0217	9.1108	1.6200	0.0765	0.0493	0.0080	0.0194
83685-05	148.	0.2586	0.2432	0.0154	8.8828	1.3927	0.0571	0.0360	0.0075	0.0196
83686-02	155.	0.1786	0.1656	0.0130	9.1101	1.7244	0.0747	0.0350	0.0060	0.0206
83687-04	147.	0.2266	0.1941	0.0325	9.1397	1.4061	0.0446	0.0392	0.0050	0.0162
MEAN	153.	0.3419	0.2771	0.0648	9.3133	1.6736	0.0782	0.0414	0.0078	0.0166
S.D.	9.2	0.15420	0.09076	0.08067	0.94452	0.18186	0.01548	0.00504	0.00131	0.00343
N	13	13	13	13	13	13	13	13	13	13

FBW = FINAL BODY WEIGHT

POFBWv4.14
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TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83681-01	153.	0.173	0.164	5.294	1.240	0.061	0.028	0.006	0.016
83680-04	179.	0.223	0.182	5.339	0.987	0.046	0.026	0.003	0.008
83677-01	142.	0.202	0.181	5.147	1.036	0.058	0.023	0.006	0.015
83679-06	141.	0.173	0.159	4.447	1.109	0.051	0.028	0.005	0.015
83678-08	114.	0.168	0.154	4.311	1.032	0.051	0.023	0.006	0.016
83677-08	153.	0.191	0.177	4.455	1.145	0.058	0.022	0.005	0.013
83679-09	156.	0.266	0.220	4.452	1.054	0.057	0.021	0.003	0.013
83683-01	137.	0.148	0.129	5.514	1.056	0.063	0.026	0.004	0.009
83685-02	141.	0.153	0.138	5.075	1.089	0.058	0.029	0.006	0.008
83682-04	166.	0.135	0.118	4.957	1.073	0.058	0.026	0.006	0.011
83684-06	139.	0.260	0.240	5.252	1.034	0.057	0.036	0.006	0.013
83684-10	147.	0.279	0.250	4.688	0.943	0.061	0.029	0.005	0.010
83686-01	152.	0.178	0.168	5.008	1.028	0.060	0.026	0.006	0.013
83689-05	150.	0.220	0.195	5.003	1.058	0.049	0.019	0.005	0.010
83687-06	154.	0.187	0.177	5.089	0.984	0.058	0.020	0.007	0.012
MEAN	148.	0.197	0.177	4.935	1.058	0.056	0.025	0.005	0.012
S.D.	14.5	0.0442	0.0377	0.3760	0.0712	0.0049	0.0044	0.0012	0.0027
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83680-02	145.	0.213	0.196	4.849	1.014	0.055	0.025	0.005	0.013
83678-06	130.	0.561	0.289	4.648	1.017	0.051	0.024	0.006	0.013
83679-10	154.	0.177	0.166	4.970	1.061	0.049	0.026	0.005	0.012
83681-07	144.	0.356	0.277	5.231	1.004	0.060	0.018	0.006	0.013
83677-02	138.	0.133	0.118	5.429	1.148	0.058	0.018	0.004	0.014
83679-01	150.	0.158	0.140	5.083	1.012	0.063	0.032	0.005	0.013
83681-03	152.	0.159	0.150	4.672	1.001	0.056	0.030	0.006	0.014
83685-06	140.	0.155	0.142	5.613	0.897	0.045	0.019	0.006	0.007
83683-07	158.	0.263	0.249	6.061	1.151	0.058	0.024	0.006	0.009
83684-08	183.	0.168	0.156	5.603	1.068	0.043	0.023	0.005	0.010
83682-03	161.	0.152	0.139	4.825	1.014	0.049	0.021	0.005	0.010
83683-05	165.	0.221	0.205	5.112	0.957	0.044	0.023	0.005	0.009
83685-10	134.	0.210	0.191	4.995	0.996	0.067	0.026	0.004	0.014
83687-08	161.	0.153	0.139	5.265	1.068	0.047	0.027	0.006	0.011
83689-04	145.	0.183	0.171	5.273	1.026	0.061	0.024	0.005	0.010
MEAN	151.	0.217	0.182	5.175	1.029	0.054	0.024	0.005	0.011
S.D.	13.7	0.1105	0.0528	0.3865	0.0650	0.0075	0.0040	0.0007	0.0022
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-04	162.	0.284	0.228	5.271	1.002	0.052	0.027	0.005	0.008
83680-05	154.	0.239	0.211	5.474	1.093	0.057	0.031	0.006	0.011
83677-10	147.	0.198	0.176	5.254	1.118	0.084	0.032	0.007	0.011
83681-09	136.	0.279	0.250	5.002	1.036	0.072	0.028	0.007	0.012
83679-04	129.	0.160	0.142	4.545	1.028	0.066	0.029	0.006	0.011
83677-04	141.	0.220	0.208	4.870	1.029	0.061	0.028	0.006	0.011
83680-01	162.	0.166	0.154	4.633	1.087	0.051	0.026	0.005	0.012
83684-02	120.	0.182	0.160	5.385	1.018	0.057	0.031	0.006	0.009
83683-02	168.	0.499	0.247	5.417	1.075	0.052	0.029	0.005	0.008
83685-03	156.	0.275	0.248	5.409	0.917	0.062	0.029	0.006	0.010
83682-09	160.	0.152	0.134	4.827	0.889	0.053	0.027	0.006	0.007
83682-01	129.	0.225	0.206	5.280	0.934	0.055	0.026	0.004	0.009
83685-07	139.	0.194	0.176	4.758	1.130	0.061	0.024	0.005	0.013
83687-09	162.	0.151	0.141	5.542	0.982	0.061	0.024	0.006	0.008
83689-01	172.	0.202	0.191	5.036	1.008	0.057	0.028	0.006	0.015
MEAN	149.	0.228	0.191	5.114	1.023	0.060	0.028	0.006	0.010
S.D.	16.0	0.0873	0.0406	0.3251	0.0717	0.0088	0.0024	0.0008	0.0022
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-03	139.	0.137	0.119	5.783	1.120	0.054	0.026	0.005	0.012
83679-05	127.	0.115	0.102	5.208	0.976	0.036	0.027	0.004	0.013
83677-03	122.	0.181	0.168	5.302	1.023	0.062	0.030	0.006	0.016
83680-03	152.	0.148	0.139	5.058	1.040	0.049	0.027	0.006	0.010
83681-06	143.	0.096	0.085	5.383	1.052	0.044	0.027	0.005	0.013
83679-08	138.	0.151	0.130	5.224	1.177	0.057	0.029	0.006	0.013
83678-01	151.	0.174	0.159	5.416	1.084	0.067	0.035	0.006	0.010
83685-04	147.	0.111	0.099	5.878	0.974	0.045	0.020	0.004	0.009
83683-08	144.	0.126	0.111	5.520	1.100	0.053	0.030	0.004	0.008
83682-08	148.	0.358	0.194	5.404	1.064	0.046	0.031	0.004	0.008
83684-03	146.	0.176	0.154	5.643	1.123	0.041	0.022	0.004	0.013
83684-04	134.	0.175	0.162	5.263	0.996	0.055	0.035	0.007	0.009
83686-05	135.	0.140	0.128	5.543	1.057	0.049	0.025	0.002	0.016
83687-02	169.	0.116	0.106	6.089	1.003	0.048	0.023	0.005	0.009
83689-08	145.	0.083	0.074	5.826	1.032	0.046	0.021	0.004	0.012
MEAN	143.	0.152	0.129	5.503	1.055	0.050	0.027	0.005	0.011
S.D.	11.2	0.0645	0.0338	0.2904	0.0582	0.0081	0.0046	0.0013	0.0026
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 5/22/2006

TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-07	150.	0.145	0.128	5.268	1.020	0.069	0.027	0.005	0.009
83681-08	149.	0.178	0.158	5.393	1.009	0.048	0.023	0.005	0.013
83680-10	161.	0.246	0.219	5.687	1.095	0.055	0.021	0.007	0.009
83679-02	140.	0.159	0.136	4.647	1.045	0.058	0.027	0.006	0.013
83677-05	150.	0.279	0.247	4.694	1.105	0.059	0.026	0.005	0.011
83681-10	143.	0.178	0.167	4.598	1.103	0.050	0.024	0.004	0.009
83678-09	149.	0.170	0.157	4.246	1.076	0.051	0.027	0.006	0.010
83685-01	145.	0.469	0.279	5.597	0.970	0.056	0.026	0.006	0.011
83683-03	147.	0.318	0.261	4.764	1.065	0.051	0.021	0.005	0.011
83684-09	158.	0.150	0.135	5.264	1.115	0.056	0.028	0.006	0.011
83682-02	154.	0.288	0.244	4.966	1.014	0.053	0.024	0.005	0.011
83682-06	150.	0.325	0.245	4.684	1.012	0.054	0.023	0.005	0.011
83683-06	154.	0.414	0.266	4.501	1.065	0.052	0.022	0.005	0.010
83686-09	149.	0.439	0.277	5.116	1.025	0.051	0.027	0.006	0.011
MEAN	150.	0.268	0.209	4.959	1.051	0.055	0.025	0.005	0.011
S.D.	5.6	0.1125	0.0582	0.4357	0.0443	0.0052	0.0024	0.0008	0.0013
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

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TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-002

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83681-05	132.	0.137	0.125	5.173	1.174	0.050	0.025	0.005	0.009
83678-10	118.	0.164	0.151	4.638	1.178	0.065	0.025	0.005	0.010
83680-07	154.	0.230	0.219	5.439	1.134	0.069	0.031	0.006	0.012
83677-07	150.	0.145	0.131	5.175	1.075	0.057	0.024	0.006	0.009
83679-03	138.	0.161	0.150	4.883	1.039	0.041	0.022	0.005	0.017
83680-09	141.	0.181	0.162	4.395	1.084	0.061	0.023	0.005	0.012
83681-02	159.	0.404	0.282	5.297	0.984	0.060	0.029	0.005	0.011
83678-02	158.	0.287	0.249	4.803	1.217	0.047	0.022	0.005	0.009
83685-09	134.	0.146	0.132	5.673	1.064	0.050	0.027	0.005	0.012
83684-07	149.	0.152	0.141	5.223	0.937	0.050	0.021	0.005	0.012
83683-09	149.	0.277	0.232	5.154	1.080	0.050	0.021	0.005	0.010
83682-10	181.	0.406	0.256	5.330	1.033	0.052	0.029	0.005	0.009
83682-05	166.	0.136	0.124	4.808	1.055	0.049	0.024	0.004	0.009
83688-04	156.	0.159	0.145	5.634	1.007	0.060	0.020	0.007	0.012
83687-05	169.	0.233	0.213	5.248	1.005	0.052	0.023	0.007	0.011
MEAN	150.	0.215	0.181	5.125	1.071	0.054	0.024	0.005	0.011
S.D.	16.0	0.0916	0.0547	0.3578	0.0776	0.0075	0.0033	0.0008	0.0021
N	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 5/22/2006

TABLE 23

PROJECT NO.:WIL-187043 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-002
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
83678-05	161.	0.118	0.100	6.493	1.037	0.056	0.025	0.005	0.006
83681-04	172.	0.291	0.251	6.802	1.053	0.053	0.027	0.006	0.010
83679-07	158.	0.341	0.243	6.161	1.178	0.051	0.025	0.006	0.008
83677-09	136.	0.206	0.186	5.835	1.193	0.079	0.037	0.006	0.011
83677-06	157.	0.143	0.127	5.335	1.105	0.048	0.023	0.004	0.014
83680-08	161.	0.299	0.223	5.822	1.241	0.050	0.028	0.005	0.011
83685-08	144.	0.227	0.209	6.404	1.064	0.055	0.030	0.005	0.011
83682-07	153.	0.432	0.243	5.652	0.999	0.047	0.025	0.005	0.009
83683-04	156.	0.147	0.136	6.017	1.191	0.056	0.025	0.006	0.010
83684-01	146.	0.239	0.224	6.240	1.110	0.052	0.034	0.005	0.013
83685-05	148.	0.175	0.164	6.002	0.941	0.039	0.024	0.005	0.013
83686-02	155.	0.115	0.107	5.877	1.113	0.048	0.023	0.004	0.013
83687-04	147.	0.154	0.132	6.217	0.957	0.030	0.027	0.003	0.011
MEAN	153.	0.222	0.180	6.066	1.091	0.051	0.027	0.005	0.011
S.D.	9.2	0.0960	0.0553	0.3831	0.0938	0.0111	0.0042	0.0009	0.0022
N	13	13	13	13	13	13	13	13	13

FBW = FINAL BODY WEIGHT

POFBWv4.14
07/13/2005
R:07/19/2005

APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

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[redacted]

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Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Opaque milky-brown viscous liquid

Storage Conditions
Ambient, store under nitrogen blanket

Expiration Date
1 May 2006

Additional Comments
Heat slightly (35-45°C) and shake well before sampling.

[redacted]

9 May 2005
Date

[redacted]

Draft Final Report

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark green viscous liquid

Storage Conditions
Ambient, store under nitrogen blanket

Expiration Date
1 May 2006

Additional Comments
Shake well before sampling.

[redacted]

9 May 2005
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

Draft Final Report

[redacted]

TITLE
The Analytical Report in Support of a Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

SUBMITTED TO SUPPORT THE TESTING OF:
[redacted] and [redacted]
WIL Research Study #WIL-187043
[redacted] Reference #05-002

AUTHOR
[redacted]

STUDY INITIATION DATE
14 April 2005

ANALYTICAL START DATE
17 May 2005

ANALYTICAL END DATE
24 June 2005

ANALYTICAL STUDY COMPLETION DATE
5 June 2007

PERFORMING LABORATORY
[redacted]

TOTAL PAGES
14

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ANALYTICAL STUDY GLP COMPLIANCE STATEMENT

All analytical tests performed by Integrated Laboratory Technologies for WIL Research Study #WIL-187043 ([redacted] Reference #05-002) were conducted in compliance with current EPA Good Laboratory Practice (GLP) standards as described by the Toxic Substances Control Act (TSCA) 40 CFR Part 792.

The stability of the test substances in corn oil over a 10-day period was not determined. The test substance is formulated for use in the high temperature and oxidative environment found in internal combustion engines. Based on information provided by the Sponsor, it is not expected to degrade under conditions used in this toxicology study.

Principal Investigator [redacted] Date: 5 June 2007

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ANALYTICAL STUDY QUALITY ASSURANCE UNIT STATEMENT

The analytical raw data and final report for the [redacted] study have been reviewed by the [redacted] Quality Assurance Team.

The report appears to accurately describe the methods and Standard Operating Procedures (SOPs) used in the study. The reported results accurately reflect the raw data of the study.

Study #
WIL Research Study #WIL-187043
[redacted] Reference #05-002

Study Title
The Analytical Report in Support of a Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

		Dates Reported to	
	Study Director	WIL Research Mgmt	[redacted] Mgmt
Study In-progress Inspection 8 June 2005	5 June 2007	5 June 2007	5 June 2007
Analytical Draft Report Review 21-22, 28-30 December 2005 5, 9-10, 12-13 January 2006 23 May and 1 June 2007	5 June 2007	5 June 2007	5 June 2007
Analytical Final Report Review 5 June 2007	5 June 2007	5 June 2007	5 June 2007

[redacted]

Date: June 5, 2007

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ABSTRACT

Samples of suspensions ([redacted] and [redacted] in corn oil) used in a female pubertal assay in rats, WIL Research Study #WIL-187043 ([redacted] Reference #05-002), were analyzed at [redacted] to verify their homogeneity, resuspension homogeneity, and nominal concentrations.

A direct dilution procedure was employed to prepare the samples for elemental analysis by Inductively Coupled Plasma-Atomic Emission Spectroscopy (ICP-AES). Homogeneity and resuspension homogeneity of [redacted] and [redacted] in corn oil were established. The nominal concentrations of all dosing suspensions were verified by the analytical data.

INTRODUCTION

The purpose of this analytical study was the determination and verification of test substance *homogeneity, resuspension homogeneity, and concentration in corn oil. The concentration* study samples were aliquots taken from mixtures prepared as dosing suspensions for a female pubertal assay in rats as outlined in the protocol for WIL Research Study #WIL-187043.

The analytical portion of the study was performed by the High Volume Services team located in the [redacted]. The analytical start and end dates were 17 May and 24 June 2005 respectively.

TEST SUBSTANCES

The test substances used in the preparation of the dosing suspensions are identified as [redacted] and [redacted] The CAS numbers are confidential; contac[redacted] for further information. The test substances were characterized and their stabilities were established prior to the initiation of the study.

EXPERIMENTAL

SAMPLES
Samples were shipped from WIL Research to [redacted] Principal Investigator. Samples were stored at room temperature and in the dark prior to analysis.

The first batch of samples was transferred to the laboratory on 16 May 2005 and analyzed on 17 May 2005. The analysis of the last set of samples was completed on 24 June 2005.

STANDARDS
Calibration standards for the ICP-AES were made from certified commercially prepared elemental concentrates (Conostan Division of Conoco, Inc.). Standard preparation data is archived by [redacted]

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ANALYTICAL METHOD
Samples were prepared as stated in [redacted] Test Code 30176, SOP ME-125 "Elemental Analysis of Additives or Additive Mixtures by Direct Dilution and ICP Analysis." The procedures outlined in SOP EQ-130, "IRIS Intrepid XDL II Radial Inductively Coupled Plasma Spectrometer," were followed during the instrumental analysis of the samples.

The approach employed in this method was to verify concentration based on the known elemental composition of [redacted] and [redacted] Aliquots of the dosing suspensions were diluted in an o-xylene diluent and the elemental composition was determined by ICP-AES. The calcium concentration of the samples was then used to ascertain the concentration of the test substance in the dosing suspensions.

DISCUSSION

METHOD VALIDATION
Method validation was performed following the recommendations outlined in the International Conference on Harmonisation's Q2B document: Guideline on the Validation of Analytical Procedures: Methodology. The limit of detection (LOD) and limit of quantitation (LOQ) were calculated to be 0.063 and 0.192 wt ppm calcium respectively. A reporting limit of 2 wt ppm calcium was determined to be appropriate for vehicle results.

SAMPLE ANALYSIS
The analytical results for the suspensions of [redacted] and [redacted] in corn oil are summarized in the tables located on pages 8 through 14. Seven calibration standards were analyzed to generate a linear calibration curve with inverse concentration weighting. All instrument control checks and quality control samples were within acceptable limits. Known amounts of calcium were spiked into 27 samples throughout the duration of the study and gave acceptable percent recoveries of 96 to 100%.

The dosing suspensions were analyzed for calcium, an element present in known concentrations in the test substances. Dosing suspension estimates of weight percent calcium were derived by the following formula:

$$Wt\%\ Ca = \left[\frac{x}{x + \left(D_2 - \frac{xD_2}{D_1}\right)}\right] \%\ Ca\ in\ [redacted]$$

where x is the solute test substance concentration in mg/μL; D_1 is the test substance density (0.9209 g/mL for [redacted] and 0.9332 g/mL for [redacted] and D_2 is the vehicle or solvent density (corn oil, 0.9195 g/mL). The concentration of calcium in [redacted] is 3.13 wt% and 3.84 wt% in [redacted] The measured results of calcium were obtained by ICP-AES and compared against the estimated values. Results were converted to wt% from ppm by multiplying by 10^{-4}.

Homogeneity was confirmed if the percent differences between the overall dose level mean and individual strata means were 10% or less. Concentration data were evaluated using percent difference between estimated and measured concentrations. The acceptable tolerance was 15%. Duplicate analyses were compared using the Contract Laboratories Program (CLP) Guidelines for Inorganic Analyses relative percent difference limit of 20%

RESULTS AND CONCLUSIONS

The confirmation of dosing suspension homogeneity and resuspension homogeneity is supported by the data presented on pages 8 through 11. The percent difference of all strata means with their respective overall mean is well below the 10% tolerance.

The analytical result summaries for the concentration studies are found on pages 12 and 13. The nominal concentrations of all dosing suspensions were verified by the analytical data. The percent difference between the estimated and measured concentrations is less than 15% for all dosing levels.

The table on page 14 presents the duplicate precision data. The agreement between the duplicates is excellent and well under the CLP relative percent difference guideline of 20%.

ARCHIVES

SAMPLES
The unused portion of all samples shall be stored in room [redacted] for a minimum of one year after the final analytical report is issued.

RAW DATA
Instrument, chemical, and standard logbook documentation shall be archived by [redacted] as facility records [redacted]). All other raw data shall be archived in the Analytical Study File in [redacted]

FINAL REPORT
The original copy of the final report shall be archived with the Analytical Study File in [redacted]

PROTOCOL AND SOP DEVIATIONS

SOP ME-125 states quality control (QC) samples should be analyzed every 10 samples. For samples analyzed on 17 May 2005, QCs were run approximately every 20 samples. This did not appear to affect the outcome of the analytical results.

STUDY PERSONNEL

PRINCIPAL INVESTIGATOR [redacted]

ANALYST [redacted]

SUPERVISORY PERSONNEL [redacted]

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SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Homogeneity Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	Estimated [redacted] mg/mL	Concentration wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
0519433001	13-May-05	13-May-05	17-May-05	RX-187043L-0001	1	1	Middle	0	0.000	<2 wt ppm			
0519433002	13-May-05	13-May-05	17-May-05	RX-187043L-0020	1	1	Middle	0	0.000	<2 wt ppm	<2 wt ppm	<2 wt ppm	0 0
0519433003	13-May-05	13-May-05	17-May-05	RX-187043L-0002	2	1	Top	12	0.041	0.040			
0519433004	13-May-05	13-May-05	17-May-05	RX-187043L-0021	2	1	Top	12	0.041	0.040	0 040		0.0
0519433005	13-May-05	13-May-05	17-May-05	RX-187043L-0003	2	1	Middle	12	0.041	0.040		0.040	
0519433006	13-May-05	13-May-05	17-May-05	RX-187043L-0022	2	1	Middle	12	0 041	0.040	0.040		0 0
0519433007	13-May-05	13-May-05	17-May-05	RX-187043L-0004	2	1	Bottom	12	0.041	0.040			
0519433008	13-May-05	13-May-05	17-May-05	RX-187043L-0023	2	1	Bottom	12	0.041	0040	0 040		0 0
0519433009	13-May-05	13-May-05	17-May-05	RX-187043L-0005	3	1	Top	50	0.170	0 170			
0519433010	13-May-05	13-May-05	17-May-05	RX-187043L-0024	3	1	Top	50	0 170	0 168	0.169		0.0
0519433011	13-May-05	13-May-05	17-May-05	RX-187043L-0006	3	1	Middle	50	0.170	0 170		0.169	
0519433012	13-May-05	13-May-05	17-May-05	RX-187043L-0025	3	1	Middle	50	0 170	0.169	0.170		0.6
0519433013	13-May-05	13-May-05	17-May-05	RX-187043L-0007	3	1	Bottom	50	0.170	0.168			
0519433014	13-May-05	13-May-05	17-May-05	RX-187043L-0026	3	1	Bottom	50	0.170	0.169	0.169		0 0
0519433015	13-May-05	13-May-05	17-May-05	RX-187043L-0008	4	1	Top	200	0.681	0.675			
0519433016	13-May-05	13-May-05	17-May-05	RX-187043L-0027	4	1	Top	200	0.681	0.671	0.673		0.1
0519433017	13-May-05	13-May-05	17-May-05	RX-187043L-0009	4	1	Middle	200	0.681	0.671		0.674	
0519433018	13-May-05	13-May-05	17-May-05	RX-187043L-0028	4	1	Middle	200	0.681	0.675	0.673		0.1
0519433019	13-May-05	13-May-05	17-May-05	RX-187043L-0010	4	1	Bottom	200	0.681	0.673			
0519433020	13-May-05	13-May-05	17-May-05	RX-187043L-0029	4	1	Bottom	200	0 681	0.678	0.676		0 3

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

Modified: 7/11/2007

187043 DF

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SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Homogeneity Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	Estimated Concentration [redacted] mg/mL	Concentration wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
0519433021	13-May-05	13-May-05	17-May-05	RX-187043L-0011	5	1	Top	12	0.050	0.049			
0519433022	13-May-05	13-May-05	17-May-05	RX-187043L-0030	5	1	Top	12	0.050	0.048	0.049		2.1
0519433023	13-May-05	13-May-05	17-May-05	RX-187043L-0012	5	1	Middle	12	0.050	0.047		0.048	
0519433024	13-May-05	13-May-05	17-May-05	RX-187043L-0031	5	1	Middle	12	0.050	0.047	0.047		2.1
0519433025	13-May-05	13-May-05	17-May-05	RX-187043L-0013	5	1	Bottom	12	0.050	0.048			
0519433026	13-May-05	13-May-05	17-May-05	RX-187043L-0032	5	1	Bottom	12	0.050	0.048	0.048		0.0
0519433027	13-May-05	13-May-05	17-May-05	RX-187043L-0014	6	1	Top	50	0.209	0.207			
0519433028	13-May-05	13-May-05	17-May-05	RX-187043L-0033	6	1	Top	50	0.209	0.207	0.207		0.0
0519433029	13-May-05	13-May-05	17-May-05	RX-187043L-0015	6	1	Middle	50	0.209	0.205		0.207	
0519433030	13-May-05	13-May-05	17-May-05	RX-187043L-0034	6	1	Middle	50	0.209	0.208	0.207		0.0
0519433031	13-May-05	13-May-05	17-May-05	RX-187043L-0016	6	1	Bottom	50	0.209	0.207			
0519433032	13-May-05	13-May-05	17-May-05	RX-187043L-0035	6	1	Bottom	50	0.209	0.207	0.207		0.0
0519433033	13-May-05	13-May-05	17-May-05	RX-187043L-0017	7	1	Top	200	0.833	0.821			
0519433034	13-May-05	13-May-05	17-May-05	RX-187043L-0036	7	1	Top	200	0.833	0.829	0.825		0.1
0519433035	13-May-05	13-May-05	17-May-05	RX-187043L-0018	7	1	Middle	200	0.833	0.823		0.826	
0519433036	13-May-05	13-May-05	17-May-05	RX-187043L-0037	7	1	Middle	200	0.833	0.828	0.826		0.0
0519433037	13-May-05	13-May-05	17-May-05	RX-187043L-0019	7	1	Bottom	200	0.833	0.826			
0519433038	13-May-05	13-May-05	17-May-05	RX-187043L-0038	7	1	Bottom	200	0.833	0.829	0.828		0.2

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

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SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Resuspension Homogeneity Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	Estimated [redacted] Concentration mg/mL	Calcium wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
0520909001	13-May-05	23-May-05	26-May-05	RX-187043L-0058	1	2	Top	0	0.000	<2 wt ppm			
0520909002	13-May-05	23-May-05	26-May-05	RX-187043L-0072	1	2	Top	0	0.000	< 2 wt ppm	<2 wt ppm		0.0
0520909003	13-May-05	23-May-05	26-May-05	RX-187043L-0059	1	2	Bottom	0	0.000	<2 wt ppm		<2 wt ppm	
0520909004	13-May-05	23-May-05	26-May-05	RX-187043L-0073	1	2	Bottom	0	0.000	<2 wt ppm	<2 wt ppm		0 0
0520909005	13-May-05	23-May-05	26-May-05	RX-187043L-0060	2	2	Top	12	0.041	0.040			
0520909006	13-May-05	23-May-05	26-May-05	RX-187043L-0074	2	2	Top	12	0.041	0.040	0 040		0.0
0520909007	13-May-05	23-May-05	26-May-05	RX-187043L-0061	2	2	Bottom	12	0.041	0.040		0.040	
0520909008	13-May-05	23-May-05	26-May-05	RX-187043L-0075	2	2	Bottom	12	0 041	0 039	0 040		0 0
0520909009	13-May-05	23-May-05	26-May-05	RX-187043L-0062	3	2	Top	50	0.170	0.167			
0520909010	13-May-05	23-May-05	26-May-05	RX-187043L-0076	3	2	Top	50	0.170	0.167	0.167		0.6
0520909011	13-May-05	23-May-05	26-May-05	RX-187043L-0063	3	2	Bottom	50	0.170	0.167		0.168	
0520909012	13-May-05	23-May-05	26-May-05	RX-187043L-0077	3	2	Bottom	50	0.170	0.169	0.168		0 0
0520909013	13-May-05	23-May-05	26-May-05	RX-187043L-0064	4	2	Top	200	0.681	0.672			
0520909014	13-May-05	23-May-05	26-May-05	RX-187043L-0078	4	2	Top	200	0.681	0.670	0.671		0.4
0520909015	13-May-05	23-May-05	26-May-05	RX-187043L-0065	4	2	Bottom	200	0.681	0.664		0.668	
0520909016	13-May-05	23-May-05	26-May-05	RX-187043L-0079	4	2	Bottom	200	0.681	0.667	0.666		0.3

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

Modified: 7/11/2007

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Resuspension Homogeneity Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	[redacted] mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
0520909017	13-May-05	23-May-05	26-May-05	RX-187043L-0066	5	2	Top	[redacted]2	0.050	0.048			
0520909018	13-May-05	23-May-05	26-May-05	RX-187043L-0080	5	2	Top	[redacted]2	0.050	0.047	0.048		0.0
0520909019	13-May-05	23-May-05	26-May-05	RX-187043L-0067	5	2	Bottom	[redacted]2	0.050	0.048		0.048	
0520909020	13-May-05	23-May-05	26-May-05	RX-187043L-0081	5	2	Bottom	12	0.050	0.048	0.048		0.0
0520909021	13-May-05	23-May-05	26-May-05	RX-187043L-0068	6	2	Top	50	0.209	0.207			
0520909022	13-May-05	23-May-05	26-May-05	RX-187043L-0082	6	2	Top	50	0.209	0.206	0.207		0.0
0520909023	13-May-05	23-May-05	26-May-05	RX-187043L-0069	6	2	Bottom	50	0.209	0.206		0.207	
0520909024	13-May-05	23-May-05	26-May-05	RX-187043L-0083	6	2	Bottom	50	0.209	0.207	0.207		0.0
0520909025	13-May-05	23-May-05	26-May-05	RX-187043L-0070	7	2	Top	200	0.833	0.826			
0520909026	13-May-05	23-May-05	26-May-05	RX-187043L-0084	7	2	Top	200	0.833	0.823	0.825		0.0
0520909027	13-May-05	23-May-05	26-May-05	RX-187043L-0071	7	2	Bottom	200	0.833	0.822		0.825	
0520909028	13-May-05	23-May-05	26-May-05	RX-187043L-0085	7	2	Bottom	200	0.833	0.829	0.826		0.1

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

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SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Concentration Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	Estimated Concentration [redacted] mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
0521420001	25-May-05	25-May-05	26-May-05	RX-187043L-0100	1	3	Middle	0	0.000	<2 wt ppm	*
0521420002	25-May-05	25-May-05	26-May-05	RX-187043L-0101	2	3	Middle	12	0.041	0.039	4.9
0521420003	25-May-05	25-May-05	26-May-05	RX-187043L-0102	3	3	Middle	50	0.170	0.166	2.4
0521420004	25-May-05	25-May-05	26-May-05	RX-187043L-0103	4	3	Middle	200	0.681	0.672	1.3
0522470001	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0114	1	4	Middle	0	0.000	<2 wt ppm	*
0522470002	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0115	2	4	Middle	12	0.041	0.039	4.9
0522470003	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0116	3	4	Middle	50	0.170	0.164	3.5
0522470004	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0117	4	4	Middle	200	0.681	0.655	3.8
0522470008	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0128	1	5	Middle	0	0.000	<2 wt ppm	*
0522470009	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0129	2	5	Middle	12	0.041	0.040	2.4
0522470010	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0130	3	5	Middle	50	0.170	0.169	0.6
0522470011	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0131	4	5	Middle	200	0.681	0.664	2.5
0522823001	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0142	1	6	Middle	0	0	<2 wt ppm	*
0522823002	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0143	2	6	Middle	12	0.041	0.039	4 9
0522823003	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0144	3	6	Middle	50	0 170	0 166	2.4
0522823004	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0145	4	6	Middle	200	0.681	0.658	3.4
0522823008	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0156	1	7	Middle	0	0.000	<2 wt ppm	*
0522823009	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0157	2	7	Middle	12	0.041	0.040	2.4
0522823010	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0158	3	7	Middle	50	0.170	0.156	8.2
0522823011	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0159	4	7	Middle	200	0.681	0.648	4.8
0523970001	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0170	1	8	Middle	0	0.000	<2 wt ppm	*
0523970002	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0171	2	8	Middle	12	0.041	0.039	4.9
0523970003	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0172	3	8	Middle	50	0.170	0.152	10.6
0523970004	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0173	4	8	Middle	200	0.681	0.639	6.2

PERCENT DIFFERENCE CALCULATION
Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

* Not a significant difference

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SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Concentration Study

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	Estimated Concentration [redacted] mg/mL	Concentration wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
0521420005	25-May-05	25-May-05	26-May-05	RX-187043L-0104	5	3	Middle		0.050	0.050	0.0
0521420006	25-May-05	25-May-05	26-May-05	RX-187043L-0105	6	3	Middle	50	0.209	0.208	0.5
0521420007	25-May-05	25-May-05	26-May-05	RX-187043L-0106	7	3	Middle	200	0.833	0.840	0.8
0522470005	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0118	5	4	Middle	12	0.050	0.053	6.0
0522470006	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0119	6	4	Middle	50	0.209	0.206	1.4
0522470007	25-May-05	01-Jun-05	08-Jun-05	RX-187043L-0120	7	4	Middle	200	0.833	0.820	1.6
0522470012	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0132	5	5	Middle	12	0.050	0.050	0.0
0522470013	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0133	6	5	Middle	50	0.209	0.209	0.0
0522470014	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0134	7	5	Middle	200	0.833	0.776	6.8
0522823005	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0146	5	6	Middle	12	0.050	0.051	2.0
0522823006	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0147	6	6	Middle	50	0.209	0.204	2.4
0522823007	01-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0148	7	6	Middle	200	0.833	0.876	5.2
0522823012	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0160	5	7	Middle	12	0.050	0.049	2.0
0522823013	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0161	6	7	Middle	50	0.209	0.210	0.5
0522823014	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0162	7	7	Middle	200	0.833	0.827	0.7
0523970005	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0174	5	8	Middle	12	0.050	0.052	4.0
0523970006	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0175	6	8	Middle	50	0.209	0.207	1.0
0523970007	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0176	7	8	Middle	200	0.833	0.842	1.1

PERCENT DIFFERENCE CALCULATION
Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN DOSING SUSPENSIONS
WIL Research #WIL-187043
[redacted] Reference #05-002

Duplicate Analysis

[redacted] StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Group #	WIL Research Accession #	Aliquot Phase	Estimated Concentration Test substance, mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Relative Percent Difference, %
0520909012	13-May-05	23-May-05	26-May-05	RX-187043L-0077	3	2	Bottom	[redacted]	0.170	0.169	
0520909012 - Dup	13-May-05	23-May-05	26-May-05	RX-187043L-0077	3	2	Bottom		0.170	0.167	1.2
0521420006	25-May-05	25-May-05	26-May-05	RX-187043L-0105	6	3	Middle		0.209	0.208	
0521420006 - Dup	25-May-05	25-May-05	26-May-05	RX-187043L-0105	6	3	Middle		0.209	0.208	0.0
0522470012	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0132	5	5	Middle		0.050	0.050	
0522470012 - Dup	01-Jun-05	01-Jun-05	08-Jun-05	RX-187043L-0132	5	5	Middle		0.050	0.051	2.0
0522823011	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0159	4	7	Middle		0.681	0.648	
0522823011 - Dup	08-Jun-05	08-Jun-05	10-Jun-05	RX-187043L-0159	4	7	Middle		0.681	0.647	0.2
0523970004	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0173	4	8	Middle		0.681	0.639	
0523970004 - Dup	08-Jun-05	16-Jun-05	24-Jun-05	RX-187043L-0173	4	8	Middle		0.681	0.645	0.9

RELATIVE PERCENT DIFFERENCE CALCULATION
Absolute value (((First Measured Concentration-Duplicate Measured Concentration)/((First Measured Concentration+Duplicate Measured Concentration)/2))*100)

APPENDIX C

Animal Room Environmental Conditions

Draft Final Report

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO.:WIL- 187043 TEMPERATURE/HUMIDITY - DAILY SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187043 DATE IN: 05/10/05 TIME IN: 11:00
DATE OUT: 06/17/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
10-May-05	70.5	21.4	49.8
11-May-05	70.4	21.4	47.5
12-May-05	70.5	21.4	43.0
13-May-05	70.5	21.4	45.6
14-May-05	70.4	21.3	47.5
15-May-05	70.5	21.4	42.6
16-May-05	70.4	21.3	41.5
17-May-05	70.4	21.4	40.5
18-May-05	70.5	21.4	38.0
19-May-05	70.5	21.4	43.0
20-May-05	70.5	21.4	47.8
21-May-05	70.5	21.4	40.1
22-May-05	70.5	21.4	47.4
23-May-05	70.5	21.4	50.5
24-May-05	70.5	21.4	46.9
25-May-05	70.5	21.4	46.1
26-May-05	70.5	21.4	47.9
27-May-05	70.4	21.3	46.9
28-May-05	70.5	21.4	47.1
29-May-05	70.5	21.4	46.3
30-May-05	70.4	21.4	48.3
31-May-05	70.5	21.4	49.8
01-Jun-05	70.5	21.4	50.7

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/19/05 13:18

Draft Final Report

STUDY SPECIFICATIONS: 187043 DATE IN: 05/10/05 TIME IN: 11:00
DATE OUT: 06/17/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
02-Jun-05	70.4	21.3	49.7
03-Jun-05	70.4	21.4	50.5
04-Jun-05	70.5	21.4	48.2
05-Jun-05	70.4	21.3	48.9
06-Jun-05	70.5	21.4	49.8
07-Jun-05	70.4	21.4	48.3
08-Jun-05	70.5	21.4	50.4
09-Jun-05	70.6	21.4	50.6
10-Jun-05	70.5	21.4	50.9
11-Jun-05	70.6	21.4	50.9
12-Jun-05	70.5	21.4	49.6
13-Jun-05	70.4	21.3	50.2
14-Jun-05	70.5	21.4	49.9
15-Jun-05	70.5	21.4	46.6
16-Jun-05	70.6	21.4	45.0
17-Jun-05	70.4	21.3	51.1

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/19/05 13:18

Draft Final Report

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO.:WIL- 187043 TEMPERATURE/HUMIDITY - DAILY SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187043 DATE IN: 05/10/05 TIME IN: 11:00
DATE OUT: 06/17/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.4	70.6
TEMPERATURE °C	21.4	21.3	21.4
HUMIDITY (%RH)	47.3	38.0	51.1
N DAYS	39		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/19/05 13:18

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ROOM SPECIFICATIONS:	B ROOM 73		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	05/10/05
HIGH TEMPERATURE:	76.0	TIME IN:	11:00
LOW HUMIDITY:	30.0	DATE OUT:	06/17/05
HIGH HUMIDITY:	70.0	TIME OUT:	8:00

ROOM B ROOM 73 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	47.2
MIN	69.6	32.5
MAX	72.4	70.0
SD	0.27	4.26
N SAMPLES	907	907
FIRST DAY	05/10/05	
LAST DAY	06/17/05	
N DAYS	39	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

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STUDY 187043 SUMMARY

MEAN	70.5	47.2
MIN	69.6	32.5
MAX	72.4	70.0
SD	0.27	4.26
N SAMPLES	907	907
FIRST DAY	05/10/05	
LAST DAY	06/17/05	
N DAYS	39	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

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APPENDIX D

WIL Reproductive Historical Control Data [Crl:CD®(SD) Rats]

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WIL Reproductive Historical Control Data — Grand Mean Summary —
Crl:CD(SD) Rat* — Parental and Neonatal Observations

ENDPOINT	TOTAL	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
TOTAL NUMBER OF DATASETS	**107**							
NO. MALES IN CONTROL GROUP	2141	27.1	3.95	79	15	40	25	30
MALE MATING INDEX (%)		96.3	4.72	77	72.0	100.0	95.7	100.0
MALE FERTILITY INDEX (%)		89.6	8.10	79	56.7	100.0	86.5	95.7
NO. FEMALES IN CONTROL GROUP	2815	26.6	3.57	106	15	40	25	30
FEMALE MATING INDEX (%)		97.5	3.60	83	84.0	100.0	96.0	100.0
FEMALE FERTILITY INDEX (%)		92.0	7.47	105	56.7	100.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	1755	27.0	3.10	65	22	40	25	30
NO. THAT DELIVERED	1583	24.4	3.22	65	17	38	23	26
NO. THAT DID NOT DELIVER	172	2.6	2.44	65	0	13	1	3
NO. THAT DIED	13	0.1	0.36	106	0	2	0	0
NO. WITH TOTAL LITTER LOSS	13	0.2	0.44	65	0	2	0	0
NO. WITH DYSTOCIA	6	0.1	0.29	65	0	1	0	0
MEAN PRE-COITAL INTERVAL (DAYS)		3.0	0.56	81	1.8	4.7	2.6	3.3
MEAN GESTATION LENGTH (DAYS)		21.8	0.15	65	21.6	22.3	21.7	21.9
MEAN NO. PUPS BORN		14.5	0.94	65	12.0	16.5	13.7	15.0
MEAN VIABLE LITTER SIZE ON PND 0		14.2	0.94	65	11.6	16.0	13.4	14.9
PUP SEX RATIO								
MEAN % MALE		49.7	2.83	65	42.7	56.6	47.7	51.8
MEAN % FEMALE		50.3	2.86	65	43.4	57.3	48.2	52.3
MEAN NO. OF FORMER IMPLANTATION SITES AT WEANING		15.3	0.83	58	13.7	17.1	14.7	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING		0.8	0.21	58	0.3	1.3	0.7	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY		15.5	0.90	40	13.8	16.8	15.1	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)		4.5	0.41	59	4.0	5.8	4.2	4.6
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM		96.4	23.11	13	50.4	132.9	87.8	107.8

EXPERIMENTAL START DATE OF OLDEST DATASET 6/17/96
DATE OF LAST NECROPSY OF MOST RECENT DATASET 2/3/04

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ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN NO. PUPS BORN	14.5	0.94	65	12.0	16.5	13.7	15.0
PUP SURVIVAL INDICES (% PER LITTER)							
PND 0 (RELATIVE TO NO. BORN)	98.0	1.42	65	92.3	100.0	97.4	99.0
PND 0 TO PND 1	99.0	1.24	65	94.3	100.0	98.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	1.08	64	93.5	100.0	98.8	99.6
PND 4 (AFTER SELECTION) TO PND 7	99.5	0.94	57	95.8	100.0	99.5	100.0
PND 7 TO PND 14	99.4	1.38	53	93.5	100.0	99.5	100.0
PND 14 TO PND 21	99.7	0.97	54	94.7	100.0	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.1	2.01	62	91.3	99.3	95.0	97.5
PND 4 (AFTER SELECTION) TO PND 21	98.7	1.96	53	91.1	100.0	98.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)							
PND 1	7.1	0.25	65	6.5	7.6	6.9	7.2
PND 4 (BEFORE SELECTION)	9.9	0.59	64	8.6	11.4	9.5	10.4
PND 7	15.4	1.34	57	11.7	17.8	15.1	16.4
PND 14	31.0	3.50	53	22.5	36.5	29.2	33.1
PND 21	48.7	5.47	54	34.9	58.0	45.4	52.1
PND 28	81.5	8.23	18	65.4	94.0	74.6	87.6
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)							
PND 1	6.7	0.25	65	6.1	7.2	6.5	6.8
PND 4 (BEFORE SELECTION)	9.4	0.57	64	8.1	10.9	8.9	9.7
PND 7	14.6	1.32	57	11.0	17.1	14.1	15.5
PND 14	29.8	3.41	53	21.2	35.1	27.6	32.1
PND 21	46.6	5.07	54	33.3	55.6	43.9	49.7
PND 28	75.3	7.25	18	59.8	86.2	69.0	79.5
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.4365	0.0509	21	1.3451	1.5175	1.4000	1.4775
SPLEEN	0.1938	0.0343	21	0.1189	0.2480	0.1755	0.2211
THYMUS GLAND	0.1933	0.0269	21	0.1392	0.2446	0.1723	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.3886	0.0459	21	1.2903	1.4597	1.3623	1.4242
SPLEEN	0.1923	0.0321	21	0.1182	0.2408	0.1722	0.2200
THYMUS GLAND	0.1969	0.0281	21	0.1338	0.2479	0.1778	0.2113

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* Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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WIL Reproductive Historical Control Data — Grand Mean Summary —
Crl:CD(SD) Rat* — Parental and Neonatal Observations

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)							
MALE	4.6	0.92	10	2.5	5.7	4.3	5.3
FEMALE	2.7	0.70	10	1.3	3.9	2.4	3.2
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.8	1.83	41	41.6	49.0	44.0	45.8
MEAN BODY WEIGHT AT ACQUISITION (G)	228.4	10.21	38	210.5	248.6	221.9	235.5
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	1.39	41	31.7	38.8	32.7	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	112.4	7.79	38	99.0	133.0	107.0	117.6
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)							
MALE	5.1	0.08	7	5.0	5.2	5.0	5.1
FEMALE	5.2	0.10	7	5.0	5.3	5.1	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)							
MALE	4.0	0.08	6	4.0	4.2	4.0	4.0
FEMALE	4.0	0.08	6	4.0	4.2	4.0	4.0
MEAN DAY OF EYE OPENING (PND)							
MALE	16.1	1.35	6	15.1	18.7	15.3	16.0
FEMALE	16.0	1.37	6	14.8	18.6	15.2	16.0
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)							
MALE	14.9	NA	1	14.9	14.9	14.9	14.9
FEMALE	14.9	NA	1	14.9	14.9	14.9	14.9
MEAN DAY OF HAIR GROWTH (PND)							
MALE	12.4	0.99	2	11.7	13.1	12.1	12.8
FEMALE	12.4	0.85	2	11.8	13.0	12.1	12.7
MEAN DAY OF INCISOR ERUPTION (PND)							
MALE	9.8	0.44	3	9.3	10.1	9.7	10.1
FEMALE	9.7	0.38	3	9.3	10.0	9.6	10.0

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WIL Reproductive Historical Control Data — Grand Mean Summary —
Crl:CD(SD) Rat* — Parental and Neonatal Observations

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHT (G)	2.20	0.295	37	1.76	2.80	1.95	2.30
MEAN RIGHT TESTIS WEIGHT (G)	1.79	0.067	55	1.65	1.93	1.73	1.84
MEAN LEFT TESTIS WEIGHT (G)	1.79	0.065	55	1.67	1.92	1.74	1.84
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.73	0.039	55	0.64	0.81	0.71	0.75
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.040	55	0.62	0.80	0.70	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3249	0.0227	55	0.2629	0.3693	0.3159	0.3366
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3282	0.0206	55	0.2714	0.3712	0.3183	0.3413
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)							
LEFT TESTIS	86.8	9.3	49	69.6	106.9	79.2	93.2
LEFT EPIDIDYMIS	460.7	54.6	49	343.6	640.1	421.3	477.0
LEFT CAUDA EPIDIDYMIS	677.5	50.3	4	618.7	738.9	651.8	701.9
MEAN SPERM PRODUCTION RATE							
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	1.5	49	11.4	17.5	13.0	15.3
% MOTILE SPERM	84.6	4.4	53	71.3	91.9	82.0	87.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)							
NORMAL	98.9	1.3	50	91.9	99.9	98.8	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.6	50	0.0	3.4	0.2	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.7	50	0.0	4.7	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)							
NORMAL	198.0	2.6	50	183.8	200.0	197.9	199.3
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.3	1.7	50	0.0	10.0	0.4	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	1.5	50	0.0	9.4	0.2	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	1	2	3	4	5
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
MALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
FEMALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	30
NO. THAT DELIVERED	25	17	28	27	28
NO. THAT DID NOT DELIVER	5	13	2	3	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	0
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	3.0	2.3	2.4	2.2
MEAN GESTATION LENGTH (DAYS)	22.3	22.0	21.8	21.8	21.8
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
MEAN VIABLE LITTER SIZE ON PND 0	11.6	12.5	13.5	13.4	13.0
PUP SEX RATIO					
MEAN % MALE	49.7	52.1	51.1	51.8	52.1
MEAN % FEMALE	50.3	47.9	48.9	48.2	47.9
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.5	14.2	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.9	0.7	1.2
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	4.2	4.1	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	11/19/97	2/23/98	11/3/98	2/3/99	9/24/98
DATE OF LAST NECROPSY	4/7/98	8/18/98	3/16/99	7/23/99	2/5/99
ROUTE	Diet	Diet	Diet	Diet	Inhalation
VEHICLE	Basal Feed	Basal Feed	Basal Feed	Basal Feed	Filtered Air

= Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	6	7	8	9	10
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	29	30	30
NO. THAT DELIVERED	29	24	26	28	28
NO. THAT DID NOT DELIVER	1	6	3	2	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	1	1	0	0	0
NO. WITH DYSTOCIA	0	1	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.5	2.6	2.7	2.7	2.8
MEAN GESTATION LENGTH (DAYS)	21.7	22.0	21.8	22.1	21.8
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
MEAN VIABLE LITTER SIZE ON PND 0	13.1	14.5	12.9	12.9	13.1
PUP SEX RATIO					
MEAN % MALE	48.6	49.2	48.6	44.0	45.0
MEAN % FEMALE	51.4	50.8	51.4	56.0	55.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	15.7	14.0	13.7	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	0.8	0.6	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.1	4.2	4.3	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	96.7	54.4	98.1	---	85.5
EXPERIMENTAL START DATE	12/24/98	2/9/99	5/27/99	11/23/98	2/25/99
DATE OF LAST NECROPSY	6/11/99	7/9/99	11/12/99	4/7/99	8/19/99
ROUTE	Inhalation	Gavage	Gavage	Diet	Diet
VEHICLE	Filtered Air	DI Water	DI Water	Basal Feed	Basal Feed

*** = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.**

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	11	12	13	14	15
NO. MALES IN CONTROL GROUP	30	30	30	30	---
MALE MATING INDEX (%)	96.6	96.7	93.3	100.0	---
MALE FERTILITY INDEX (%)	89.7	96.7	86.7	100.0	---
NO. FEMALES IN CONTROL GROUP	30	30	30	30	25
FEMALE MATING INDEX (%)	96.7	96.7	93.3	100.0	---
FEMALE FERTILITY INDEX (%)	90.0	96.7	86.7	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	25
NO. THAT DELIVERED	27	29	26	30	25
NO. THAT DID NOT DELIVER	3	1	4	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	1
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.7	3.3	2.6	2.0	---
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	21.8	21.6	21.8
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
MEAN VIABLE LITTER SIZE ON PND 0	13.3	13.1	13.2	14.4	14.4
PUP SEX RATIO					
MEAN % MALE	56.4	50.6	51.3	50.0	49.0
MEAN % FEMALE	43.6	49.4	48.7	50.0	51.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	---	15.6	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	---	0.8	0.8
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	87.8	96.9	---	---	---
EXPERIMENTAL START DATE	1/14/97	4/15/97	4/15/97	11/4/97	8/31/98
DATE OF LAST NECROPSY	6/3/97	11/29/97	11/29/97	11/25/97	10/9/98
ROUTE	Inhalation	Inhalation	Inhalation	Inhalation	Gavage
VEHICLE	Filtered Air	Filtered Air	Filtered Air	Filtered Air	0.4% MC

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DATASET NO.	16	17	18	19	20
NO. MALES IN CONTROL GROUP	25	24	---	25	25
MALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	92.0	95.8	---	100.0	96.0
NO. FEMALES IN CONTROL GROUP	25	24	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	95.8	92.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	24	25	---	---
NO. THAT DELIVERED	23	23	23	---	---
NO. THAT DID NOT DELIVER	2	1	2	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	---
NO. WITH DYSTOCIA	0	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	2.4	---	2.8	2.7
MEAN GESTATION LENGTH (DAYS)	21.8	21.6	21.8	---	---
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
MEAN VIABLE LITTER SIZE ON PND 0	13.9	15.0	14.7	---	---
PUP SEX RATIO					
MEAN % MALE	52.1	49.7	51.9	---	---
MEAN % FEMALE	47.9	50.3	48.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.1	15.9	15.7	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	0.9	1.0	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	16.4	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/14/98	7/7/98	9/23/98	10/27/98	3/29/99
DATE OF LAST NECROPSY	2/1/99	10/1/98	11/23/98	3/1/99	5/4/99
ROUTE	Gavage	Diet	Gavage	Gavage	Gavage
VEHICLE	0.4% MC	Basal Feed	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80

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DATASET NO.	21	22	23	24	25
NO. MALES IN CONTROL GROUP	---	25	---	25	---
MALE MATING INDEX (%)	---	96.0	---	72.0	---
MALE FERTILITY INDEX (%)	---	88.0	---	72.0	---
NO. FEMALES IN CONTROL GROUP	25	25	22	25	25
FEMALE MATING INDEX (%)	---	96.0	---	84.0	---
FEMALE FERTILITY INDEX (%)	100.0	88.0	95.5	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25	22	---	25
NO. THAT DELIVERED	25	22	21	---	25
NO. THAT DID NOT DELIVER	0	3	1	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	0
NO. WITH DYSTOCIA	0	0	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	2.2	---	3.5	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.8	21.8	---	22.0
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	13.8	14.9	14.6	---	14.7
PUP SEX RATIO					
MEAN % MALE	47.7	49.8	47.7	---	47.7
MEAN % FEMALE	52.3	50.2	52.3	---	52.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.9	15.4	---	15.7
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.8	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	13.9	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.2	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	10/26/98	11/17/98	1/12/99	2/3/99	7/27/98
DATE OF LAST NECROPSY	12/13/98	4/13/99	3/1/99	6/15/99	9/12/98
ROUTE	SubQ	SubQ	SubQ	SubQ	Gavage
VEHICLE	20 mM Na Phosphate	21 mM Na Phosphate	Sponsor-Supplied	Sponsor-Supplied	0.75% MC

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DATASET NO.	26	27	28	29	30
NO. MALES IN CONTROL GROUP	25	---	---	25	---
MALE MATING INDEX (%)	96.0	---	---	96.0	---
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	96.0	---
FEMALE FERTILITY INDEX (%)	92.0	88.0	96.0	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	25	25	25
NO. THAT DELIVERED	---	22	23	24	25
NO. THAT DID NOT DELIVER	---	3	2	1	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	0	0
NO. WITH DYSTOCIA	---	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	---	---	2.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.7	21.7	21.7	21.7
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	15.9	14.7	15.0
PUP SEX RATIO					
MEAN % MALE	---	50.8	54.0	50.8	48.5
MEAN % FEMALE	---	49.2	46.0	49.2	51.5
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.8	16.7	---	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.6	0.5	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	13.8	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/18/98	9/13/99	8/2/99	8/17/99	8/9/99
DATE OF LAST NECROPSY	12/29/98	10/31/99	9/12/99	1/10/00	9/25/99
ROUTE	Gavage	Gavage	Gavage	Gavage	Intranasal
VEHICLE	0.75% MC	0.1 M Na Phosphate	0.4% MC	0.4% MC	MC

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Crl:CD(SD) Rat*

DATASET NO.	31	32	33	34	35
NO. MALES IN CONTROL GROUP	25	40	---	---	40
MALE MATING INDEX (%)	82.6	97.5	---	---	---
MALE FERTILITY INDEX (%)	73.9	95.0	---	---	75.0
NO. FEMALES IN CONTROL GROUP	25	40	25	25	40
FEMALE MATING INDEX (%)	95.8	97.5	100.0	100.0	---
FEMALE FERTILITY INDEX (%)	87.5	95.0	92.0	96.0	---
NO. FEMALES SELECTED TO DELIVER	---	40	---	---	---
NO. THAT DELIVERED	---	38	---	---	---
NO. THAT DID NOT DELIVER	---	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	---	---	---
NO. WITH DYSTOCIA	---	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	2.8	2.6	3.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.6	---	---	---
MEAN NO. PUPS BORN	---	15.4	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	---	48.8	---	---	---
MEAN % FEMALE	---	51.2	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.9	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.1	---	15.4	15.6	16.5
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/31/99	6/17/96	9/29/98	11/6/98	3/4/99
DATE OF LAST NECROPSY	1/11/00	11/15/96	11/24/98	12/31/98	4/14/99
ROUTE	Intranasal	Inhalation	Gavage	Gavage	Dermal
VEHICLE	MC	Filtered Air	1% Avicel-5% Tween 80 50mM Sodium Acetate	0.5% Aqueous MC	Fire Pond Water

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	36	37	38	39	40
NO. MALES IN CONTROL GROUP	20	25	---	25	25
MALE MATING INDEX (%)	---	96.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	95.0	88.0	---	92.0	100.0
NO. FEMALES IN CONTROL GROUP	20	25	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	92.0	96.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	---	25	25	---
NO. THAT DELIVERED	---	---	24	23	---
NO. THAT DID NOT DELIVER	---	---	1	2	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	1	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.2	---	2.6	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	21.6	21.7	---
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	14.8	14.4	---
PUP SEX RATIO					
MEAN % MALE	---	---	55.2	50.9	---
MEAN % FEMALE	---	---	44.8	49.1	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	15.4	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.9	15.3	---	---	15.8
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/15/99	4/9/99	6/15/99	6/17/96	11/18/99
DATE OF LAST NECROPSY	6/24/99	6/17/99	7/31/99	11/17/99	1/28/00
ROUTE	Dermal	Gavage	Gavage	Untreated	Untreated
VEHICLE	Fire Pond Water	10mM Lactic Acid in DI Water	5% Acacia	Not Applicable	Not Applicable

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	41	42	43	44	45
NO. MALES IN CONTROL GROUP	---	24	35	15	30
MALE MATING INDEX (%)	---	95.7	97.1	100.0	100.0
MALE FERTILITY INDEX (%)	---	91.3	91.4	86.7	96.7
NO. FEMALES IN CONTROL GROUP	25	24	35	15	30
FEMALE MATING INDEX (%)	---	100.0	97.1	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	95.7	94.3	86.7	96.7
NO. FEMALES SELECTED TO DELIVER	25	23	---	---	30
NO. THAT DELIVERED	24	21	---	---	28
NO. THAT DID NOT DELIVER	1	2	---	---	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	1
NO. WITH TOTAL LITTER LOSS	0	0	---	---	0
NO. WITH DYSTOCIA	0	0	---	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.3	2.2	2.2	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	21.8	---	---	21.7
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	15.5	15.0	---	---	14.7
PUP SEX RATIO					
MEAN % MALE	53.1	47.3	---	---	46.7
MEAN % FEMALE	46.9	52.7	---	---	53.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.3	16.0	---	---	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	---	---	0.6
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	15.4	16.6	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.3	---	---	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/21/99	11/3/99	10/1/99	1/12/00	10/1/99
DATE OF LAST NECROPSY	11/7/99	3/9/00	1/17/00	8/17/00	2/11/00
ROUTE	Gavage	Untreated	Dermal	Untreated Recovery	Gavage
VEHICLE	10% Aqueous Acacia	Not Applicable	Sponsor-Supplied Placebo	Not Applicable	Citric Acid Solution

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WIL Reproductive Historical Control Data **Individual Study Data**

Crl:CD(SD) Rat*

DATASET NO.	**46**	**47**	**48**	**49**	**50**
NO. MALES IN CONTROL GROUP	29	25	25	24	25
MALE MATING INDEX (%)	93.1	100.0	96.0	100.0	96.0
MALE FERTILITY INDEX (%)	79.3	84.0	92.0	87.5	92.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	93.1	100.0	96.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	79.3	84.0	92.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	29	---	25	25	---
NO. THAT DELIVERED	23	---	23	22	---
NO. THAT DID NOT DELIVER	6	---	2	3	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	---
NO. WITH DYSTOCIA	0	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	4.3	2.6	3.4	3.8	2.9
MEAN GESTATION LENGTH (DAYS)	21.8	---	22.0	22.0	---
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
MEAN VIABLE LITTER SIZE ON PND 0	14.7	---	14.4	14.5	---
PUP SEX RATIO					
MEAN % MALE	48.3	---	53.7	44.7	---
MEAN % FEMALE	51.7	---	46.3	56.3	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.7	---	15.3	15.5	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.3	0.5	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.2	---	---	16.3
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.4	4.1	4.2	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	107.8	105.6	---
EXPERIMENTAL START DATE	1/25/00	10/25/99	11/3/99	2/29/00	11/19/99
DATE OF LAST NECROPSY	6/22/00	12/30/99	3/20/00	7/25/00	1/21/00
ROUTE	Gavage	SubQ	Inhalation	Inhalation	Intranasal
VEHICLE	Citric Acid Solution	Sponsor-Supplied Placebo	Filtered Air	Filtered Air	Sponsor-Supplied Placebo

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DATASET NO.	51	52	53	54	55
NO. MALES IN CONTROL GROUP	25	25	30	30	25
MALE MATING INDEX (%)	96.0	92.0	93.3	93.3	96.0
MALE FERTILITY INDEX (%)	88.0	92.0	83.3	80.0	92.0
NO. FEMALES IN CONTROL GROUP	25	25	30	30	25
FEMALE MATING INDEX (%)	100.0	100.0	93.3	93.3	96.0
FEMALE FERTILITY INDEX (%)	92.0	100.0	83.3	80.0	92.0
NO. FEMALES SELECTED TO DELIVER	---	---	30	30	---
NO. THAT DELIVERED	---	---	25	24	---
NO. THAT DID NOT DELIVER	---	---	5	6	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	0	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.6	3.6	3.5	3.7	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	22.0	21.6	---
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	13.0	13.9	---
PUP SEX RATIO					---
MEAN % MALE	---	---	49.7	50.3	---
MEAN % FEMALE	---	---	50.3	49.7	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.0	15.3	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.8	1.0	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.2	16.7	---	---	15.9
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.3	---	4.4	4.9	4.5
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	114.9	---
EXPERIMENTAL START DATE	1/14/00	1/25/00	2/4/00	5/30/00	2/7/00
DATE OF LAST NECROPSY	3/20/00	3/8/00	6/16/00	10/23/00	3/19/00
ROUTE	Gavage	Dermal	Diet	Diet	Gavage
VEHICLE	0.5% CMC	Sponsor-Supplied Placebo	Basal Feed	Basal Feed	0.5% MC-0.10% Tween 80

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DATASET NO.	56	57	58	59	60
NO. MALES IN CONTROL GROUP	25	---	25	25	---
MALE MATING INDEX (%)	95.8	---	100.0	84.0	---
MALE FERTILITY INDEX (%)	95.8	---	96.0	84.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	95.8	---	100.0	84.0	---
FEMALE FERTILITY INDEX (%)	95.8	92.0	96.0	84.0	96.0
NO. FEMALES SELECTED TO DELIVER	---	25	---	---	25
NO. THAT DELIVERED	---	23	---	---	24
NO. THAT DID NOT DELIVER	---	2	---	---	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	---	---	0
NO. WITH DYSTOCIA	---	0	---	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.6	---	2.9	2.4	---
MEAN GESTATION LENGTH (DAYS)	---	21.8	---	---	21.8
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	---	---	16.0
PUP SEX RATIO					
MEAN % MALE	---	50.4	---	---	52.0
MEAN % FEMALE	---	49.6	---	---	48.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	16.0	---	---	17.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.9	---	---	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.3	---	13.9	16.1	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.0	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/7/00	2/8/00	2/7/00	3/31/00	5/15/00
DATE OF LAST NECROPSY	6/6/00	3/26/00	7/11/00	6/12/00	7/4/00
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.5% MC-0.10% Tween 80	0.5% CMC	0.5% CMC	0.5% CMC	0.5% Aqueous CMC

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Modified: 1/24/2005

DATASET NO.	61	62	63	64	65
NO. MALES IN CONTROL GROUP	25	----	23	25	25
MALE MATING INDEX (%)	100.0	----	95.7	100.0	100.0
MALE FERTILITY INDEX (%)	100.0	----	91.3	84.0	100.0
NO. FEMALES IN CONTROL GROUP	25	25	23	25	25
FEMALE MATING INDEX (%)	100.0	---	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	96.0	91.3	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	23	---	---
NO. THAT DELIVERED	---	24	20	---	---
NO. THAT DID NOT DELIVER	---	1	3	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	---	---
NO. WITH DYSTOCIA	---	1	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	----	3.1	---	2.1
MEAN GESTATION LENGTH (DAYS)	---	21.8	21.9	---	---
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.0	13.1	---	---
PUP SEX RATIO					
MEAN % MALE	---	50.5	51.8	---	---
MEAN % FEMALE	---	49.5	48.2	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.7	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.0	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.0	---	---	15.4	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.3	4.1	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	6/28/00	7/4/00	8/15/00	8/25/00	9/25/00
DATE OF LAST NECROPSY	10/12/00	8/21/00	12/21/00	10/6/00	11/10/00
ROUTE	Untreated	Gavage	Untreated	Diet	Diet
VEHICLE	Not Applicable	10% Aqueous Acacia	Not Applicable	Basal Feed	Basal Feed

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DATASET NO.	66	67	68	69	70
NO. MALES IN CONTROL GROUP	---	25	25	25	---
MALE MATING INDEX (%)	----	100.0	92.0	96.0	---
MALE FERTILITY INDEX (%)	----	87.5	80.0	92.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	---	100.0	92.0	96.0	---
FEMALE FERTILITY INDEX (%)	76.0	88.0	80.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	23
NO. THAT DELIVERED	19	---	20	---	23
NO. THAT DID NOT DELIVER	6	---	5	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	2
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	----	3.8	2.7	2.2	---
MEAN GESTATION LENGTH (DAYS)	21.9	---	22.0	---	22.0
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
MEAN VIABLE LITTER SIZE ON PND 0	14.0	---	14.6	---	14.3
PUP SEX RATIO					
MEAN % MALE	46.9	---	51.9	---	51.2
MEAN % FEMALE	53.1	---	48.1	---	48.8
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.3	---	15.4	---	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.7	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.6	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.2	4.8	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/22/00	10/4/00	10/27/00	12/5/00	1/19/01
DATE OF LAST NECROPSY	10/8/00	1/23/01	3/3/01	1/31/01	3/6/01
ROUTE	Gavage	Untreated	Gavage	IV	Gavage
VEHICLE	Aqueous 10% Lactic Acid	Not Applicable	Sesame Oil	Saline	DI Water

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DATASET NO.	71	72	73	74	75
NO. MALES IN CONTROL GROUP	23	---	25	25	40
MALE MATING INDEX (%)	95.5	---	88.0	96.0	97.5
MALE FERTILITY INDEX (%)	90.9	---	84.0	87.5	90.0
NO. FEMALES IN CONTROL GROUP	23	25	25	25	40
FEMALE MATING INDEX (%)	95.7	---	92.0	100.0	97.5
FEMALE FERTILITY INDEX (%)	91.3	100.0	88.0	92.0	90.0
NO. FEMALES SELECTED TO DELIVER	23	25	---	---	---
NO. THAT DELIVERED	21	25	---	---	---
NO. THAT DID NOT DELIVER	2	0	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	---	---	---
NO. WITH DYSTOCIA	0	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.3	---	3.1	3.1	2.7
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	---	---	---
MEAN NO. PUPS BORN	12.6	15.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	12.6	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	47.6	50.5	---	---	---
MEAN % FEMALE	52.4	49.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	16.2	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.3	0.7	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.3	16.6	16.6
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.4	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/3/01	2/19/01	3/28/01	2/20/01	3/20/01
DATE OF LAST NECROPSY	7/2/01	4/2/01	7/10/01	4/26/01	7/5/01
ROUTE	Untreated	Gavage	Untreated	Gavage	Gavage
VEHICLE	Not Applicable	Reverse Osmosis-Purified Water	Not Applicable	Reverse Osmosis-Purified Water	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water

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DATASET NO.	76	77	78	79	80
NO. MALES IN CONTROL GROUP	---	30	29	---	30
MALE MATING INDEX (%)	---	100.0	96.6	---	100.0
MALE FERTILITY INDEX (%)	---	96.7	86.2	---	93.3
NO. FEMALES IN CONTROL GROUP	25	30	30	25	30
FEMALE MATING INDEX (%)	96.0	100.0	96.6	92.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	96.7	86.2	92.0	93.3
NO. FEMALES SELECTED TO DELIVER	---	30	29	---	---
NO. THAT DELIVERED	---	29	25	---	---
NO. THAT DID NOT DELIVER	---	1	4	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	---	2	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.1	2.7	2.6	3.4	2.8
MEAN GESTATION LENGTH (DAYS)	---	21.6	21.8	---	---
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.2	13.9	---	---
PUP SEX RATIO					
MEAN % MALE	---	51.2	49.2	---	---
MEAN % FEMALE	---	48.8	50.8	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.6	15.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	0.9	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.6	---	---	14.9	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.5	4.9	5.5	5.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	132.9	---	---
EXPERIMENTAL START DATE	4/20/01	6/12/01	10/4/01	6/15/01	7/12/01
DATE OF LAST NECROPSY	6/11/01	10/22/01	3/8/02	7/30/01	10/5/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water	0.5% MC

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DATASET NO.	81	82	83	84	85
NO. MALES IN CONTROL GROUP	25	25	25	25	25
MALE MATING INDEX (%)	92.0	92.0	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	84.0	92.0	100.0	91.7	100.0
NO. FEMALES IN CONTROL GROUP	25	25	25	24	25
FEMALE MATING INDEX (%)	100.0	96.0	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	88.0	92.0	100.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	25	---	---	---
NO. THAT DELIVERED	20	23	---	---	---
NO. THAT DID NOT DELIVER	5	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	1	0	0	0
NO. WITH TOTAL LITTER LOSS	1	1	---	---	---
NO. WITH DYSTOCIA	0	1	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.8	4.7	2.8	2.5	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	22.0	---	---	---
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	14.3	12.7	---	---	---
PUP SEX RATIO					
MEAN % MALE	46.6	47.1	---	---	---
MEAN % FEMALE	53.4	52.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	14.3	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.8	15.1	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.8	4.9	5.2	---	5.0
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	50.4	---	---	---
EXPERIMENTAL START DATE	8/6/01	11/28/01	8/6/01	9/7/01	7/17/01
DATE OF LAST NECROPSY	12/10/01	4/27/02	9/18/01	11/21/01	10/16/01
ROUTE	Inhalation/ Gavage	Inhalation/ Gavage	Gavage	Gavage	Gavage
VEHICLE	Filtered Air/ Olive Oil	Filtered Air/ Olive Oil	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	PEG 1000/ Carbowax PEG 400 in DI Water

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DATASET NO.	86	87	88	89	90
NO. MALES IN CONTROL GROUP	---	30	30	25	25
MALE MATING INDEX (%)	---	86.7	96.7	100.0	100.0
MALE FERTILITY INDEX (%)	---	73.3	73.3	96.0	100.0
NO. FEMALES IN CONTROL GROUP	25	30	30	25	25
FEMALE MATING INDEX (%)	100.0	86.7	96.7	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	73.3	73.3	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	30	30	---	---
NO. THAT DELIVERED	---	22	22	---	---
NO. THAT DID NOT DELIVER	---	8	8	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	2.8	4.0	2.5	2.6
MEAN GESTATION LENGTH (DAYS)	---	22.0	22.0	---	---
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	13.6	13.0	---	---
PUP SEX RATIO					
MEAN % MALE	---	49.6	46.9	---	---
MEAN % FEMALE	---	50.4	53.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.1	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	1.2	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.7	---	---	16.8	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	5.3	4.7	4.6	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	114.6	---	---
EXPERIMENTAL START DATE	8/26/01	9/2/01	1/2/02	10/12/01	10/19/01
DATE OF LAST NECROPSY	10/21/01	1/15/02	5/31/02	12/14/01	12/27/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	DI Water	2.5%HPMC in 50mM Sodium Acetate

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DATASET NO.	91	92	93	94	95
NO. MALES IN CONTROL GROUP	---	25	30	30	30
MALE MATING INDEX (%)	---	95.5	96.7	96.7	100.0
MALE FERTILITY INDEX (%)	---	95.5	93.3	80.0	93.3
NO. FEMALES IN CONTROL GROUP	25	25	30	30	30
FEMALE MATING INDEX (%)	---	95.8	96.7	96.7	100.0
FEMALE FERTILITY INDEX (%)	100.0	95.8	93.3	80.0	93.3
NO. FEMALES SELECTED TO DELIVER	25	---	30	30	30
NO. THAT DELIVERED	25	---	28	24	27
NO. THAT DID NOT DELIVER	0	---	2	6	3
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	0
NO. WITH DYSTOCIA	0	---	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.0	3.5	3.1	1.8
MEAN GESTATION LENGTH (DAYS)	21.7	---	21.9	22.1	21.7
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
MEAN VIABLE LITTER SIZE ON PND 0	14.9	---	14.7	13.0	14.8
PUP SEX RATIO					
MEAN % MALE	49.1	---	42.7	56.6	45.9
MEAN % FEMALE	50.9	---	57.3	43.4	54.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.0	---	15.7	13.9	15.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	---	0.8	0.8	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	13.9	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.0	4.5	4.5	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	107.0	---
EXPERIMENTAL START DATE	12/3/01	1/8/02	2/15/02	6/21/02	12/26/01
DATE OF LAST NECROPSY	1/14/02	4/24/02	7/11/02	11/6/02	5/7/02
ROUTE	Gavage	Untreated	Diet	Diet	Drinking Water
VEHICLE	DI Water	Not Applicable	Basal Feed	Basal Feed	Drinking Water

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DATASET NO.	96	97	98	99	100
NO. MALES IN CONTROL GROUP	30	---	25	---	25
MALE MATING INDEX (%)	96.7	---	96.0	---	96.0
MALE FERTILITY INDEX (%)	86.7	---	92.0	---	96.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	96.7	---	100.0	---	100.0
FEMALE FERTILITY INDEX (%)	86.7	96.0	96.0	88.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	25	---	25	25
NO. THAT DELIVERED	26	24	---	22	24
NO. THAT DID NOT DELIVER	4	1	---	3	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	1	0
NO. WITH TOTAL LITTER LOSS	0	0	---	0	0
NO. WITH DYSTOCIA	0	0	---	1	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.9	---	3.1	---	4.0
MEAN GESTATION LENGTH (DAYS)	22.0	21.7	---	21.8	21.8
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
MEAN VIABLE LITTER SIZE ON PND 0	14.3	15.0	---	15.3	14.2
PUP SEX RATIO					
MEAN % MALE	53.5	48.4	---	45.8	48.9
MEAN % FEMALE	46.5	51.6	---	54.2	51.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.7	---	17.1	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.7	---	1.1	1.1
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.5	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.0	---	4.2	---	4.3
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/18/02	10/22/02	2/11/03	11/18/02	3/10/03
DATE OF LAST NECROPSY	9/12/02	12/9/02	3/20/03	12/30/02	5/8/03
ROUTE	Drinking Water	Gavage	Gavage	Gavage	Gavage
VEHICLE	Drinking Water	2.5%HPMC in 50mM Sodium Acetate	2.5%HPMC in 50mM Sodium Acetate	0.5% MC	0.5% MC

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WIL Reproductive Historical Control Data — Individual Study Data — Page 21
Crl:CD(SD) Rat*

DATASET NO.	101	102	103	104	105
NO. MALES IN CONTROL GROUP	25	---	---	25	25
MALE MATING INDEX (%)	96.0	---	---	96.0	96.0
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	72.0
NO. FEMALES IN CONTROL GROUP	25	---	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	100.0	96.0
FEMALE FERTILITY INDEX (%)	92.0	---	96.0	100.0	72.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	25
NO. THAT DELIVERED	23	---	24	---	18
NO. THAT DID NOT DELIVER	2	---	1	---	7
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	---	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	---	---	3.5	3.4
MEAN GESTATION LENGTH (DAYS)	22.0	---	21.9	---	21.9
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
MEAN VIABLE LITTER SIZE ON PND 0	13.9	---	15.3	---	13.4
PUP SEX RATIO					
MEAN % MALE	52.6	---	47.9	---	53.7
MEAN % FEMALE	47.4	---	52.1	---	46.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.5	---	16.1	---	14.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	---	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	15.4	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	4.2	4.7
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	1/7/03	1/7/03	7/22/03	11/10/03	6/10/03
DATE OF LAST NECROPSY	5/30/03	6/20/03	10/28/03	12/16/03	10/12/03
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.10% Sodium Phosphate Buffer	0.10% Sodium Phosphate Buffer	DI Water	DI Water	1.0% MC

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DATASET NO.	106	107
NO. MALES IN CONTROL GROUP	---	---
MALE MATING INDEX (%)	---	---
MALE FERTILITY INDEX (%)	---	---
NO. FEMALES IN CONTROL GROUP	25	25
FEMALE MATING INDEX (%)	---	---
FEMALE FERTILITY INDEX (%)	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25
NO. THAT DELIVERED	25	25
NO. THAT DID NOT DELIVER	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0
NO. WITH TOTAL LITTER LOSS	0	0
NO. WITH DYSTOCIA	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.7
MEAN NO. PUPS BORN	15.9	15.5
MEAN VIABLE LITTER SIZE ON PND 0	15.7	15.3
PUP SEX RATIO		
MEAN % MALE	49.4	46.3
MEAN % FEMALE	50.6	53.7
MEAN NO. OF IMPLANTATION SITES AT WEANING	17.0	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---
EXPERIMENTAL START DATE	10/27/03	10/28/03
DATE OF LAST NECROPSY	2/2/04	2/3/04
ROUTE	Gavage	Gavage
VEHICLE	1.0% MC	1.0% MC

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WIL Reproductive Historical Control Data
Crl:CD(SD) Rat*

Individual Study Data

DATASET NO.	1	2	3	4	5
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	92.3	97.5	99.3	99.2	99.4
PND 0 TO PND 1	100.0	99.6	99.2	99.4	99.2
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	98.6	99.3	100.0	99.3
PND 4 (AFTER SELECTION) TO PND 7	99.5	100.0	100.0	99.1	100.0
PND 7 TO PND 14	100.0	100.0	100.0	100.0	100.0
PND 14 TO PND 21	100.0	98.5	100.0	100.0	99.6
BIRTH TO PND 4 (BEFORE SELECTION)	92.3	95.9	97.8	98.7	97.9
PND 4 (AFTER SELECTION) TO PND 21	99.5	98.5	100.0	99.1	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.4	7.1	7.2	7.0	7.2
PND 4 (BEFORE SELECTION)	10.6	10.6	10.1	10.2	10.4
PND 7	17.2	17.2	16.4	16.8	15.1
PND 14	33.7	35.8	29.9	35.0	27.8
PND 21	53.8	58.0	45.4	53.1	44.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.8	6.8	6.6	6.7
PND 4 (BEFORE SELECTION)	10.0	10.0	9.5	9.7	9.7
PND 7	16.1	16.3	15.5	16.2	14.1
PND 14	32.1	34.3	28.9	33.9	26.3
PND 21	51.6	54.8	44.1	51.0	42.2
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3915
SPLEEN	---	---	---	---	0.1698
THYMUS GLAND	---	---	---	---	0.1690
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3530
SPLEEN	---	---	---	---	0.1722
THYMUS GLAND	---	---	---	---	0.1743

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DATASET NO.	6	7	8	9	10
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.3	96.6	97.7	98.2	97.7
PND 0 TO PND 1	99.8	94.5	99.4	99.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	97.8	99.4	97.8	99.7	100.0
PND 4 (AFTER SELECTION) TO PND 7	100.0	100.0	99.5	100.0	100.0
PND 7 TO PND 14	96.6	100.0	100.0	100.0	96.9
PND 14 TO PND 21	99.6	100.0	100.0	100.0	97.8
BIRTH TO PND 4 (BEFORE SELECTION)	96.0	91.3	95.2	97.7	97.4
PND 4 (AFTER SELECTION) TO PND 21	96.1	100.0	99.5	100.0	96.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	6.8	6.8	7.3	7.1
PND 4 (BEFORE SELECTION)	10.2	9.6	9.6	10.5	10.4
PND 7	15.3	15.3	15.4	16.4	16.6
PND 14	28.5	31.1	31.8	33.1	33.4
PND 21	45.3	51.0	49.5	50.6	52.1
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.5	6.3	6.9	6.7
PND 4 (BEFORE SELECTION)	9.5	9.1	9.0	10.0	9.7
PND 7	14.3	14.5	14.6	15.7	15.6
PND 14	27.5	29.7	30.8	32.2	31.2
PND 21	43.5	47.9	47.7	49.2	49.0
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4000	1.4926	1.4660	---	---
SPLEEN	0.1805	0.2106	0.1901	---	---
THYMUS GLAND	0.1790	0.2155	0.2076	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3682	1.4242	1.4214	---	---
SPLEEN	0.1846	0.1975	0.1929	---	---
THYMUS GLAND	0.1853	0.2113	0.2099	---	---

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WIL Reproductive Historical Control Data — Individual Study Data —
Crl:CD(SD) Rat*

DATASET NO.	11	12	13	14	15
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.4	97.6	97.8	97.0	95.7
PND 0 TO PND 1	99.3	98.9	99.4	99.6	95.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	99.6	99.2	98.8	100.0
PND 4 (AFTER SELECTION) TO PND 7	97.2	99.6	---	---	100.0
PND 7 TO PND 14	96.3	---	---	---	99.5
PND 14 TO PND 21	100.0	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.5	96.2	96.4	95.4	94.0
PND 4 (AFTER SELECTION) TO PND 21	95.4	98.5	---	---	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.6	7.0	6.9	7.1
PND 4 (BEFORE SELECTION)	9.1	8.9	9.3	9.5	10.0
PND 7	11.7	12.3	---	---	16.2
PND 14	22.5	24.6	---	---	32.5
PND 21	34.9	38.2	---	---	51.4
PND 28	65.4	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	6.2	6.5	6.4	6.7
PND 4 (BEFORE SELECTION)	8.5	8.4	8.8	9.0	9.5
PND 7	11.0	11.5	---	---	15.4
PND 14	21.2	23.4	---	---	31.7
PND 21	33.3	37.0	---	---	49.1
PND 28	59.8	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3616	1.4033	---	---	---
SPLEEN	0.1189	0.1544	---	---	---
THYMUS GLAND	0.1392	0.1640	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.2903	1.3390	---	---	---
SPLEEN	0.1182	0.1539	---	---	---
THYMUS GLAND	0.1338	0.1612	---	---	---

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WIL Reproductive Historical Control Data
Crl:CD(SD) Rat*

Individual Study Data

DATASET NO.	16	17	18	19	20
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.5	97.3	99.0	---	---
PND 0 TO PND 1	100.0	98.5	98.8	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.4	99.0	99.6	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	94.9	97.5	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	100.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	6.7	7.1	---	---
PND 4 (BEFORE SELECTION)	10.3	9.2	10.2	---	---
PND 7	---	13.1	16.5	---	---
PND 14	---	25.1	34.9	---	---
PND 21	---	39.5	54.7	---	---
PND 28	---	70.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.3	6.7	---	---
PND 4 (BEFORE SELECTION)	9.8	8.7	9.7	---	---
PND 7	---	12.6	15.9	---	---
PND 14	---	24.1	33.7	---	---
PND 21	---	38.0	52.4	---	---
PND 28	---	66.8	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.6	98.7	99.0	---	99.8
PND 0 TO PND 1	99.7	99.1	100.0	---	100.0
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	99.8	98.8	---	99.5
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	---	100.0
PND 7 TO PND 14	99.5	---	100.0	---	100.0
PND 14 TO PND 21	100.0	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.4	97.5	97.8	---	99.3
PND 4 (AFTER SELECTION) TO PND 21	99.5	---	100.0	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.1	7.4	---	6.8
PND 4 (BEFORE SELECTION)	10.2	10.4	10.7	---	9.6
PND 7	16.7	---	17.8	---	15.7
PND 14	34.8	---	36.5	---	32.4
PND 21	53.3	---	55.3	---	52.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.7	6.9	---	6.5
PND 4 (BEFORE SELECTION)	9.7	9.7	10.0	---	9.1
PND 7	16.1	---	16.8	---	14.9
PND 14	33.5	---	34.7	---	31.2
PND 21	50.9	---	53.1	---	50.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.9	97.7	98.9	99.5
PND 0 TO PND 1	---	94.3	96.7	98.2	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.6	98.8	98.8	99.4
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	99.5
PND 7 TO PND 14	---	99.3	100.0	---	98.5
PND 14 TO PND 21	---	100.0	100.0	---	98.8
BIRTH TO PND 4 (BEFORE SELECTION)	---	92.1	93.8	96.0	98.0
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	100.0	---	97.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	6.7	7.1	6.5
PND 4 (BEFORE SELECTION)	---	9.4	9.4	9.8	8.6
PND 7	---	15.1	15.1	---	13.0
PND 14	---	31.3	32.9	---	27.1
PND 21	---	48.1	50.9	---	41.3
PND 28	---	86.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.4	6.4	6.6	6.1
PND 4 (BEFORE SELECTION)	---	8.9	8.8	9.1	8.1
PND 7	---	14.1	14.3	---	12.2
PND 14	---	29.4	31.2	---	25.7
PND 21	---	45.0	48.0	---	39.4
PND 28	---	79.4	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN NO. PUPS BORN	---	15.4	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.3	---	---	---
PND 0 TO PND 1	---	99.3	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	99.7	---	---	---
PND 7 TO PND 14	---	99.7	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	97.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	---	---	---
PND 4 (BEFORE SELECTION)	---	10.1	---	---	---
PND 7	---	14.8	---	---	---
PND 14	---	27.2	---	---	---
PND 21	---	45.5	---	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	---	---	---
PND 4 (BEFORE SELECTION)	---	9.6	---	---	---
PND 7	---	14.0	---	---	---
PND 14	---	26.3	---	---	---
PND 21	---	43.8	---	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	36	37	38	39	40
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	95.8	97.7	---
PND 0 TO PND 1	---	---	98.7	98.9	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	97.7	98.1	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	---	---
PND 7 TO PND 14	---	---	99.5	---	---
PND 14 TO PND 21	---	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	92.4	94.8	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.8	6.8	---
PND 4 (BEFORE SELECTION)	---	---	9.5	9.2	---
PND 7	---	---	15.0	---	---
PND 14	---	---	31.8	---	---
PND 21	---	---	48.9	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.4	6.3	---
PND 4 (BEFORE SELECTION)	---	---	8.9	8.8	---
PND 7	---	---	14.1	---	---
PND 14	---	---	30.5	---	---
PND 21	---	---	46.7	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.5	98.6	---	---	99.1
PND 0 TO PND 1	99.7	99.6	---	---	98.6
PND 1 TO PND 4 (BEFORE SELECTION)	99.1	98.4	---	---	99.8
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.7	---	---	99.6
PND 7 TO PND 14	100.0	---	---	---	100.0
PND 14 TO PND 21	100.0	---	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	---	---	97.5
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	---	---	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	7.4	---	---	6.6
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	9.0
PND 7	15.3	15.2	---	---	14.9
PND 14	32.5	---	---	---	31.1
PND 21	51.4	---	---	---	45.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.9	---	---	6.2
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	8.5
PND 7	14.5	14.4	---	---	14.2
PND 14	31.3	---	---	---	30.0
PND 21	49.5	---	---	---	44.5
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.4163
SPLEEN	---	---	---	---	0.1822
THYMUS GLAND	---	---	---	---	0.1758
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3876
SPLEEN	---	---	---	---	0.1915
THYMUS GLAND	---	---	---	---	0.1852

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DATASET NO.	46	47	48	49	50
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.5	---	96.6	97.3	---
PND 0 TO PND 1	100.0	---	100.0	99.7	---
PND 1 TO PND 4 (BEFORE SELECTION)	98.4	---	99.5	99.7	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	100.0	---
PND 7 TO PND 14	100.0	---	99.5	100.0	---
PND 14 TO PND 21	100.0	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	---	96.1	96.8	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	99.5	100.0	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	---	7.3	7.1	---
PND 4 (BEFORE SELECTION)	9.3	---	10.7	10.3	---
PND 7	15.1	---	15.4	15.5	---
PND 14	32.1	---	28.8	29.2	---
PND 21	51.1	---	48.4	49.5	---
PND 28	---	---	88.1	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.2	---	6.9	6.7	---
PND 4 (BEFORE SELECTION)	8.7	---	10.1	9.6	---
PND 7	14.0	---	14.5	14.5	---
PND 14	30.4	---	27.4	27.6	---
PND 21	47.5	---	45.9	46.6	---
PND 28	---	---	79.5	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4763	---	1.4897	1.4728	---
SPLEEN	0.2176	---	0.2063	0.2189	---
THYMUS GLAND	0.1990	---	0.1951	0.1958	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4261	---	1.4332	1.3957	---
SPLEEN	0.2042	---	0.1977	0.2087	---
THYMUS GLAND	0.1986	---	0.2001	0.1895	---

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DATASET NO.	51	52	53	54	55
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	98.7	97.6	---
PND 0 TO PND 1	---	---	100.0	99.5	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	99.3	99.2	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	99.5	---
PND 7 TO PND 14	---	---	100.0	100.0	---
PND 14 TO PND 21	---	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	98.0	96.3	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	100.0	99.5	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.6	7.2	---
PND 4 (BEFORE SELECTION)	---	---	11.2	10.2	---
PND 7	---	---	17.7	16.9	---
PND 14	---	---	35.1	35.2	---
PND 21	---	---	57.6	55.2	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.2	6.8	---
PND 4 (BEFORE SELECTION)	---	---	10.7	9.7	---
PND 7	---	---	17.1	16.2	---
PND 14	---	---	35.1	33.7	---
PND 21	---	---	55.6	52.2	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.5175	1.4836	---
SPLEEN	---	---	0.2476	0.2227	---
THYMUS GLAND	---	---	0.2372	0.2446	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4597	1.4341	---
SPLEEN	---	---	0.2302	0.2200	---
THYMUS GLAND	---	---	0.2479	0.2407	---

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DATASET NO.	56	57	58	59	60
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.9	---	---	97.3
PND 0 TO PND 1	---	98.6	---	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	---	93.5	---	---	100.0
PND 4 (AFTER SELECTION) TO PND 7	---	99.4	---	---	100.0
PND 7 TO PND 14	---	100.0	---	---	100.0
PND 14 TO PND 21	---	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	---	91.6	---	---	95.9
PND 4 (AFTER SELECTION) TO PND 21	---	99.4	---	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.0	---	---	7.1
PND 4 (BEFORE SELECTION)	---	9.6	---	---	9.7
PND 7	---	16.1	---	---	16.1
PND 14	---	33.9	---	---	34.4
PND 21	---	52.4		---	54.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.6	---	---	6.7
PND 4 (BEFORE SELECTION)	---	9.2	---	---	9.2
PND 7	---	15.1	---	---	15.2
PND 14	---	32.5	---	---	32.8
PND 21	---	49.2	---	---	52.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	95.6	95.8	---	---
PND 0 TO PND 1	---	95.4	98.1	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	98.9	99.3	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	93.1	93.3	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	7.1	---	---
PND 4 (BEFORE SELECTION)	---	9.9	10.7	---	---
PND 7	---	15.7	---	---	---
PND 14	---	30.0	---	---	---
PND 21	---	48.4	---	---	---
PND 28	---	88.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	6.8	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.1	---	---
PND 7	---	14.9	---	---	---
PND 14	---	28.9	---	---	---
PND 21	---	46.6	---	---	---
PND 28	---	80.5	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.0	---	98.8	---	97.8
PND 0 TO PND 1	99.0	---	98.1	---	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	95.7	---	99.7	---	99.3
PND 4 (AFTER SELECTION) TO PND 7	95.8	---	100.0	---	98.4
PND 7 TO PND 14	100.0	---	100.0	---	99.4
PND 14 TO PND 21	99.2	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	91.9	---	96.6	---	96.7
PND 4 (AFTER SELECTION) TO PND 21	95.2	---	100.0	---	97.8
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	---	7.1	---	7.2
PND 4 (BEFORE SELECTION)	10.3	---	9.8	---	10.1
PND 7	16.3	---	15.3	---	15.1
PND 14	32.5	---	32.3	---	30.9
PND 21	49.4	---	52.1	---	48.2
PND 28	89.8	---	---	---	83.2
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	---	6.6	---	6.8
PND 4 (BEFORE SELECTION)	9.7	---	9.1	---	9.4
PND 7	15.8	---	14.5	---	14.1
PND 14	32.8	---	31.1	---	29.5
PND 21	50.2	---	49.7	---	46.3
PND 28	86.2	---	---	---	77.9
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	71	72	73	74	75
MEAN NO. PUPS BORN	12.6	15.5	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.6	97.4	---	---	---
PND 0 TO PND 1	98.5	99.8	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	99.0	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.4	99.5	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.1	96.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	7.0	---	---	---
PND 4 (BEFORE SELECTION)	10.8	9.7	---	---	---
PND 7	17.4	15.4	---	---	---
PND 14	---	32.4	---	---	---
PND 21	---	50.0	---	---	---
PND 28	---	87.8	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.6	---	---	---
PND 4 (BEFORE SELECTION)	10.4	9.1	---	---	---
PND 7	16.5	14.4	---	---	---
PND 14	---	30.9	---	---	---
PND 21	---	47.3	---	---	---
PND 28	---	82.1	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.3	97.5	---	---
PND 0 TO PND 1	---	98.0	99.5	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	98.8	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	96.6	100.0	---	---
PND 7 TO PND 14	---	94.4	99.0	---	---
PND 14 TO PND 21	---	95.9	99.5	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	94.9	95.7	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	92.2	98.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	7.2	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.5	---	---
PND 7	---	12.8	15.0	---	---
PND 14	---	24.8	29.7	---	---
PND 21	---	39.1	45.1	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	8.9	9.9	---	---
PND 7	---	11.8	14.3	---	---
PND 14	---	23.6	28.3	---	---
PND 21	---	39.1	42.9	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3553	1.4080	---	---
SPLEEN	---	0.1471	0.1755	---	---
THYMUS GLAND	---	0.1723	0.1901	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3241	1.3683	---	---
SPLEEN	---	0.1471	0.1850	---	---
THYMUS GLAND	---	0.1710	0.2032	---	---

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DATASET NO.	81	82	83	84	85
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.0	93.3	---	---	---
PND 0 TO PND 1	100.0	100.0	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.6	99.3	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.0	100.0	---	---	---
PND 7 TO PND 14	93.5	100.0	---	---	---
PND 14 TO PND 21	94.7	99.5	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.7	92.7	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	91.1	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.4	---	---	---
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	---
PND 7	12.8	15.2	---	---	---
PND 14	23.3	---	---	---	---
PND 21	38.4	42.6	---	---	---
PND 28	74.0	79.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	7.1	---	---	---
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	---
PND 7	12.2	14.3	---	---	---
PND 14	22.7	---	---	---	---
PND 21	37.6	40.5	---	---	---
PND 28	69.3	73.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3451	1.4458	---	---	---
SPLEEN	0.1503	0.1817	---	---	---
THYMUS GLAND	0.1617	0.1971	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3142	1.3833	---	---	---
SPLEEN	0.1515	0.1686	---	---	---
THYMUS GLAND	0.1669	0.1948	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.8	98.8	---	---
PND 0 TO PND 1	---	100.0	99.4	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.7	99.7	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	99.4	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	95.5	97.9	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.4	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.9	7.3	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.4	---	---
PND 7	---	12.9	14.6	---	---
PND 14	---	24.0	27.3	---	---
PND 21	---	38.5	43.9	---	---
PND 28	---	72.0	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	9.0	9.8	---	---
PND 7	---	12.5	13.9	---	---
PND 14	---	23.3	26.2	---	---
PND 21	---	36.9	41.9	---	---
PND 28	---	66.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3987	---	---
SPLEEN	---	---	0.1815	---	---
THYMUS GLAND	---	---	0.1678	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3623	---	---
SPLEEN	---	---	0.1905	---	---
THYMUS GLAND	---	---	0.1778	---	---

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DATASET NO.	91	92	93	94	95
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	96.8	---	99.1	98.7	98.7
PND 0 TO PND 1	100.0	---	98.9	97.0	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	99.8	---	99.0	99.2	99.8
PND 4 (AFTER SELECTION) TO PND 7	99.0	---	99.6	99.5	100.0
PND 7 TO PND 14	98.0	---	100.0	100.0	100.0
PND 14 TO PND 21	99.0	---	99.6	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.5	---	97.1	94.9	97.6
PND 4 (AFTER SELECTION) TO PND 21	96.0	---	99.1	99.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	7.1	7.5	6.9
PND 4 (BEFORE SELECTION)	9.2	---	9.9	10.8	9.5
PND 7	14.0	---	15.7	17.3	15.5
PND 14	24.6	---	32.2	35.3	32.6
PND 21	37.8	---	50.5	56.7	51.3
PND 28	69.8	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	---	6.7	7.0	6.4
PND 4 (BEFORE SELECTION)	8.8	---	9.4	10.1	8.9
PND 7	13.3	---	15.0	16.3	14.6
PND 14	24.2	---	31.3	33.9	31.2
PND 21	36.9	---	48.9	53.5	49.3
PND 28	67.4	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4143	1.4899	1.4775
SPLEEN	---	---	0.2232	0.2480	0.2220
THYMUS GLAND	---	---	0.1943	0.2330	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3958	1.4378	1.4216
SPLEEN	---	---	0.2335	0.2408	0.2229
THYMUS GLAND	---	---	0.2120	0.2363	0.2265

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DATASET NO.	96	97	98	99	100
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.9	100.0	---	96.1	99.0
PND 0 TO PND 1	99.5	99.5	---	99.7	98.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	97.4	---	96.8	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	97.3	---	96.9	---
PND 7 TO PND 14	100.0	99.4	---	99.3	---
PND 14 TO PND 21	100.0	100.0	---	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.2	96.9	---	92.4	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	96.8	---	96.3	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.9	---	7.0	7.3
PND 4 (BEFORE SELECTION)	9.9	9.3	---	9.5	---
PND 7	16.2	14.5	---	15.4	---
PND 14	33.0	30.7	---	32.7	---
PND 21	50.0	49.7	---	51.6	---
PND 28	---	83.5	---	87.1	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.6	---	6.6	6.9
PND 4 (BEFORE SELECTION)	9.4	8.9	---	9.0	---
PND 7	15.5	13.9	---	14.4	---
PND 14	31.9	29.5	---	30.7	---
PND 21	48.5	47.6	---	48.6	---
PND 28	---	77.7	---	78.4	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4605	---	---	---	---
SPLEEN	0.2211	---	---	---	---
THYMUS GLAND	0.2123	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4199	---	---	---	---
SPLEEN	0.2261	---	---	---	---
THYMUS GLAND	0.2078	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.7	---	99.2	---	98.3
PND 0 TO PND 1	99.4	---	99.4	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	99.2	---	99.2	---	99.2
PND 4 (AFTER SELECTION) TO PND 7	99.6	---	99.5	---	100.0
PND 7 TO PND 14	99.6	---	99.5	---	---
PND 14 TO PND 21	100.0	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	97.8	---	---
PND 4 (AFTER SELECTION) TO PND 21	99.1	---	99.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	---	7.3	---	7.6
PND 4 (BEFORE SELECTION)	10.5	---	10.1	---	11.4
PND 7	16.1	---	16.4	---	16.4
PND 14	31.1	---	34.0	---	---
PND 21	49.0	---	53.8	---	---
PND 28	76.4	---	94.0	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	6.9	---	7.2
PND 4 (BEFORE SELECTION)	9.9	---	9.6	---	10.9
PND 7	15.4	---	15.5	---	15.7
PND 14	29.9	---	32.8	---	---
PND 21	47.0	---	51.6	---	---
PND 28	68.9	---	85.3	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	106	107
MEAN NO. PUPS BORN	15.9	15.5
PUP SURVIVAL INDICES (% PER LITTER)		
PND 0 (RELATIVE TO NO. BORN)	98.6	98.6
PND 0 TO PND 1	99.2	99.5
PND 1 TO PND 4 (BEFORE SELECTION)	99.5	98.7
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.5
PND 7 TO PND 14	100.0	100.0
PND 14 TO PND 21	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.3	96.8
PND 4 (AFTER SELECTION) TO PND 21	100.0	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)		
PND 1	7.0	6.8
PND 4 (BEFORE SELECTION)	9.5	9.4
PND 7	15.1	15.3
PND 14	31.8	31.6
PND 21	50.5	50.2
PND 28	86.6	85.3
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)		
PND 1	6.5	6.3
PND 4 (BEFORE SELECTION)	8.9	8.8
PND 7	14.0	14.4
PND 14	30.0	30.4
PND 21	48.0	47.7
PND 28	79.1	77.0
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---

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DATASET NO.	1	2	3	4	5
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	43.3	---	46.7	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	230.4	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.2	---	33.1	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	106.9	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	6	7	8	9	10
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	5.3	5.7	---	---
FEMALE	---	3.2	3.9	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.0	---	44.6	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	217.9	---	223.0	---	232.0
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	---	34.4	---	32.6
MEAN BODY WEIGHT AT ACQUISITION (G)	105.1	---	118.9	---	112.2
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	11	12	13	14	15
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	5.3	5.3	---	---	---
FEMALE	3.3	3.1	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	47.0	47.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	38.8	32.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	5.2
FEMALE	---	---	---	---	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	4.8	---	---	---
FEMALE	---	2.7	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	41.6	---	41.8	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	210.5	---	212.2	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	32.5	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	107.4	---	117.7	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	4.0	---	---
FEMALE	---	---	4.0	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	16.1	---	---
FEMALE	---	---	16.1	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.0	---	42.4	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	227.1	---	229.0	---	226.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.4	---	31.9	---	33.2
MEAN BODY WEIGHT AT ACQUISITION (G)	115.2	---	109.9	---	119.1
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.0	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.2	---	---	---	---
FEMALE	14.8	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.1	---	43.8	49.0
MEAN BODY WEIGHT AT ACQUISITION (G)	---	247.9	---	229.2	248.0
MEAN DAY OF VAGINAL PATENCY (PND)	---	31.9	---	33.2	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	103.8	---	119.5	102.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	49.0	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	248.0	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	33.7	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	102.8	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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Crl:CD(SD) Rat*

Individual Study Data

DATASET NO.	36	37	38	39	40
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.7	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	235.1	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	112.1	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.1	---	---	---	46.3
MEAN BODY WEIGHT AT ACQUISITION (G)	240.3	---	---	---	231.0
MEAN DAY OF VAGINAL PATENCY (PND)	32.7	---	---	---	31.7
MEAN BODY WEIGHT AT ACQUISITION (G)	114.7	---	---	---	99.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.1	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	18.7	---	---	---	---
FEMALE	18.6	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	46	47	48	49	50
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.2	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	228.9	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	36.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	130.3	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	51	52	53	54	55
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	42.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	227.0	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	34.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	133.0	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	56	57	58	59	60
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	42.0	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	---	215.7	---	---	248.6
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.9	---	---	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	112.6	---	---	125.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.7	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	238.3	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	107.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	5.1	---	---	---
FEMALE	---	5.2	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	4.2	---	---	---
FEMALE	---	4.2	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	15.5	---	---	---
FEMALE	---	15.5	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.7	---	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	224.7	---	---	---	220.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.1	---	---	---	33.1
MEAN BODY WEIGHT AT ACQUISITION (G)	114.4	---	---	---	107.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	14.9
FEMALE	---	---	---	---	14.9
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	10.1
FEMALE	---	---	---	---	10.0

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DATASET NO.	71	72	73	74	75
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.4	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	231.8	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.2	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	117.2	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	2.45	4.41	---	---
FEMALE	---	1.34	2.57	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	219.5	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	37.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	119.8	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	81	82	83	84	85
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.6	45.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	223.2	222.2	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	35.1	33.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	114.0	109.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.2	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	4.0	---	---	---
FEMALE	4.0	4.0	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.7	15.1	---	---	---
FEMALE	15.7	15.1	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	13.1	11.7	---	---	---
FEMALE	13.0	11.8	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	10.0	9.3	---	---	---
FEMALE	9.9	9.3	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	49.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	236.1	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	35.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	109.0	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	91	92	93	94	95
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	4.34	4.32	---
FEMALE	---	---	2.41	2.37	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.8	---	46.1	---	44.4
MEAN BODY WEIGHT AT ACQUISITION (G)	213.8	---	236.6	---	212.8
MEAN DAY OF VAGINAL PATENCY (PND)	33.8	---	34.2	---	33.0
MEAN BODY WEIGHT AT ACQUISITION (G)	99.5	---	121.9	---	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	96	97	98	99	100
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	4.36	---	---	---	---
FEMALE	2.28	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.0	---	44.8	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	220.2	---	235.6	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.9	---	33.5	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	115.1	---	111.5	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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Crl:CD(SD) Rat*

DATASET NO.	101	102	103	104	105
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.7	---	42.3	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	221.8	---	223.8	---	225.2
MEAN DAY OF VAGINAL PATENCY (PND)	33.0	---	33.0	---	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	103.4	---	119.0	---	109.7
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	106	107
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.4	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	238.2	228.2
MEAN DAY OF VAGINAL PATENCY (PND)	32.9	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	112.1	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)		
MALE	5.1	5.0
FEMALE	5.3	5.1
MEAN DAY OF PINNAL DETACHMENT (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF EYE OPENING (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF HAIR GROWTH (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF INCISOR ERUPTION (PND)		
MALE	---	---
FEMALE	---	---

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DATASET NO.	1	2	3	4	5
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.55	2.64	2.73	1.95	2.70
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.85	1.72	1.84	1.71
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.88	1.74	1.85	1.71
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.71	0.75	0.74	0.74	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.76	0.72	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3266	0.3293	0.3185	0.3164	0.3022
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3197	0.3423	0.3280	0.3295	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	85.2	89.1	99.3	87.0	87.3
LEFT EPIDIDYMIS	449.0	407.9	436.1	413.4	343.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.0	14.6	16.3	14.3	14.3
% MOTILE SPERM	84.9	82.4	85.5	87.6	80.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.6	99.4	99.9	99.6	99.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	0.5	0.0	0.3	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.1	0.0	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.2	198.8	199.9	199.1	198.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.4	0.9	0.1	0.6	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	1.3	0.3	0.1	0.3	0.9
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	6	7	8	9	10
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.05	1.88	1.82	2.80	1.76
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.72	1.72	1.73	1.79
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.73	1.75	1.75	1.81
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.75	0.68	0.71	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.70	0.69	0.74	0.76
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3269	0.3364	0.2812	0.3157	0.3210
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3225	0.3242	0.3057	0.3280	0.3271
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.6	81.7	104.8	90.8	95.8
LEFT EPIDIDYMIS	517.5	410.6	534.3	452.1	416.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	13.4	17.2	14.9	15.7
% MOTILE SPERM	80.8	85.3	82.3	87.6	85.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.7	99.8	99.0	99.8	96.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.8	0.1	0.7	0.2	2.0
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.1	0.3	0.1	1.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.4	199.6	198.0	199.5	192.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.6	0.3	1.5	0.3	4.0
HEAD ABSENT WITH NORMAL FLAGELLUM	1.0	0.1	0.5	0.2	3.2
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	11	12	13	14	15
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.64	2.73	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.76	1.73	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.76	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	0.72	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.70	0.70	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3262	0.3174	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3064	0.2950	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	72.9	94.1	---	---	---
LEFT EPIDIDYMIS	456.0	467.9	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	11.9	15.4	---	---	---
% MOTILE SPERM	80.2	75.4	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.5	99.6	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.9	0.1	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.3	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.0	199.2	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.9	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	1.1	0.6	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.1	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---

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Modified: 1/24/2005

DATASET NO.	16	17	18	19	20
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.65	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.67	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2807	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2943	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	96.6	---	---	---
LEFT EPIDIDYMIS	---	438.8	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.8	---	---	---
% MOTILE SPERM	---	80.9	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.8	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.0	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.9	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.		22	23	24	25
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.45	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.73	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3160	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3293	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	91.7	---	---	---
LEFT EPIDIDYMIS	---	478.5	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.0	---	---	---
% MOTILE SPERM	---	86.2	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.1	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.3	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	1.77
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.68
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3092
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	106.7
LEFT EPIDIDYMIS	---	---	---	---	442.7
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	17.5
% MOTILE SPERM	---	---	---	---	81.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0

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DATASET NO.	36	37	38	39	40
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.80	1.76	---	---	1.93
MEAN LEFT TESTIS WEIGHT (G)	1.88	1.75	---	---	1.90
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.78	0.67	---	---	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.80	0.67	---	---	0.77
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3402	0.2857	---	---	0.3552
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3712	0.3061	---	---	0.3380
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.0	95.5	---	---	83.8
LEFT EPIDIDYMIS	393.1	556.7	---	---	418.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.1	15.7	---	---	13.7
% MOTILE SPERM	77.3	79.3	---	---	86.4
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.8	---	---	---	98.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.4	---	---	---	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.5	---	---	---	197.6
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	---	---	---	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	1.8	---	---	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0

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DATASET NO.	41	42	43	44	45
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	1.79	1.87	1.83	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.90	1.82	1.76	1.79
MEAN LEFT TESTIS WEIGHT (G)	---	1.89	1.84	1.82	1.80
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.81	0.78	0.78	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.77	0.77	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3586	0.3495	0.3272	0.3338
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3374	0.3555	0.3487	0.3149
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	95.5	76.7	74.1	---
LEFT EPIDIDYMIS	---	476.1	421.3	407.1	477.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.7	12.6	12.1	---
% MOTILE SPERM	---	85.9	87.1	75.9	89.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.8	99.4	99.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.3	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.5	198.8	199.4	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	0.7	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.6	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---

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DATASET NO.	46	47	48	49	50
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.15	2.14	---
MEAN RIGHT TESTIS WEIGHT (G)	1.83	1.70	1.79	1.84	1.69
MEAN LEFT TESTIS WEIGHT (G)	1.84	1.71	1.79	1.80	1.72
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.75	0.67	0.72	0.74	0.67
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.68	0.74	0.72	0.66
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3291	0.2817	0.3327	0.3178	0.3080
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3298	0.2967	0.3252	0.3304	0.3025
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	94.7	84.8	106.9	82.4
LEFT EPIDIDYMIS	539.2	500.8	471.9	640.1	503.2
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.5	13.9	17.5	13.5
% MOTILE SPERM	88.1	89.2	86.8	88.9	79.2
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.5	99.7	99.5	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.3	0.2	0.2	0.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.3	0.1	0.2	0.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	198.9	199.4	199.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.5	0.4	0.0	0.9
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.6	0.1	0.0	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	51	52	53	54	55
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.24	2.28
MEAN RIGHT TESTIS WEIGHT (G)	1.73	---	1.82	1.89	1.77
MEAN LEFT TESTIS WEIGHT (G)	1.69	---	1.80	1.92	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	---	0.81	0.75	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.69	---	0.76	0.78	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3121	---	0.3548	0.3431	0.3396
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3084	---	0.3387	0.3504	0.3475
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	90.5	---	105.4	83.8	---
LEFT EPIDIDYMIS	462.7	---	454.6	412.9	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.8	---	17.3	13.7	
% MOTILE SPERM	91.6	---	91.1	85.3	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.8	---	99.8	99.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.1	---	0.2	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	199.6	199.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	---	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---

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DATASET NO.	56	57	58	59	60
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---		---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.73	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.69	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.2962	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3168	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	91.0	---
LEFT EPIDIDYMIS	447.6	---	---	585.8	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	14.9	---
% MOTILE SPERM	86.3	---	---	84.2	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.3	---	---	99.5	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	---	---	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	198.6	---	---	199.1	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.1	---	---	0.4	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.3	---	---	0.5	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---

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WIL Reproductive Historical Control Data
Crl:CD(SD) Rat*

Individual Study Data

DATASET NO.	61	62	63	64	65
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	----	1.92	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	----	1.80	---	1.80
MEAN LEFT TESTIS WEIGHT (G)	---	----	1.79	---	1.75
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.67
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3189	---	0.3368
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3449	---	0.3239
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	----	79.8	---	77.8
LEFT EPIDIDYMIS	---	----	506.2	---	417.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	----	13.1	---	12.8
% MOTILE SPERM	---	----	91.9	---	71.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	----	99.4	---	91.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.4	---	3.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.2	---	4.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	----	198.8	---	183.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.8	---	6.7
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.4	---	9.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0

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DATASET NO.	66	67	68	69	70
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	----	----	1.95	1.82	---
MEAN RIGHT TESTIS WEIGHT (G)	----	----	1.85	1.71	---
MEAN LEFT TESTIS WEIGHT (G)	----	----	1.83	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	----	----	0.71	0.64	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	----	----	0.70	0.62	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.2972	0.2629	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.3065	0.2714	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	----	----	81.0	---	---
LEFT EPIDIDYMIS	----	----	443.9	480.0	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	----	----	13.3	---	---
% MOTILE SPERM	----	----	87.3	82.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	----	----	98.9	97.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	0.7	1.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.4	0.9	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	----	----	197.9	195.8	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	1.4	1.7	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.8	2.4	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.1	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---

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DATASET NO.	71	72	73	74	75
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.68	1.90
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.69	1.91
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.68	0.78
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3057	0.3564
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3143	0.3693
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	75.0	69.6
LEFT EPIDIDYMIS	---	---	---	458.8	466.3
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	12.3	11.4
% MOTILE SPERM	---	---	---	82.0	83.1
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	99.0	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	0.5	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	0.5	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	198.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	1.0	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	1.0	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0

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DATASET NO.	76	77	78	79	80
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.26	2.29	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.84	---	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	1.84	1.87	---	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.74	---	0.74
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.76	---	0.74
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3354	0.3364	---	0.3397
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3460	0.3498	---	0.3377
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	77.7	90.8	---	74.3
LEFT EPIDIDYMIS	---	454.3	436.0	---	353.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	12.6	14.9	---	12.2
% MOTILE SPERM	---	87.5	87.0	---	84.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	96.1	99.2	---	98.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.6	0.4	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	2.3	0.5	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	192.2	198.3	---	197.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	3.1	0.7	---	1.2
HEAD ABSENT WITH NORMAL FLAGELLUM	---	4.6	0.9	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0

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DATASET NO.	81	82	83	84	85
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.13	2.15	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.84	1.80	---	1.76	1.75
MEAN LEFT TESTIS WEIGHT (G)	1.81	1.80	---	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.80	0.73	---	0.79	0.70
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.76	0.73	---	0.78	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3686	0.3270	---	0.3682	0.3326
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3595	0.3243	---	0.3706	0.3286
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	79.1	96.6	---	79.2	84.6
LEFT EPIDIDYMIS	---	---	---	469.0	452.3
LEFT CAUDA EPIDIDYMIS	738.9	618.7	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	13.0	15.8	---	13.0	13.9
% MOTILE SPERM	88.6	84.3	---	89.7	78.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.5	99.3	---	99.3	97.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	0.4	---	0.5	1.8
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	0.2	---	0.3	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	199.0	198.7	---	198.6	195.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.9	---	0.9	3.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.4	0.4	---	0.5	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0

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DATASET NO.	86	87	88	89	90
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	2.30		---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.79	1.76	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	1.83	1.80	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.69	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.71	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3055	0.3194	0.3257	0.3352
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3306	0.3226	0.3384	0.3310
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	88.8	81.6	86.7	87.4
LEFT EPIDIDYMIS	---	476.2	434.0	475.8	461.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	14.5	13.4	14.2	14.3
% MOTILE SPERM	---	83.0	87.0	83.4	81.7
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.9	97.3	99.7	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.3	0.4	0.1	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.8	0.3	0.2	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.8	198.6	199.4	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.6	0.8	0.3	10.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.6	0.6	0.3	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	91	92	93	94	95
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.22	2.09
MEAN RIGHT TESTIS WEIGHT (G)	---	---	1.85	1.90	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	---	1.82	1.91	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.76	0.72
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.77	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3234	0.3424	0.3162
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3421	0.3460	0.3212
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	75.9	93.2	78.1
LEFT EPIDIDYMIS	---	---	---	---	406.0
LEFT CAUDA EPIDIDYMIS	---	---	689.5	662.8	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	12.4	15.3	12.8
% MOTILE SPERM	---	---	91.0	82.0	88.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	99.4	99.7	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.4	0.2	0.3
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.2	0.1	0.1
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	198.9	199.4	199.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.8	0.4	1.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.3	0.2	0.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0

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DATASET NO.	96	97	98	99	100
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	1.98	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.86	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.82	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.63	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3264	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3232	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	76.2	---	---	---	---
LEFT EPIDIDYMIS	548.6	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	12.5	---	---	---	---
% MOTILE SPERM	89.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.7	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.2	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.23	2.04	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.87	1.92	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.73	1.85	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.78	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.68	0.74	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3336	0.3693	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.2858	0.3405	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

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DATASET NO.	106	107
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)		
LEFT TESTIS	---	---
LEFT EPIDIDYMIS	---	---
LEFT CAUDA EPIDIDYMIS	---	---
MEAN SPERM PRODUCTION RATE		
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---
% MOTILE SPERM	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---

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APPENDIX E

Study Protocol

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PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number:
05-002

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

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1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]

2.2 WIL Study Director:

[redacted]

2.3 WIL Deputy Director:

[redacted]

2.4 WIL Departmental Responsibilities:

[redacted]

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[redacted]

3 STUDY SCHEDULE:

Proposed Animal Receipt Date (Experimental Starting Date):	May 10, 2005
Proposed Experimental Start Date:	May 26, 2205
Proposed Experimental Termination/ Completion Date:	June 17, 2005
Proposed Audited Report Date:	August 26, 2005

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

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4.1.1 Lot Number:

[redacted]

4.1.2 Purity:

100%.

4.1.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.1.4 Physical Description:

Viscous liquid.

4.1.5 Storage Conditions:

Store at ambient conditions under nitrogen.

4.1.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.1.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

4.2 Identification:

[redacted]

4.2.1 Lot Number:

[redacted]

4.2.2 Purity:

100%.

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4.2.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.2.4 Physical Description:

Viscous liquid.

4.2.5 Storage Conditions:

Store at ambient conditions under nitrogen.

4.2.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.2.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat.

5.2 Strain:

Sprague-Dawley Crl:CD®(SD)

5.3 Source:

Charles River Laboratories
Portage, Michigan

5.4 Number on Study:

105 Females (maximum of 130 females and 13 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 4-6 days old upon receipt. Animals not assigned to the study will be transferred to the stock animal colony

or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and discarded.

5.5 Body Weight Range:

At randomization: 30-50 g. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal eartag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed-O'Cobs®). Following randomization, the juvenile female animals will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. Control animals (Group 1) will be housed on a separate rack from exposed animals. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL standard operating procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

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6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol-specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available ad libitum. Filters servicing the automatic watering system are changed regularly according to WIL standard operating procedures. The municipal water supplying the laboratory is analyzed according to WIL standard operating procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered ad libitum during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

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7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Each of 7 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[redacted]	60	12	5	15
3	[redacted]	250	50	5	15
4	[redacted]	1000	200	5	15
5	[redacted]	60	12	5	15
6	[redacted]	250	50	5	15
7	[redacted]	1000	200	5	15

7.4.2 Vehicle Control Article:

Corn oil

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7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 of age and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Article Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5 mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions under nitrogen. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

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7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of the data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The methods employed will be one or more of the following:

[redacted] SOP #ME-125

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of $\pm$ 0.0005 g. Each sample will be stored at ambient temperature under nitrogen. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will be observed also approximately one hour following dosing and the observations will be recorded. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded.

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7.6.2 Body Weights:

Daily body weights will be recorded individually (to the nearest 0.1 gram PND 22-42, with the exception of the weight collected the day prior to dosing and the final body weight) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized by carbon dioxide inhalation and necropsied as described in section 9.

8 HOROMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH) Thyroxine (T4)

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9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized in extremis. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. The following tissues will be collected and placed in 10% neutral-buffered formalin at study termination:

Cervix and Uterine Body (one longitudinal section)	Thyroid
Ovaries	Uterine horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized in extremis.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in the same sequence as which dosing occurred. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

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The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

9.2.2 Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Ovaries and oviducts
Liver	Pituitary gland
Kidneys	Thyroid (following fixation)

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 Microscopic Examination:

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination.

The vagina, ovaries, and thyroid from each animal will be similarly preserved with the uterus.

Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

Ovaries	Thyroid
Cervix and Uterine Body (one longitudinal section)	Uterine Horns (four sections per horn)

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10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age of first estrous and estrous cycle length will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL standard operating procedures and the appropriate provisions of EPA/TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Good Laboratory Practice Regulations [C (97) 186/Final]. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

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15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional paper copies of the final report may result in additional charges.

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

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Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via mail on March 24, 2005.

[redacted]

15 April 2005
Date

WIL Research Laboratories, LLC

[redacted]

4/14/2005
Date

[redacted]

4/14/2005
Date

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REVISED ABBREVIATED AUDITED DRAFT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [ ] AND [ ]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187044

COMPANY SANITIZED

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

14 April 2005

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

05-003

SPONSOR

[ ]
[ ]

COMPLIANCE STATEMENT

This study, designated WIL-187044, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 160), 16 October 1989; the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor. **A Certificate of Analysis was provided by the sponsor (presented in Appendix A); the characterization analyses were conducted according to Good Laboratory Practices (GLP)/unknown standards [sponsor-supplied documentation required].**

_____ _____

[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] or [ ], in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to 3 groups each of 15 Crl:CD®(SD) immature female rats. Dosage levels for each test article were 60, 250 and 1000 mg/kg/day, and the dosage volume was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director. Due to mortality, dosing procedures were performed after 1200 hours (approximately 1 hour later than on previous days) beginning on 11 June 2005, when the animals were 31-33 days of age.

Dosing procedures were performed from 31 May 2005 through 21 June 2005, when the animals were 22 to 41 days of age; the start of dose administration was staggered, based on age. At the initiation of dose administration, body weights ranged from 41.1 g to 62.8 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[ ]	60	12	5	15
3	[ ]	250	50	5	15
4	[ ]	1000	200	5	15
5	[ ]	60	12	5	15
6	[ ]	250	50	5	15
7	[ ]	1000	200	5	15

Due to spacing constraints, the dosage group names are presented on the tables and figures as corn oil, [ ]/60, [ ]/250 and [ ]/1000 for the vehicle control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively and [ ]/60, [ ]/250 and [ ]/1000 for the 60, 250 and 1000 mg/kg/day [ ] groups, respectively.

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (100% pure corn oil, exp. date: 6 April 2006) was dispensed into a storage container and stirred throughout use. The [ ] and [ ] dosing formulations were prepared as follows. [ ] and [ ] were heated to approximately 40°C to 50°C, then inverted or shaken prior to use. The appropriate amount of test article for each group was weighed into a tared, calibrated glass container. A stir bar and approximately 80% of the vehicle were added to each container, and the mixtures were stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The [ ] and [ ] dosing formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature under nitrogen. Three samples from the control group formulation and 3 sets of samples from the top, middle and bottom strata of the test article formulations were collected prior to the initiation of dose administration. Additional samples (3 sets) were collected for resuspension homogeneity from the same formulations following 10 days of room temperature storage. Two sets of samples for concentration verification were collected on each day of preparation and 2 sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and 6 sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC, for possible future analysis.

Thirteen dams with 10 female pups each (130 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on 17 May 2005. The pups were 6 to

8 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam for 14 to 16 days) during the acclimation period until randomization of the pups on postnatal day (PND) 21. Following randomization, the female pups were weaned, identified by metal eartag and housed 3 per cage in plastic maternity cages. Environmental controls were set to maintain an average daily temperature of 71°F ± 5°F and an average daily relative humidity of 50%±20%. Actual mean daily temperatures ranged from 70.1°F to 70.6°F (21.2°C to 21.4°C) and mean daily relative humidity ranged from 38.0% to 50.9%. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse osmosis-purified water were offered ad libitum.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on PND 25 (Adams et al., 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (i.e., the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia). Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A gross necropsy was performed only

on animals that were found dead or euthanized in extremis. Beginning on 8 June 2005, blood was collected from all animals euthanized in extremis or found dead following dose administration for hematology and serum chemistry evaluation (see Appendix E); the lungs, heart, liver, kidneys, esophagus and gastrointestinal tract from these animals, as well as from all animals found dead, were also retained in 10% neutral-buffered formalin. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum thyroxine (T_4) and thyroid stimulating hormone (TSH) levels. Additional serum samples (taken from the samples used for TSH and T_4 analysis) were collected and stored frozen for possible future serological analysis. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, adrenal glands, pituitary gland and thyroid glands were weighed. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The ovaries, uterus (horns and body), cervix, vagina, pituitary gland, thyroid glands and gross lesions were retained from all females, including those found dead.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. Mean body weights, body weight changes, days of acquisition of vaginal patency, estrous cycle lengths, ages at the first occurrence of estrus, serum hormone levels, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
17 May 2005	Experimental starting date (animal receipt)
31 May 2005	Experimental start date (first day of dose administration)
31 May - 21 June 2005	Test article administration
22 June 2005	Experimental termination/completion date (last euthanasia)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS - [ ]

Clear material on various body surfaces (primarily around the mouth) was noted in females, primarily in the 1000 mg/kg/day [ ] group, with infrequent occurrences in the 250 mg/kg/day group 1 hour following dose administration. These findings were attributed to the test article, but were not considered adverse.

One, 3, 7 and 7 females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively, were found dead at 23-32 days of age as a result of test article administration. Three females in the 1000 mg/kg/day [ ] group were found dead at 23 days of age following 1 dose on the previous day. The remaining 3, 6 and 4 females in the 60, 250 and 1000 mg/kg/day [ ] groups, respectively, died within approximately 1.5 hours of dose administration at 28 to 32 days of age. There were no deaths after PND 30 in the 250 and 1000 mg/kg/day [ ] groups, and no females were

found dead after the administration time was changed. One female in the 1000 mg/kg/day [ ] group was hypoactive with shallow respiration 1 hour following dose administration on PND 22. No other remarkable clinical findings exclusive to animals that were found dead were noted in the 1000 mg/kg/day [ ] group. Necropsy findings in the 1000 mg/kg/day [ ] group consisted of dark red discoloration of the lungs (2 females), lungs not fully collapsed (2 females) and clear tracheal contents (1 female). Prior to death (at 28, 29 or 30 days of age), 1 female each in the 250 mg/kg/day [ ] group had labored respiration or hypoactivity noted on the day of death. Necropsy findings in the 250 mg/kg/day [ ] group consisted of 1 female with cystic kidneys, lungs that were not fully collapsed and dark red discoloration of the skeletal muscle dorsal to the thyroid glands. Another female in this group had lungs that were not fully collapsed and dark red discoloration of the skeletal muscle at the approximate level of thoracic vertebrae nos. 1-3, and a third female in this group had dark red discoloration of the lungs. In the 60 mg/kg/day group, 1 female (found dead at 30 days of age) was hypoactive and prostrate with shallow respiration at the time of dose administration on the day of death. In this same group, 1 female had no clinical findings and another female was hypoactive and had tan material around the mouth 1 hour following dose administration on the day of death; both of these females were 32 days of age at death. At necropsy, 2 females in the 60 mg/kg/day [ ] group had lungs that were not fully collapsed; another female had dark red discoloration of the lungs. The control group female died on PND 31 and had no clinical findings prior to death and no internal findings at necropsy. All other animals survived to the scheduled euthanasia.

Mean body weight gains in the 1000 mg/kg/day [ ] group were lower than the control group values following the first 3 days of dose administration. The differences were statistically significant ($p<0.01$) from PND 22-23 to PND 23-24. Throughout the remainder of the dosing period and when the entire treatment period (PND 22-42) was evaluated, mean body weight gains in this group were generally similar to those in the control group. Mean body weights in this group were 5.4% to 11.6% lower than the

control group values from PND 23-35. The differences were statistically significant ($p<0.05$ or $p<0.01$) from PND 24-29. By PND 42, mean body weight in the surviving females in the 1000 mg/kg/day [ ] group was similar to the control group. Mean body weights and body weight gains in the 60 and 250 mg/kg/day [ ] groups were generally similar to those in the control group throughout the study; none of the differences were statistically significant.

A test article-related delay in the mean age of attainment of vaginal patency was noted in the 1000 mg/kg/day [ ] group. Mean ages of attainment were 33.7, 33.7, 34.6 and 35.5 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. Mean body weights at the age of attainment in these groups were similar to the control group value. No statistically significant differences in either parameter were noted; however, only 8 females each in the 250 and 1000 mg/kg/day [ ] groups were available for evaluation compared to 14 females in the control group.

The ages of the first occurrence of estrus in the 60, 250 and 1000 mg/kg/day [ ] groups (35.2, 36.9 and 37.5 days, respectively) were similar to that in the control group (37.1 days of age); the differences were not statistically significant. No differences in mean estrous cycle length were observed when the 60 (n=7) and 250 (n=3) mg/kg/day [ ] groups were compared to the control group (n=7); only 1 of 8 surviving females in the 1000 mg/kg/day group had a complete cycle prior to necropsy. Estrous cycle lengths in females of this age are highly variable. Estrous cycle length could only be determined for 7/14, 7/12, 3/8 and 1/8 surviving females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively, due to an increase in the number of females with incomplete cycles. The delay in completing 1 estrous cycle in the 250 and 1000 mg/kg/day [ ] groups was potentially test article-related. However, the small group size (N=8) in these groups confounds the interpretation of these results.

Test article-related changes in thyroid hormone levels were observed in the 1000 mg/kg/day [ ] group. The mean total T_4 level in this group was lower than the

control group value; the difference was statistically significant ($p<0.05$). The mean TSH level in the 1000 mg/kg/day [ ] group was higher than that in the control group. The difference was not statistically significant. There were no effects on thyroid gland weight in this group. Mean total T_4 and TSH levels in the 60 and 250 mg/kg/day [ ] groups were generally similar to those in the control group; there was no dose-response relationship in these groups.

Mean absolute and/or relative (to final body weight) liver weights in the 1000 mg/kg/day [ ] group were increased compared to the control group values; the difference in mean relative liver weight was statistically significant ($p<0.01$). These increases were attributed to the test article. No other test article-related changes in organ weights were observed. Mean wet (absolute and relative) uterus weight and mean absolute luminal fluid weight in the 60 mg/kg/day [ ] group were increased compared to the control group values. The differences were not statistically significant, and no dose-response relationship was observed. In addition, luminal fluid weights were highly variable, and no attempt was made to euthanize the females at the same stage of estrous. Therefore, the increases in wet uterus and luminal fluid weights in the 60 mg/kg/day [ ] group were not considered test article-related.

1.6. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in no apparent estrogenic effects for surviving females at 60, 250 and 1000 mg/kg/day. However, the number of animals available for evaluation in the 250 and 1000 mg/kg/day groups may not be sufficient to determine such effects due to the high mortality rate in these groups. Attainment of vaginal patency was delayed in the 1000 mg/kg/day [ ] group with no difference in body weight at the age of attainment. Following the attainment of vaginal patency, the number of females completing 1 estrous cycle was reduced in the 250 and 1000 mg/kg/day [ ] groups. The mean T_4 level was decreased and the mean TSH level was increased in the 1000 mg/kg/day [ ] group; no changes in thyroid weights were noted.

1.7. RESULTS - [ ]

Low incidences of clear material around the mouth and/or nose were observed 1 hour following dose administration in the 250 and 1000 mg/kg/day [ ] group females, including 1 occurrence in each of the females found dead. These findings were attributed to the test article, but were not considered adverse.

Three, 2 and 1 females in the 60, 250 and 1000 mg/kg/day [ ] groups, respectively, were found dead at 22 to 31 days of age. Because no dose-related trend was evident, 1 control group animal was found dead and there was no evidence of systemic toxicity at any [ ] dosage level, these deaths were not attributed to test article administration. In the 1000 mg/kg/day [ ] group, female no. 84028-02 was found dead at 29 days of age 12 minutes following dose administration. The only internal finding at necropsy for this female was lungs that were not fully collapsed. In the 250 mg/kg/day [ ] group, female no. 84034-08 was found dead at 22 days of age approximately 1 hour following administration of the first dose; this female had no clinical findings prior to death and no internal findings at necropsy. Female no. 84023-03 in the same group was found dead at 25 days of age following 3 days of dose administration. This female was cannibalized and could not be examined macroscopically. Female nos. 84030-08, 84029-08 and 84031-07 in the 60 mg/kg/day group were found dead at 27, 30 and 31 days of age, respectively; no clinical findings were noted for these females prior to death. At necropsy, female nos. 84029-08 and 84031-07 had dark red discoloration of the lungs; female no. 84029-08 also had lungs that were not fully collapsed; no internal findings were noted for female no. 84030-08. All other females survived to the scheduled euthanasia.

Mean body weights and body weight gains in the 60, 250 and 1000 mg/kg/day [ ] groups were generally similar to those in the control group throughout the study. No statistically significant differences were noted.

There were no test article-related effects on the mean age of attainment of vaginal patency or body weight at the age of attainment of patency. Mean days of attainment were 33.7, 33.3, 33.7 and 34.2 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. No statistically significant differences were noted.

The ages of the first occurrence of estrus in the 60, 250 and 1000 mg/kg/day [ ] groups (35.1, 36.3 and 36.6 days of age, respectively) were similar to that in the control group (37.1 days of age). The differences were not statistically significant. Two females in the 1000 mg/kg/day [ ] group had no occurrences for estrus; 1 of these females was in extended diestrus (11 days). No test article-related differences in mean estrous cycle length were observed when the [ ]-treated groups were compared to the control group. However, estrous cycle lengths could only be determined for 7/14, 6/12, 7/13 and 7/14 females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively, due to incomplete cycles.

Mean T_4 and TSH levels in the 60, 250 and 1000 mg/kg/day [ ] groups were similar to the control group values. No statistically significant differences or dose-related trends were evident.

No test article-related changes in organ weights were observed in the [ ]-treated groups. Differences from the control group were not statistically significant. Mean wet (absolute and relative) uterus weight and mean absolute luminal fluid weight in the 250 and 1000 mg/kg/day [ ] groups were increased (not statistically significant) compared to the control group values. However, no attempt was made to euthanize the females at the same stage of estrous. In addition, luminal fluid weights were highly variable. Therefore, the increases in wet uterus and luminal fluid weights in the 250 and 1000 mg/kg/day [ ] groups were not considered test article-related.

1.8. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in no apparent estrogenic effects in the 60, 250 and 1000 mg/kg/day groups.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____
[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____
[ ] Date
Senior Study Analyst

Report Reviewed By:

_____ _____
[ ] Date
Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

[ ]	Manager, Clinical Pathology
[ ]	Senior Operations Manager, Vivarium
[ ]	Manager, Gross Pathology and Developmental Toxicology Laboratory
[ ]	Group Supervisor, Formulations Laboratory
[ ]	Director, Metabolism and Analytical Chemistry
[ ]	Operations Manager, Developmental, Reproductive and Neurotoxicology
[ ]	Acting Manager, Reporting and Regulatory Technical Services

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
07-Jun-2005	Vaginal Perforation	07-Jun-2005	25-Jul-2005	[ ] [ ]
20-Jul-2005	Study Records (I-1)	28-Jul-2005	25-Aug-2005	[ ]
20-Jul-2005, 21-Jul-2005	Study Records (I-2)	01-Aug-2005	__-Sep-2005	[ ]
25-Jul-2005, 26-Jul-2005	Study Records (N-1)	02-Aug-2005	__-Sep-2005	[ ]
26-Jul-2005, 27-Jul-2005	Study Records (Rx-1)	27-Jul-2005	25-Aug-2005	[ ]
01-Aug-2005	Study Records (C-1)	01-Aug-2005	__-Sep-2005	[ ]
02-Aug-2005	Study Records (C-4)	02-Aug-2005	__-Sep-2005	[ ]
19-Aug-2005, 22-Aug-2005, 23-Aug-2005	Draft Report	23-Aug-2005	__-Sep-2005	[ ]
23-Aug-2005	Study Records (Rx-1) Supplemental	23-Aug-2005	___-Sep-2005	[ ]

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Parts 160 and 792), the OECD Principles of Good Laboratory Practice, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendment with the following exceptions. The data located in Appendices A (Certificates of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____
[ ] Date
Associate Compliance Specialist

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Sections 4.1.5, 4.2.5 and 7.5.4** state that the test articles and the dosing formulation samples would be stored at ambient conditions under nitrogen. There is no documentation that dosing formulation samples and the bulk test article were stored under nitrogen on 6 June 2005.
- **Protocol Section 5.3** states that the animals would be supplied by Charles River Laboratories, Inc., Portage, Michigan. Animals were supplied by the Raleigh, North Carolina facility of Charles River Laboratories, Inc.
- **Protocol Section 7.5.4** states that the vial plus the sample weight would be recorded with an accuracy of ±0.0005. The vial plus the sample weight from all formulations were weighed to 5 decimal places instead of 4 decimal places.
- **Protocol Section 7.6.1** states that the rats would be observed twice daily for appearance, behavior, moribundity and mortality. Documentation of the afternoon observation was not recorded on 21 May 2005 (pretest period).
- **Protocol Section 7.6.1** states that the animals would be observed approximately 1 hour following dose administration. The following deviations from the target time of approximately 1 hour were noted:

Date (2005)	Group	Number Of Animals	Time After Dose Administration
31 May	Control	1	1 hour, 16 minutes
2 June	250 mg/kg/day [ ]	9	1 hour, 16 minutes to 1 hour, 21 minutes
5 June	1000 mg/kg/day [ ]	5	42 to 44 minutes
6 June	Control	1	1 hour, 16 minutes
6 June	1000 mg/kg/day [ ]	10	1 hour, 16 minutes to 1 hour, 20 minutes
9 June	Control	2	1 hour, 16 minutes
12 June	Control	5	1 hour, 16 minutes to 1 hour, 17 minutes

- **Protocol Section 7.6.2** states that body weights would be recorded to the nearest 0.1 g, except on the day prior to dosing and the final body weight. However, body weights were recorded to the nearest 0.1 g on the day prior to dosing.

- **Protocol Section 9.1** states that blood would be collected from animals that were found dead or euthanized in extremis. Due to the amount of time that had elapsed between dosing and death, animal nos. 84030-09 (control group), 84027-01 (60 mg/kg/day [ ] group) and 84032-05 (250 mg/kg/day [ ] group) did not have blood collected.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1-12

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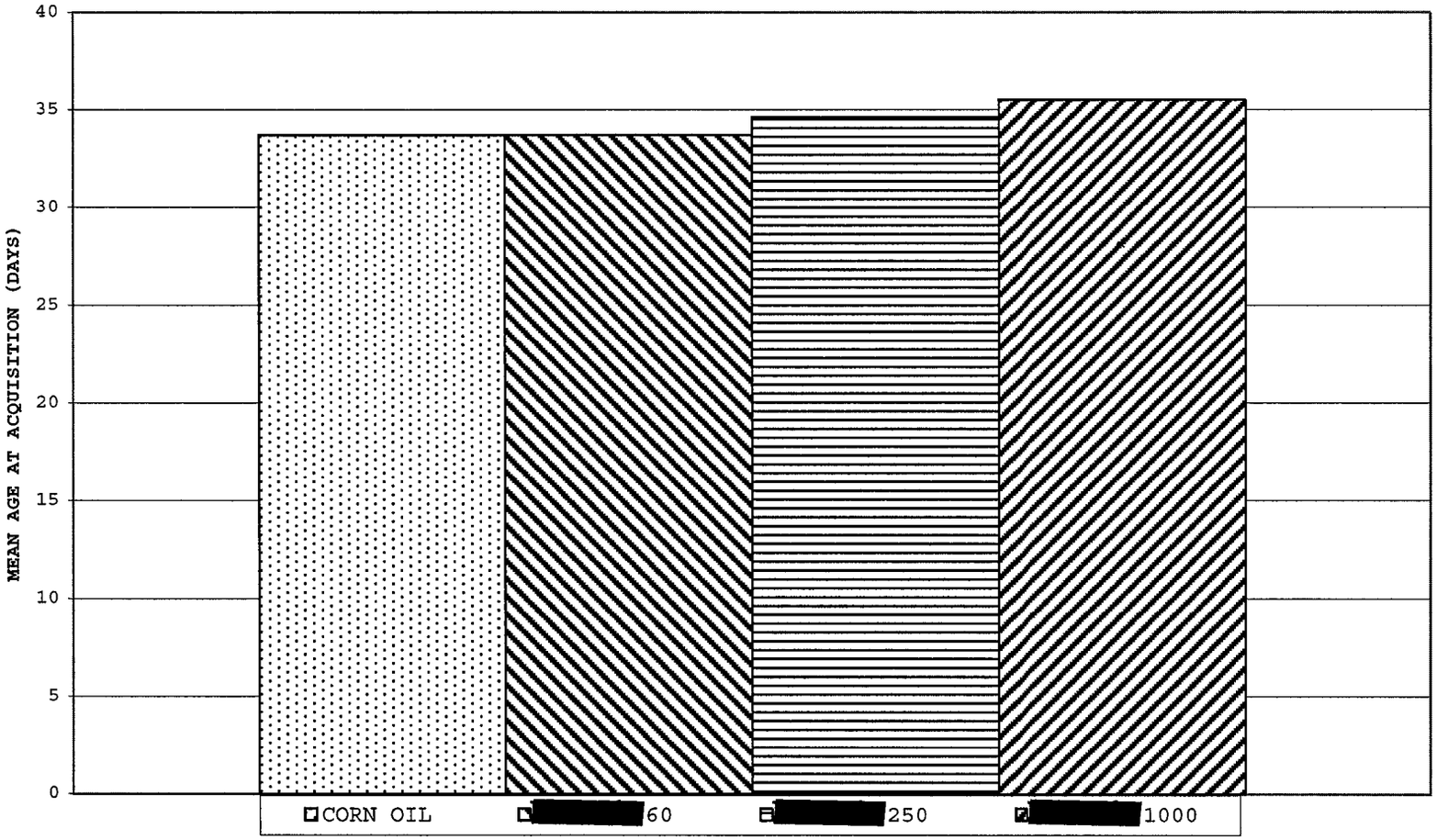
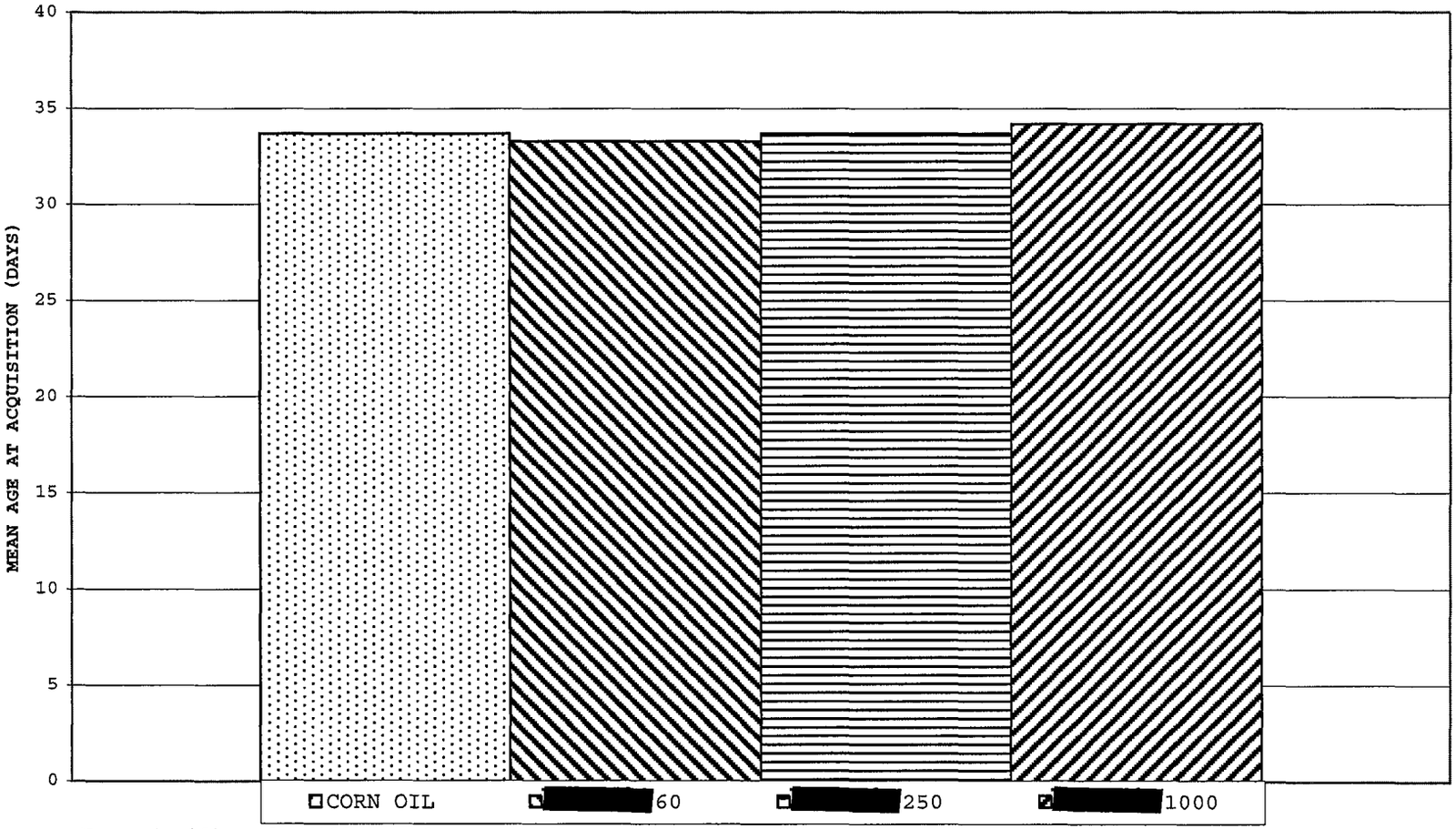
PROJECT NO.:WIL-187044 FIGURE 1 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



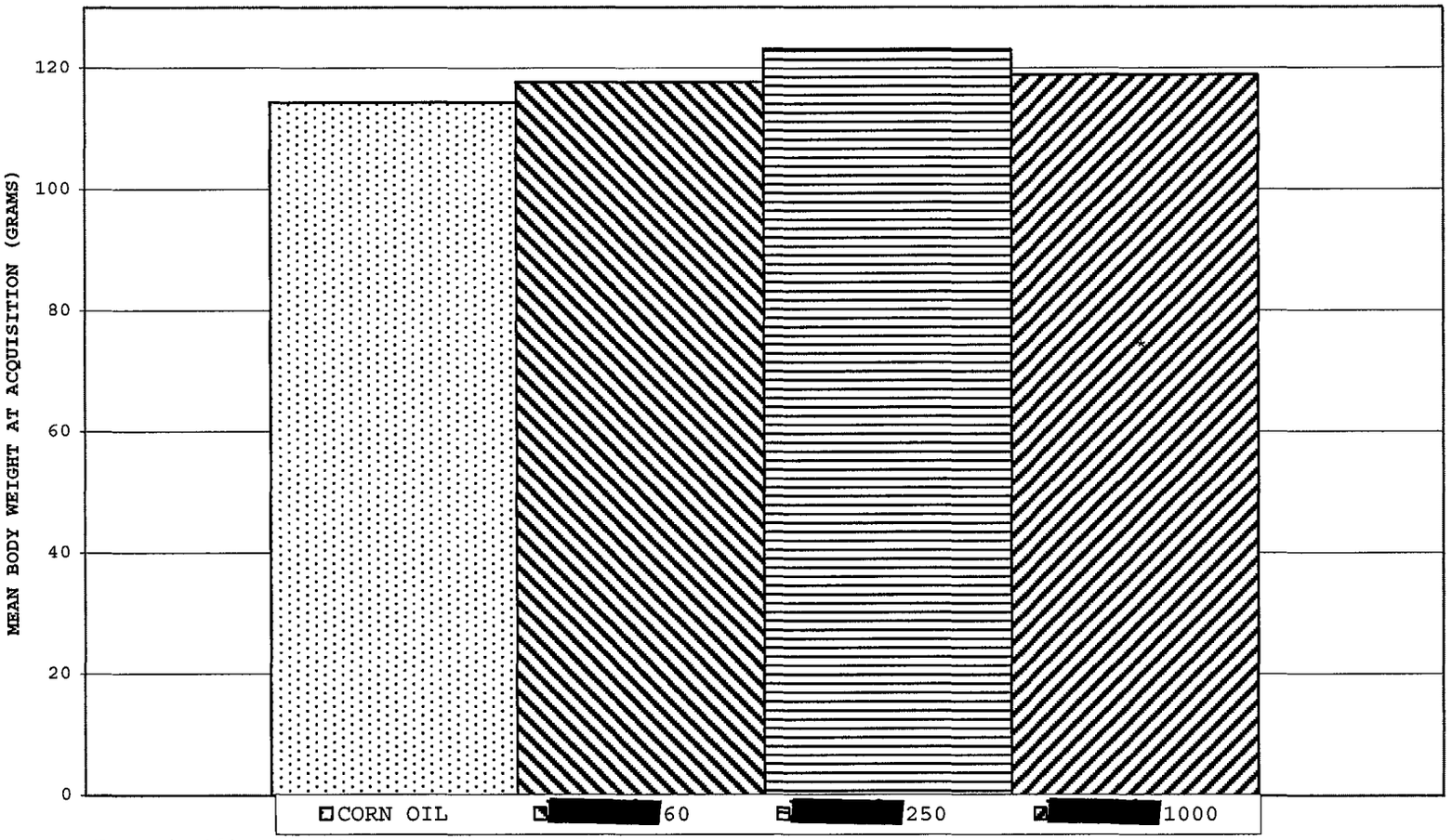
None significantly different from control group

PROJECT NO.:WIL-187044 FIGURE 2 [redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN AGE (DAYS) AT ACQUISITION OF VAGINAL PATENCY



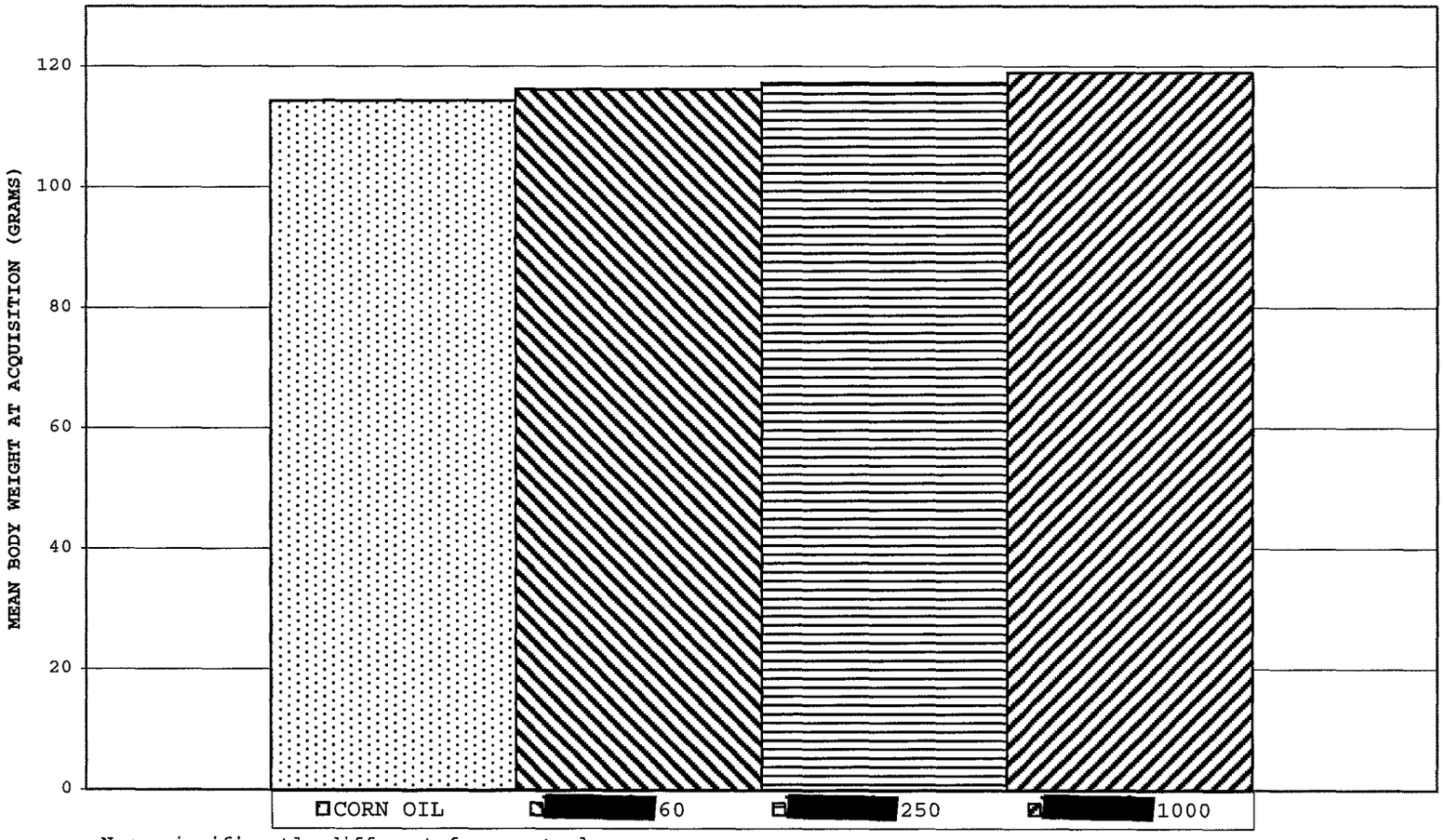
None significantly different from control group

PROJECT NO.:WIL-187044 FIGURE 3 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN BODY WEIGHT (GRAMS) AT ACQUISITION OF VAGINAL PATENCY



None significantly different from control group

PROJECT NO.:WIL-187044 FIGURE 4 [redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN BODY WEIGHTS (GRAMS) AT ACQUISITION OF VAGINAL PATENCY



None significantly different from control group

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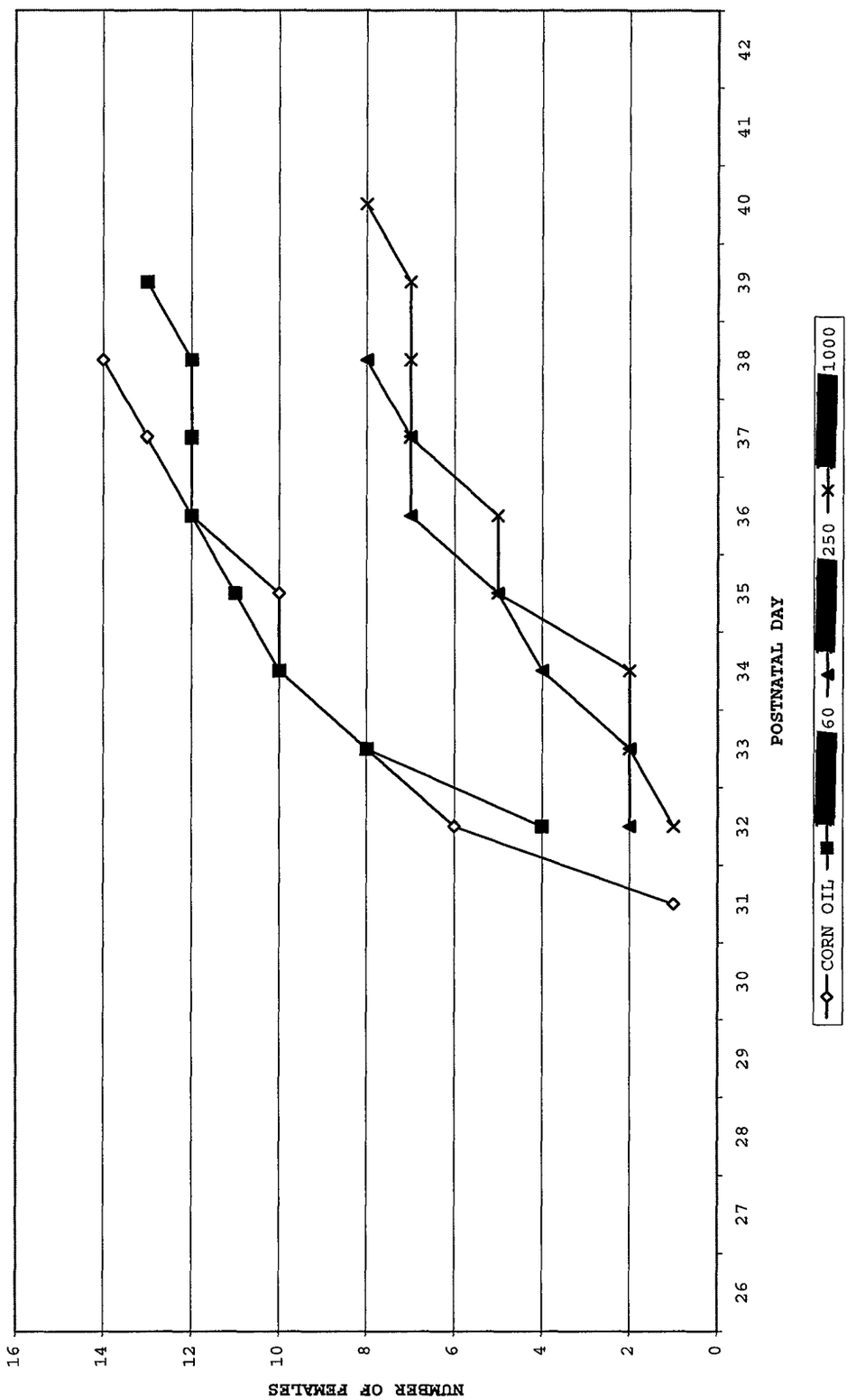
PROJECT NO.:WIL-187044
SPONSOR:[redacted]
SPONSOR NO.:05-003

FIGURE 5 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY



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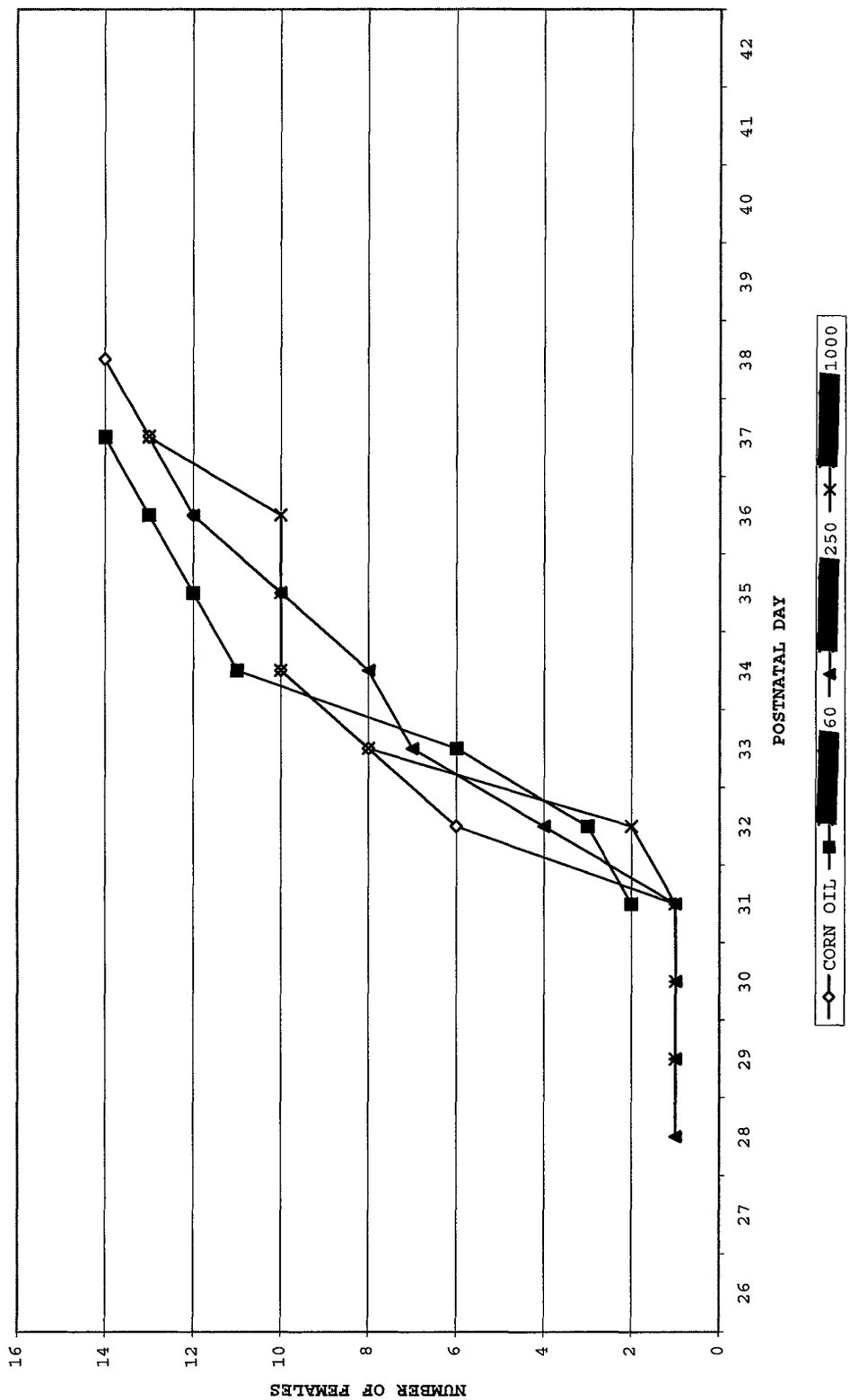
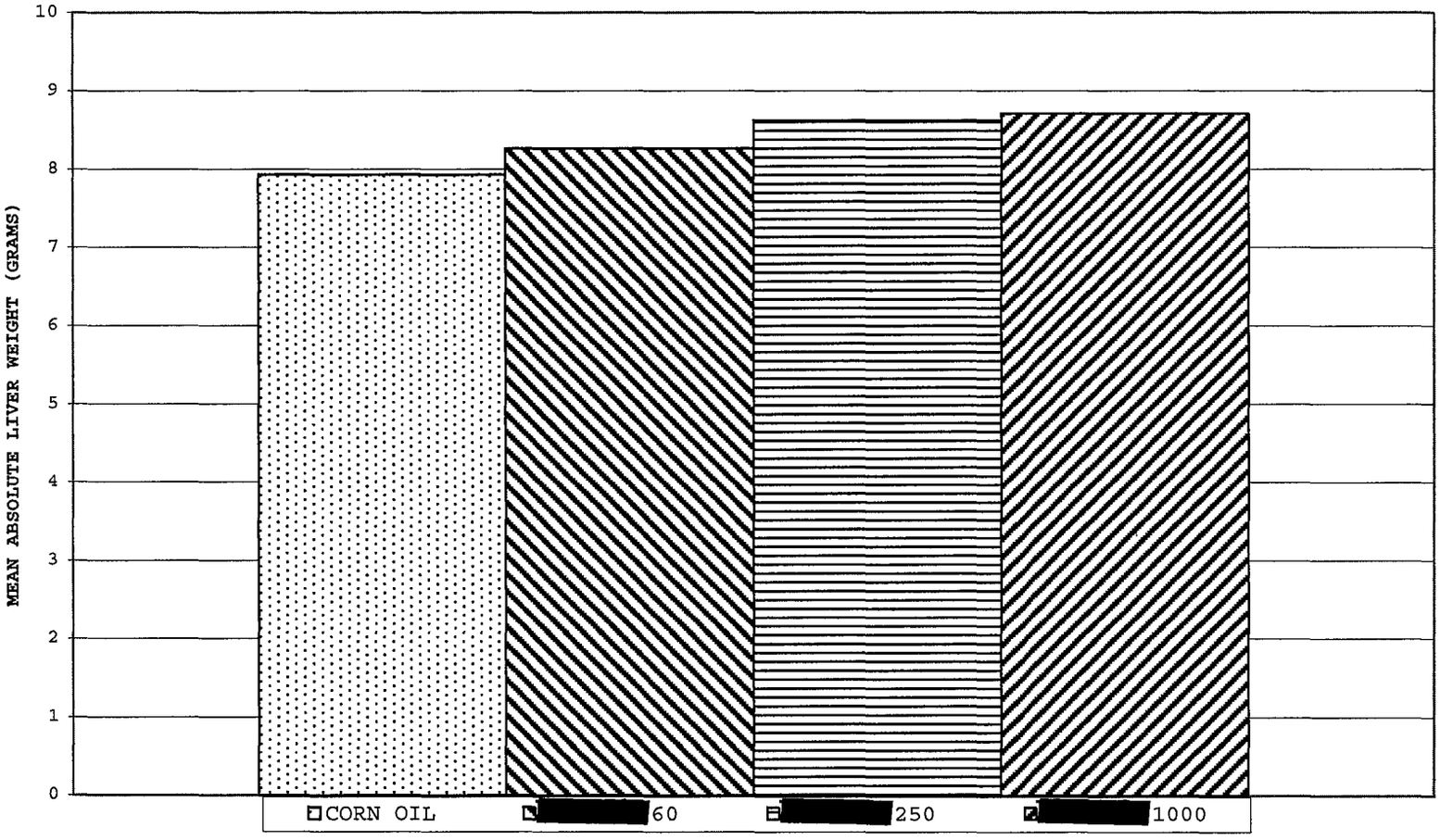
PROJECT NO.:WIL-187044
SPONSOR:[redacted]
SPONSOR NO.:05-003

FIGURE 6 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
CUMULATIVE NUMBER OF FEMALES WITH VAGINAL PATENCY

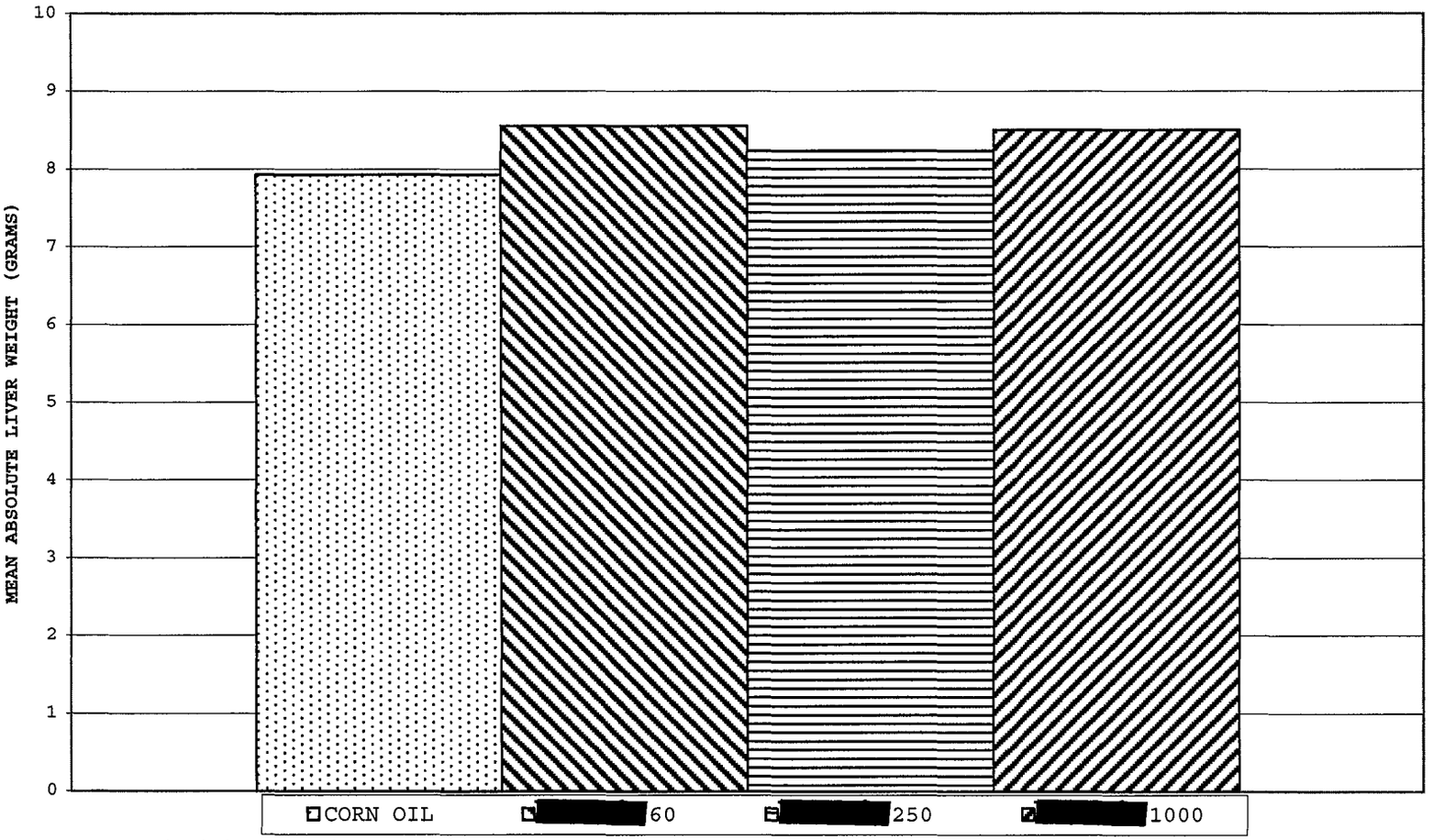


PROJECT NO.:WIL-187044 FIGURE 7 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN ABSOLUTE LIVER WEIGHT (GRAMS)



None significantly significant from control group

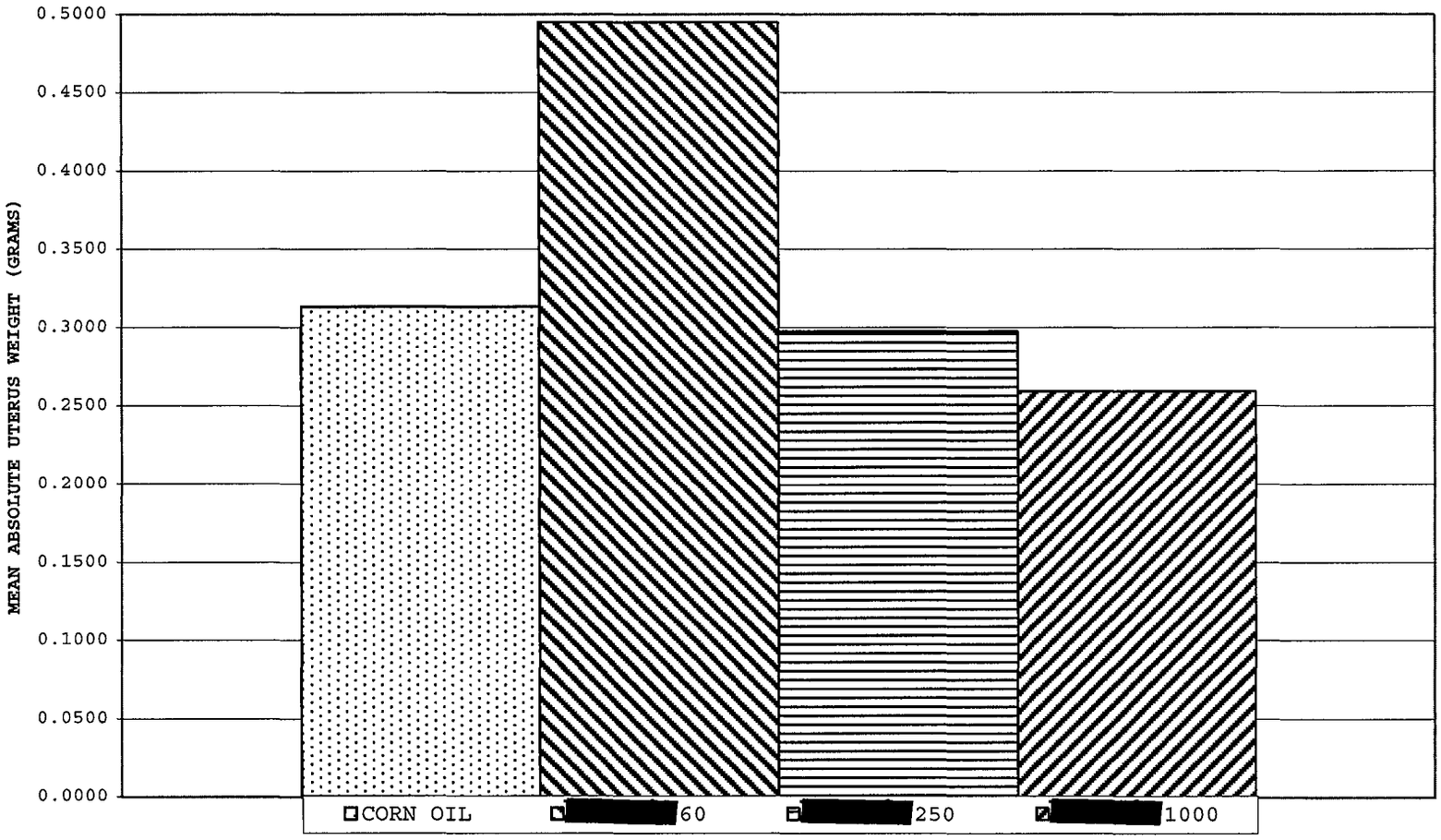
PROJECT NO.:WIL-187044 FIGURE 8 [redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN ABSOLUTE LIVER WEIGHT (GRAMS)



None significantly different from control group

Revised Audited Draft

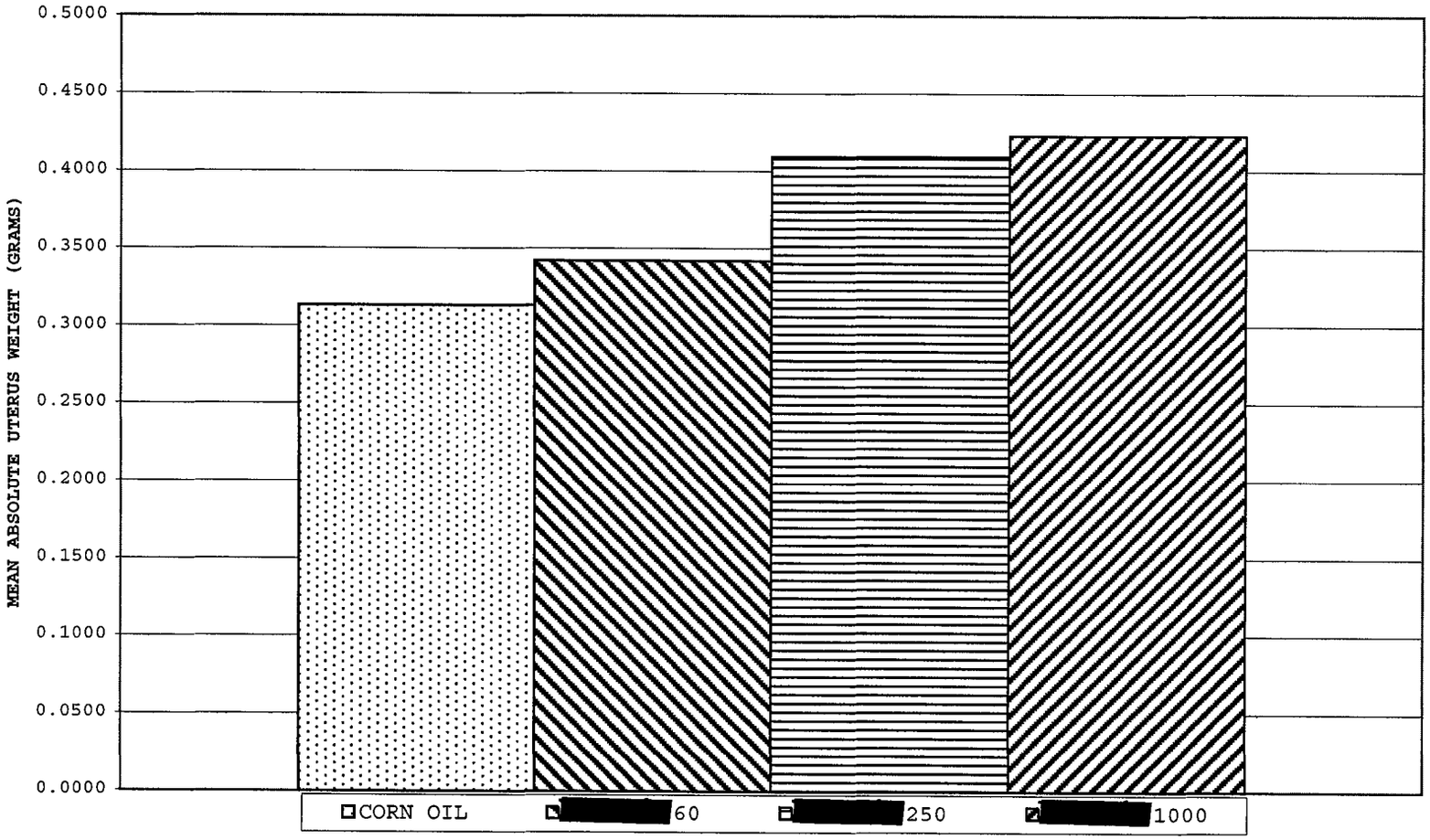
PROJECT NO.:WIL-187044 FIGURE 9 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN ABSOLUTE UTERUS (WET) WEIGHT (GRAMS)



None significantly different from control group

Revised Audited Draft

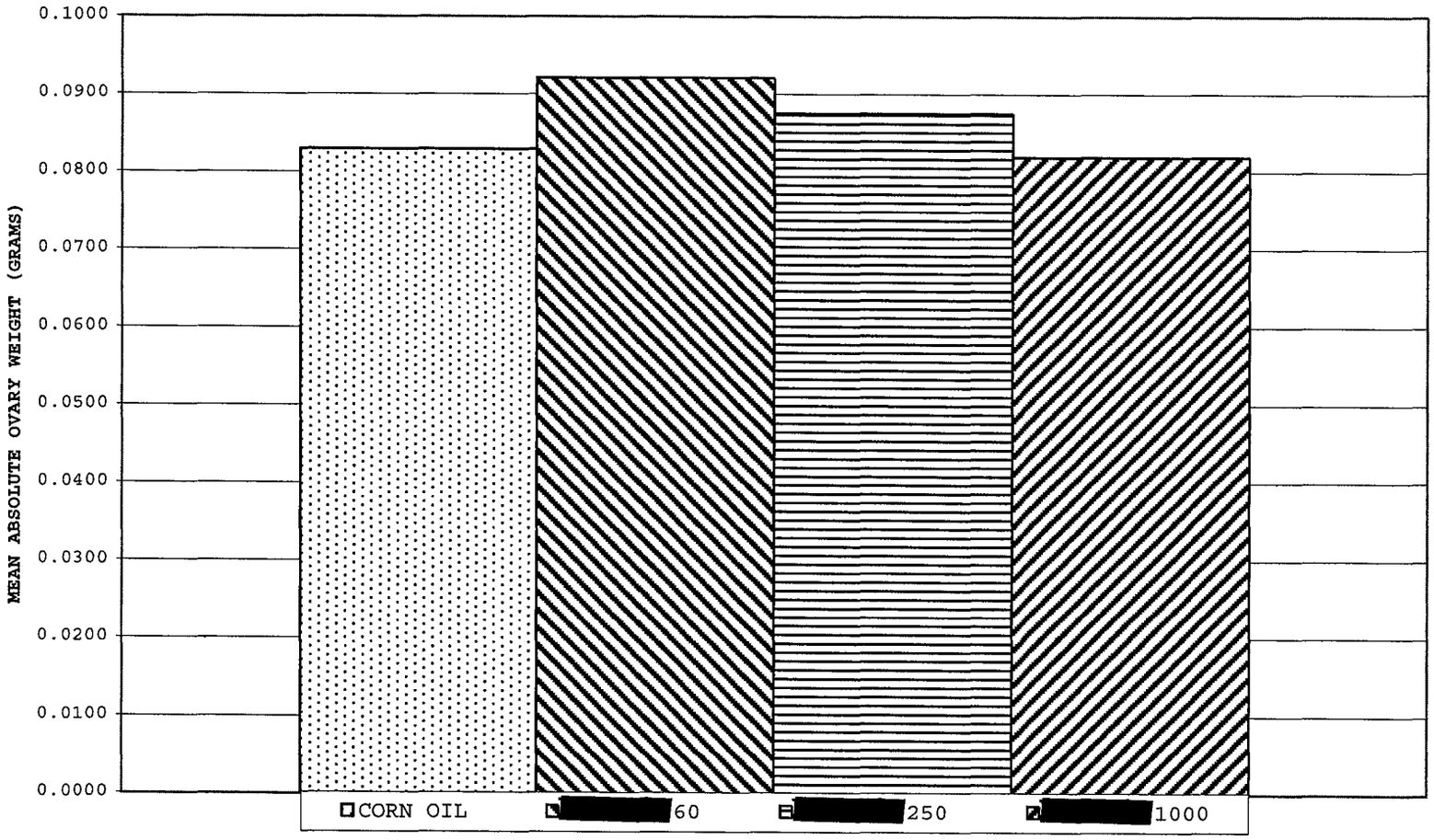
PROJECT NO.:WIL-187044 FIGURE 10 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN ABSOLUTE UTERUS (WET) WEIGHT (GRAMS)



None significantly different from control group

Revised Audited Draft

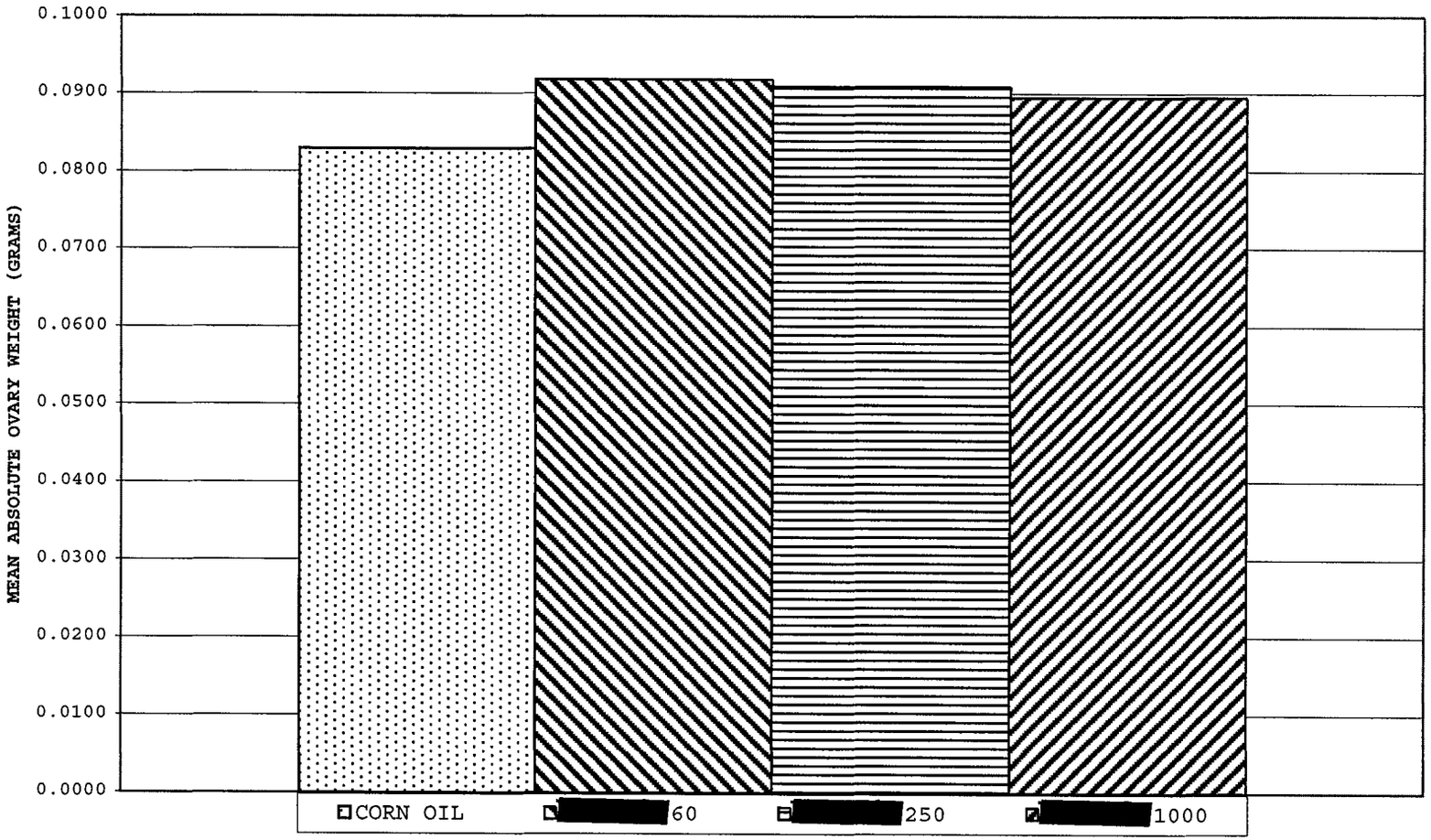
PROJECT NO.:WIL-187044 FIGURE 11 ([redacted])
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



None significantly different from control group

Revised Audited Draft

PROJECT NO.:WIL-187044 FIGURE 12 [redacted]
SPONSOR:[redacted] PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR NO.:05-003 MEAN ABSOLUTE OVARY WEIGHT (GRAMS)



None significantly different from control group

TABLES 1-23

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Revised Audited Draft

TABLE 1

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	1				2				3				4			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	12	3	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	12	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0	12	0	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0	12	0	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0	12	0	0	0
28	15	0	0	0	15	0	0	0	14	1	0	0	10	2	0	0
29	15	0	0	0	15	0	0	0	11	3	0	0	9	1	0	0
30	15	0	0	0	14	1	0	0	8	3	0	0	8	1	0	0
31	14	1	0	0	14	0	0	0	8	0	0	0	8	0	0	0
32	14	0	0	0	12	2	0	0	8	0	0	0	8	0	0	0
33	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
34	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
35	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
36	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
37	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
38	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
39	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
40	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
41	14	0	0	0	12	0	0	0	8	0	0	0	8	0	0	0
42	15	0	0	14	15	0	0	12	15	0	0	8	15	0	0	8

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- CORN OIL 2- [redacted]60 3- [redacted]100 4- [redacted]1000

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TABLE 1

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	5				6				7			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	14	1	0	0	15	0	0	0
23	15	0	0	0	14	0	0	0	15	0	0	0
24	15	0	0	0	14	0	0	0	15	0	0	0
25	15	0	0	0	13	1	0	0	15	0	0	0
26	15	0	0	0	13	0	0	0	15	0	0	0
27	14	1	0	0	13	0	0	0	15	0	0	0
28	14	0	0	0	13	0	0	0	15	0	0	0
29	14	0	0	0	13	0	0	0	14	1	0	0
20	13	1	0	0	13	0	0	0	14	0	0	0
31	12	1	0	0	13	0	0	0	14	0	0	0
32	12	0	0	0	13	0	0	0	14	0	0	0
33	12	0	0	0	13	0	0	0	14	0	0	0
34	12	0	0	0	13	0	0	0	14	0	0	0
35	12	0	0	0	13	0	0	0	14	0	0	0
36	12	0	0	0	13	0	0	0	14	0	0	0
37	12	0	0	0	13	0	0	0	14	0	0	0
38	12	0	0	0	13	0	0	0	14	0	0	0
39	12	0	0	0	13	0	0	0	14	0	0	0
40	12	0	0	0	13	0	0	0	14	0	0	0
41	12	0	0	0	13	0	0	0	14	0	0	0
42	15	0	0	12	15	0	0	13	15	0	0	14

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

5- [redacted]60 6- [redacted]100 7- [redacted]1000

PSURVv4.08
07/11/2005
R:07/26/2005

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TABLE 2 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	05-31-05 TO 06-22-05						
GROUP:	1	2	3	4	5	6	7
NORMAL							
-NO SIGNIFICANT CLINICAL OBSERVATIONS	304/15	283/15	225/15	202/15	277/15	277/15	302/15
DISPOSITION							
-FOUND DEAD	1/ 1	3/ 3	7/ 7	7/ 7	3/ 3	2/ 2	1/ 1
-SCHEDULED EUTHANASIA	14/14	12/12	8/ 8	8/ 8	12/12	13/13	14/14

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
07/21/2005

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TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:05-003

----- F E M A L E -----

TABLE RANGE:	05-31-05 TO 06-21-05						
GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-HYPOACTIVITY	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0
-PROSTRATE	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0
CARDIO-PULMONARY							
-SHALLOW RESPIRATION	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0
ORAL/DENTAL							
-SALIVATION PRIOR TO DOSING	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
07/21/2005
R:07/21/2005

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	05-31-05 TO 06-21-05						
GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-HYPOACTIVITY	0/ 0	1/ 1	1/ 1	1/ 1	0/ 0	0/ 0	0/ 0
BODY/INTEGUMENT							
-WET CLEAR MATERIAL VENTRAL NECK	0/ 0	0/ 0	1/ 1	2/ 2	0/ 0	0/ 0	0/ 0
-DRIED CLEAR MATERIAL VENTRAL NECK	0/ 0	0/ 0	0/ 0	1/ 1	1/ 1	0/ 0	0/ 0
-DRIED CLEAR MATERIAL LEFT FORELIMB	0/ 0	0/ 0	0/ 0	2/ 2	0/ 0	0/ 0	0/ 0
-DRIED CLEAR MATERIAL RIGHT FORELIMB	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
-WET CLEAR MATERIAL DORSAL THORACIC AREA	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0
-WET CLEAR MATERIAL RIGHT FORELIMB	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
-WET CLEAR MATERIAL LEFT FORELIMB	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
CARDIO-PULMONARY							
-LABORED RESPIRATION	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
-SHALLOW RESPIRATION	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
EYES/EARS/NOSE							
-WET CLEAR MATERIAL AROUND NOSE	0/ 0	0/ 0	3/ 3	3/ 3	0/ 0	2/ 2	0/ 0
-WET RED MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
ORAL/DENTAL							
-WET CLEAR MATERIAL AROUND MOUTH	1/ 1	1/ 1	4/ 4	31/ 8	0/ 0	3/ 3	1/ 1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	05-31-05 TO 06-21-05						
GROUP:	1	2	3	4	5	6	7
ORAL/DENTAL							
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	4/ 3	0/ 0	2/ 2	7/ 5
-WET TAN MATERIAL AROUND MOUTH	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
07/25/2005
R:08/02/2005

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Modified: 11/4/2005

TABLE 5

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22								
	MEAN	52.0	53.0	51.8	50.8	52.8	52.5	51.8
	S.D.	4.17	5.73	4.57	5.58	5.64	4.93	4.13
	N	15	15	15	15	15	15	15
PND 23								
	MEAN	57.1	57.9	56.6	54.0	58.2	56.8	56.5
	S.D.	4.26	5.62	4.45	7.62	5.84	4.97	4.25
	N	15	15	15	12	15	14	15
PND 24								
	MEAN	62.5	63.0	61.9	56.5a	63.2	61.8	61.6
	S.D.	4.84	6.10	4.63	8.95	6.08	5.11	4.84
	N	15	15	15	12	15	14	15
PND 25								
	MEAN	67.2	68.1	64.8	59.4b	68.1	66.1	66.4
	S.D.	4.80	6.45	4.09	9.15	6.67	4.97	5.19
	N	15	15	15	12	15	13	15
PND 26								
	MEAN	72.0	73.2	70.0	65.0a	73.7	71.8	71.6
	S.D.	5.30	7.05	5.11	8.81	6.94	5.58	5.14
	N	15	15	15	12	15	13	15
PND 27								
	MEAN	77.4	77.6	76.2	70.4a	78.6	77.3	76.6
	S.D.	5.45	7.41	5.25	8.91	7.51	6.13	5.51
	N	15	15	15	12	15	13	15

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28								
	MEAN	82.3	83.1	81.6	75.7a	84.3	82.8	81.6
	S.D.	5.87	7.73	5.01	9.41	8.76	6.61	5.82
	N	15	15	15	12	14	13	15
PND 29								
	MEAN	87.7	88.9	86.9	79.3a	89.9	88.3	87.5
	S.D.	5.75	8.52	5.78	9.31	9.03	6.61	6.52
	N	15	15	14	10	14	13	15
PND 30								
	MEAN	93.9	95.1	93.2	85.7	96.2	94.3	93.7
	S.D.	6.32	9.22	6.89	10.72	9.15	7.07	7.35
	N	15	15	10	9	14	13	14
PND 31								
	MEAN	99.4	100.2	100.2	91.6	103.5	99.8	99.3
	S.D.	6.34	10.09	7.68	10.89	10.02	7.63	8.15
	N	15	14	8	8	13	13	14
PND 32								
	MEAN	104.6	106.7	106.7	96.9	108.9	106.1	105.6
	S.D.	6.50	10.83	7.70	10.80	10.98	7.52	8.34
	N	14	14	8	8	12	13	14
PND 33								
	MEAN	110.6	113.2	111.6	103.3	114.2	112.0	111.2
	S.D.	6.55	11.64	7.35	10.57	11.93	9.12	9.48
	N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34								
	MEAN	116.5	119.2	118.0	109.5	120.9	118.5	117.5
	S.D.	7.70	12.97	8.04	11.61	11.92	8.98	10.69
	N	14	12	8	8	12	13	14
PND 35								
	MEAN	121.7	124.2	123.6	114.9	126.4	123.3	123.5
	S.D.	8.99	13.58	8.10	11.76	12.80	9.15	11.24
	N	14	12	8	8	12	13	14
PND 36								
	MEAN	127.0	129.7	129.8	120.8	131.5	129.0	129.4
	S.D.	8.64	15.10	8.16	11.81	12.73	9.53	12.02
	N	14	12	8	8	12	13	14
PND 37								
	MEAN	132.7	134.1	135.8	125.3	137.4	134.2	135.3
	S.D.	9.59	15.72	8.86	11.76	13.92	9.61	12.27
	N	14	12	8	8	12	13	14
PND 38								
	MEAN	138.5	140.4	141.9	132.9	142.2	138.5	140.1
	S.D.	10.05	16.53	7.26	12.26	14.91	9.60	12.51
	N	14	12	8	8	12	13	14
PND 39								
	MEAN	143.3	145.1	146.3	138.0	146.8	143.9	146.2
	S.D.	11.08	17.33	7.06	13.05	14.63	10.03	12.69
	N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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TABLE 5

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40								
	MEAN	147.3	150.3	152.8	143.7	151.3	149.2	150.7
	S.D.	11.67	18.32	8.48	12.33	15.95	10.61	13.83
	N	14	12	8	8	12	13	14
PND 41								
	MEAN	152.0	154.9	156.7	146.7	156.6	154.8	155.2
	S.D.	12.84	18.96	9.36	12.71	17.23	9.69	14.30
	N	14	12	8	8	12	13	14
PND 42								
	MEAN	157.0	158.8	162.3	152.5	161.6	158.3	159.1
	S.D.	14.15	20.13	9.43	12.35	17.06	10.31	14.23
	N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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07/21/2005

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TABLE 6

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22- 23	MEAN	5.1	4.9	4.8	2.4b	5.4	4.8	4.7
	S.D.	0.91	1.22	1.77	3.20	0.99	0.80	1.55
	N	15	15	15	12	15	14	15
PND 23- 24	MEAN	5.4	5.1	5.4	2.5b	5.0	5.1	5.1
	S.D.	1.05	1.07	1.39	2.84	1.22	0.86	1.55
	N	15	15	15	12	15	14	15
PND 24- 25	MEAN	4.7	5.1	2.9	2.9	4.9	4.2	4.8
	S.D.	0.78	0.96	3.93	3.52	1.23	2.15	1.43
	N	15	15	15	12	15	13	15
PND 25- 26	MEAN	4.8	5.1	5.3	5.5	5.6	5.7	5.2
	S.D.	1.21	1.17	1.72	3.05	0.88	0.94	1.12
	N	15	15	15	12	15	13	15
PND 26- 27	MEAN	5.4	4.4	6.1	5.4	5.0	5.5	5.0
	S.D.	0.99	0.90	1.79	1.74	1.00	1.14	1.10
	N	15	15	15	12	15	13	15
PND 27- 28	MEAN	4.8	5.6	5.4	5.3	5.4	5.6	5.0
	S.D.	1.59	0.88	1.10	1.35	1.44	1.05	0.76
	N	15	15	15	12	14	13	15

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28- 29								
	MEAN	5.4	5.7	5.5	5.6	5.5	5.5	5.9
	S.D.	0.99	1.60	1.29	1.80	1.60	1.21	1.53
	N	15	15	14	10	14	13	15
PND 29- 30								
	MEAN	6.2	6.3	6.6	6.2	6.3	6.0	6.2
	S.D.	1.61	1.23	1.35	1.45	1.34	1.25	1.44
	N	15	15	10	9	14	13	14
PND 30- 31								
	MEAN	5.5	5.5	5.9	4.9	6.5	5.5	5.6
	S.D.	1.08	1.45	1.13	0.83	1.73	1.02	1.66
	N	15	14	8	8	13	13	14
PND 31- 32								
	MEAN	5.4	6.5	6.5	5.3	6.0	6.3	6.3
	S.D.	0.71	1.83	1.67	2.71	1.54	0.94	1.70
	N	14	14	8	8	12	13	14
PND 32- 33								
	MEAN	6.0	5.4	5.0	6.4	5.3	6.0	5.6
	S.D.	1.84	2.58	1.74	1.77	2.01	2.44	2.06
	N	14	12	8	8	12	13	14
PND 33- 34								
	MEAN	5.9	6.1	6.3	6.3	6.7	6.5	6.3
	S.D.	2.04	2.81	1.82	1.44	2.05	2.09	2.45
	N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHT CHANGES [G]

FEMALES

GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34- 35								
	MEAN	5.2	5.0	5.7	5.4	5.4	4.8	6.0
	S.D.	2.44	1.99	1.22	1.57	1.31	1.45	1.65
	N	14	12	8	8	12	13	14
PND 35- 36								
	MEAN	5.3	5.5	6.2	5.9	5.1	5.7	5.9
	S.D.	1.77	3.59	2.00	2.50	2.70	1.28	1.92
	N	14	12	8	8	12	13	14
PND 36- 37								
	MEAN	5.7	4.4	5.9	4.4	5.9	5.2	5.9
	S.D.	1.64	1.18	1.56	2.21	2.09	2.14	1.37
	N	14	12	8	8	12	13	14
PND 37- 38								
	MEAN	5.8	6.3	6.2	7.6	4.8	4.3	4.8
	S.D.	1.91	2.19	3.12	2.62	2.38	2.12	2.53
	N	14	12	8	8	12	13	14
PND 38- 39								
	MEAN	4.8	4.7	4.4	5.1	4.6	5.4	6.1
	S.D.	1.77	1.76	2.40	2.28	2.56	2.15	2.04
	N	14	12	8	8	12	13	14
PND 39- 40								
	MEAN	4.0	5.2	6.5	5.7	4.5	5.3	4.5
	S.D.	2.50	2.82	2.44	1.57	2.95	2.17	2.69
	N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

Revised Audited Draft

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TABLE 6

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40- 41								
	MEAN	4.8	4.7	3.8	3.0	5.4	5.6	4.5
	S.D.	2.62	1.63	2.00	3.06	2.49	2.01	2.12
	N	14	12	8	8	12	13	14
PND 41- 42								
	MEAN	5.0	3.9	5.6	5.8	4.9	3.5	3.9
	S.D.	3.45	2.41	2.05	3.28	3.02	3.39	2.29
	N	14	12	8	8	12	13	14
PND 22- 42								
	MEAN	105.3	105.2	109.6	101.3	107.7	106.3	107.3
	S.D.	13.36	16.38	9.82	10.13	13.23	8.56	12.11
	N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.13
07/21/2005

187044 RAD

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TABLE 7

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
VAGINAL PATENCY (PND)							
MEAN	33.7	33.7	34.6	35.5	33.3	33.7	34.2
S.D.	2.20	2.02	2.07	2.51	2.22	2.25	2.69
N	14	13	8	8	12	13	14
BODY WEIGHT (GRAMS)							
MEAN	114.3	117.6	123.1	118.8	116.2	117.2	118.9
S.D.	8.87	19.56	17.40	15.77	15.67	16.23	15.52
N	14	13	8	8	12	13	14

PND= POSTNATAL DAY
MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PJTBBv1.14
07/21/2005
R:07/21/2005

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TABLE 8

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ESTROUS CYCLE DATA
SPONSOR NO.:05-003

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ESTROUS CYCLE LENGTH (DAYS)							
MEAN	4.9	5.1	6.0	5.0	5.1	4.9	5.1
S.D.	0.69	0.73	2.65	0.00	0.53	0.38	0.73
N	7	7	3	1	6	7	7
MEAN AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)							
MEAN	37.1	35.2	36.9	37.5	35.1	36.3	36.6
S.D.	3.69	2.52	2.95	1.85	3.15	2.02	3.12
N	14	12	8	8	12	13	12

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PCYCv5.23
07/21/2005
R:08/30/2005

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TABLE 9

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF SERUM HORMONE VALUES

ANALYSIS	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
		FEMALES						
TOTAL T4 (uG/dL)								
DAY 42	MEAN	4.06	4.27	4.19	2.99a	4.83	4.13	4.12
	S.D.	1.035	1.152	0.591	0.712	1.317	1.031	1.005
	N	14	12	8	8	12	13	14
TSH (ng/ml)								
DAY 42	MEAN	7.7	8.9	8.0	9.3	6.7	8.0	8.1
	S.D.	1.67	3.09	2.02	3.44	0.88	1.84	1.54
	N	14	12	8	8	12	13	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test

PCPSv5.21
08/03/2005
R:08/03/2005

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TABLE 10 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF MACROSCOPIC FINDINGS

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

		----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	30	30	30	30	30	30	30
NUMBER OF ANIMALS EXAMINED	1	3	7	7	3	2-A	1
KIDNEYS							
-CYST(S)	0	0	1	0	0	0	0
LUNGS							
-DISCOLORATION, DARK RED	0	1	1	2	2	0	0
-NOT FULLY COLLAPSED	0	2	2	2	1	0	1
SKIN							
-MATTING, CLEAR	0	0	0	1	0	0	0
TRACHEA							
-CONTENTS, CLEAR FLUID	0	0	0	1	0	0	0
SKELETAL MUSCLE							
-DISCOLORATION, DARK RED	0	0	2	0	0	0	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	1	0	4	4	1	1	0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000
A = ONE FEMALE WAS CANNIBALIZED

PGRSI2v4.05
11/04/2005
R:11/04/2005

187044 RAD

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TABLE 11

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS [G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
UTERUS- WET (G)							
MEAN	0.3132	0.4949	0.2976	0.2592	0.3420	0.4094	0.4228
S.D.	0.11097	0.37141	0.09901	0.06191	0.13538	0.21041	0.31680
N	14	12	8	8	12	13	14
UTERUS- BLOTTED (G)							
MEAN	0.2763	0.3151	0.2680	0.2319	0.2876	0.3102	0.2966
S.D.	0.06831	0.09792	0.07327	0.05461	0.07276	0.07088	0.07766
N	14	12	8	8	12	13	14
LUMINAL FLUID (G)							
MEAN	0.0369	0.1797	0.0296	0.0273	0.0544	0.0991	0.1262
S.D.	0.04980	0.31288	0.02965	0.01690	0.08356	0.14992	0.27477
N	14	12	8	8	12	13	14
LIVER (G)							
MEAN	7.9285	8.2631	8.6180	8.7076	8.5517	8.2328	8.4974
S.D.	0.98880	1.31989	0.49709	0.66720	1.23280	0.74984	1.22857
N	14	12	8	8	12	13	14
KIDNEYS (G)							
MEAN	1.6237	1.7005	1.6791	1.6201	1.6802	1.6746	1.6838
S.D.	0.13976	0.15710	0.12565	0.14519	0.21118	0.15028	0.17730
N	14	12	8	8	12	13	14
OVARIES/OVIDUCTS (G)							
MEAN	0.0829	0.0921	0.0875	0.0819	0.0918	0.0909	0.0895
S.D.	0.00891	0.01375	0.01026	0.01292	0.01063	0.01157	0.01487
N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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TABLE 11

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS [G]
SPONSOR NO.:05-003

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ADRENAL GLANDS (G)							
MEAN	0.0416	0.0434	0.0434	0.0427	0.0469	0.0450	0.0447
S.D.	0.00548	0.00479	0.00652	0.01009	0.00374	0.00469	0.00515
N	14	12	8	8	12	13	14
PITUITARY (G)							
MEAN	0.0092	0.0095	0.0083	0.0082	0.0093	0.0099	0.0093
S.D.	0.00131	0.00158	0.00092	0.00187	0.00115	0.00100	0.00138
N	14	12	8	8	12	13	14
THYROID GLANDS (G)							
MEAN	0.0158	0.0149	0.0172	0.0160	0.0167	0.0163	0.0165
S.D.	0.00309	0.00269	0.00213	0.00096	0.00170	0.00212	0.00266
N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

POFBSTv5.05
07/21/2005
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TABLE 12

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
FINAL BODY WT (G)							
MEAN	157.	159.	162.	153.	162.	158.	159.
S.D.	14.2	20.2	9.6	12.3	17.0	10.3	14.3
N	14	12	8	8	12	13	14
UTERUS- WET							
MEAN	0.200	0.307	0.183	0.170	0.215	0.259	0.261
S.D.	0.0666	0.2150	0.0577	0.0387	0.0973	0.1304	0.1852
N	14	12	8	8	12	13	14
UTERUS- BLOTTED							
MEAN	0.177	0.199	0.165	0.152	0.179	0.197	0.185
S.D.	0.0442	0.0611	0.0423	0.0351	0.0455	0.0501	0.0387
N	14	12	8	8	12	13	14
LIVER							
MEAN	5.035	5.185	5.320	5.713b	5.272	5.190	5.321
S.D.	0.3304	0.2954	0.3788	0.1380	0.3122	0.2394	0.3852
N	14	12	8	8	12	13	14
KIDNEYS							
MEAN	1.035	1.078	1.034	1.064	1.039	1.057	1.057
S.D.	0.0619	0.0824	0.0494	0.0731	0.0658	0.0666	0.0430
N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test

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TABLE 12

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
OVARIES/OVIDUCTS							
MEAN	0.053	0.059	0.054	0.054	0.057	0.057	0.056
S.D.	0.0076	0.0090	0.0050	0.0083	0.0071	0.0065	0.0068
N	14	12	8	8	12	13	14
ADRENAL GLANDS							
MEAN	0.027	0.028	0.027	0.028	0.029	0.029	0.028
S.D.	0.0041	0.0049	0.0037	0.0059	0.0031	0.0040	0.0015
N	14	12	8	8	12	13	14
PITUITARY							
MEAN	0.006	0.006	0.005	0.005	0.006	0.006	0.006
S.D.	0.0009	0.0009	0.0005	0.0009	0.0008	0.0005	0.0007
N	14	12	8	8	12	13	14
THYROID GLANDS							
MEAN	0.010	0.009	0.011	0.010	0.011	0.010	0.010
S.D.	0.0017	0.0012	0.0016	0.0012	0.0014	0.0013	0.0014
N	14	12	8	8	12	13	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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07/21/2005
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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:05-003

TABLE RANGE: 05-31-05 TO 06-22-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84024-10	F	CORN OIL	DISPOSITION	06-20-05	8:20	P	SCHEDULED EUTHANASIA
84023-06	F	CORN OIL	DISPOSITION	06-20-05	8:20	P	SCHEDULED EUTHANASIA
84025-06	F	CORN OIL	DISPOSITION	06-20-05	8:20	P	SCHEDULED EUTHANASIA
84027-05	F	CORN OIL	DISPOSITION	06-20-05	8:20	P	SCHEDULED EUTHANASIA
84026-04	F	CORN OIL	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84027-03	F	CORN OIL	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84023-05	F	CORN OIL	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84028-10	F	CORN OIL	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84031-02	F	CORN OIL	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84029-09	F	CORN OIL	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84030-09	F	CORN OIL	DISPOSITION	06-10-05	13:45	P	FOUND DEAD
84031-01	F	CORN OIL	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84028-05	F	CORN OIL	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84034-03	F	CORN OIL	DISPOSITION	06-22-05	6:38	P	SCHEDULED EUTHANASIA
84035-10	F	CORN OIL	DISPOSITION	06-22-05	6:38	P	SCHEDULED EUTHANASIA
84024-02	F	[redacted]60	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84025-09	F	[redacted]60	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84026-05	F	[redacted]60	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84023-09	F	[redacted]60	DISPOSITION	06-10-05	11:38	P	FOUND DEAD
84027-01	F	[redacted]60	DISPOSITION	06-10-05	12:34	P	FOUND DEAD
84025-05	F	[redacted]60	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84024-06	F	[redacted]60	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84029-03	F	[redacted]60	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84030-04	F	[redacted]60	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84031-06	F	[redacted]60	DISPOSITION	06-09-05	11:57	P	FOUND DEAD
84028-01	F	[redacted]60	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84028-07	F	[redacted]60	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84029-10	F	[redacted]60	DISPOSITION	06-21-05	7:39	P	SCHEDULED EUTHANASIA
84032-01	F	[redacted]60	DISPOSITION	06-22-05	6:38	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:05-003

TABLE RANGE: 05-31-05 TO 06-22-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84034-01	F	[redacted]60	DISPOSITION	06-22-05	6:38	P	SCHEDULED EUTHANASIA
84026-03	F	[redacted]250	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84023-04	F	[redacted]250	DISPOSITION	06-20-05	8:21	P	SCHEDULED EUTHANASIA
84024-04	F	[redacted]250	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84027-04	F	[redacted]250	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84025-07	F	[redacted]250	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84025-10	F	[redacted]250	DISPOSITION	06-08-05	11:50	P	FOUND DEAD
84026-09	F	[redacted]250	DISPOSITION	06-06-05	12:21	P	FOUND DEAD
84029-01	F	[redacted]250	DISPOSITION	06-08-05	11:50	P	FOUND DEAD
84030-05	F	[redacted]250	DISPOSITION	06-08-05	11:49	P	FOUND DEAD
84031-08	F	[redacted]250	DISPOSITION	06-08-05	11:50	P	FOUND DEAD
84028-04	F	[redacted]250	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84030-02	F	[redacted]250	DISPOSITION	06-09-05	11:57	P	FOUND DEAD
84029-07	F	[redacted]250	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84034-09	F	[redacted]250	DISPOSITION	06-22-05	6:38	P	SCHEDULED EUTHANASIA
84032-05	F	[redacted]250	DISPOSITION	06-10-05	6:52	P	FOUND DEAD
84023-08	F	[redacted]1000	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84026-01	F	[redacted]1000	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84025-04	F	[redacted]1000	DISPOSITION	06-07-05	12:22	P	FOUND DEAD
84027-07	F	[redacted]1000	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84023-07	F	[redacted]1000	DISPOSITION	06-08-05	11:49	P	FOUND DEAD
84024-09	F	[redacted]1000	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84029-04	F	[redacted]1000	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84028-03	F	[redacted]1000	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84030-07	F	[redacted]1000	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84031-03	F	[redacted]1000	DISPOSITION	06-07-05	12:22	P	FOUND DEAD
84031-05	F	[redacted]1000	DISPOSITION	06-07-05	12:22	P	FOUND DEAD
84033-01	F	[redacted]1000	DISPOSITION	06-03-05	7:13	P	FOUND DEAD
84035-07	F	[redacted]1000	DISPOSITION	06-03-05	7:13	P	FOUND DEAD

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:05-003

TABLE RANGE: 05-31-05 TO 06-22-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84032-10	F	[redacted]1000	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84034-06	F	[redacted]1000	DISPOSITION	06-03-05	7:13	P	FOUND DEAD
84023-01	F	[redacted]60	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84024-05	F	[redacted]60	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84025-03	F	[redacted]60	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84026-08	F	[redacted]60	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84027-10	F	[redacted]60	DISPOSITION	06-20-05	8:22	P	SCHEDULED EUTHANASIA
84026-02	F	[redacted]60	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84027-06	F	[redacted]60	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84029-08	F	[redacted]60	DISPOSITION	06-09-05	11:56	P	FOUND DEAD
84030-10	F	[redacted]60	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84031-07	F	[redacted]60	DISPOSITION	06-10-05	11:27	P	FOUND DEAD
84028-06	F	[redacted]60	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84031-10	F	[redacted]60	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84030-08	F	[redacted]60	DISPOSITION	06-06-05	12:20	P	FOUND DEAD
84034-02	F	[redacted]60	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84035-04	F	[redacted]60	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84024-08	F	[redacted]250	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84027-08	F	[redacted]250	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84025-02	F	[redacted]250	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84023-02	F	[redacted]250	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84026-10	F	[redacted]250	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84023-03	F	[redacted]250	DISPOSITION	06-03-05	7:13	P	FOUND DEAD
84024-07	F	[redacted]250	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84029-02	F	[redacted]250	DISPOSITION	06-21-05	7:41	P	SCHEDULED EUTHANASIA
84030-06	F	[redacted]250	DISPOSITION	06-21-05	7:41	P	SCHEDULED EUTHANASIA
84031-04	F	[redacted]250	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84028-09	F	[redacted]250	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84028-08	F	[redacted]250	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 13 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:05-003

TABLE RANGE: 05-31-05 TO 06-22-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84029-05	F	[redacted] 250	DISPOSITION	06-21-05	7:40	P	SCHEDULED EUTHANASIA
84034-08	F	250	DISPOSITION	06-02-05	12:35	P	FOUND DEAD
84035-01	F	250	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84024-03	F	1000	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84023-10	F	1000	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84026-06	F	1000	DISPOSITION	06-20-05	8:23	P	SCHEDULED EUTHANASIA
84025-01	F	1000	DISPOSITION	06-20-05	8:24	P	SCHEDULED EUTHANASIA
84027-02	F	1000	DISPOSITION	06-20-05	8:24	P	SCHEDULED EUTHANASIA
84026-07	F	1000	DISPOSITION	06-20-05	8:24	P	SCHEDULED EUTHANASIA
84029-06	F	1000	DISPOSITION	06-21-05	7:41	P	SCHEDULED EUTHANASIA
84028-02	F	1000	DISPOSITION	06-08-05	11:49	P	FOUND DEAD
84031-09	F	1000	DISPOSITION	06-21-05	7:41	P	SCHEDULED EUTHANASIA
84030-01	F	1000	DISPOSITION	06-21-05	7:41	P	SCHEDULED EUTHANASIA
84030-03	F	1000	DISPOSITION	06-21-05	7:41	P	SCHEDULED EUTHANASIA
84035-05	F	1000	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84032-09	F	1000	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84033-05	F	1000	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA
84034-10	F	1000	DISPOSITION	06-22-05	6:39	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (AT TIME OF DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-31-05 TO 06-21-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84031-06	F	[redacted]60	BEHAVIOR/CNS	06-09-05	11:10	P	HYPOACTIVITY
				06-09-05	11:10	P	PROSTRATE
84031-06	F	[redacted]60	CARDIO-PULMONARY	06-09-05	11:10	P	SHALLOW RESPIRATION
84028-03	F	[redacted]1000	ORAL/DENTAL	06-12-05	12:19	2	SALIVATION PRIOR TO DOSING

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-003

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-31-05 TO 06-21-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84028-10	F	CORN OIL	ORAL/DENTAL	06-01-05	11:38	1	WET CLEAR MATERIAL AROUND MOUTH
84023-09	F	[redacted]60	ORAL/DENTAL	06-01-05	11:39	1	WET CLEAR MATERIAL AROUND MOUTH
84027-01	F	[redacted]60	BEHAVIOR/CNS	06-10-05	11:54	P	HYPOACTIVITY
84027-01	F	[redacted]60	ORAL/DENTAL	06-10-05	11:54	1	WET TAN MATERIAL AROUND MOUTH
84026-03	F	[redacted]250	EYES/EARS/NOSE	06-02-05	12:06	1	WET CLEAR MATERIAL AROUND NOSE
84026-03	F	[redacted]250	ORAL/DENTAL	06-02-05	12:05	1	WET CLEAR MATERIAL AROUND MOUTH
84026-09	F	[redacted]250	CARDIO-PULMONARY	06-06-05	11:47	P	LABORED RESPIRATION
84026-09	F	[redacted]250	EYES/EARS/NOSE	06-06-05	11:45	1	WET CLEAR MATERIAL AROUND NOSE
84026-09	F	[redacted]250	ORAL/DENTAL	06-06-05	11:45	1	WET CLEAR MATERIAL AROUND MOUTH
84031-08	F	[redacted]250	ORAL/DENTAL	06-02-05	12:07	1	WET CLEAR MATERIAL AROUND MOUTH
84029-07	F	[redacted]250	BODY/INTEGUMENT	06-02-05	12:08	1	WET CLEAR MATERIAL VENTRAL NECK
84029-07	F	[redacted]250	ORAL/DENTAL	06-02-05	12:08	1	WET CLEAR MATERIAL AROUND MOUTH
84032-05	F	[redacted]250	BEHAVIOR/CNS	06-09-05	11:54	P	HYPOACTIVITY
84032-05	F	[redacted]250	BODY/INTEGUMENT	06-09-05	11:53	1	WET CLEAR MATERIAL RIGHT FORELIMB
				06-09-05	11:53	1	WET CLEAR MATERIAL LEFT FORELIMB
84032-05	F	[redacted]250	EYES/EARS/NOSE	06-09-05	11:52	2	WET CLEAR MATERIAL AROUND NOSE
84032-05	F	[redacted]250	ORAL/DENTAL	06-09-05	11:52	2	DRIED CLEAR MATERIAL AROUND MOUTH
84023-08	F	[redacted]1000	BODY/INTEGUMENT	06-02-05	12:09	1	DRIED CLEAR MATERIAL VENTRAL NECK
84023-08	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:09	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-16-05	13:36	1	WET CLEAR MATERIAL AROUND MOUTH
84027-07	F	[redacted]1000	BODY/INTEGUMENT	06-08-05	12:09	1	DRIED CLEAR MATERIAL LEFT FORELIMB
84023-07	F	[redacted]1000	BODY/INTEGUMENT	06-02-05	12:12	1	DRIED CLEAR MATERIAL LEFT FORELIMB
				06-02-05	12:12	1	DRIED CLEAR MATERIAL RIGHT FORELIMB
84023-07	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:10	2	DRIED CLEAR MATERIAL AROUND MOUTH
84024-09	F	[redacted]1000	BODY/INTEGUMENT	06-02-05	12:10	1	WET CLEAR MATERIAL VENTRAL NECK
84024-09	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:10	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				06-16-05	13:37	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:05-003

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-31-05 TO 06-21-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84024-09	F	[redacted]1000	ORAL/DENTAL	06-17-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				06-18-05	13:16	2	WET CLEAR MATERIAL AROUND MOUTH
				06-19-05	13:12	1	WET CLEAR MATERIAL AROUND MOUTH
84028-03	F	[redacted]1000	ORAL/DENTAL	06-12-05	13:16	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				06-14-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	13:18	1	WET CLEAR MATERIAL AROUND MOUTH
				06-16-05	13:37	1	WET CLEAR MATERIAL AROUND MOUTH
				06-17-05	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				06-18-05	13:16	2	WET CLEAR MATERIAL AROUND MOUTH
				06-19-05	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				06-20-05	13:05	1	WET CLEAR MATERIAL AROUND MOUTH
84030-07	F	[redacted]1000	BODY/INTEGUMENT	06-19-05	13:15	1	WET CLEAR MATERIAL VENTRAL NECK
84030-07	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:12	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-12-05	13:16	1	WET CLEAR MATERIAL AROUND MOUTH
				06-13-05	13:14	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-14-05	13:14	1	WET CLEAR MATERIAL AROUND MOUTH
				06-15-05	13:18	1	WET CLEAR MATERIAL AROUND MOUTH
				06-16-05	13:37	1	WET CLEAR MATERIAL AROUND MOUTH
				06-17-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				06-18-05	13:16	2	WET CLEAR MATERIAL AROUND MOUTH
				06-19-05	13:15	1	WET CLEAR MATERIAL AROUND MOUTH
				06-20-05	13:06	1	WET CLEAR MATERIAL AROUND MOUTH
84033-01	F	[redacted]1000	EYES/EARS/NOSE	06-02-05	12:14	1	WET CLEAR MATERIAL AROUND NOSE
84033-01	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:14	2	WET CLEAR MATERIAL AROUND MOUTH
84035-07	F	[redacted]1000	EYES/EARS/NOSE	06-02-05	12:15	1	WET CLEAR MATERIAL AROUND NOSE
84035-07	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:14	2	WET CLEAR MATERIAL AROUND MOUTH
84032-10	F	[redacted]1000	ORAL/DENTAL	06-18-05	13:16	2	WET CLEAR MATERIAL AROUND MOUTH
				06-19-05	13:16	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 05-31-05 TO 06-21-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
84032-10	F	[redacted]1000	ORAL/DENTAL	06-21-05	13:01	1	WET CLEAR MATERIAL AROUND MOUTH
84034-06	F	[redacted]1000	BEHAVIOR/CNS	06-02-05	12:19	P	HYPOACTIVITY
84034-06	F	[redacted]1000	CARDIO-PULMONARY	06-02-05	12:18	P	SHALLOW RESPIRATION
84034-06	F	[redacted]1000	EYES/EARS/NOSE	06-02-05	12:18	1	WET CLEAR MATERIAL AROUND NOSE
84034-06	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:17	1	WET CLEAR MATERIAL AROUND MOUTH
84026-08	F	[redacted]60	BODY/INTEGUMENT	06-02-05	12:28	1	DRIED CLEAR MATERIAL VENTRAL NECK
84024-08	F	[redacted]250	ORAL/DENTAL	06-02-05	12:31	1	WET CLEAR MATERIAL AROUND MOUTH
84025-02	F	[redacted]250	BODY/INTEGUMENT	06-02-05	12:31	1	WET CLEAR MATERIAL DORSAL THORACIC AREA
84025-02	F	[redacted]250	EYES/EARS/NOSE	06-02-05	12:30	1	WET CLEAR MATERIAL AROUND NOSE
84025-02	F	[redacted]250	ORAL/DENTAL	06-02-05	12:30	1	WET CLEAR MATERIAL AROUND MOUTH
84023-03	F	[redacted]250	EYES/EARS/NOSE	06-02-05	12:32	1	WET CLEAR MATERIAL AROUND NOSE
84023-03	F	[redacted]250	ORAL/DENTAL	06-02-05	12:32	2	WET CLEAR MATERIAL AROUND MOUTH
84029-05	F	[redacted]250	ORAL/DENTAL	06-02-05	12:36	1	DRIED CLEAR MATERIAL AROUND MOUTH
84035-01	F	[redacted]250	ORAL/DENTAL	06-02-05	12:36	1	DRIED CLEAR MATERIAL AROUND MOUTH
84023-10	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:44	1	WET CLEAR MATERIAL AROUND MOUTH
84025-01	F	[redacted]1000	ORAL/DENTAL	05-31-05	12:07	1	DRIED CLEAR MATERIAL AROUND MOUTH
84027-02	F	[redacted]1000	ORAL/DENTAL	05-31-05	12:07	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-02-05	12:45	1	DRIED CLEAR MATERIAL AROUND MOUTH
				06-14-05	13:24	1	DRIED CLEAR MATERIAL AROUND MOUTH
84029-06	F	[redacted]1000	EYES/EARS/NOSE	06-08-05	12:27	1	WET RED MATERIAL AROUND NOSE
84028-02	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:45	1	DRIED CLEAR MATERIAL AROUND MOUTH
84030-01	F	[redacted]1000	ORAL/DENTAL	06-09-05	12:31	1	DRIED CLEAR MATERIAL AROUND MOUTH
84033-05	F	[redacted]1000	ORAL/DENTAL	06-02-05	12:48	1	DRIED CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: CORN OIL												
84024-10	59.3	64.8	70.4	74.5	80.9	87.2	91.3	96.5	102.6	107.4	113.3	116.3
84023-06	55.6	60.9	66.8	70.9	76.6	80.7	87.2	92.2	99.0	103.9	108.7	113.6
84025-06	48.2	54.6	59.4	64.6	69.7	75.3	81.3	86.5	95.1	101.6	108.2	112.8
84027-05	49.2	55.3	59.6	64.5	69.3	74.6	80.2	84.8	91.9	98.0	102.5	109.2
84026-04	49.3	54.7	59.1	63.6	65.1	71.4	75.9	79.9	86.0	88.9	93.7	100.2
84027-03	51.0	56.2	60.8	65.0	69.5	75.3	81.0	84.5	92.0	97.1	102.1	110.3
84023-05	55.1	58.8	64.9	69.9	75.0	82.3	87.6	94.3	100.6	106.5	112.2	118.5
84028-10	43.9	49.1	52.8	57.0	61.5	66.9	71.7	79.0	82.1	87.9	93.7	100.5
84031-02	52.7	58.5	63.4	67.3	72.9	78.0	80.7	86.1	90.3	95.2	100.6	106.7
84029-09	52.6	57.1	62.9	69.6	72.7	78.1	84.7	90.2	98.2	104.0	108.6	117.6
84030-09	55.3	61.1	66.5	71.9	76.9	84.0	87.8	93.4	98.4	102.4		
84031-01	53.6	59.3	67.4	72.3	77.9	82.4	87.9	92.7	100.8	106.0	111.2	120.2
84028-05	47.1	51.9	57.1	62.8	68.8	73.1	78.5	84.9	88.8	95.1	100.3	104.6
84034-03	57.1	61.9	67.8	71.7	75.9	80.2	85.9	91.3	97.1	103.8	109.0	113.2
84035-10	49.3	52.2	58.4	62.8	67.4	72.2	72.7	78.9	85.8	92.8	99.7	104.5
MEAN	52.0	57.1	62.5	67.2	72.0	77.4	82.3	87.7	93.9	99.4	104.6	110.6
S.D.	4.17	4.26	4.84	4.80	5.30	5.45	5.87	5.75	6.32	6.34	6.50	6.55
N	15	15	15	15	15	15	15	15	15	15	14	14

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: CORN OIL									
84024-10	122.5	126.1	127.3	132.5	137.9	141.6	139.2	141.1	150.0
84023-06	120.3	123.1	128.1	132.6	140.6	147.2	151.0	154.3	159.0
84025-06	123.0	128.5	135.1	142.1	150.9	157.8	161.3	169.0	174.9
84027-05	114.7	118.4	125.1	131.5	137.8	143.3	147.8	153.3	152.5
84026-04	104.7	107.4	111.7	116.2	123.1	126.0	128.1	133.9	132.8
84027-03	115.4	120.7	127.9	134.0	140.5	144.0	146.7	153.0	158.4
84023-05	128.2	136.6	140.4	148.4	155.1	160.5	167.5	176.5	183.5
84028-10	105.7	110.4	119.0	121.5	127.3	134.4	141.3	148.2	155.6
84031-02	111.1	115.0	120.1	125.7	132.9	134.9	140.0	145.1	150.6
84029-09	124.1	129.5	133.7	142.1	146.3	151.4	153.4	158.2	165.6
84031-01	124.1	133.3	139.0	144.0	148.7	156.2	160.9	166.1	168.8
84028-05	110.1	111.6	117.4	121.3	124.6	127.9	131.8	136.4	136.5
84034-03	119.5	127.7	133.7	138.8	144.1	148.4	155.5	156.6	165.7
84035-10	107.2	115.5	120.1	127.4	128.9	132.0	137.3	136.6	144.0
MEAN	116.5	121.7	127.0	132.7	138.5	143.3	147.3	152.0	157.0
S.D.	7.70	8.99	8.64	9.59	10.05	11.08	11.67	12.84	14.15
N	14	14	14	14	14	14	14	14	14

Revised Audited Draft

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: [redacted]60												
84024-02	62.2	67.2	71.9	77.5	82.8	87.4	94.0	98.1	105.9	111.0	115.6	120.4
84025-09	56.7	62.9	67.9	71.5	77.5	82.9	88.2	94.8	103.2	108.2	115.8	115.7
84026-05	49.6	55.5	59.8	64.9	69.6	72.7	79.1	83.7	89.7	93.7	101.7	104.1
84023-09	47.5	53.5	58.8	64.8	69.2	74.6	80.7	84.9	91.8	97.1	102.9	
84027-01	47.1	52.5	57.1	61.7	66.2	70.7	75.7	81.7	88.5	92.3	98.6	
84025-05	46.4	51.3	55.6	59.5	65.3	68.8	73.1	78.7	84.4	87.3	92.6	97.3
84024-06	62.3	65.3	73.8	78.7	86.7	90.9	96.9	105.3	112.3	118.9	129.0	135.6
84029-03	43.0	48.6	53.2	57.5	61.6	65.1	69.6	75.1	80.6	86.0	90.2	96.6
84030-04	51.2	56.2	61.3	65.9	70.4	73.4	79.2	83.9	88.3	95.5	102.3	108.5
84031-06	56.8	62.1	67.6	72.9	78.3	82.7	87.3	95.0	102.0			
84028-01	58.3	64.4	69.4	75.3	81.3	85.8	91.3	98.8	104.1	111.8	115.8	125.9
84028-07	55.1	60.4	65.2	72.8	76.3	82.6	88.2	95.6	103.5	110.1	118.2	122.6
84029-10	52.0	55.2	61.0	65.7	71.6	76.0	81.1	87.3	92.5	99.8	108.1	114.3
84032-01	54.5	59.4	63.2	68.2	71.6	75.6	83.2	85.9	91.6	97.6	102.4	108.1
84034-01	52.2	54.3	59.4	64.4	69.4	74.3	79.6	84.3	88.8	93.2	100.8	108.7
MEAN	53.0	57.9	63.0	68.1	73.2	77.6	83.1	88.9	95.1	100.2	106.7	113.2
S.D.	5.73	5.62	6.10	6.45	7.05	7.41	7.73	8.52	9.22	10.09	10.83	11.64
N	15	15	15	15	15	15	15	15	15	14	14	12

Revised Audited Draft

Modified: 11/4/2005

TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: [redacted]60									
84024-02	128.3	132.9	132.1	136.7	144.0	148.4	148.1	152.2	157.8
84025-09	128.2	131.1	138.7	144.5	151.2	157.0	164.2	169.8	175.9
84026-05	110.6	115.4	116.3	119.5	124.3	125.8	130.2	131.9	134.3
84025-05	101.4	102.6	104.7	107.9	109.3	113.9	115.3	119.8	120.9
84024-06	143.2	149.3	156.7	161.8	168.4	175.1	180.1	186.4	193.3
84029-03	102.4	107.4	113.3	115.8	125.9	130.9	137.0	140.7	146.8
84030-04	114.7	119.3	125.4	129.8	137.3	143.1	145.6	152.3	155.9
84028-01	132.2	139.6	145.2	148.2	157.0	162.5	168.3	171.3	178.5
84028-07	128.7	134.1	144.6	149.6	154.7	157.2	166.5	170.9	170.9
84029-10	119.9	122.8	134.1	140.4	146.4	153.5	159.1	166.4	168.8
84032-01	108.9	115.9	120.0	125.1	130.1	132.4	139.7	144.8	147.2
84034-01	112.0	120.0	124.8	129.4	135.6	140.9	149.0	152.5	155.1
MEAN	119.2	124.2	129.7	134.1	140.4	145.1	150.3	154.9	158.8
S.D.	12.97	13.58	15.10	15.72	16.53	17.33	18.32	18.96	20.13
N	12	12	12	12	12	12	12	12	12

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: [redacted]250												
84026-03	61.4	67.7	74.4	68.1	74.6	82.1	87.5	93.8	102.9	109.2	114.8	119.9
84023-04	53.5	58.9	62.4	66.3	71.4	76.4	81.0	86.3	91.4	95.4	100.9	105.1
84024-04	53.0	60.1	66.7	66.0	74.4	82.1	87.6	96.6	103.8	110.6	116.4	120.8
84027-04	48.3	55.5	61.6	56.6	57.3	65.4	70.9	76.8	83.4	88.2	95.9	99.6
84025-07	45.6	52.6	58.2	62.5	68.1	75.2	81.2	84.9	92.9	100.0	105.0	111.4
84025-10	43.9	48.7	55.8	56.7	61.9	66.6	74.4	79.2	85.6			
84026-09	52.6	57.2	63.3	66.8	74.0	78.5	83.6					
84029-01	51.0	54.4	59.5	65.8	70.7	75.9	82.3	85.8				
84030-05	53.1	57.8	63.2	68.2	74.4	79.6	86.1	91.5				
84031-08	53.2	57.8	60.0	64.4	70.1	79.5	85.1	91.2				
84028-04	57.4	57.9	64.7	70.6	75.7	83.4	87.5	93.5	99.7	105.0	114.9	116.9
84030-02	49.0	54.6	60.4	66.2	70.0	76.5	79.8	85.4	91.9			
84029-07	46.8	50.6	55.8	60.9	66.7	73.1	77.3	82.4	89.0	94.6	101.6	108.6
84034-09	55.4	59.0	63.5	68.5	73.2	76.3	82.0	87.3	91.6	98.6	103.8	110.7
84032-05	52.2	55.7	59.3	64.2	68.2	72.0	77.1	82.5	NA			
MEAN	51.8	56.6	61.9	64.8	70.0	76.2	81.6	86.9	93.2	100.2	106.7	111.6
S.D.	4.57	4.45	4.63	4.09	5.11	5.25	5.01	5.78	6.89	7.68	7.70	7.35
N	15	15	15	15	15	15	15	14	10	8	8	8

NA = NOT APPLICABLE

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Modified: 11/4/2005

TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: [redacted]250									
84026-03	125.7	131.8	138.1	143.0	147.0	151.9	157.4	160.0	166.0
84023-04	110.3	114.0	117.8	123.8	130.3	132.1	138.5	139.3	145.3
84024-04	130.2	134.2	140.2	148.0	150.8	154.4	164.2	167.0	173.6
84027-04	107.0	113.5	121.8	128.4	140.0	146.6	152.6	158.2	163.9
84025-07	118.1	124.2	127.9	132.2	142.4	144.6	148.5	152.5	158.1
84028-04	123.9	131.2	137.4	145.4	149.7	152.2	161.6	166.0	173.5
84029-07	114.6	120.5	130.1	136.1	141.4	146.2	154.2	161.5	162.3
84034-09	113.8	119.4	125.4	129.1	133.9	142.7	145.7	148.7	155.5
MEAN	118.0	123.6	129.8	135.8	141.9	146.3	152.8	156.7	162.3
S.D.	8.04	8.10	8.16	8.86	7.26	7.06	8.48	9.36	9.43
N	8	8	8	8	8	8	8	8	8

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: [redacted]1000												
84023-08	55.4	56.1	60.6	64.1	70.9	76.5	81.5	87.0	94.4	99.0	102.1	109.0
84026-01	51.5	55.8	54.3	55.1	64.3	70.8	76.9	86.7	93.3	97.5	107.9	112.1
84025-04	50.0	49.7	50.0	54.4	62.0	66.6	70.0	76.7				
84027-07	43.6	41.8	42.5	46.0	51.8	60.7	65.2	70.5	77.2	82.5	86.5	91.9
84023-07	54.0	58.6	65.4	59.2	57.2	63.4	67.3	71.0	78.3			
84024-09	62.8	67.5	72.1	76.3	80.5	86.1	90.4	96.4	104.5	109.7	114.2	119.4
84029-04	48.3	44.6	43.5	47.0	54.9	59.0	64.4	71.0	74.9	81.3	89.6	95.4
84028-03	52.0	54.3	58.6	63.7	67.8	72.0	77.8	81.7	86.4	92.0	95.3	105.2
84030-07	53.7	56.9	60.3	64.7	69.4	72.2	79.2	83.6	89.7	93.7	96.8	104.5
84031-03	55.9	61.4	60.4	60.7	69.9	75.8	83.9					
84031-05	50.3	57.5	62.2	70.6	75.0	82.4	87.9					
84033-01	52.3	NA										
84035-07	49.1	NA										
84032-10	42.7	44.2	48.6	51.5	56.0	59.3	63.5	68.0	72.6	76.8	82.6	88.6
84034-06	41.1	NA										
MEAN	50.8	54.0	56.5	59.4	65.0	70.4	75.7	79.3	85.7	91.6	96.9	103.3
S.D.	5.58	7.62	8.95	9.15	8.81	8.91	9.41	9.31	10.72	10.89	10.80	10.57
N	15	12	12	12	12	12	12	10	9	8	8	8

NA = NOT APPLICABLE

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: [redacted]1000									
84023-08	115.7	120.0	126.2	127.5	138.0	141.6	146.7	149.8	158.4
84026-01	120.8	129.0	137.7	142.5	152.8	159.9	163.5	169.4	174.7
84027-07	98.6	104.5	109.9	114.3	123.6	128.1	134.3	138.5	146.8
84024-09	127.0	131.5	132.5	139.7	144.1	149.3	154.2	150.4	159.3
84029-04	100.8	104.8	112.1	118.8	127.9	128.6	137.2	142.0	144.1
84028-03	110.8	114.4	122.6	127.1	134.7	142.7	148.3	152.6	156.2
84030-07	109.6	116.3	122.7	123.9	127.9	134.4	141.4	145.6	146.6
84032-10	92.9	98.9	102.8	108.2	113.8	119.3	123.8	125.1	134.0
MEAN	109.5	114.9	120.8	125.3	132.9	138.0	143.7	146.7	152.5
S.D.	11.61	11.76	11.81	11.76	12.26	13.05	12.33	12.71	12.35
N	8	8	8	8	8	8	8	8	8

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: [redacted]60												
84023-01	60.2	66.1	71.8	77.3	83.1	88.5	94.6	102.5	107.5	113.3	119.8	124.3
84024-05	58.1	64.8	69.2	74.9	80.7	85.9	92.3	99.0	106.1	112.7	119.4	124.9
84025-03	51.5	57.3	62.2	66.5	70.6	75.3	80.4	86.0	91.4	96.4	100.6	105.1
84026-08	48.0	55.3	59.1	63.1	69.2	72.9	80.0	83.8	89.4	92.8	98.6	102.8
84027-10	46.2	52.0	57.4	58.8	65.1	68.0	72.2	75.1	81.3	86.0	90.9	93.1
84026-02	49.0	55.2	59.1	63.4	69.7	74.2	78.3	83.7	90.9	95.3	102.4	105.3
84027-06	55.9	60.8	62.7	67.1	71.6	77.4	82.6	89.0	92.8	99.6	104.7	110.3
84029-08	43.6	48.6	53.6	58.1	63.5	67.2	70.6	77.6	84.9			
84030-10	50.3	54.4	61.5	67.9	73.9	78.7	83.0	89.8	96.0	102.6	110.3	116.7
84031-07	54.1	59.3	65.0	70.8	77.0	83.9	88.5	95.7	101.0	110.3		
84028-06	60.7	65.4	71.2	77.6	82.7	87.6	94.5	97.5	106.9	114.6	118.7	128.0
84031-10	54.2	59.2	64.1	69.2	74.8	80.3	85.2	89.4	95.3	103.5	108.3	116.4
84030-08	48.2	53.5	58.4	63.9	68.2	74.1						
84034-02	61.9	68.2	74.6	79.0	86.3	91.8	100.4	105.1	111.7	120.0	129.3	133.6
84035-04	49.7	53.2	58.4	63.7	68.5	73.6	78.2	84.0	91.1	98.3	104.1	110.0
MEAN	52.8	58.2	63.2	68.1	73.7	78.6	84.3	89.9	96.2	103.5	108.9	114.2
S.D.	5.64	5.84	6.08	6.67	6.94	7.51	8.76	9.03	9.15	10.02	10.98	11.93
N	15	15	15	15	15	15	14	14	14	13	12	12

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: [redacted]60									
84023-01	135.6	141.8	140.8	146.9	149.5	158.9	161.0	163.0	170.3
84024-05	133.3	141.0	145.3	150.6	158.9	165.1	168.5	178.0	181.2
84025-03	111.9	115.3	120.5	124.3	125.0	130.1	133.8	137.5	138.8
84026-08	108.2	113.7	116.6	121.2	127.3	131.0	133.0	135.6	142.1
84027-10	101.3	104.6	111.6	114.8	117.0	122.8	127.6	133.8	139.9
84026-02	113.5	119.6	124.0	126.6	131.4	135.7	139.7	142.8	143.5
84027-06	117.7	122.1	125.2	131.7	137.5	141.2	141.8	145.8	155.0
84030-10	122.0	128.1	137.0	143.0	151.9	153.1	156.8	163.2	167.6
84028-06	133.2	139.5	145.0	152.9	157.4	160.5	168.1	173.3	175.5
84031-10	120.5	126.9	132.3	141.2	146.8	155.0	166.2	175.9	178.0
84034-02	138.7	144.0	152.4	159.4	163.8	164.4	171.9	177.3	184.0
84035-04	115.3	119.8	126.8	135.7	139.5	143.6	146.7	153.3	162.7
MEAN	120.9	126.4	131.5	137.4	142.2	146.8	151.3	156.6	161.6
S.D.	11.92	12.80	12.73	13.92	14.91	14.63	15.95	17.23	17.06
N	12	12	12	12	12	12	12	12	12

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-003

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 6: [redacted]250												
84024-08	60.8	67.1	71.2	71.0	77.3	82.5	89.0	93.2	99.5	103.7	109.1	113.0
84027-08	54.5	59.6	66.1	69.4	77.1	81.1	87.9	93.7	100.4	107.3	113.1	118.7
84025-02	49.2	55.0	60.0	61.0	66.0	71.8	76.8	83.5	88.9	93.5	100.8	105.2
84023-02	49.0	53.8	57.6	60.6	65.9	69.3	73.6	78.5	83.3	87.5	93.2	97.3
84026-10	45.6	50.2	54.6	59.9	65.1	69.3	75.6	80.9	87.8	92.8	98.0	103.6
84023-03	51.2	56.5	61.1	NA								
84024-07	51.7	55.5	60.9	67.4	73.9	80.5	88.0	90.8	98.6	103.3	108.9	115.6
84029-02	46.8	51.6	56.6	62.3	68.2	73.9	78.3	84.4	91.2	96.0	104.6	105.9
84030-06	52.5	57.0	60.7	65.4	71.0	76.7	81.1	87.7	92.7	99.0	105.3	110.8
84031-04	52.8	58.5	63.7	67.1	72.7	78.2	83.5	90.8	95.7	101.0	106.9	115.6
84028-09	56.9	60.7	67.0	73.3	78.9	84.8	91.1	97.3	102.6	109.0	115.9	125.2
84028-08	59.3	64.1	69.5	75.1	81.6	89.3	94.4	100.2	107.4	114.5	120.1	130.3
84029-05	46.4	49.9	55.6	62.5	66.5	72.9	78.7	83.1	86.6	92.5	98.7	105.7
84034-08	59.9											
84035-01	50.6	55.0	60.6	64.2	68.9	74.3	78.8	83.9	91.1	97.5	104.3	109.5
MEAN	52.5	56.8	61.8	66.1	71.8	77.3	82.8	88.3	94.3	99.8	106.1	112.0
S.D.	4.93	4.97	5.11	4.97	5.58	6.13	6.61	6.61	7.07	7.63	7.52	9.12
N	15	14	14	13	13	13	13	13	13	13	13	13

NA = NOT APPLICABLE

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 12
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 6: [redacted]250									
84024-08	121.5	125.6	130.6	133.7	138.8	143.1	149.2	157.8	154.9
84027-08	128.4	133.3	137.2	145.3	149.0	157.5	159.6	165.5	170.3
84025-02	113.5	117.9	121.2	127.4	131.6	136.1	139.6	147.7	153.7
84023-02	104.7	107.1	111.8	116.9	119.3	127.1	130.2	138.3	141.1
84026-10	108.0	113.9	119.1	123.5	127.1	131.1	135.5	140.0	142.6
84024-07	122.2	127.9	133.2	142.2	145.6	152.7	158.4	161.6	170.7
84029-02	115.7	121.8	128.1	135.6	136.5	143.7	151.1	157.1	163.3
84030-06	116.0	121.7	129.1	133.5	137.9	145.0	151.2	154.3	160.5
84031-04	119.8	125.6	131.6	133.5	141.8	146.5	155.8	161.1	158.5
84028-09	130.4	137.3	143.5	145.7	147.1	154.3	162.7	166.7	168.5
84028-08	135.1	137.1	144.6	149.9	155.1	159.1	162.4	166.0	170.9
84029-05	109.5	113.9	120.1	125.8	132.7	135.6	140.7	145.3	148.6
84035-01	115.7	119.5	126.5	131.3	137.7	139.2	143.1	151.1	154.4
MEAN	118.5	123.3	129.0	134.2	138.5	143.9	149.2	154.8	158.3
S.D.	8.98	9.15	9.53	9.61	9.60	10.03	10.61	9.69	10.31
N	13	13	13	13	13	13	13	13	13

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 7: [redacted]1000												
84024-03	58.7	63.4	69.8	76.4	80.7	87.0	92.9	98.3	105.7	111.4	119.7	124.5
84023-10	56.8	60.6	66.0	66.2	69.2	74.1	79.6	86.3	93.7	97.5	103.4	108.7
84026-06	50.0	56.2	60.3	64.9	69.1	74.7	80.8	85.5	90.6	98.2	104.4	106.5
84025-01	47.9	54.5	59.3	64.2	69.9	76.5	81.3	86.8	93.2	99.3	102.8	110.1
84027-02	47.0	50.6	55.4	60.1	66.4	69.6	73.6	76.2	81.5	86.1	90.8	94.5
84026-07	57.1	59.9	67.8	73.3	78.4	82.2	87.6	94.6	103.8	110.8	116.9	123.9
84029-06	49.4	54.1	59.1	63.8	70.3	74.0	78.2	87.5	92.2	99.6	106.8	116.1
84028-02	51.4	58.1	58.8	63.1	69.7	76.7	82.4	87.5				
84031-09	53.9	60.4	66.2	71.1	76.3	82.3	87.7	94.3	100.5	105.8	111.6	118.8
84030-01	55.8	60.6	65.2	71.4	76.5	81.7	86.6	93.4	97.3	103.3	107.7	113.6
84030-03	51.1	56.7	61.5	67.2	71.2	75.6	79.4	84.9	89.7	95.1	100.0	106.6
84035-05	52.9	57.2	63.5	68.1	73.9	78.9	83.4	89.2	95.1	99.4	108.3	114.1
84032-09	51.1	56.4	61.7	67.0	73.3	78.3	82.6	90.0	97.2	106.0	111.6	118.5
84033-05	50.3	51.3	57.0	62.2	68.2	72.6	78.5	83.9	91.6	94.9	103.9	107.7
84034-10	43.7	48.1	52.4	56.6	60.3	64.9	69.4	73.9	79.5	83.0	90.6	92.8
MEAN	51.8	56.5	61.6	66.4	71.6	76.6	81.6	87.5	93.7	99.3	105.6	111.2
S.D.	4.13	4.25	4.84	5.19	5.14	5.51	5.82	6.52	7.35	8.15	8.34	9.48
N	15	15	15	15	15	15	15	15	14	14	14	14

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TABLE 16

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 7: [redacted]1000									
84024-03	135.1	142.1	148.2	153.6	154.5	162.0	168.1	171.0	174.5
84023-10	115.8	120.8	126.9	133.2	137.4	145.3	146.2	153.0	155.7
84026-06	115.3	121.1	124.5	131.6	134.3	144.1	143.3	146.7	149.8
84025-01	116.8	123.4	127.1	133.8	139.2	145.6	150.2	152.9	157.9
84027-02	98.8	103.5	109.0	116.5	119.6	128.2	129.0	133.7	138.3
84026-07	132.4	138.5	146.5	152.7	156.5	162.5	167.0	173.2	174.4
84029-06	121.5	128.7	135.4	143.3	148.0	154.8	162.3	166.9	171.6
84031-09	123.3	128.9	131.4	138.0	142.3	146.3	152.8	154.3	157.4
84030-01	121.8	123.6	131.1	136.8	139.2	144.1	149.4	153.7	157.7
84030-03	107.3	113.4	120.7	124.8	128.6	130.6	136.4	142.8	144.3
84035-05	119.7	127.8	134.1	140.3	149.4	153.4	162.2	168.3	178.1
84032-09	123.7	131.4	139.5	143.7	152.3	158.5	162.0	164.5	165.5
84033-05	115.4	123.3	131.1	135.9	145.0	151.4	157.2	165.8	169.9
84034-10	98.1	103.0	106.3	109.5	114.9	119.8	123.8	125.6	132.1
MEAN	117.5	123.5	129.4	135.3	140.1	146.2	150.7	155.2	159.1
S.D.	10.69	11.24	12.02	12.27	12.51	12.69	13.83	14.30	14.23
N	14	14	14	14	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: CORN OIL												
84024-10	5.5	5.6	4.1	6.4	6.3	4.1	5.2	6.1	4.8	5.9	3.0	6.2
84023-06	5.3	5.9	4.1	5.7	4.1	6.5	5.0	6.8	4.9	4.8	4.9	6.7
84025-06	6.4	4.8	5.2	5.1	5.6	6.0	5.2	8.6	6.5	6.6	4.6	10.2
84027-05	6.1	4.3	4.9	4.8	5.3	5.6	4.6	7.1	6.1	4.5	6.7	5.5
84026-04	5.4	4.4	4.5	1.5	6.3	4.5	4.0	6.1	2.9	4.8	6.5	4.5
84027-03	5.2	4.6	4.2	4.5	5.8	5.7	3.5	7.5	5.1	5.0	8.2	5.1
84023-05	3.7	6.1	5.0	5.1	7.3	5.3	6.7	6.3	5.9	5.7	6.3	9.7
84028-10	5.2	3.7	4.2	4.5	5.4	4.8	7.3	3.1	5.8	5.8	6.8	5.2
84031-02	5.8	4.9	3.9	5.6	5.1	2.7	5.4	4.2	4.9	5.4	6.1	4.4
84029-09	4.5	5.8	6.7	3.1	5.4	6.6	5.5	8.0	5.8	4.6	9.0	6.5
84030-09	5.8	5.4	5.4	5.0	7.1	3.8	5.6	5.0	4.0			
84031-01	5.7	8.1	4.9	5.6	4.5	5.5	4.8	8.1	5.2	5.2	9.0	3.9
84028-05	4.8	5.2	5.7	6.0	4.3	5.4	6.4	3.9	6.3	5.2	4.3	5.5
84034-03	4.8	5.9	3.9	4.2	4.3	5.7	5.4	5.8	6.7	5.2	4.2	6.3
84035-10	2.9	6.2	4.4	4.6	4.8	0.5	6.2	6.9	7.0	6.9	4.8	2.7
MEAN	5.1	5.4	4.7	4.8	5.4	4.8	5.4	6.2	5.5	5.4	6.0	5.9
S.D.	0.91	1.05	0.78	1.21	0.99	1.59	0.99	1.61	1.08	0.71	1.84	2.04
N	15	15	15	15	15	15	15	15	15	14	14	14

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: CORN OIL									
84024-10	3.6	1.2	5.2	5.4	3.7	-2.4	1.9	8.9	90.7
84023-06	2.8	5.0	4.5	8.0	6.6	3.8	3.3	4.7	103.4
84025-06	5.5	6.6	7.0	8.8	6.9	3.5	7.7	5.9	126.7
84027-05	3.7	6.7	6.4	6.3	5.5	4.5	5.5	-0.8	103.3
84026-04	2.7	4.3	4.5	6.9	2.9	2.1	5.8	-1.1	83.5
84027-03	5.3	7.2	6.1	6.5	3.5	2.7	6.3	5.4	107.4
84023-05	8.4	3.8	8.0	6.7	5.4	7.0	9.0	7.0	128.4
84028-10	4.7	8.6	2.5	5.8	7.1	6.9	6.9	7.4	111.7
84031-02	3.9	5.1	5.6	7.2	2.0	5.1	5.1	5.5	97.9
84029-09	5.4	4.2	8.4	4.2	5.1	2.0	4.8	7.4	113.0
84031-01	9.2	5.7	5.0	4.7	7.5	4.7	5.2	2.7	115.2
84028-05	1.5	5.8	3.9	3.3	3.3	3.9	4.6	0.1	89.4
84034-03	8.2	6.0	5.1	5.3	4.3	7.1	1.1	9.1	108.6
84035-10	8.3	4.6	7.3	1.5	3.1	5.3	-0.7	7.4	94.7
MEAN	5.2	5.3	5.7	5.8	4.8	4.0	4.8	5.0	105.3
S.D.	2.44	1.77	1.64	1.91	1.77	2.50	2.62	3.45	13.36
N	14	14	14	14	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-003

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: [redacted]60												
84024-02	5.0	4.7	5.6	5.3	4.6	6.6	4.1	7.8	5.1	4.6	4.8	7.9
84025-09	6.2	5.0	3.6	6.0	5.4	5.3	6.6	8.4	5.0	7.6	-0.1	12.5
84026-05	5.9	4.3	5.1	4.7	3.1	6.4	4.6	6.0	4.0	8.0	2.4	6.5
84023-09	6.0	5.3	6.0	4.4	5.4	6.1	4.2	6.9	5.3	5.8		
84027-01	5.4	4.6	4.6	4.5	4.5	5.0	6.0	6.8	3.8	6.3		
84025-05	4.9	4.3	3.9	5.8	3.5	4.3	5.6	5.7	2.9	5.3	4.7	4.1
84024-06	3.0	8.5	4.9	8.0	4.2	6.0	8.4	7.0	6.6	10.1	6.6	7.6
84029-03	5.6	4.6	4.3	4.1	3.5	4.5	5.5	5.5	5.4	4.2	6.4	5.8
84030-04	5.0	5.1	4.6	4.5	3.0	5.8	4.7	4.4	7.2	6.8	6.2	6.2
84031-06	5.3	5.5	5.3	5.4	4.4	4.6	7.7	7.0				
84028-01	6.1	5.0	5.9	6.0	4.5	5.5	7.5	5.3	7.7	4.0	10.1	6.3
84028-07	5.3	4.8	7.6	3.5	6.3	5.6	7.4	7.9	6.6	8.1	4.4	6.1
84029-10	3.2	5.8	4.7	5.9	4.4	5.1	6.2	5.2	7.3	8.3	6.2	5.6
84032-01	4.9	3.8	5.0	3.4	4.0	7.6	2.7	5.7	6.0	4.8	5.7	0.8
84034-01	2.1	5.1	5.0	5.0	4.9	5.3	4.7	4.5	4.4	7.6	7.9	3.3
MEAN	4.9	5.1	5.1	5.1	4.4	5.6	5.7	6.3	5.5	6.5	5.4	6.1
S.D.	1.22	1.07	0.96	1.17	0.90	0.88	1.60	1.23	1.45	1.83	2.58	2.81
N	15	15	15	15	15	15	15	15	14	14	12	12

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: [redacted]60									
84024-02	4.6	-0.8	4.6	7.3	4.4	-0.3	4.1	5.6	95.6
84025-09	2.9	7.6	5.8	6.7	5.8	7.2	5.6	6.1	119.2
84026-05	4.8	0.9	3.2	4.8	1.5	4.4	1.7	2.4	84.7
84025-05	1.2	2.1	3.2	1.4	4.6	1.4	4.5	1.1	74.5
84024-06	6.1	7.4	5.1	6.6	6.7	5.0	6.3	6.9	131.0
84029-03	5.0	5.9	2.5	10.1	5.0	6.1	3.7	6.1	103.8
84030-04	4.6	6.1	4.4	7.5	5.8	2.5	6.7	3.6	104.7
84028-01	7.4	5.6	3.0	8.8	5.5	5.8	3.0	7.2	120.2
84028-07	5.4	10.5	5.0	5.1	2.5	9.3	4.4	0.0	115.8
84029-10	2.9	11.3	6.3	6.0	7.1	5.6	7.3	2.4	116.8
84032-01	7.0	4.1	5.1	5.0	2.3	7.3	5.1	2.4	92.7
84034-01	8.0	4.8	4.6	6.2	5.3	8.1	3.5	2.6	102.9
MEAN	5.0	5.5	4.4	6.3	4.7	5.2	4.7	3.9	105.2
S.D.	1.99	3.59	1.18	2.19	1.76	2.82	1.63	2.41	16.38
N	12	12	12	12	12	12	12	12	12

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: [redacted]250												
84026-03	6.3	6.7	-6.3	6.5	7.5	5.4	6.3	9.1	6.3	5.6	5.1	5.8
84023-04	5.4	3.5	3.9	5.1	5.0	4.6	5.3	5.1	4.0	5.5	4.2	5.2
84024-04	7.1	6.6	-0.7	8.4	7.7	5.5	9.0	7.2	6.8	5.8	4.4	9.4
84027-04	7.2	6.1	-5.0	0.7	8.1	5.5	5.9	6.6	4.8	7.7	3.7	7.4
84025-07	7.0	5.6	4.3	5.6	7.1	6.0	3.7	8.0	7.1	5.0	6.4	6.7
84025-10	4.8	7.1	0.9	5.2	4.7	7.8	4.8	6.4				
84026-09	4.6	6.1	3.5	7.2	4.5	5.1						
84029-01	3.4	5.1	6.3	4.9	5.2	6.4	3.5					
84030-05	4.7	5.4	5.0	6.2	5.2	6.5	5.4					
84031-08	4.6	2.2	4.4	5.7	9.4	5.6	6.1					
84028-04	0.5	6.8	5.9	5.1	7.7	4.1	6.0	6.2	5.3	9.9	2.0	7.0
84030-02	5.6	5.8	5.8	3.8	6.5	3.3	5.6	6.5				
84029-07	3.8	5.2	5.1	5.8	6.4	4.2	5.1	6.6	5.6	7.0	7.0	6.0
84034-09	3.6	4.5	5.0	4.7	3.1	5.7	5.3	4.3	7.0	5.2	6.9	3.1
84032-05	3.5	3.6	4.9	4.0	3.8	5.1	5.4	NA				
MEAN	4.8	5.4	2.9	5.3	6.1	5.4	5.5	6.6	5.9	6.5	5.0	6.3
S.D.	1.77	1.39	3.93	1.72	1.79	1.10	1.29	1.35	1.13	1.67	1.74	1.82
N	15	15	15	15	15	15	14	10	8	8	8	8

NA = NOT APPLICABLE

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: [redacted]250									
84026-03	6.1	6.3	4.9	4.0	4.9	5.5	2.6	6.0	104.6
84023-04	3.7	3.8	6.0	6.5	1.8	6.4	0.8	6.0	91.8
84024-04	4.0	6.0	7.8	2.8	3.6	9.8	2.8	6.6	120.6
84027-04	6.5	8.3	6.6	11.6	6.6	6.0	5.6	5.7	115.6
84025-07	6.1	3.7	4.3	10.2	2.2	3.9	4.0	5.6	112.5
84028-04	7.3	6.2	8.0	4.3	2.5	9.4	4.4	7.5	116.1
84029-07	5.9	9.6	6.0	5.3	4.8	8.0	7.3	0.8	115.5
84034-09	5.6	6.0	3.7	4.8	8.8	3.0	3.0	6.8	100.1
MEAN	5.7	6.2	5.9	6.2	4.4	6.5	3.8	5.6	109.6
S.D.	1.22	2.00	1.56	3.12	2.40	2.44	2.00	2.05	9.82
N	8	8	8	8	8	8	8	8	8

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: [redacted]1000												
84023-08	0.7	4.5	3.5	6.8	5.6	5.0	5.5	7.4	4.6	3.1	6.9	6.7
84026-01	4.3	-1.5	0.8	9.2	6.5	6.1	9.8	6.6	4.2	10.4	4.2	8.7
84025-04	-0.3	0.3	4.4	7.6	4.6	3.4	6.7					
84027-07	-1.8	0.7	3.5	5.8	8.9	4.5	5.3	6.7	5.3	4.0	5.4	6.7
84023-07	4.6	6.8	-6.2	-2.0	6.2	3.9	3.7	7.3				
84024-09	4.7	4.6	4.2	4.2	5.6	4.3	6.0	8.1	5.2	4.5	5.2	7.6
84029-04	-3.7	-1.1	3.5	7.9	4.1	5.4	6.6	3.9	6.4	8.3	5.8	5.4
84028-03	2.3	4.3	5.1	4.1	4.2	5.8	3.9	4.7	5.6	3.3	9.9	5.6
84030-07	3.2	3.4	4.4	4.7	2.8	7.0	4.4	6.1	4.0	3.1	7.7	5.1
84031-03	5.5	-1.0	0.3	9.2	5.9	8.1						
84031-05	7.2	4.7	8.4	4.4	7.4	5.5						
84033-01	NA											
84035-07	NA											
84032-10	1.5	4.4	2.9	4.5	3.3	4.2	4.5	4.6	4.2	5.8	6.0	4.3
84034-06	NA											
MEAN	2.4	2.5	2.9	5.5	5.4	5.3	5.6	6.2	4.9	5.3	6.4	6.3
S.D.	3.20	2.84	3.52	3.05	1.74	1.35	1.80	1.45	0.83	2.71	1.77	1.44
N	12	12	12	12	12	12	10	9	8	8	8	8

NA = NOT APPLICABLE

Revised Audited Draft

Modified: 11/4/2005

TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: [redacted]1000									
84023-08	4.3	6.2	1.3	10.5	3.6	5.1	3.1	8.6	103.0
84026-01	8.2	8.7	4.8	10.3	7.1	3.6	5.9	5.3	123.2
84027-07	5.9	5.4	4.4	9.3	4.5	6.2	4.2	8.3	103.2
84024-09	4.5	1.0	7.2	4.4	5.2	4.9	-3.8	8.9	96.5
84029-04	4.0	7.3	6.7	9.1	0.7	8.6	4.8	2.1	95.8
84028-03	3.6	8.2	4.5	7.6	8.0	5.6	4.3	3.6	104.2
84030-07	6.7	6.4	1.2	4.0	6.5	7.0	4.2	1.0	92.9
84032-10	6.0	3.9	5.4	5.6	5.5	4.5	1.3	8.9	91.3
MEAN	5.4	5.9	4.4	7.6	5.1	5.7	3.0	5.8	101.3
S.D.	1.57	2.50	2.21	2.62	2.28	1.57	3.06	3.28	10.13
N	8	8	8	8	8	8	8	8	8

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-003

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: [redacted]60												
84023-01	5.9	5.7	5.5	5.8	5.4	6.1	7.9	5.0	5.8	6.5	4.5	11.3
84024-05	6.7	4.4	5.7	5.8	5.2	6.4	6.7	7.1	6.6	6.7	5.5	8.4
84025-03	5.8	4.9	4.3	4.1	4.7	5.1	5.6	5.4	5.0	4.2	4.5	6.8
84026-08	7.3	3.8	4.0	6.1	3.7	7.1	3.8	5.6	3.4	5.8	4.2	5.4
84027-10	5.8	5.4	1.4	6.3	2.9	4.2	2.9	6.2	4.7	4.9	2.2	8.2
84026-02	6.2	3.9	4.3	6.3	4.5	4.1	5.4	7.2	4.4	7.1	2.9	8.2
84027-06	4.9	1.9	4.4	4.5	5.8	5.2	6.4	3.8	6.8	5.1	5.6	7.4
84029-08	5.0	5.0	4.5	5.4	3.7	3.4	7.0	7.3				
84030-10	4.1	7.1	6.4	6.0	4.8	4.3	6.8	6.2	6.6	7.7	6.4	5.3
84031-07	5.2	5.7	5.8	6.2	6.9	4.6	7.2	5.3	9.3			
84028-06	4.7	5.8	6.4	5.1	4.9	6.9	3.0	9.4	7.7	4.1	9.3	5.2
84031-10	5.0	4.9	5.1	5.6	5.5	4.9	4.2	5.9	8.2	4.8	8.1	4.1
84030-08	5.3	4.9	5.5	4.3	5.9							
84034-02	6.3	6.4	4.4	7.3	5.5	8.6	4.7	6.6	8.3	9.3	4.3	5.1
84035-04	3.5	5.2	5.3	4.8	5.1	4.6	5.8	7.1	7.2	5.8	5.9	5.3
MEAN	5.4	5.0	4.9	5.6	5.0	5.4	5.5	6.3	6.5	6.0	5.3	6.7
S.D.	0.99	1.22	1.23	0.88	1.00	1.44	1.60	1.34	1.73	1.54	2.01	2.05
N	15	15	15	15	15	14	14	14	13	12	12	12

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-003

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: [redacted]60									
84023-01	6.2	-1.0	6.1	2.6	9.4	2.1	2.0	7.3	110.1
84024-05	7.7	4.3	5.3	8.3	6.2	3.4	9.5	3.2	123.1
84025-03	3.4	5.2	3.8	0.7	5.1	3.7	3.7	1.3	87.3
84026-08	5.5	2.9	4.6	6.1	3.7	2.0	2.6	6.5	94.1
84027-10	3.3	7.0	3.2	2.2	5.8	4.8	6.2	6.1	93.7
84026-02	6.1	4.4	2.6	4.8	4.3	4.0	3.1	0.7	94.5
84027-06	4.4	3.1	6.5	5.8	3.7	0.6	4.0	9.2	99.1
84030-10	6.1	8.9	6.0	8.9	1.2	3.7	6.4	4.4	117.3
84028-06	6.3	5.5	7.9	4.5	3.1	7.6	5.2	2.2	114.8
84031-10	6.4	5.4	8.9	5.6	8.2	11.2	9.7	2.1	123.8
84034-02	5.3	8.4	7.0	4.4	0.6	7.5	5.4	6.7	122.1
84035-04	4.5	7.0	8.9	3.8	4.1	3.1	6.6	9.4	113.0
MEAN	5.4	5.1	5.9	4.8	4.6	4.5	5.4	4.9	107.7
S.D.	1.31	2.70	2.09	2.38	2.56	2.95	2.49	3.02	13.23
N	12	12	12	12	12	12	12	12	12

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-003

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 6: [redacted]250												
84024-08	6.3	4.1	-0.2	6.3	5.2	6.5	4.2	6.3	4.2	5.4	3.9	8.5
84027-08	5.1	6.5	3.3	7.7	4.0	6.8	5.8	6.7	6.9	5.8	5.6	9.7
84025-02	5.8	5.0	1.0	5.0	5.8	5.0	6.7	5.4	4.6	7.3	4.4	8.3
84023-02	4.8	3.8	3.0	5.3	3.4	4.3	4.9	4.8	4.2	5.7	4.1	7.4
84026-10	4.6	4.4	5.3	5.2	4.2	6.3	5.3	6.9	5.0	5.2	5.6	4.4
84023-03	5.3	4.6	NA									
84024-07	3.8	5.4	6.5	6.5	6.6	7.5	2.8	7.8	4.7	5.6	6.7	6.6
84029-02	4.8	5.0	5.7	5.9	5.7	4.4	6.1	6.8	4.8	8.6	1.3	9.8
84030-06	4.5	3.7	4.7	5.6	5.7	4.4	6.6	5.0	6.3	6.3	5.5	5.2
84031-04	5.7	5.2	3.4	5.6	5.5	5.3	7.3	4.9	5.3	5.9	8.7	4.2
84028-09	3.8	6.3	6.3	5.6	5.9	6.3	6.2	5.3	6.4	6.9	9.3	5.2
84028-08	4.8	5.4	5.6	6.5	7.7	5.1	5.8	7.2	7.1	5.6	10.2	4.8
84029-05	3.5	5.7	6.9	4.0	6.4	5.8	4.4	3.5	5.9	6.2	7.0	3.8
84035-01	4.4	5.6	3.6	4.7	5.4	4.5	5.1	7.2	6.4	6.8	5.2	6.2
MEAN	4.8	5.1	4.2	5.7	5.5	5.6	5.5	6.0	5.5	6.3	6.0	6.5
S.D.	0.80	0.86	2.15	0.94	1.14	1.05	1.21	1.25	1.02	0.94	2.44	2.09
N	14	14	13	13	13	13	13	13	13	13	13	13

NA = NOT APPLICABLE

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 6: [redacted]250									
84024-08	4.1	5.0	3.1	5.1	4.3	6.1	8.6	-2.9	94.1
84027-08	4.9	3.9	8.1	3.7	8.5	2.1	5.9	4.8	115.8
84025-02	4.4	3.3	6.2	4.2	4.5	3.5	8.1	6.0	104.5
84023-02	2.4	4.7	5.1	2.4	7.8	3.1	8.1	2.8	92.1
84026-10	5.9	5.2	4.4	3.6	4.0	4.4	4.5	2.6	97.0
84024-07	5.7	5.3	9.0	3.4	7.1	5.7	3.2	9.1	119.0
84029-02	6.1	6.3	7.5	0.9	7.2	7.4	6.0	6.2	116.5
84030-06	5.7	7.4	4.4	4.4	7.1	6.2	3.1	6.2	108.0
84031-04	5.8	6.0	1.9	8.3	4.7	9.3	5.3	-2.6	105.7
84028-09	6.9	6.2	2.2	1.4	7.2	8.4	4.0	1.8	111.6
84028-08	2.0	7.5	5.3	5.2	4.0	3.3	3.6	4.9	111.6
84029-05	4.4	6.2	5.7	6.9	2.9	5.1	4.6	3.3	102.2
84035-01	3.8	7.0	4.8	6.4	1.5	3.9	8.0	3.3	103.8
MEAN	4.8	5.7	5.2	4.3	5.4	5.3	5.6	3.5	106.3
S.D.	1.45	1.28	2.14	2.12	2.15	2.17	2.01	3.39	8.56
N	13	13	13	13	13	13	13	13	13

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 7: [redacted]1000												
84024-03	4.7	6.4	6.6	4.3	6.3	5.9	5.4	7.4	5.7	8.3	4.8	10.6
84023-10	3.8	5.4	0.2	3.0	4.9	5.5	6.7	7.4	3.8	5.9	5.3	7.1
84026-06	6.2	4.1	4.6	4.2	5.6	6.1	4.7	5.1	7.6	6.2	2.1	8.8
84025-01	6.6	4.8	4.9	5.7	6.6	4.8	5.5	6.4	6.1	3.5	7.3	6.7
84027-02	3.6	4.8	4.7	6.3	3.2	4.0	2.6	5.3	4.6	4.7	3.7	4.3
84026-07	2.8	7.9	5.5	5.1	3.8	5.4	7.0	9.2	7.0	6.1	7.0	8.5
84029-06	4.7	5.0	4.7	6.5	3.7	4.2	9.3	4.7	7.4	7.2	9.3	5.4
84028-02	6.7	0.7	4.3	6.6	7.0	5.7	5.1					
84031-09	6.5	5.8	4.9	5.2	6.0	5.4	6.6	6.2	5.3	5.8	7.2	4.5
84030-01	4.8	4.6	6.2	5.1	5.2	4.9	6.8	3.9	6.0	4.4	5.9	8.2
84030-03	5.6	4.8	5.7	4.0	4.4	3.8	5.5	4.8	5.4	4.9	6.6	0.7
84035-05	4.3	6.3	4.6	5.8	5.0	4.5	5.8	5.9	4.3	8.9	5.8	5.6
84032-09	5.3	5.3	5.3	6.3	5.0	4.3	7.4	7.2	8.8	5.6	6.9	5.2
84033-05	1.0	5.7	5.2	6.0	4.4	5.9	5.4	7.7	3.3	9.0	3.8	7.7
84034-10	4.4	4.3	4.2	3.7	4.6	4.5	4.5	5.6	3.5	7.6	2.2	5.3
MEAN	4.7	5.1	4.8	5.2	5.0	5.0	5.9	6.2	5.6	6.3	5.6	6.3
S.D.	1.55	1.55	1.43	1.12	1.10	0.76	1.53	1.44	1.66	1.70	2.06	2.45
N	15	15	15	15	15	15	15	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 7: [redacted]1000									
84024-03	7.0	6.1	5.4	0.9	7.5	6.1	2.9	3.5	115.8
84023-10	5.0	6.1	6.3	4.2	7.9	0.9	6.8	2.7	98.9
84026-06	5.8	3.4	7.1	2.7	9.8	-0.8	3.4	3.1	99.8
84025-01	6.6	3.7	6.7	5.4	6.4	4.6	2.7	5.0	110.0
84027-02	4.7	5.5	7.5	3.1	8.6	0.8	4.7	4.6	91.3
84026-07	6.1	8.0	6.2	3.8	6.0	4.5	6.2	1.2	117.3
84029-06	7.2	6.7	7.9	4.7	6.8	7.5	4.6	4.7	122.2
84031-09	5.6	2.5	6.6	4.3	4.0	6.5	1.5	3.1	103.5
84030-01	1.8	7.5	5.7	2.4	4.9	5.3	4.3	4.0	101.9
84030-03	6.1	7.3	4.1	3.8	2.0	5.8	6.4	1.5	93.2
84035-05	8.1	6.3	6.2	9.1	4.0	8.8	6.1	9.8	125.2
84032-09	7.7	8.1	4.2	8.6	6.2	3.5	2.5	1.0	114.4
84033-05	7.9	7.8	4.8	9.1	6.4	5.8	8.6	4.1	119.6
84034-10	4.9	3.3	3.2	5.4	4.9	4.0	1.8	6.5	88.4
MEAN	6.0	5.9	5.9	4.8	6.1	4.5	4.5	3.9	107.3
S.D.	1.65	1.92	1.37	2.53	2.04	2.69	2.12	2.29	12.11
N	14	14	14	14	14	14	14	14	14

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TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: CORN OIL SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84024-10	32	113.9	N	N	N	N	Y								
84023-06	32	108.4	N	N	N	N	Y								
84025-06	32	108.5	N	N	N	N	Y								
84027-05	37	131.7	N	N	N	N	N	N	N	N	N	Y			
84026-04	38	121.8	N	N	N	N	N	N	N	N	N	N	Y		
84027-03	34	116.1	N	N	N	N	N	N	Y						
84023-05	33	118.7	N	N	N	N	N	Y							
84028-10	34	105.2	N	N	N	N	N	N	Y						
84031-02	36	123.6	N	N	N	N	N	N	N	N	Y				
84029-09	32	110.7	N	N	N	N	Y								
84030-09	RESPONSE NOT EXHIBITED BY DAY 31, DAY OF DEATH														
84031-01	33	120.4	N	N	N	N	N	Y							
84028-05	32	99.9	N	N	N	N	Y								
84034-03	31	103.1	N	N	N	Y									
84035-10	36	118.7	N	N	N	N	N	N	N	N	Y				
MEAN	33.7	114.3													
S.D.	2.20	8.87													
N	14	14													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84024-02	32	117.8	N	N	N	N	Y								
84025-09	32	116.1	N	N	N	N	Y								
84026-05	34	110.8	N	N	N	N	N	N	Y						
84023-09	RESPONSE NOT EXHIBITED BY DAY 32, DAY OF DEATH														
84027-01	32	99.0	N	N	N	N	Y								
84025-05	33	97.4	N	N	N	N	N	Y							
84024-06	34	144.4	N	N	N	N	N	N	Y						
84029-03	32	91.1	N	N	N	N	Y								
84030-04	35	119.6	N	N	N	N	N	N	N	Y					
84031-06	RESPONSE NOT EXHIBITED BY DAY 30, DAY OF DEATH														
84028-01	39	164.6	N	N	N	N	N	N	N	N	N	N	N	Y	
84028-07	33	124.1	N	N	N	N	N	Y							
84029-10	33	115.4	N	N	N	N	N	Y							
84032-01	36	120.8	N	N	N	N	N	N	N	N	Y				
84034-01	33	107.7	N	N	N	N	N	Y							
MEAN	33.7	117.6													
S.D.	2.02	19.56													
N	13	13													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Audited Draft

Modified: 11/4/2005

TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84026-03	32	114.8	N	N	N	N	Y								
84023-04	32	101.7	N	N	N	N	Y								
84024-04	38	153.4	N	N	N	N	N	N	N	N	N	N	Y		
84027-04	34	107.1	N	N	N	N	N	N	Y						
84025-07	34	117.7	N	N	N	N	N	N	Y						
84025-10	RESPONSE NOT EXHIBITED BY DAY 30, DAY OF DEATH														
84026-09	RESPONSE NOT EXHIBITED BY DAY 28, DAY OF DEATH														
84029-01	RESPONSE NOT EXHIBITED BY DAY 29, DAY OF DEATH														
84030-05	RESPONSE NOT EXHIBITED BY DAY 29, DAY OF DEATH														
84031-08	RESPONSE NOT EXHIBITED BY DAY 29, DAY OF DEATH														
84028-04	36	142.3	N	N	N	N	N	N	N	N	Y				
84030-02	RESPONSE NOT EXHIBITED BY DAY 30, DAY OF DEATH														
84029-07	36	126.9	N	N	N	N	N	N	N	N	Y				
84034-09	35	120.8	N	N	N	N	N	N	N	Y					
84032-05	RESPONSE NOT EXHIBITED BY DAY 29, DAY OF DEATH														
MEAN	34.6	123.1													
S.D.	2.07	17.40													
N	8	8													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Audited Draft

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TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84023-08	37	133.7	N	N	N	N	N	N	N	N	N	Y			
84026-01	37	143.6	N	N	N	N	N	N	N	N	N	Y			
84025-04	RESPONSE NOT EXHIBITED BY DAY 29, DAY OF DEATH														
84027-07	40	131.4	N	N	N	N	N	N	N	N	N	N	N	N	Y
84023-07	RESPONSE NOT EXHIBITED BY DAY 30, DAY OF DEATH														
84024-09	32	114.2	N	N	N	N	Y								
84029-04	35	104.8	N	N	N	N	N	N	N	Y					
84028-03	35	116.8	N	N	N	N	N	N	N	Y					
84030-07	33	106.0	N	N	N	N	N	Y							
84031-03	RESPONSE NOT EXHIBITED BY DAY 28, DAY OF DEATH														
84031-05	RESPONSE NOT EXHIBITED BY DAY 28, DAY OF DEATH														
84032-10	35	99.8	N	N	N	N	N	N	N	Y					
MEAN	35.5	118.8													
S.D.	2.51	15.77													
N	8	8													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Audited Draft

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TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84023-01	28	94.8	Y												
84024-05	32	119.6	N	N	N	N	Y								
84025-03	36	121.2	N	N	N	N	N	N	N	N	Y				
84026-08	33	105.5	N	N	N	N	N	Y							
84027-10	32	91.3	N	N	N	N	Y								
84026-02	33	105.9	N	N	N	N	N	Y							
84027-06	32	106.1	N	N	N	N	Y								
84029-08	RESPONSE NOT EXHIBITED BY DAY 30, DAY OF DEATH														
84030-10	35	127.6	N	N	N	N	N	N	N	Y					
84031-07	RESPONSE NOT EXHIBITED BY DAY 31, DAY OF DEATH														
84028-06	33	128.8	N	N	N	N	N	Y							
84031-10	34	122.1	N	N	N	N	N	N	Y						
84030-08	RESPONSE NOT EXHIBITED BY DAY 27, DAY OF DEATH														
84034-02	35	145.0	N	N	N	N	N	N	N	Y					
84035-04	36	126.7	N	N	N	N	N	N	N	N	Y				
MEAN	33.3	116.2													
S.D.	2.22	15.67													
N	12	12													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Audited Draft

Modified: 11/4/2005

TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84024-08	37	133.4	N	N	N	N	N	N	N	N	N	Y			
84027-08	33	121.9	N	N	N	N	N	Y							
84025-02	34	114.6	N	N	N	N	N	N	Y						
84023-02	33	98.9	N	N	N	N	N	Y							
84026-10	33	106.5	N	N	N	N	N	Y							
84024-07	37	141.5	N	N	N	N	N	N	N	N	N	Y			
84029-02	37	134.3	N	N	N	N	N	N	N	N	N	Y			
84030-06	34	115.1	N	N	N	N	N	N	Y						
84031-04	33	116.4	N	N	N	N	N	Y							
84028-09	33	123.9	N	N	N	N	N	Y							
84028-08	33	129.6	N	N	N	N	N	Y							
84029-05	29	83.2	N	Y											
84035-01	32	103.9	N	N	N	N	Y								
MEAN	33.7	117.2													
S.D.	2.25	16.23													
N	13	13													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 18

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:05-003

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 28	29	30	31	32	33	34	35	36	37	38	39	40
84024-03	33	126.9	N	N	N	N	N	Y							
84023-10	33	111.4	N	N	N	N	N	Y							
84026-06	33	107.4	N	N	N	N	N	Y							
84025-01	38	140.7	N	N	N	N	N	N	N	N	N	N	Y		
84027-02	40	131.2	N	N	N	N	N	N	N	N	N	N	N	N	Y
84026-07	32	117.4	N	N	N	N	Y								
84029-06	34	121.9	N	N	N	N	N	N	Y						
84028-02	RESPONSE NOT EXHIBITED BY DAY 29, DAY OF DEATH														
84031-09	32	112.4	N	N	N	N	Y								
84030-01	33	114.3	N	N	N	N	N	Y							
84030-03	37	126.0	N	N	N	N	N	N	N	N	N	Y			
84035-05	34	121.2	N	N	N	N	N	N	Y						
84032-09	37	145.7	N	N	N	N	N	N	N	N	N	Y			
84033-05	32	104.3	N	N	N	N	Y								
84034-10	31	84.4	N	N	N	Y									
MEAN	34.2	118.9													
S.D.	2.69	15.52													
N	14	14													

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

PJTBBv1.14
07/21/2005
R:10/31/2005

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TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-003

FEMALES FROM GROUP 1: CORN OIL

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84024-10	N N N N D D D P E D D D E E D	5.0
84023-06	N N N N M D D D E D D D E M D	4.0
84025-06	N N N N E M D D E D D P E D D	4.0
84027-05	N N N N N N N N N D D D D P E	A
84026-04	N N N N N N N N N N M D D D E	A
84027-03	N N N N N N P E D D D P E D D	5.0
84023-05	N N N N N D D D E D D D D D D	A
84028-10	N N N N N N N D D D D P E D D D	A
84031-02	N N N N N N N N N D D D D P E D	A
84029-09	N N N N N D D D P D M D D E E D	6.0
84030-09	N N N N N	A
84031-01	N N N N N N N D D D D P E D D D P	A
84028-05	N N N N N E D D D D E D D P E E	5.0
84034-03	N N N N N E M D D P E D D P E E D	5.0
84035-10	N N N N N N N N N N D D P E D D P	A
	MEAN	4.9
	S.D.	0.69
	N	7

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

Revised Audited Draft

Modified: 11/4/2005

TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-003

FEMALES FROM GROUP 2: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84024-02	N N N N D D D P E D D D P E D	5.0
84025-09	N N N N E D D D D P E D D D D	6.0
84026-05	N N N N N N E D D D D P E D D	6.0
84023-09	N N N N N	A
84027-01	N N N N E	A
84025-05	N N N N N D D D E E D D D P	A
84024-06	N N N N N N M D D D E D D D D	A
84029-03	N N N N N E D D D P E D D P E D	4.5
84030-04	N N N N N N N N E D D D P E D D	5.0
84031-06	N N N N	A
84028-01	N N N N N N N N N N N N D D D D	A
84028-07	N N N N N N D D D P E D D P E E	A
84029-10	N N N N N N E D D D D E M D D E	5.0
84032-01	N N N N N N N N N N D D D P E M D D	A
84034-01	N N N N N N N D D D P E D D D E D	4.0
	MEAN	5.1
	S.D.	0.73
	N	7

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
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N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-003

FEMALES FROM GROUP 3: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84026-03	N N N N E M D D D D D D E D	9.0
84023-04	N N N N D D P E D D D D E D D	5.0
84024-04	N N N N N N N N N N D D E D D	A
84027-04	N N N N N N E D D D D D D D D	A
84025-07	N N N N N N D D P E M D D E D	4.0
84025-10	N N N	A
84026-09	N	A
84029-01	N N N	A
84030-05	N N N	A
84031-08	N N N	A
84028-04	N N N N N N N N N D P E D D D P	A
84030-02	N N N N	A
84029-07	N N N N N N N N N D D D E D D D	A
84034-09	N N N N N N N N N D D D D P E E D	A
84032-05	N N N N N	A
	MEAN	6.0
	S.D.	2.65
	N	3

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 4: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84023-08	N N N N N N N N N E D D D D D	A
84026-01	N N N N N N N N N E M D D P E	A
84025-04	N N	A
84027-07	N N N N N N N N N N N N P E D	A
84023-07	N N N	A
84024-09	N N N N D D D P E D D D E E D	5.0
84029-04	N N N N N N N N D D D D E E D D	A
84028-03	N N N N N N N N E D D D D D D D	A
84030-07	N N N N N N D D D P E D D D P E	A
84031-03	N N	A
84031-05	N N	A
84033-01		A
84035-07		A
84032-10	N N N N N N N N N M D D E D D D D	A
84034-06		A
	MEAN	5.0
	S.D.	0.00
	N	1

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-003

FEMALES FROM GROUP 5: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84023-01	E D P E M D D D E D D D P E D	4.3
84024-05	N N N N E M D D D D D D D D D	A
84025-03	N N N N N N N N D P E D D D E	A
84026-08	N N N N N D D P E M D D P E D	5.0
84027-10	N N N N E M D D D P E D D D P	6.0
84026-02	N N N N N D D D P E D D D P E	A
84027-06	N N N N D D D D E D D D P E D	5.0
84029-08	N N N N	A
84030-10	N N N N N N N N E D D D P E D D	5.0
84031-07	N N N N N	A
84028-06	N N N N N N N D D D D D E D D D E	A
84031-10	N N N N N N N N E D D D D D D D D	A
84030-08	N	A
84034-02	N N N N N N N N N M D D D E D D P	A
84035-04	N N N N N N N N N N E D D D P E D	5.0
	MEAN	5.1
	S.D.	0.53
	N	6

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-003

FEMALES FROM GROUP 6: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84024-08	N N N N N N N N E D D D D E	A
84027-08	N N N N N D D P E D D D D E D	5.0
84025-02	N N N N N N D D E D D D E D D	4.0
84023-02	N N N N N E M D D D E D D D E	5.0
84026-10	N N N N N E D D D P E D D D P	5.0
84023-03		A
84024-07	N N N N N N N N N D D P E D D	A
84029-02	N N N N N N N N N N D E D D D D	A
84030-06	N N N N N N N D D D P E D D D D	A
84031-04	N N N N N N N D D D D E D D D E	A
84028-09	N N N N N N D D D D D E D D D E	A
84028-08	N N N N N N D D D E D D D P E D	5.0
84029-05	N N D D D D D P E D D D D E D D	5.0
84034-08		A
84035-01	N N N N N N D D P E D D D P E D D	5.0
	MEAN	4.9
	S.D.	0.38
	N	7

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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TABLE 19

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:05-003

FEMALES FROM GROUP 7: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
84024-03	N N N N N E M D D D E D D D D	5.0
84023-10	N N N N N D P E D D D P E D D	5.0
84026-06	N N N N N D D D E M D D D E D	5.0
84025-01	N N N N N N N N N N D D D E D	A
84027-02	N N N N N N N N N N N D D D	A
84026-07	N N N N E D D D D P E D D D E	6.0
84029-06	N N N N N N N D D D P E D D D P	A
84028-02	N N N	A
84031-09	N N N N N P D D P E D D D D E D	4.5
84030-01	N N N N N N E D D D D D E D D D	6.0
84030-03	N N N N N N N N N N D D D D P E	A
84035-05	N N N N N N N N D D D D P E D D P	A
84032-09	N N N N N N N N N N E D D D E E	A
84033-05	N N N N N N D D D D D D D D D D	A
84034-10	N N N N N D D D D D D E D D P E D	4.0
	MEAN	5.1
	S.D.	0.73
	N	7

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

PCYCv5.23
07/21/2005
R:07/21/2005

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TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP:	CORN OIL	FEMALES
84024-10	2.30	6.1
84023-06	3.30	6.3
84025-06	3.30	9.6
84027-05	4.90	7.1
84026-04	6.30	6.3
84027-03	4.80	6.4
84023-05	5.10	5.8
84028-10	3.60	8.4
84031-02	4.20	7.6
84029-09	3.70	10.3
84031-01	4.10	10.2
84028-05	4.60	8.0
84034-03	2.80	9.8
84035-10	3.80	6.1
MEAN	4.06	7.7
S.D.	1.035	1.67
N	14	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]60	FEMALES	
84024-02	3.40	6.8
84025-09	5.60	8.2
84026-05	3.30	7.1
84025-05	5.10	10.1
84024-06	5.50	16.2
84029-03	2.30	6.3
84030-04	2.50	8.0
84028-01	5.00	8.6
84028-07	4.50	12.0
84029-10	5.30	5.1
84032-01	4.70	7.0
84034-01	4.00	11.5
MEAN	4.27	8.9
S.D.	1.152	3.09
N	12	12

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]250	FEMALES	
84026-03	4.00	9.4
84023-04	3.80	9.5
84024-04	5.20	5.1
84027-04	3.90	8.4
84025-07	4.20	11.0
84028-04	3.80	7.0
84029-07	5.00	8.1
84034-09	3.60	5.6
MEAN	4.19	8.0
S.D.	0.591	2.02
N	8	8

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

Revised Audited Draft

Modified: 11/4/2005

TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]1000	FEMALES	
84023-08	4.60	6.6
84026-01	3.10	12.9
84027-07	2.60	8.1
84024-09	2.60	7.3
84029-04	2.50	8.3
84028-03	3.20	9.4
84030-07	2.90	15.8
84032-10	2.40	5.6
MEAN	2.99	9.3
S.D.	0.712	3.44
N	8	8

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]60	FEMALES	
84023-01	4.30	6.7
84024-05	3.80	6.3
84025-03	6.10	6.5
84026-08	5.10	5.6
84027-10	6.40	8.0
84026-02	6.90	5.3
84027-06	3.60	6.5
84030-10	2.80	7.5
84028-06	5.30	6.2
84031-10	5.40	6.8
84034-02	5.20	6.6
84035-04	3.10	8.3
MEAN	4.83	6.7
S.D.	1.317	0.88
N	12	12

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]250	FEMALES	
84024-08	4.80	8.8
84027-08	3.10	6.5
84025-02	3.50	6.2
84023-02	6.10	11.7
84026-10	5.80	6.0
84024-07	3.60	6.3
84029-02	4.70	8.7
84030-06	4.40	7.5
84031-04	4.50	8.7
84028-09	3.30	7.5
84028-08	3.90	11.0
84029-05	3.20	8.7
84035-01	2.80	6.3
MEAN	4.13	8.0
S.D.	1.031	1.84
N	13	13

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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Modified: 11/4/2005

TABLE 20

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:05-003

ANIMAL	TOTAL T4	TSH
	uG/dL	ng/ml
GROUP: [redacted]1000	FEMALES	
84024-03	4.40	9.3
84023-10	3.20	8.3
84026-06	2.30	5.7
84025-01	3.90	10.6
84027-02	5.00	5.6
84026-07	4.80	8.3
84029-06	3.70	9.3
84031-09	2.70	10.5
84030-01	4.40	8.1
84030-03	5.20	7.4
84035-05	4.00	7.3
84032-09	3.40	9.0
84033-05	5.90	6.8
84034-10	4.80	7.8
MEAN	4.12	8.1
S.D.	1.005	1.54
N	14	14

uG/dL = MICROGRAMS/DECILITER, ng/ml = NANOGRAMS/MILLILITER

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84030-09 GROUP 1: CORN OIL FEMALE FOUND DEAD 06/10/05 DATE OF DEATH: 06/10/05

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84023-09 GROUP 2: [redacted]60 FEMALE FOUND DEAD 06/10/05 DATE OF DEATH: 06/10/05

			GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		
	ADRENAL GLANDS	BRAIN	ESOPHAGUS
	HEART	INTESTINE	KIDNEYS
	LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS
	PANCREAS	PITUITARY	SPINAL CORD
	SKIN	SPLEEN	STOMACH
	THYROID GLANDS	TRACHEA	URINARY BLADDER
	CERVIX	VAGINA	

EYES
LIVER
OVARIES
SAL. GLAND MAND
THYMUS
UTERUS

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TABLE 21 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84027-01 GROUP 2: [redacted]60 FEMALE FOUND DEAD 06/10/05 DATE OF DEATH: 06/10/05

		GRADE
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84031-06 GROUP 2: [redacted]60 FEMALE FOUND DEAD 06/09/05 DATE OF DEATH: 06/09/05

			GRADE
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		
	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
	HEART	INTESTINE	KIDNEYS	LIVER
	LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
	PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
	SKIN	SPLEEN	STOMACH	THYMUS
	THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
	CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-003

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84025-10 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84026-09 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/06/05 DATE OF DEATH: 06/06/05

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84029-01 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

		GRADE
KIDNEYS	GROSS: CYST(S) MULTIPLE, PINPOINT, BILATERAL	P
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES	P
SKELETAL MUSCLE	GROSS: DISCOLORATION, DARK RED DORSAL TO THYROID GLAND, BILATERAL	P

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES, HEART, INTESTINE, LIVER, LYMPH NODE, MES, MAMMARY GLAND, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN, STOMACH, THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84030-05 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

		GRADE
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES	P
SKELETAL MUSCLE	GROSS: DISCOLORATION, DARK RED AT APPROXIMATE LEVEL OF THORACIC VERTEBRAE #1 THROUGH #3	P

NO SIGNIFICANT CHANGES OBSERVED GROSS:

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84031-08 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

		GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPINAL CORD
SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84030-02 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/09/05 DATE OF DEATH: 06/09/05

			GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84032-05 GROUP 3: [redacted]250 FEMALE FOUND DEAD 06/10/05 DATE OF DEATH: 06/10/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-003

ANIMAL NO.84025-04 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/07/05 DATE OF DEATH: 06/07/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84023-07 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

		GRADE
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES, HEART, INTESTINE, KIDNEYS, LIVER, LYMPH NODE, MES, MAMMARY GLAND, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN, STOMACH, THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER, UTERUS, CERVIX, VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Audited Draft

Modified: 11/4/2005

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84031-03 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/07/05 DATE OF DEATH: 06/07/05

			GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		
	ADRENAL GLANDS	BRAIN	ESOPHAGUS
	EYES	HEART	INTESTINE
	KIDNEYS	LIVER	LYMPH NODE, MES
	MAMMARY GLAND	OVARIES	OVIDUCTS
	PANCREAS	PITUITARY	SAL. GLAND MAND
	SPINAL CORD	SKIN	SPLEEN
	STOMACH	THYMUS	THYROID GLANDS
	TRACHEA	UTERUS	URINARY BLADDER
	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84031-05 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/07/05 DATE OF DEATH: 06/07/05

		GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES	P
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES	P
SKIN	GROSS: MATTING, CLEAR BUCCAL; NASAL	P
TRACHEA	GROSS: CONTENTS, CLEAR FLUID	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SPLEEN	STOMACH	THYMUS	THYROID GLANDS
URINARY BLADDER	UTERUS	CERVIX	VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84033-01 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/03/05 DATE OF DEATH: 06/03/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84035-07 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/03/05 DATE OF DEATH: 06/03/05

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84034-06 GROUP 4: [redacted]1000 FEMALE FOUND DEAD 06/03/05 DATE OF DEATH: 06/03/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84029-08 GROUP 5: [redacted]60 FEMALE FOUND DEAD 06/09/05 DATE OF DEATH: 06/09/05

		GRADE
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES	P
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES	P

NO SIGNIFICANT CHANGES OBSERVED GROSS:

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Audited Draft

Modified: 11/4/2005

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84031-07 GROUP 5: [redacted]60 FEMALE FOUND DEAD 06/10/05 DATE OF DEATH: 06/10/05

			GRADE
LUNGS	GROSS: DISCOLORATION, DARK RED ALL LOBES		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		
	ADRENAL GLANDS	BRAIN	ESOPHAGUS
	EYES	HEART	INTESTINE
	KIDNEYS	LIVER	LYMPH NODE, MES
	MAMMARY GLAND	OVIDUCTS	OVARIES
	PANCREAS	PITUITARY	SAL. GLAND MAND
	SPINAL CORD	SPLEEN	STOMACH
	THYMUS	THYROID GLANDS	TRACHEA
	URINARY BLADDER	CERVIX	UTERUS
	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84030-08 GROUP 5: [redacted]60 FEMALE FOUND DEAD 06/06/05 DATE OF DEATH: 06/06/05

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84023-03 GROUP 6: [redacted]250 FEMALE FOUND DEAD 06/03/05 DATE OF DEATH: 06/03/05

					GRADE
GENERAL COMMENT	GROSS: CANNIBALIZED				P
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES	
	HEART	INTESTINE	KIDNEYS	LIVER	
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS	
	OVARIES	PANCREAS	PITUITARY	SPINAL CORD	
	SAL. GLAND MAND	SKIN	SPLEEN	STOMACH	
	THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER	
	UTERUS	CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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Modified: 11/4/2005

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:05-003

ANIMAL NO.84034-08 GROUP 6: [redacted]250 FEMALE FOUND DEAD 06/02/05 DATE OF DEATH: 06/02/05

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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Modified: 11/4/2005

TABLE 21 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.84028-02 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 06/08/05 DATE OF DEATH: 06/08/05

			GRADE
LUNGS	GROSS: NOT FULLY COLLAPSED ALL LOBES		P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.52
11/04/2005

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TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-10	150.	0.2353	0.2111	0.0242	7.3220	1.5043	0.0935	0.0447	0.0093	0.0136
84023-06	159.	0.3127	0.2947	0.0180	8.2218	1.7574	0.0744	0.0496	0.0114	0.0172
84025-06	175.	0.2897	0.2756	0.0141	9.2219	1.7946	0.0806	0.0374	0.0105	0.0188
84027-05	153.	0.3345	0.3162	0.0183	7.8060	1.6166	0.0781	0.0333	0.0094	0.0141
84026-04	133.	0.2523	0.2357	0.0166	6.4417	1.3302	0.0730	0.0408	0.0067	0.0128
84027-03	158.	0.2882	0.2717	0.0165	7.4705	1.5214	0.0870	0.0360	0.0102	0.0212
84023-05	184.	0.2639	0.2410	0.0229	9.3661	1.8380	0.0771	0.0434	0.0088	0.0207
84028-10	156.	0.2842	0.2485	0.0357	8.8196	1.6154	0.0718	0.0403	0.0084	0.0168
84031-02	151.	0.1945	0.1789	0.0156	8.0067	1.6012	0.0782	0.0350	0.0084	0.0133
84029-09	166.	0.2788	0.2467	0.0321	7.9553	1.6014	0.0985	0.0462	0.0096	0.0159
84031-01	169.	0.6674	0.4598	0.2076	7.8286	1.6620	0.0758	0.0403	0.0089	0.0134
84028-05	137.	0.3350	0.3028	0.0322	6.4228	1.6389	0.0946	0.0467	0.0109	0.0183
84034-03	166.	0.2796	0.2404	0.0392	9.2766	1.7786	0.0921	0.0507	0.0094	0.0135
84035-10	144.	0.3687	0.3453	0.0234	6.8393	1.4712	0.0859	0.0374	0.0072	0.0115
MEAN	157.	0.3132	0.2763	0.0369	7.9285	1.6237	0.0829	0.0416	0.0092	0.0158
S.D.	14.2	0.11097	0.06831	0.04980	0.98880	0.13976	0.00891	0.00548	0.00131	0.00309
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

187044 RAD

Revised Audited Draft

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TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-02	158.	0.2560	0.2264	0.0296	7.6941	1.7362	0.0859	0.0419	0.0103	0.0155
84025-09	176.	0.6666	0.4664	0.2002	9.6085	1.8650	0.0962	0.0426	0.0112	0.0173
84026-05	134.	0.1998	0.1745	0.0253	6.7306	1.4439	0.0876	0.0376	0.0059	0.0109
84025-05	121.	0.6293	0.3883	0.2410	5.7238	1.4906	0.0777	0.0503	0.0085	0.0092
84024-06	193.	0.8844	0.4434	0.4410	9.8478	1.7458	0.0920	0.0479	0.0090	0.0184
84029-03	147.	0.2473	0.2350	0.0123	7.5255	1.7416	0.0863	0.0351	0.0091	0.0155
84030-04	156.	0.2653	0.2288	0.0365	8.2506	1.5462	0.0804	0.0375	0.0098	0.0166
84028-01	179.	0.2720	0.2542	0.0178	10.0290	1.9691	0.0959	0.0465	0.0112	0.0147
84028-07	171.	1.4621	0.3822	1.0799	9.5021	1.8170	0.0903	0.0471	0.0100	0.0136
84029-10	169.	0.3841	0.3692	0.0149	8.1587	1.7853	0.1072	0.0466	0.0111	0.0177
84032-01	147.	0.4127	0.3698	0.0429	7.5869	1.5902	0.0791	0.0415	0.0076	0.0145
84034-01	155.	0.2588	0.2435	0.0153	8.4991	1.6755	0.1269	0.0460	0.0097	0.0147
MEAN	159.	0.4949	0.3151	0.1797	8.2631	1.7005	0.0921	0.0434	0.0095	0.0149
S.D.	20.2	0.37141	0.09792	0.31288	1.31989	0.15710	0.01375	0.00479	0.00158	0.00269
N	12	12	12	12	12	12	12	12	12	12

FBW = FINAL BODY WEIGHT

Revised Audited Draft

Modified: 11/4/2005

TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84026-03	166.	0.2236	0.2083	0.0153	8.3111	1.8007	0.1011	0.0501	0.0080	0.0156
84023-04	145.	0.2763	0.2619	0.0144	8.0024	1.4469	0.0772	0.0374	0.0068	0.0182
84024-04	174.	0.2901	0.2796	0.0105	8.9450	1.8037	0.0924	0.0437	0.0096	0.0207
84027-04	164.	0.2152	0.2040	0.0112	8.7968	1.6185	0.0741	0.0321	0.0075	0.0158
84025-07	158.	0.2479	0.2357	0.0122	8.3411	1.7492	0.0924	0.0415	0.0087	0.0187
84028-04	174.	0.4324	0.3781	0.0543	8.1618	1.7057	0.0986	0.0502	0.0093	0.0160
84029-07	162.	0.4704	0.3769	0.0935	9.4861	1.7425	0.0859	0.0427	0.0079	0.0183
84034-09	156.	0.2245	0.1993	0.0252	8.8995	1.5652	0.0779	0.0496	0.0082	0.0142
MEAN	162.	0.2976	0.2680	0.0296	8.6180	1.6791	0.0875	0.0434	0.0083	0.0172
S.D.	9.6	0.09901	0.07327	0.02965	0.49709	0.12565	0.01026	0.00652	0.00092	0.00213
N	8	8	8	8	8	8	8	8	8	8

FBW = FINAL BODY WEIGHT

187044 RAD

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TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G}
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84023-08	158.	0.2771	0.2159	0.0612	8.8548	1.6341	0.0671	0.0346	0.0080	0.0152
84026-01	175.	0.3208	0.2882	0.0326	10.1105	1.8244	0.0961	0.0494	0.0112	0.0166
84027-07	147.	0.2195	0.1944	0.0251	8.4997	1.6183	0.0830	0.0397	0.0075	0.0154
84024-09	159.	0.2623	0.2328	0.0295	8.6388	1.7736	0.0976	0.0618	0.0109	0.0151
84029-04	144.	0.2299	0.2147	0.0152	8.2103	1.7140	0.0751	0.0287	0.0068	0.0156
84028-03	156.	0.1724	0.1705	0.0019	9.0064	1.4965	0.0646	0.0411	0.0073	0.0159
84030-07	147.	0.3667	0.3370	0.0297	8.4567	1.4593	0.0936	0.0470	0.0081	0.0180
84032-10	134.	0.2248	0.2014	0.0234	7.8837	1.4409	0.0778	0.0393	0.0060	0.0163
MEAN	153.	0.2592	0.2319	0.0273	8.7076	1.6201	0.0819	0.0427	0.0082	0.0160
S.D.	12.3	0.06191	0.05461	0.01690	0.66720	0.14519	0.01292	0.01009	0.00187	0.00096
N	8	8	8	8	8	8	8	8	8	8

FBW = FINAL BODY WEIGHT

Revised Audited Draft

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TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84023-01	170.	0.3037	0.2856	0.0181	9.3354	2.0495	0.0984	0.0458	0.0092	0.0197
84024-05	181.	0.4974	0.4342	0.0632	10.0753	1.8542	0.0828	0.0507	0.0087	0.0174
84025-03	139.	0.3045	0.2814	0.0231	7.0666	1.4614	0.0851	0.0449	0.0098	0.0167
84026-08	142.	0.2387	0.2245	0.0142	6.9159	1.5138	0.0787	0.0397	0.0085	0.0185
84027-10	140.	0.6938	0.3774	0.3164	6.9791	1.4830	0.0843	0.0514	0.0076	0.0158
84026-02	144.	0.2976	0.2637	0.0339	6.8833	1.3566	0.0892	0.0445	0.0080	0.0141
84027-06	155.	0.2908	0.2553	0.0355	8.5585	1.5510	0.1074	0.0443	0.0088	0.0150
84030-10	168.	0.2668	0.2324	0.0344	9.5493	1.7481	0.0820	0.0487	0.0108	0.0175
84028-06	176.	0.4232	0.3844	0.0388	9.2831	1.7454	0.1028	0.0524	0.0089	0.0185
84031-10	178.	0.2390	0.2216	0.0174	9.7729	1.9261	0.0835	0.0440	0.0095	0.0165
84034-02	184.	0.3159	0.2825	0.0334	9.2005	1.8151	0.1012	0.0497	0.0106	0.0149
84035-04	163.	0.2324	0.2086	0.0238	9.0010	1.6577	0.1067	0.0467	0.0114	0.0155
MEAN	162.	0.3420	0.2876	0.0544	8.5517	1.6802	0.0918	0.0469	0.0093	0.0167
S.D.	17.0	0.13538	0.07276	0.08356	1.23280	0.21118	0.01063	0.00374	0.00115	0.00170
N	12	12	12	12	12	12	12	12	12	12

FBW = FINAL BODY WEIGHT

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TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-08	155.	0.3448	0.3103	0.0345	8.0629	1.6121	0.1009	0.0541	0.0111	0.0155
84027-08	170.	0.3016	0.2875	0.0141	8.8918	1.8539	0.0986	0.0409	0.0097	0.0173
84025-02	154.	0.2883	0.2681	0.0202	8.0989	1.6203	0.0837	0.0452	0.0093	0.0169
84023-02	141.	0.3338	0.2990	0.0348	6.8667	1.4263	0.0819	0.0530	0.0083	0.0138
84026-10	143.	0.6091	0.4504	0.1587	7.6650	1.6929	0.0848	0.0414	0.0101	0.0172
84024-07	171.	0.2756	0.2563	0.0193	8.4961	1.7483	0.0813	0.0404	0.0096	0.0140
84029-02	163.	0.2851	0.2660	0.0191	8.7472	1.5872	0.0775	0.0414	0.0095	0.0183
84030-06	161.	0.8346	0.4147	0.4199	8.6348	1.8502	0.0811	0.0455	0.0093	0.0189
84031-04	159.	0.3489	0.3165	0.0324	8.4993	1.5501	0.1005	0.0454	0.0114	0.0161
84028-09	169.	0.8457	0.4128	0.4329	8.6376	1.7661	0.0925	0.0455	0.0102	0.0171
84028-08	171.	0.2671	0.2278	0.0393	9.5188	1.9469	0.1194	0.0496	0.0112	0.0187
84029-05	149.	0.2902	0.2477	0.0425	6.9641	1.5764	0.0891	0.0420	0.0109	0.0159
84035-01	154.	0.2971	0.2760	0.0211	7.9436	1.5388	0.0909	0.0403	0.0085	0.0116
MEAN	158.	0.4094	0.3102	0.0991	8.2328	1.6746	0.0909	0.0450	0.0099	0.0163
S.D.	10.3	0.21041	0.07088	0.14992	0.74984	0.15028	0.01157	0.00469	0.00100	0.00212
N	13	13	13	13	13	13	13	13	13	13

FBW = FINAL BODY WEIGHT

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TABLE 22

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G}
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-03	175.	0.4864	0.4209	0.0655	9.5827	1.9767	0.0991	0.0481	0.0113	0.0163
84023-10	156.	0.3174	0.2848	0.0326	8.2180	1.6795	0.0812	0.0456	0.0094	0.0165
84026-06	150.	0.3071	0.2759	0.0312	8.4388	1.5997	0.0929	0.0421	0.0086	0.0165
84025-01	158.	0.2526	0.2153	0.0373	7.9805	1.6664	0.0957	0.0415	0.0083	0.0123
84027-02	138.	0.1853	0.1631	0.0222	6.5181	1.3950	0.0564	0.0392	0.0070	0.0124
84026-07	174.	0.3265	0.2944	0.0321	9.1736	1.8194	0.1164	0.0510	0.0101	0.0206
84029-06	172.	0.7181	0.4221	0.2960	9.8485	1.8073	0.1037	0.0504	0.0115	0.0177
84031-09	157.	0.2417	0.2116	0.0301	8.2865	1.7446	0.0961	0.0402	0.0099	0.0191
84030-01	158.	0.3353	0.3163	0.0190	7.4659	1.7819	0.0822	0.0443	0.0088	0.0196
84030-03	144.	0.2900	0.2690	0.0210	7.0461	1.4213	0.0780	0.0415	0.0069	0.0137
84035-05	178.	0.3760	0.3013	0.0747	10.7342	1.8222	0.1007	0.0497	0.0089	0.0146
84032-09	166.	1.4259	0.3778	1.0481	9.5064	1.7539	0.0949	0.0521	0.0104	0.0172
84033-05	170.	0.3989	0.3596	0.0393	9.1582	1.7227	0.0776	0.0450	0.0101	0.0195
84034-10	132.	0.2576	0.2396	0.0180	7.0067	1.3828	0.0786	0.0346	0.0089	0.0151
MEAN	159.	0.4228	0.2966	0.1262	8.4974	1.6838	0.0895	0.0447	0.0093	0.0165
S.D.	14.3	0.31680	0.07766	0.27477	1.22857	0.17730	0.01487	0.00515	0.00138	0.00266
N	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

POFBWv4.14
07/21/2005
R:10/31/2005

Revised Audited Draft

Modified: 11/4/2005

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-003

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-10	150.	0.157	0.141	4.881	1.003	0.062	0.030	0.006	0.009
84023-06	159.	0.197	0.185	5.171	1.105	0.047	0.031	0.007	0.011
84025-06	175.	0.166	0.157	5.270	1.025	0.046	0.021	0.006	0.011
84027-05	153.	0.219	0.207	5.102	1.057	0.051	0.022	0.006	0.009
84026-04	133.	0.190	0.177	4.843	1.000	0.055	0.031	0.005	0.010
84027-03	158.	0.182	0.172	4.728	0.963	0.055	0.023	0.006	0.013
84023-05	184.	0.143	0.131	5.090	0.999	0.042	0.024	0.005	0.011
84028-10	156.	0.182	0.159	5.654	1.036	0.046	0.026	0.005	0.011
84031-02	151.	0.129	0.118	5.302	1.060	0.052	0.023	0.006	0.009
84029-09	166.	0.168	0.149	4.792	0.965	0.059	0.028	0.006	0.010
84031-01	169.	0.395	0.272	4.632	0.983	0.045	0.024	0.005	0.008
84028-05	137.	0.245	0.221	4.688	1.196	0.069	0.034	0.008	0.013
84034-03	166.	0.168	0.145	5.588	1.071	0.055	0.031	0.006	0.008
84035-10	144.	0.256	0.240	4.750	1.022	0.060	0.026	0.005	0.008
MEAN	157.	0.200	0.177	5.035	1.035	0.053	0.027	0.006	0.010
S.D.	14.2	0.0666	0.0442	0.3304	0.0619	0.0076	0.0041	0.0009	0.0017
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

Revised Audited Draft

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-02	158.	0.162	0.143	4.870	1.099	0.054	0.027	0.007	0.010
84025-09	176.	0.379	0.265	5.459	1.060	0.055	0.024	0.006	0.010
84026-05	134.	0.149	0.130	5.023	1.078	0.065	0.028	0.004	0.008
84025-05	121.	0.520	0.321	4.730	1.232	0.064	0.042	0.007	0.008
84024-06	193.	0.458	0.230	5.102	0.905	0.048	0.025	0.005	0.010
84029-03	147.	0.168	0.160	5.119	1.185	0.059	0.024	0.006	0.011
84030-04	156.	0.170	0.147	5.289	0.991	0.052	0.024	0.006	0.011
84028-01	179.	0.152	0.142	5.603	1.100	0.054	0.026	0.006	0.008
84028-07	171.	0.855	0.224	5.557	1.063	0.053	0.028	0.006	0.008
84029-10	169.	0.227	0.218	4.828	1.056	0.063	0.028	0.007	0.010
84032-01	147.	0.281	0.252	5.161	1.082	0.054	0.028	0.005	0.010
84034-01	155.	0.167	0.157	5.483	1.081	0.082	0.030	0.006	0.009
MEAN	159.	0.307	0.199	5.185	1.078	0.059	0.028	0.006	0.009
S.D.	20.2	0.2150	0.0611	0.2954	0.0824	0.0090	0.0049	0.0009	0.0012
N	12	12	12	12	12	12	12	12	12

FBW = FINAL BODY WEIGHT

Revised Audited Draft

Modified: 11/4/2005

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84026-03	166.	0.135	0.125	5.007	1.085	0.061	0.030	0.005	0.009
84023-04	145.	0.191	0.181	5.519	0.998	0.053	0.026	0.005	0.013
84024-04	174.	0.167	0.161	5.141	1.037	0.053	0.025	0.006	0.012
84027-04	164.	0.131	0.124	5.364	0.987	0.045	0.020	0.005	0.010
84025-07	158.	0.157	0.149	5.279	1.107	0.058	0.026	0.006	0.012
84028-04	174.	0.249	0.217	4.691	0.980	0.057	0.029	0.005	0.009
84029-07	162.	0.290	0.233	5.856	1.076	0.053	0.026	0.005	0.011
84034-09	156.	0.144	0.128	5.705	1.003	0.050	0.032	0.005	0.009
MEAN	162.	0.183	0.165	5.320	1.034	0.054	0.027	0.005	0.011
S.D.	9.6	0.0577	0.0423	0.3788	0.0494	0.0050	0.0037	0.0005	0.0016
N	8	8	8	8	8	8	8	8	8

FBW = FINAL BODY WEIGHT

Revised Audited Draft

Modified: 11/4/2005

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84023-08	158.	0.175	0.137	5.604	1.034	0.042	0.022	0.005	0.010
84026-01	175.	0.183	0.165	5.777	1.043	0.055	0.028	0.006	0.009
84027-07	147.	0.149	0.132	5.782	1.101	0.056	0.027	0.005	0.010
84024-09	159.	0.165	0.146	5.433	1.115	0.061	0.039	0.007	0.009
84029-04	144.	0.160	0.149	5.702	1.190	0.052	0.020	0.005	0.011
84028-03	156.	0.111	0.109	5.773	0.959	0.041	0.026	0.005	0.010
84030-07	147.	0.249	0.229	5.753	0.993	0.064	0.032	0.006	0.012
84032-10	134.	0.168	0.150	5.883	1.075	0.058	0.029	0.004	0.012
MEAN	153.	0.170	0.152	5.713	1.064	0.054	0.028	0.005	0.010
S.D.	12.3	0.0387	0.0351	0.1380	0.0731	0.0083	0.0059	0.0009	0.0012
N	8	8	8	8	8	8	8	8	8

FBW = FINAL BODY WEIGHT

Revised Audited Draft

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84023-01	170.	0.179	0.168	5.491	1.206	0.058	0.027	0.005	0.012
84024-05	181.	0.275	0.240	5.566	1.024	0.046	0.028	0.005	0.010
84025-03	139.	0.219	0.202	5.084	1.051	0.061	0.032	0.007	0.012
84026-08	142.	0.168	0.158	4.870	1.066	0.055	0.028	0.006	0.013
84027-10	140.	0.496	0.270	4.985	1.059	0.060	0.037	0.005	0.011
84026-02	144.	0.207	0.183	4.780	0.942	0.062	0.031	0.006	0.010
84027-06	155.	0.188	0.165	5.522	1.001	0.069	0.029	0.006	0.010
84030-10	168.	0.159	0.138	5.684	1.041	0.049	0.029	0.006	0.010
84028-06	176.	0.240	0.218	5.274	0.992	0.058	0.030	0.005	0.011
84031-10	178.	0.134	0.124	5.490	1.082	0.047	0.025	0.005	0.009
84034-02	184.	0.172	0.154	5.000	0.986	0.055	0.027	0.006	0.008
84035-04	163.	0.143	0.128	5.522	1.017	0.065	0.029	0.007	0.010
MEAN	162.	0.215	0.179	5.272	1.039	0.057	0.029	0.006	0.011
S.D.	17.0	0.0973	0.0455	0.3122	0.0658	0.0071	0.0031	0.0008	0.0014
N	12	12	12	12	12	12	12	12	12

FBW = FINAL BODY WEIGHT

Revised Audited Draft

Modified: 11/4/2005

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:05-003

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-08	155.	0.222	0.200	5.202	1.040	0.065	0.035	0.007	0.010
84027-08	170.	0.177	0.169	5.230	1.091	0.058	0.024	0.006	0.010
84025-02	154.	0.187	0.174	5.259	1.052	0.054	0.029	0.006	0.011
84023-02	141.	0.237	0.212	4.870	1.012	0.058	0.038	0.006	0.010
84026-10	143.	0.426	0.315	5.360	1.184	0.059	0.029	0.007	0.012
84024-07	171.	0.161	0.150	4.968	1.022	0.048	0.024	0.006	0.008
84029-02	163.	0.175	0.163	5.366	0.974	0.048	0.025	0.006	0.011
84030-06	161.	0.518	0.258	5.363	1.149	0.050	0.028	0.006	0.012
84031-04	159.	0.219	0.199	5.345	0.975	0.063	0.029	0.007	0.010
84028-09	169.	0.500	0.244	5.111	1.045	0.055	0.027	0.006	0.010
84028-08	171.	0.156	0.133	5.567	1.139	0.070	0.029	0.007	0.011
84029-05	149.	0.195	0.166	4.674	1.058	0.060	0.028	0.007	0.011
84035-01	154.	0.193	0.179	5.158	0.999	0.059	0.026	0.006	0.008
MEAN	158.	0.259	0.197	5.190	1.057	0.057	0.029	0.006	0.010
S.D.	10.3	0.1304	0.0501	0.2394	0.0666	0.0065	0.0040	0.0005	0.0013
N	13	13	13	13	13	13	13	13	13

FBW = FINAL BODY WEIGHT

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Revised Audited Draft

Modified: 11/4/2005

TABLE 23

PROJECT NO.:WIL-187044 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROID GLANDS
84024-03	175.	0.278	0.241	5.476	1.130	0.057	0.027	0.006	0.009
84023-10	156.	0.203	0.183	5.268	1.077	0.052	0.029	0.006	0.011
84026-06	150.	0.205	0.184	5.626	1.066	0.062	0.028	0.006	0.011
84025-01	158.	0.160	0.136	5.051	1.055	0.061	0.026	0.005	0.008
84027-02	138.	0.134	0.118	4.723	1.011	0.041	0.028	0.005	0.009
84026-07	174.	0.188	0.169	5.272	1.046	0.067	0.029	0.006	0.012
84029-06	172.	0.418	0.245	5.726	1.051	0.060	0.029	0.007	0.010
84031-09	157.	0.154	0.135	5.278	1.111	0.061	0.026	0.006	0.012
84030-01	158.	0.212	0.200	4.725	1.128	0.052	0.028	0.006	0.012
84030-03	144.	0.201	0.187	4.893	0.987	0.054	0.029	0.005	0.010
84035-05	178.	0.211	0.169	6.030	1.024	0.057	0.028	0.005	0.008
84032-09	166.	0.859	0.228	5.727	1.057	0.057	0.031	0.006	0.010
84033-05	170.	0.235	0.212	5.387	1.013	0.046	0.026	0.006	0.011
84034-10	132.	0.195	0.182	5.308	1.048	0.060	0.026	0.007	0.011
MEAN	159.	0.261	0.185	5.321	1.057	0.056	0.028	0.006	0.010
S.D.	14.3	0.1852	0.0387	0.3852	0.0430	0.0068	0.0015	0.0007	0.0014
N	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

POFBWv4.14
07/21/2005
R:07/21/2005

APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

Revised Audited Draft

[redacted]

[redacted]

[redacted]

Test Substance Certificate

[redacted]

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown viscous liquid

Storage Conditions
Ambient

Expiration Date
1 April 2006

Additional Comments
None

[redacted]

23 May 2005
Date

Revised Audited Draft

[redacted]

Revised Audited Draft

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown viscous liquid

Storage Conditions
Ambient

Expiration Date
1 June 2006

Additional Comments
None

[redacted]

23 May 2005
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

Revised Audited Draft

APPENDIX C

Animal Room Environmental Conditions

Revised Audited Draft

Revised Audited Draft

Modified: 7/22/2005

STUDY SPECIFICATIONS: 187044

DATE IN: 05/17/05 TIME IN: 11:00
DATE OUT: 06/22/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
09-Jun-05	70.6	21.4	50.6
10-Jun-05	70.5	21.4	50.9
11-Jun-05	70.6	21.4	50.9
12-Jun-05	70.5	21.4	49.6
13-Jun-05	70.4	21.3	50.2
14-Jun-05	70.5	21.4	49.9
15-Jun-05	70.5	21.4	46.6
16-Jun-05	70.6	21.4	45.0
17-Jun-05	70.5	21.4	47.6
18-Jun-05	70.5	21.4	45.0
19-Jun-05	70.5	21.4	45.0
20-Jun-05	70.4	21.3	49.7
21-Jun-05	70.5	21.4	45.6
22-Jun-05	70.1	21.2	48.6

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.1	70.6
TEMPERATURE °C	21.4	21.2	21.4
HUMIDITY (%RH)	47.5	38.0	50.9
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/22/05 14:51

Revised Audited Draft

Modified: 7/22/2005

ROOM SPECIFICATIONS:	B ROOM 73				
SPECIES:	RAT				
LOW TEMPERATURE:	66.0	DATE IN:	05/17/05		
HIGH TEMPERATURE:	76.0	TIME IN:	11:00		
LOW HUMIDITY:	30.0	DATE OUT:	06/22/05		
HIGH HUMIDITY:	70.0	TIME OUT:	8:00		

ROOM B ROOM 73 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	47.6
MIN	68.9	32.5
MAX	72.4	70.0
SD	0.28	4.11
N SAMPLES	859	859
FIRST DAY	05/17/05	
LAST DAY	06/22/05	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

Revised Audited Draft

Modified: 7/22/2005

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO.:WIL- 187044 TEMPERATURE/HUMIDITY - DAILY SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187044 DATE IN: 05/17/05 TIME IN: 11:00
DATE OUT: 06/22/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
17-May-05	70.4	21.3	39.7
18-May-05	70.5	21.4	38.0
19-May-05	70.5	21.4	43.0
20-May-05	70.5	21.4	47.8
21-May-05	70.5	21.4	40.1
22-May-05	70.5	21.4	47.4
23-May-05	70.5	21.4	50.5
24-May-05	70.5	21.4	46.9
25-May-05	70.5	21.4	46.1
26-May-05	70.5	21.4	47.9
27-May-05	70.4	21.3	46.9
28-May-05	70.5	21.4	47.1
29-May-05	70.5	21.4	46.3
30-May-05	70.4	21.4	48.3
31-May-05	70.5	21.4	49.8
01-Jun-05	70.5	21.4	50.7
02-Jun-05	70.4	21.3	49.7
03-Jun-05	70.4	21.4	50.5
04-Jun-05	70.5	21.4	48.2
05-Jun-05	70.4	21.3	48.9
06-Jun-05	70.5	21.4	49.8
07-Jun-05	70.4	21.4	48.3
08-Jun-05	70.5	21.4	50.4

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/22/05 14:51

Revised Audited Draft

Modified: 7/22/2005

STUDY SPECIFICATIONS: 187044 DATE IN: 05/17/05 TIME IN: 11:00
DATE OUT: 06/22/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73 LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
SPECIES: RAT LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
09-Jun-05	70.6	21.4	50.6
10-Jun-05	70.5	21.4	50.9
11-Jun-05	70.6	21.4	50.9
12-Jun-05	70.5	21.4	49.6
13-Jun-05	70.4	21.3	50.2
14-Jun-05	70.5	21.4	49.9
15-Jun-05	70.5	21.4	46.6
16-Jun-05	70.6	21.4	45.0
17-Jun-05	70.5	21.4	47.6
18-Jun-05	70.5	21.4	45.0
19-Jun-05	70.5	21.4	45.0
20-Jun-05	70.4	21.3	49.7
21-Jun-05	70.5	21.4	45.6
22-Jun-05	70.1	21.2	48.6

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.1	70.6
TEMPERATURE °C	21.4	21.2	21.4
HUMIDITY (%RH)	47.5	38.0	50.9
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/22/05 14:51

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Modified: 7/22/2005

ROOM SPECIFICATIONS:	B ROOM 73		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	05/17/05
HIGH TEMPERATURE:	76.0	TIME IN:	11:00
LOW HUMIDITY:	30.0	DATE OUT:	06/22/05
HIGH HUMIDITY:	70.0	TIME OUT:	8:00

ROOM B ROOM 73 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	47.6
MIN	68.9	32.5
MAX	72.4	70.0
SD	0.28	4.11
N SAMPLES	859	859
FIRST DAY	05/17/05	
LAST DAY	06/22/05	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

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Modified: 7/22/2005

STUDY 187044 SUMMARY

MEAN	70.5	47.6
MIN	68.9	32.5
MAX	72.4	70.0
SD	0.28	4.11
N SAMPLES	859	859
FIRST DAY	05/17/05	
LAST DAY	06/22/05	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

REPORT 5
VERSION 1.10
7/22/05 14:54

APPENDIX D

Clinical Pathology Methods, Procedures And References

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CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Serum Chemistry - Hitachi 912

Albumin - Bromcresol Green (BCG) Method, Modification of the Doumas reaction. Default unit: g/dL. Hitachi 912 Application Code 413. Roche Reagent, catalog number 11970569.

A/G Ratio - Calculated from Albumin and Globulin Results. Default unit: %.

Alkaline Phosphatase - based on the International Federation of Clinical Chemistry (IFCC) Method (Tietz *et al.* J Clin Chem Clin Biochem 1983; 21:731-748). Default unit: U/L. Hitachi 912 Application Code 158. Roche Reagent, catalog number 2172933.

Alanine Aminotransferase - Modification of the International Federation of Clinical Chemistry (IFCC) recommended method. Default unit: U/L. Hitachi 912 Application Code 706. Roche Reagent, catalog number 450065.

Aspartate Aminotransferase - Kinetic method based on the International Federation of Clinical Chemistry (IFCC) recommendations. Default unit: U/L. Hitachi 912 Application Code 715. Roche Reagent, catalog number 450064.

Bilirubin (Total) – Total bilirubin is coupled with a diazonium ion in a strongly acidic medium resulting in production of azobilirubin. Intensity of color of azobilirubin is proportional to the total bilirubin concentration and is measured photometrically. Method developed by Wahlefeld *et al.* Scan J Clin Lab Invest. 1972; 29: Supplement 126. Default unit: mg/dL. Hitachi 912 Application Code 18. Roche Reagent, catalog number 1822730.

Blood Urea Nitrogen (BUN) - A urease-triggered methodology based upon the method of Talke and Schubert Klin Wschr, 1965; 43:174. Default unit: mg/dL. Hitachi 912 Application Code 427. Roche Reagent, catalog number 1489321.

Calcium - Modified method using a gamma-amino-butyric acid (GABA) buffer. Default unit: mg/dL. Hitachi 912 Application Code 180. Roche Reagent, catalog number 1125621.

Chloride - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog numbers 820638, 836246 and 820639.

Cholesterol - Enzymatic reaction as described by Trinder. Ann Clin Biochem 1974; 12:266. Default unit: mg/dL. Hitachi 912 Application Code 722. Roche Reagent, catalog number 450061.

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Creatinine - Modified Jaffe reaction based on the work of Poper *et al.* Biochem Z 1937; 291:354, and Seelig and Wuest. Aerztl Labor 1969; 15:34. Default unit: mg/dL. Hitachi 912 Application Code 727. Roche Reagent, catalog number 450019.

Gamma-Glutamyltransferase (GGT) - Method based on the studies of Persijn and Van der Slik, J Clin Chem Clin Biochem, 1976; 14:421-427. Default unit: U/L. Hitachi 912 Application Code 479. Roche Reagent, catalog number 2016885.

Globulin - Calculation obtained by subtracting Albumin from Total Protein. Default unit: g/dL.

Glucose - Glucose hexokinase method based on the work of Schmidt, Peterson and Young. Klin Wschr 1961; 39:1244. Methods of Enzymatic Analysis, 2nd Eng ed. New York, Academic Press, 1974; 1196. Anal Biochemistry 1958; 23:301. Default unit: mg/dL. Hitachi 912 Application Code 767. Roche Reagent, catalog number 450058.

Phosphorus - Method involves the formation of ammonium phosphomolybdate. Default unit: mg/dL. Hitachi 912 Application Code 714. Roche Reagent, catalog number 1040898.

Potassium - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog numbers 820638, 836246 and 820639.

Sodium - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog number 820638, 836246 and 820639.

Total Protein - Endpoint biuret method that utilizes a sample blank. Default unit: g/dL. Hitachi 912 Application Code 756. Roche Reagent, catalog number 1040901.

Hematology - Manual Methods

White Cell Differential - Manual method of counting 100 white cells stained with Wright Giemsa and entered on-line into the data files.

Reticulocyte Count - Manual method of counting the reticulocytes present in 1000 red blood cells stained with New Methylene Blue and entered on-line into the data files.

Red Blood Cell Morphology - Manual method of evaluating red blood cells on a Wright Giemsa-stained slide and entered on-line into the data files.

Platelet Estimate- Manual method of evaluating platelets on a Wright Giemsa-stained slide. Platelet estimation is evaluated and entered on-line into the data files as decreased, adequate or increased. Platelet clumps present on the slide will be reported as part of the RBC morphology.

Immunoassay- DPC Immulite®

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

Rat Thyroid Stimulating Hormone (rTSH) - ^{125}I assay system with magnetic separation for the quantitative measurement of (rTSH). DPC GAMMA C-12 gamma counter. Biotrak™ rat thyroid stimulating hormone ^{125}I assay system. Amersham Pharmacia Biotech. Package insert.

Hematology-Bayer Advia® 120

WBC Count - The whole blood sample is mixed with ADVIA® 120 BASO reagent that contains acid and surfactant. The red cells are hemolyzed, and the white blood cells are then analyzed using two angle laser light scatter signals. Default unit: x 10^3 cells/µL

RBC / Platelet Count - Both red blood cells and platelets are analyzed by a single optical cytometer after appropriate dilution of the blood sample with ADVIA® 120 RBC/PLT reagent. The red blood cells are isovolumetrically sphered and lightly fixed with glutaraldehyde to preserve the spherical shape. Red cells and platelets are counted from the signals from a common detector with 2 different gain settings. Default unit RBC: x 10^6cells/µL. Default unit PLT: x 10^3 cells/µL

Hgb - Hemoglobin: The hemoglobin method is a modification of the manual cyanmethemoglobin method developed by the International Committee for standardization in Hematology (ICSH). Default unit: g/dL.

Hematocrit - The percentage of blood volume that is occupied by red blood cells. Also referred to as the packed red cell volume. On the ADVIA® 120 Hematology System this parameter is derived from the measured red cell volume (MCV) and the red cell count (RBC). Default unit: %.

MCH - Mean Corpuscular Hemoglobin: the average weight of hemoglobin in the red blood cells, calculated from the RBC and Hgb measurements. Default unit: pg.

MCHC - Mean Corpuscular Hemoglobin Concentration: the average concentration of

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hemoglobin in the red blood cells. This parameter is computed from the measured hemoglobin and the computed hematocrit. Default unit: g/dL.

MCV - Mean Corpuscular Volume: the average volume of the red blood cells. Default unit: fL

White blood cell differential - The ADVIA® 120 Hematology System White Blood Cell Differential (WBC DIFF) methods, consists of both the Peroxidase method and the Basophil/Lobularity method. The ADVIA® 120 Hematology System performs a six-part differential that consists of basophils, eosinophils, large unstained cells, lymphocytes, monocytes, and neutrophils. The white blood cell differential count is reported in percent and the actual number of each type of cell per microliter of blood.

Reticulocyte - This method uses a nucleic acid dye (oxazine 750) to stain cellular RNA. The ADVIA® 120 autoRETIC reagent isovolumetrically spheres the erythroid cells and stains cellular RNA. Low-angle laser light scatter, high-angle laser light scatter, and absorption characteristics of all cells are counted and measured. The absorption data are used to classify each cell as a reticulocyte or mature red blood cell based on its RNA content. The reticulocyte is reported in percent and actual number x 10 cells/Liter.

References:

ADVIA® 120 Hematology System Operator's Guide: Copyright© 1997, 1998 Bayer Corporation.

Immulite®. Diagnostics Products Corporation. Package Insert.

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APPENDIX E

Individual Clinical Pathology Data (Unscheduled Deaths)

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL
GROUP: [redacted]60	FEMALES							
84023-09	6.95	6.19	12.7	43.1	69.6	20.5	29.5	1589.
84031-06	6.26	5.30	10.1	37.6	70.9	19.1	26.9	1489.
MEAN	6.61	5.75	11.4	40.4	70.3	19.8	28.2	1539.
S.D.	0.488	0.629	1.84	3.89	0.92	0.99	1.84	70.7
N	2	2	2	2	2	2	2	2

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: [redacted]60	FEMALES							
84023-09	10.1	625.4	12.1	81.9	3.7	0.6	0.4	1.4
84031-06	17.1	906.2	19.5	74.6	3.4	0.4	0.4	1.7
MEAN	13.6	765.8	15.8	78.3	3.6	0.5	0.4	1.6
S.D.	4.95	198.56	5.23	5.16	0.21	0.14	0.00	0.21
N	2	2	2	2	2	2	2	2

thous/uL = THOUSANDS/MICROLITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: [redacted]60	FEMALES					
84023-09	0.84	5.69	0.26	0.04	0.03	0.10
84031-06	1.22	4.67	0.21	0.02	0.03	0.11
MEAN	1.03	5.18	0.24	0.03	0.03	0.11
S.D.	0.269	0.721	0.035	0.014	0.000	0.007
N	2	2	2	2	2	2

thous/uL = THOUSANDS/MICROLITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL
GROUP: [redacted]250	FEMALES							
84025-10	6.92	5.98	13.0	48.2	80.6	21.8	27.0	184.
84029-01	5.96	5.62	11.7	41.8	74.4	20.9	28.1	114.
84030-05	3.07	5.28	11.3	40.8	77.4	21.4	27.7	112.
84031-08	4.89	5.98	11.3	42.0	70.2	18.9	26.9	814.
84030-02	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
MEAN	5.21	5.72	11.8	43.2	75.7	20.8	27.4	306.
S.D.	1.650	0.336	0.81	3.37	4.43	1.29	0.57	340.3
N	4	4	4	4	4	4	4	4

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: [redacted]250		FEMALES						
84025-10	12.6	751.0	12.0	83.2	3.3	0.1	0.6	0.7
84029-01	14.2	797.0	5.4	88.9	1.3	0.2	3.1	1.2
84030-05	12.8	677.9	13.7	81.8	3.3	0.1	0.1	0.9
84031-08	14.2	851.4	15.2	80.8	2.7	0.2	0.4	0.8
84030-02	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
MEAN	13.5	769.3	11.6	83.7	2.7	0.2	1.1	0.9
S.D.	0.87	73.48	4.32	3.62	0.94	0.06	1.38	0.22
N	4	4	4	4	4	4	4	4

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: [redacted]250	FEMALES					
84025-10	0.83	5.76	0.23	0.01	0.04	0.05
84029-01	0.32	5.30	0.08	0.01	0.18	0.07
84030-05	0.42	2.51	0.10	0.00	0.00	0.03
84031-08	0.74	3.95	0.13	0.01	0.02	0.04
84030-02	CLT	CLT	CLT	CLT	CLT	CLT
MEAN	0.58	4.38	0.14	0.01	0.06	0.05
S.D.	0.246	1.464	0.067	0.005	0.082	0.017
N	4	4	4	4	4	4

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL
GROUP: [redacted]1000 FEMALES								
84023-07	4.77	5.90	11.9	42.7	72.4	20.1	27.8	1212.
MEAN	4.77	5.90	11.9	42.7	72.4	20.1	27.8	1212.
S.D.	0.000	0.000	0.00	0.00	0.00	0.00	0.00	0.0
N	1	1	1	1	1	1	1	1

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: [redacted]1000 FEMALES								
84023-07	9.2	540.6	14.9	78.2	4.6	0.2	0.6	1.5
MEAN	9.2	540.6	14.9	78.2	4.6	0.2	0.6	1.5
S.D.	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
N	1	1	1	1	1	1	1	1

thous/uL = THOUSANDS/MICROLITER

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Modified: 11/4/2005

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted] UNSCHEDULED DEATHS
SPONSOR NO.:05-003 INDIVIDUAL HEMATOLOGY VALUES WEEK 1

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: [redacted]1000 FEMALES						
84023-07	0.71	3.73	0.22	0.01	0.03	0.07
MEAN	0.71	3.73	0.22	0.01	0.03	0.07
S.D.	0.000	0.000	0.000	0.000	0.000	0.000
N	1	1	1	1	1	1

thous/uL = THOUSANDS/MICROLITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL
GROUP: [redacted]60	FEMALES							
84029-08	6.41	5.43	12.4	38.5	70.9	22.9	32.2	1133.
84031-07	9.07	5.76	11.8	40.4	70.2	20.5	29.2	1563.
MEAN	7.74	5.60	12.1	39.5	70.6	21.7	30.7	1348.
S.D.	1.881	0.233	0.42	1.34	0.49	1.70	2.12	304.1
N	2	2	2	2	2	2	2	2

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: [redacted]60 FEMALES								
84029-08	11.8	643.0	16.5	77.3	3.7	0.6	0.4	1.4
84031-07	11.5	660.2	15.2	78.2	4.8	0.0	0.6	1.1
MEAN	11.7	651.6	15.9	77.8	4.3	0.3	0.5	1.3
S.D.	0.21	12.16	0.92	0.64	0.78	0.42	0.14	0.21
N	2	2	2	2	2	2	2	2

thous/uL = THOUSANDS/MICROLITER

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Modified: 11/4/2005

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 12
SPONSOR:[redacted] UNSCHEDULED DEATHS
SPONSOR NO.:05-003 INDIVIDUAL HEMATOLOGY VALUES WEEK 1

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: [redacted]60	FEMALES					
84029-08	1.06	4.96	0.23	0.04	0.03	0.09
84031-07	1.38	7.09	0.43	0.00	0.06	0.10
MEAN	1.22	6.03	0.33	0.02	0.05	0.10
S.D.	0.226	1.506	0.141	0.028	0.021	0.007
N	2	2	2	2	2	2

thous/uL = THOUSANDS/MICROLITER

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Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL
GROUP: [redacted]1000 FEMALES								
84028-02	5.75	6.96	14.2	50.0	71.8	20.5	28.5	289.
MEAN	5.75	6.96	14.2	50.0	71.8	20.5	28.5	289.
S.D.	0.000	0.000	0.00	0.00	0.00	0.00	0.00	0.0
N	1	1	1	1	1	1	1	1

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: [redacted]1000 FEMALES								
84028-02	12.9	897.2	21.4	73.1	3.7	0.1	0.4	1.2
MEAN	12.9	897.2	21.4	73.1	3.7	0.1	0.4	1.2
S.D.	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
N	1	1	1	1	1	1	1	1

thous/uL = THOUSANDS/MICROLITER

Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:05-003

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: [redacted]1000 FEMALES						
84028-02	1.23	4.20	0.21	0.01	0.02	0.07
MEAN	1.23	4.20	0.21	0.01	0.02	0.07
S.D.	0.000	0.000	0.000	0.000	0.000	0.000
N	1	1	1	1	1	1

thous/uL = THOUSANDS/MICROLITER

PHEMAv1.32
08/30/2005

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UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL SERUM CHEMISTRY VALUES
SPONSOR NO.:05-003

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER	GLUTAMYL TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L	U/L
GROUP: [redacted]60 FEMALES											
84023-09	4.1	5.6	1.6	2.60	0.1	16.4	0.3	410.	65.	99.	UR
84031-06	4.2	5.9	1.6	2.62	0.1	16.6	0.3	500.	64.	143.	UR
MEAN	4.2	5.8	1.6	2.61	0.1	16.5	0.3	455.	65.	121.	NA
S.D.	0.07	0.21	0.00	0.014	0.00	0.14	0.00	63.6	0.7	31.1	
N	2	2	2	2	2	2	2	2	2	2	

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Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL SERUM CHEMISTRY VALUES
SPONSOR NO.:05-003

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L
GROUP: [redacted]60 FEMALES							
84023-09	413.	75.	15.9	97.	18.4	13.32	136.
84031-06	439.	72.	15.4	100.	16.6	10.72	142.
MEAN	426.	74.	15.7	99.	17.5	12.02	139.
S.D.	18.4	2.1	0.35	2.1	1.27	1.838	4.2
N	2	2	2	2	2	2	2

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003

INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER	GLUTAMYL TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L	U/L
GROUP: [redacted]250 FEMALES											
84025-10	3.9	QNS	QNS	QNS	QNS	QNS	QNS	511.	127.	209.	QNS
84029-01	3.7	5.3	1.7	2.20	0.1	18.3	0.3	376.	94.	242.	UR
84030-05	4.4	6.2	1.9	2.37	0.2	18.1	0.3	390.	103.	239.	UR
84031-08	4.0	5.7	1.7	2.40	0.1	14.6	0.5	447.	78.	224.	UR
84030-02	3.9	5.3	1.4	2.84	0.1	20.0	0.2	368.	71.	134.	UR
MEAN	4.0	5.6	1.7	2.45	0.1	17.8	0.3	418.	95.	210.	NA
S.D.	0.26	0.43	0.21	0.273	0.05	2.27	0.13	60.3	22.1	44.3	
N	5	4	4	4	4	4	4	5	5	5	

QNS = QUANTITY NOT SUFFICIENT, UR = BELOW INSTRUMENT RANGE, NA = NOT APPLICABLE

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Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-003

INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L
GROUP: [redacted]250	FEMALES						
84025-10	415.	QNS	QNS	QNS	QNS	QNS	QNS
84029-01	537.	111.	14.7	98.	18.7	11.60	138.
84030-05	568.	85.	19.8	97.	22.3	17.50	135.
84031-08	523.	85.	17.2	101.	22.4	13.77	140.
84030-02	340.	86.	17.6	98.	17.6	11.70	140.
MEAN	477.	92.	17.3	99.	20.3	13.64	138.
S.D.	95.7	12.8	2.09	1.7	2.47	2.759	2.4
N	5	4	4	4	4	4	4

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Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:05-003
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER	GLUTAMYL TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L	U/L
GROUP: [redacted]1000 FEMALES											
84023-07	3.4	4.7	1.4	2.49	0.1	15.7	0.3	223.	80.	188.	UR
MEAN	3.4	4.7	1.4	2.49	0.1	15.7	0.3	223.	80.	188.	NA
S.D.	0.00	0.00	0.00	0.000	0.00	0.00	0.00	0.0	0.0	0.0	
N	1	1	1	1	1	1	1	1	1	1	

UR = BELOW INSTRUMENT RANGE, NA = NOT APPLICABLE

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Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL SERUM CHEMISTRY VALUES
SPONSOR NO.:05-003

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L
GROUP: [redacted]1000 FEMALES							
84023-07	266.	109.	14.4	102.	13.8	8.96	145.
MEAN	266.	109.	14.4	102.	13.8	8.96	145.
S.D.	0.0	0.0	0.00	0.0	0.00	0.000	0.0
N	1	1	1	1	1	1	1

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003

INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER	GLUTAMYL TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L	U/L
GROUP: [redacted]60 FEMALES											
84029-08	4.0	5.5	1.5	2.61	0.1	17.0	0.2	382.	90.	174.	UR
84031-07	4.4	6.1	1.7	2.66	0.1	14.0	0.3	414.	65.	113.	UR
MEAN	4.2	5.8	1.6	2.64	0.1	15.5	0.3	398.	78.	144.	NA
S.D.	0.28	0.42	0.14	0.035	0.00	2.12	0.07	22.6	17.7	43.1	
N	2	2	2	2	2	2	2	2	2	2	

UR = BELOW INSTRUMENT RANGE, NA = NOT APPLICABLE

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Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L
GROUP: [redacted]60	FEMALES						
84029-08	345.	85.	14.2	100.	16.2	14.12	137.
84031-07	376.	96.	16.0	95.	18.8	12.00	138.
MEAN	361.	91.	15.1	98.	17.5	13.06	138.
S.D.	21.9	7.8	1.27	3.5	1.84	1.499	0.7
N	2	2	2	2	2	2	2

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL SERUM CHEMISTRY VALUES

SPONSOR NO.:05-003

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER	GLUTAMYL TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L	U/L
GROUP: [redacted]1000 FEMALES											
84028-02	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS

QNS = QUANTITY NOT SUFFICIENT

Revised Audited Draft

Modified: 11/4/2005

UNSCHEDULED DEATHS

PROJECT NO.:WIL-187044U PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:05-003
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L
GROUP: [redacted]1000 FEMALES							
84028-02	QNS	QNS	QNS	QNS	QNS	QNS	QNS

QNS = QUANTITY NOT SUFFICIENT

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APPENDIX F

WIL Reproductive Historical Control Data (WIL Research Laboratories, LLC)

Revised Audited Draft

Revised Audited Draft

Modified: 1/24/2005

WIL Reproductive Historical Control Data — Grand Mean Summary —
Crl:CD(SD) Rat* — Parental and Neonatal Observations

ENDPOINT	TOTAL	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
TOTAL NUMBER OF DATASETS	**107**							
NO. MALES IN CONTROL GROUP	2141	27.1	3.95	79	15	40	25	30
MALE MATING INDEX (%)		96.3	4.72	77	72.0	100.0	95.7	100.0
MALE FERTILITY INDEX (%)		89.6	8.10	79	56.7	100.0	86.5	95.7
NO. FEMALES IN CONTROL GROUP	2815	26.6	3.57	106	15	40	25	30
FEMALE MATING INDEX (%)		97.5	3.60	83	84.0	100.0	96.0	100.0
FEMALE FERTILITY INDEX (%)		92.0	7.47	105	56.7	100.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	1755	27.0	3.10	65	22	40	25	30
NO. THAT DELIVERED	1583	24.4	3.22	65	17	38	23	26
NO. THAT DID NOT DELIVER	172	2.6	2.44	65	0	13	1	3
NO. THAT DIED	13	0.1	0.36	106	0	2	0	0
NO. WITH TOTAL LITTER LOSS	13	0.2	0.44	65	0	2	0	0
NO. WITH DYSTOCIA	6	0.1	0.29	65	0	1	0	0
MEAN PRE-COITAL INTERVAL (DAYS)		3.0	0.56	81	1.8	4.7	2.6	3.3
MEAN GESTATION LENGTH (DAYS)		21.8	0.15	65	21.6	22.3	21.7	21.9
MEAN NO. PUPS BORN		14.5	0.94	65	12.0	16.5	13.7	15.0
MEAN VIABLE LITTER SIZE ON PND 0		14.2	0.94	65	11.6	16.0	13.4	14.9
PUP SEX RATIO								
MEAN % MALE		49.7	2.83	65	42.7	56.6	47.7	51.8
MEAN % FEMALE		50.3	2.86	65	43.4	57.3	48.2	52.3
MEAN NO. OF FORMER IMPLANTATION SITES AT WEANING		15.3	0.83	58	13.7	17.1	14.7	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING		0.8	0.21	58	0.3	1.3	0.7	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY		15.5	0.90	40	13.8	16.8	15.1	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)		4.5	0.41	59	4.0	5.8	4.2	4.6
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM		96.4	23.11	13	50.4	132.9	87.8	107.8

EXPERIMENTAL START DATE OF OLDEST DATASET 6/17/96
DATE OF LAST NECROPSY OF MOST RECENT DATASET 2/3/04

187044 RAD

= Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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Modified: 1/24/2005

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN NO. PUPS BORN	14.5	0.94	65	12.0	16.5	13.7	15.0
PUP SURVIVAL INDICES (% PER LITTER)							
PND 0 (RELATIVE TO NO. BORN)	98.0	1.42	65	92.3	100.0	97.4	99.0
PND 0 TO PND 1	99.0	1.24	65	94.3	100.0	98.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	1.08	64	93.5	100.0	98.8	99.6
PND 4 (AFTER SELECTION) TO PND 7	99.5	0.94	57	95.8	100.0	99.5	100.0
PND 7 TO PND 14	99.4	1.38	53	93.5	100.0	99.5	100.0
PND 14 TO PND 21	99.7	0.97	54	94.7	100.0	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.1	2.01	62	91.3	99.3	95.0	97.5
PND 4 (AFTER SELECTION) TO PND 21	98.7	1.96	53	91.1	100.0	98.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)							
PND 1	7.1	0.25	65	6.5	7.6	6.9	7.2
PND 4 (BEFORE SELECTION)	9.9	0.59	64	8.6	11.4	9.5	10.4
PND 7	15.4	1.34	57	11.7	17.8	15.1	16.4
PND 14	31.0	3.50	53	22.5	36.5	29.2	33.1
PND 21	48.7	5.47	54	34.9	58.0	45.4	52.1
PND 28	81.5	8.23	18	65.4	94.0	74.6	87.6
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)							
PND 1	6.7	0.25	65	6.1	7.2	6.5	6.8
PND 4 (BEFORE SELECTION)	9.4	0.57	64	8.1	10.9	8.9	9.7
PND 7	14.6	1.32	57	11.0	17.1	14.1	15.5
PND 14	29.8	3.41	53	21.2	35.1	27.6	32.1
PND 21	46.6	5.07	54	33.3	55.6	43.9	49.7
PND 28	75.3	7.25	18	59.8	86.2	69.0	79.5
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.4365	0.0509	21	1.3451	1.5175	1.4000	1.4775
SPLEEN	0.1938	0.0343	21	0.1189	0.2480	0.1755	0.2211
THYMUS GLAND	0.1933	0.0269	21	0.1392	0.2446	0.1723	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)							
BRAIN	1.3886	0.0459	21	1.2903	1.4597	1.3623	1.4242
SPLEEN	0.1923	0.0321	21	0.1182	0.2408	0.1722	0.2200
THYMUS GLAND	0.1969	0.0281	21	0.1338	0.2479	0.1778	0.2113

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

Revised Audited Draft

WIL Reproductive Historical Control Data — Grand Mean Summary — Page 3
Crl:CD(SD) Rat* — Parental and Neonatal Observations

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)							
MALE	4.6	0.92	10	2.5	5.7	4.3	5.3
FEMALE	2.7	0.70	10	1.3	3.9	2.4	3.2
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.8	1.83	41	41.6	49.0	44.0	45.8
MEAN BODY WEIGHT AT ACQUISITION (G)	228.4	10.21	38	210.5	248.6	221.9	235.5
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	1.39	41	31.7	38.8	32.7	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	112.4	7.79	38	99.0	133.0	107.0	117.6
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)							
MALE	5.1	0.08	7	5.0	5.2	5.0	5.1
FEMALE	5.2	0.10	7	5.0	5.3	5.1	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)							
MALE	4.0	0.08	6	4.0	4.2	4.0	4.0
FEMALE	4.0	0.08	6	4.0	4.2	4.0	4.0
MEAN DAY OF EYE OPENING (PND)							
MALE	16.1	1.35	6	15.1	18.7	15.3	16.0
FEMALE	16.0	1.37	6	14.8	18.6	15.2	16.0
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)							
MALE	14.9	NA	1	14.9	14.9	14.9	14.9
FEMALE	14.9	NA	1	14.9	14.9	14.9	14.9
MEAN DAY OF HAIR GROWTH (PND)							
MALE	12.4	0.99	2	11.7	13.1	12.1	12.8
FEMALE	12.4	0.85	2	11.8	13.0	12.1	12.7
MEAN DAY OF INCISOR ERUPTION (PND)							
MALE	9.8	0.44	3	9.3	10.1	9.7	10.1
FEMALE	9.7	0.38	3	9.3	10.0	9.6	10.0

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

Revised Audited Draft

Modified: 1/24/2005

WIL Reproductive Historical Control Data — Grand Mean Summary —
Crl:CD(SD) Rat* — Parental and Neonatal Observations

ENDPOINT	MEAN	SD	N	MIN	MAX	25TH QUARTILE	75TH QUARTILE
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHT (G)	2.20	0.295	37	1.76	2.80	1.95	2.30
MEAN RIGHT TESTIS WEIGHT (G)	1.79	0.067	55	1.65	1.93	1.73	1.84
MEAN LEFT TESTIS WEIGHT (G)	1.79	0.065	55	1.67	1.92	1.74	1.84
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.73	0.039	55	0.64	0.81	0.71	0.75
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.040	55	0.62	0.80	0.70	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3249	0.0227	55	0.2629	0.3693	0.3159	0.3366
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3282	0.0206	55	0.2714	0.3712	0.3183	0.3413
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)							
LEFT TESTIS	86.8	9.3	49	69.6	106.9	79.2	93.2
LEFT EPIDIDYMIS	460.7	54.6	49	343.6	640.1	421.3	477.0
LEFT CAUDA EPIDIDYMIS	677.5	50.3	4	618.7	738.9	651.8	701.9
MEAN SPERM PRODUCTION RATE							
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	1.5	49	11.4	17.5	13.0	15.3
% MOTILE SPERM	84.6	4.4	53	71.3	91.9	82.0	87.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)							
NORMAL	98.9	1.3	50	91.9	99.9	98.8	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.6	50	0.0	3.4	0.2	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.7	50	0.0	4.7	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)							
NORMAL	198.0	2.6	50	183.8	200.0	197.9	199.3
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.3	1.7	50	0.0	10.0	0.4	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	1.5	50	0.0	9.4	0.2	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	50	0.0	0.1	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	50	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	50	0.0	0.0	0.0	0.0

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	1	2	3	4	5
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
MALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	90.0	100.0
FEMALE FERTILITY INDEX (%)	83.3	56.7	93.3	90.0	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	30
NO. THAT DELIVERED	25	17	28	27	28
NO. THAT DID NOT DELIVER	5	13	2	3	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	0
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	3.0	2.3	2.4	2.2
MEAN GESTATION LENGTH (DAYS)	22.3	22.0	21.8	21.8	21.8
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
MEAN VIABLE LITTER SIZE ON PND 0	11.6	12.5	13.5	13.4	13.0
PUP SEX RATIO					
MEAN % MALE	49.7	52.1	51.1	51.8	52.1
MEAN % FEMALE	50.3	47.9	48.9	48.2	47.9
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.5	14.2	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.9	0.7	1.2
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	4.2	4.1	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	11/19/97	2/23/98	11/3/98	2/3/99	9/24/98
DATE OF LAST NECROPSY	4/7/98	8/18/98	3/16/99	7/23/99	2/5/99
ROUTE	Diet	Diet	Diet	Diet	Inhalation
VEHICLE	Basal Feed	Basal Feed	Basal Feed	Basal Feed	Filtered Air

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DATASET NO.	6	7	8	9	10
NO. MALES IN CONTROL GROUP	30	30	30	30	30
MALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES IN CONTROL GROUP	30	30	30	30	30
FEMALE MATING INDEX (%)	100.0	93.3	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.7	80.0	89.7	93.3	93.3
NO. FEMALES SELECTED TO DELIVER	30	30	29	30	30
NO. THAT DELIVERED	29	24	26	28	28
NO. THAT DID NOT DELIVER	1	6	3	2	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	1	1	0	0	0
NO. WITH DYSTOCIA	0	1	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.5	2.6	2.7	2.7	2.8
MEAN GESTATION LENGTH (DAYS)	21.7	22.0	21.8	22.1	21.8
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
MEAN VIABLE LITTER SIZE ON PND 0	13.1	14.5	12.9	12.9	13.1
PUP SEX RATIO					
MEAN % MALE	48.6	49.2	48.6	44.0	45.0
MEAN % FEMALE	51.4	50.8	51.4	56.0	55.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	15.7	14.0	13.7	14.2
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	0.8	0.6	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.1	4.2	4.3	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	96.7	54.4	98.1	---	85.5
EXPERIMENTAL START DATE	12/24/98	2/9/99	5/27/99	11/23/98	2/25/99
DATE OF LAST NECROPSY	6/11/99	7/9/99	11/12/99	4/7/99	8/19/99
ROUTE	Inhalation	Gavage	Gavage	Diet	Diet
VEHICLE	Filtered Air	DI Water	DI Water	Basal Feed	Basal Feed

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Crl:CD(SD) Rat*

DATASET NO.	11	12	13	14	15
NO. MALES IN CONTROL GROUP	30	30	30	30	---
MALE MATING INDEX (%)	96.6	96.7	93.3	100.0	---
MALE FERTILITY INDEX (%)	89.7	96.7	86.7	100.0	---
NO. FEMALES IN CONTROL GROUP	30	30	30	30	25
FEMALE MATING INDEX (%)	96.7	96.7	93.3	100.0	---
FEMALE FERTILITY INDEX (%)	90.0	96.7	86.7	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	30	30	30	25
NO. THAT DELIVERED	27	29	26	30	25
NO. THAT DID NOT DELIVER	3	1	4	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	1	0	0	0	1
NO. WITH DYSTOCIA	0	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.7	3.3	2.6	2.0	---
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	21.8	21.6	21.8
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
MEAN VIABLE LITTER SIZE ON PND 0	13.3	13.1	13.2	14.4	14.4
PUP SEX RATIO					
MEAN % MALE	56.4	50.6	51.3	50.0	49.0
MEAN % FEMALE	43.6	49.4	48.7	50.0	51.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	---	15.6	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	---	0.8	0.8
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	87.8	96.9	---	---	---
EXPERIMENTAL START DATE	1/14/97	4/15/97	4/15/97	11/4/97	8/31/98
DATE OF LAST NECROPSY	6/3/97	11/29/97	11/29/97	11/25/97	10/9/98
ROUTE	Inhalation	Inhalation	Inhalation	Inhalation	Gavage
VEHICLE	Filtered Air	Filtered Air	Filtered Air	Filtered Air	0.4% MC

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WIL Reproductive Historical Control Data **Individual Study Data**
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DATASET NO.	16	17	18	19	20
NO. MALES IN CONTROL GROUP	25	24	---	25	25
MALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	92.0	95.8	---	100.0	96.0
NO. FEMALES IN CONTROL GROUP	25	24	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	95.8	92.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	24	25	---	---
NO. THAT DELIVERED	23	23	23	---	---
NO. THAT DID NOT DELIVER	2	1	2	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	---
NO. WITH DYSTOCIA	0	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	2.4	---	2.8	2.7
MEAN GESTATION LENGTH (DAYS)	21.8	21.6	21.8	---	---
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
MEAN VIABLE LITTER SIZE ON PND 0	13.9	15.0	14.7	---	---
PUP SEX RATIO					
MEAN % MALE	52.1	49.7	51.9	---	---
MEAN % FEMALE	47.9	50.3	48.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.1	15.9	15.7	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	0.9	1.0	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	16.4	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/14/98	7/7/98	9/23/98	10/27/98	3/29/99
DATE OF LAST NECROPSY	2/1/99	10/1/98	11/23/98	3/1/99	5/4/99
ROUTE	Gavage	Diet	Gavage	Gavage	Gavage
VEHICLE	0.4% MC	Basal Feed	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80	1% Avicel-5% Tween 80

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DATASET NO.	21	22	23	24	25
NO. MALES IN CONTROL GROUP	---	25	---	25	---
MALE MATING INDEX (%)	---	96.0	---	72.0	---
MALE FERTILITY INDEX (%)	---	88.0	---	72.0	---
NO. FEMALES IN CONTROL GROUP	25	25	22	25	25
FEMALE MATING INDEX (%)	---	96.0	---	84.0	---
FEMALE FERTILITY INDEX (%)	100.0	88.0	95.5	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25	22	---	25
NO. THAT DELIVERED	25	22	21	---	25
NO. THAT DID NOT DELIVER	0	3	1	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	0	---	0
NO. WITH DYSTOCIA	0	0	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	2.2	---	3.5	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.8	21.8	---	22.0
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	13.8	14.9	14.6	---	14.7
PUP SEX RATIO					
MEAN % MALE	47.7	49.8	47.7	---	47.7
MEAN % FEMALE	52.3	50.2	52.3	---	52.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.9	15.4	---	15.7
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.8	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	13.9	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.2	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	10/26/98	11/17/98	1/12/99	2/3/99	7/27/98
DATE OF LAST NECROPSY	12/13/98	4/13/99	3/1/99	6/15/99	9/12/98
ROUTE	SubQ	SubQ	SubQ	SubQ	Gavage
VEHICLE	20 mM Na Phosphate	21 mM Na Phosphate	Sponsor-Supplied	Sponsor-Supplied	0.75% MC

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DATASET NO.	26	27	28	29	30
NO. MALES IN CONTROL GROUP	25	---	---	25	---
MALE MATING INDEX (%)	96.0	---	---	96.0	---
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	96.0	---
FEMALE FERTILITY INDEX (%)	92.0	88.0	96.0	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	25	25	25
NO. THAT DELIVERED	---	22	23	24	25
NO. THAT DID NOT DELIVER	---	3	2	1	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	0	0
NO. WITH DYSTOCIA	---	0	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.4	---	---	2.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.7	21.7	21.7	21.7
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	15.9	14.7	15.0
PUP SEX RATIO					
MEAN % MALE	---	50.8	54.0	50.8	48.5
MEAN % FEMALE	---	49.2	46.0	49.2	51.5
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.8	16.7	---	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.6	0.5	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	13.8	---	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/18/98	9/13/99	8/2/99	8/17/99	8/9/99
DATE OF LAST NECROPSY	12/29/98	10/31/99	9/12/99	1/10/00	9/25/99
ROUTE	Gavage	Gavage	Gavage	Gavage	Intranasal
VEHICLE	0.75% MC	0.1 M Na Phosphate	0.4% MC	0.4% MC	MC

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DATASET NO.	31	32	33	34	35
NO. MALES IN CONTROL GROUP	25	40	---	---	40
MALE MATING INDEX (%)	82.6	97.5	---	---	---
MALE FERTILITY INDEX (%)	73.9	95.0	---	---	75.0
NO. FEMALES IN CONTROL GROUP	25	40	25	25	40
FEMALE MATING INDEX (%)	95.8	97.5	100.0	100.0	---
FEMALE FERTILITY INDEX (%)	87.5	95.0	92.0	96.0	---
NO. FEMALES SELECTED TO DELIVER	---	40	---	---	---
NO. THAT DELIVERED	---	38	---	---	---
NO. THAT DID NOT DELIVER	---	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	---	---	---
NO. WITH DYSTOCIA	---	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	2.8	2.6	3.9	---
MEAN GESTATION LENGTH (DAYS)	---	21.6	---	---	---
MEAN NO. PUPS BORN	---	15.4	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	---	48.8	---	---	---
MEAN % FEMALE	---	51.2	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.9	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.1	---	15.4	15.6	16.5
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/31/99	6/17/96	9/29/98	11/6/98	3/4/99
DATE OF LAST NECROPSY	1/11/00	11/15/96	11/24/98	12/31/98	4/14/99
ROUTE	Intranasal	Inhalation	Gavage	Gavage	Dermal
VEHICLE	MC	Filtered Air	1% Avicel-5% Tween 80 50mM Sodium Acetate	0.5% Aqueous MC	Fire Pond Water

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DATASET NO.	36	37	38	39	40
NO. MALES IN CONTROL GROUP	20	25	---	25	25
MALE MATING INDEX (%)	---	96.0	---	100.0	100.0
MALE FERTILITY INDEX (%)	95.0	88.0	---	92.0	100.0
NO. FEMALES IN CONTROL GROUP	20	25	25	25	25
FEMALE MATING INDEX (%)	100.0	100.0	---	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	92.0	96.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	---	25	25	---
NO. THAT DELIVERED	---	---	24	23	---
NO. THAT DID NOT DELIVER	---	---	1	2	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	1	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.2	---	2.6	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	21.6	21.7	---
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	14.8	14.4	---
PUP SEX RATIO					
MEAN % MALE	---	---	55.2	50.9	---
MEAN % FEMALE	---	---	44.8	49.1	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	15.4	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.9	15.3	---	---	15.8
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---	---	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/15/99	4/9/99	6/15/99	6/17/96	11/18/99
DATE OF LAST NECROPSY	6/24/99	6/17/99	7/31/99	11/17/99	1/28/00
ROUTE	Dermal	Gavage	Gavage	Untreated	Untreated
VEHICLE	Fire Pond Water	10mM Lactic Acid in DI Water	5% Acacia	Not Applicable	Not Applicable

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DATASET NO.	41	42	43	44	45
NO. MALES IN CONTROL GROUP	---	24	35	15	30
MALE MATING INDEX (%)	---	95.7	97.1	100.0	100.0
MALE FERTILITY INDEX (%)	---	91.3	91.4	86.7	96.7
NO. FEMALES IN CONTROL GROUP	25	24	35	15	30
FEMALE MATING INDEX (%)	---	100.0	97.1	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	95.7	94.3	86.7	96.7
NO. FEMALES SELECTED TO DELIVER	25	23	---	---	30
NO. THAT DELIVERED	24	21	---	---	28
NO. THAT DID NOT DELIVER	1	2	---	---	2
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	1
NO. WITH TOTAL LITTER LOSS	0	0	---	---	0
NO. WITH DYSTOCIA	0	0	---	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.3	2.2	2.2	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	21.8	---	---	21.7
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
MEAN VIABLE LITTER SIZE ON PND 0	15.5	15.0	---	---	14.7
PUP SEX RATIO					
MEAN % MALE	53.1	47.3	---	---	46.7
MEAN % FEMALE	46.9	52.7	---	---	53.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.3	16.0	---	---	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.8	---	---	0.6
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	15.4	16.6	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.3	---	---	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	9/21/99	11/3/99	10/1/99	1/12/00	10/1/99
DATE OF LAST NECROPSY	11/7/99	3/9/00	1/17/00	8/17/00	2/11/00
ROUTE	Gavage	Untreated	Dermal	Untreated Recovery	Gavage
VEHICLE	10% Aqueous Acacia	Not Applicable	Sponsor-Supplied Placebo	Not Applicable	Citric Acid Solution

187044 RAD

= Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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WIL Reproductive Historical Control Data **Individual Study Data**

Crl:CD(SD) Rat*

DATASET NO.	46	47	48	49	50
NO. MALES IN CONTROL GROUP	29	25	25	24	25
MALE MATING INDEX (%)	93.1	100.0	96.0	100.0	96.0
MALE FERTILITY INDEX (%)	79.3	84.0	92.0	87.5	92.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	93.1	100.0	96.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	79.3	84.0	92.0	88.0	96.0
NO. FEMALES SELECTED TO DELIVER	29	---	25	25	---
NO. THAT DELIVERED	23	---	23	22	---
NO. THAT DID NOT DELIVER	6	---	2	3	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	---
NO. WITH DYSTOCIA	0	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	4.3	2.6	3.4	3.8	2.9
MEAN GESTATION LENGTH (DAYS)	21.8	---	22.0	22.0	---
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
MEAN VIABLE LITTER SIZE ON PND 0	14.7	---	14.4	14.5	---
PUP SEX RATIO					
MEAN % MALE	48.3	---	53.7	44.7	---
MEAN % FEMALE	51.7	---	46.3	56.3	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.7	---	15.3	15.5	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.3	0.5	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.2	---	---	16.3
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.4	4.1	4.2	4.5	4.4
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	107.8	105.6	---
EXPERIMENTAL START DATE	1/25/00	10/25/99	11/3/99	2/29/00	11/19/99
DATE OF LAST NECROPSY	6/22/00	12/30/99	3/20/00	7/25/00	1/21/00
ROUTE	Gavage	SubQ	Inhalation	Inhalation	Intranasal
VEHICLE	Citric Acid Solution	Sponsor-Supplied Placebo	Filtered Air	Filtered Air	Sponsor-Supplied Placebo

= Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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Modified: 1/24/2005

Crl:CD(SD) Rat*

DATASET NO.	51	52	53	54	55
NO. MALES IN CONTROL GROUP	25	25	30	30	25
MALE MATING INDEX (%)	96.0	92.0	93.3	93.3	96.0
MALE FERTILITY INDEX (%)	88.0	92.0	83.3	80.0	92.0
NO. FEMALES IN CONTROL GROUP	25	25	30	30	25
FEMALE MATING INDEX (%)	100.0	100.0	93.3	93.3	96.0
FEMALE FERTILITY INDEX (%)	92.0	100.0	83.3	80.0	92.0
NO. FEMALES SELECTED TO DELIVER	---	---	30	30	---
NO. THAT DELIVERED	---	---	25	24	---
NO. THAT DID NOT DELIVER	---	---	5	6	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	---	0	0	---
NO. WITH DYSTOCIA	---	---	0	0	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.6	3.6	3.5	3.7	2.4
MEAN GESTATION LENGTH (DAYS)	---	---	22.0	21.6	---
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
MEAN VIABLE LITTER SIZE ON PND 0	---	---	13.0	13.9	---
PUP SEX RATIO					---
MEAN % MALE	---	---	49.7	50.3	---
MEAN % FEMALE	---	---	50.3	49.7	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	---	14.0	15.3	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	---	0.8	1.0	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.2	16.7	---	---	15.9
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.3	---	4.4	4.9	4.5
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	114.9	---
EXPERIMENTAL START DATE	1/14/00	1/25/00	2/4/00	5/30/00	2/7/00
DATE OF LAST NECROPSY	3/20/00	3/8/00	6/16/00	10/23/00	3/19/00
ROUTE	Gavage	Dermal	Diet	Diet	Gavage
VEHICLE	0.5% CMC	Sponsor-Supplied Placebo	Basal Feed	Basal Feed	0.5% MC-0.10% Tween 80

187044 RAD

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	56	57	58	59	60
NO. MALES IN CONTROL GROUP	25	---	25	25	---
MALE MATING INDEX (%)	95.8	---	100.0	84.0	---
MALE FERTILITY INDEX (%)	95.8	---	96.0	84.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	95.8	---	100.0	84.0	---
FEMALE FERTILITY INDEX (%)	95.8	92.0	96.0	84.0	96.0
NO. FEMALES SELECTED TO DELIVER	---	25	---	---	25
NO. THAT DELIVERED	---	23	---	---	24
NO. THAT DID NOT DELIVER	---	2	---	---	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	---	---	0
NO. WITH DYSTOCIA	---	0	---	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.6	---	2.9	2.4	---
MEAN GESTATION LENGTH (DAYS)	---	21.8	---	---	21.8
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
MEAN VIABLE LITTER SIZE ON PND 0	---	14.9	---	---	16.0
PUP SEX RATIO					
MEAN % MALE	---	50.4	---	---	52.0
MEAN % FEMALE	---	49.6	---	---	48.0
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	16.0	---	---	17.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	0.9	---	---	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	15.3	---	13.9	16.1	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.0	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/7/00	2/8/00	2/7/00	3/31/00	5/15/00
DATE OF LAST NECROPSY	6/6/00	3/26/00	7/11/00	6/12/00	7/4/00
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.5% MC-0.10% Tween 80	0.5% CMC	0.5% CMC	0.5% CMC	0.5% Aqueous CMC

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DATASET NO.	61	62	63	64	65
NO. MALES IN CONTROL GROUP	25	----	23	25	25
MALE MATING INDEX (%)	100.0	----	95.7	100.0	100.0
MALE FERTILITY INDEX (%)	100.0	----	91.3	84.0	100.0
NO. FEMALES IN CONTROL GROUP	25	25	23	25	25
FEMALE MATING INDEX (%)	100.0	---	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	100.0	96.0	91.3	84.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	25	23	---	---
NO. THAT DELIVERED	---	24	20	---	---
NO. THAT DID NOT DELIVER	---	1	3	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	1	0	---	---
NO. WITH DYSTOCIA	---	1	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.2	----	3.1	---	2.1
MEAN GESTATION LENGTH (DAYS)	---	21.8	21.9	---	---
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.0	13.1	---	---
PUP SEX RATIO					
MEAN % MALE	---	50.5	51.8	---	---
MEAN % FEMALE	---	49.5	48.2	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.7	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.0	0.6	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.0	---	---	15.4	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.3	4.1	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	6/28/00	7/4/00	8/15/00	8/25/00	9/25/00
DATE OF LAST NECROPSY	10/12/00	8/21/00	12/21/00	10/6/00	11/10/00
ROUTE	Untreated	Gavage	Untreated	Diet	Diet
VEHICLE	Not Applicable	10% Aqueous Acacia	Not Applicable	Basal Feed	Basal Feed

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WIL Reproductive Historical Control Data — Individual Study Data —
Crl:CD(SD) Rat*

DATASET NO.	66	67	68	69	70
NO. MALES IN CONTROL GROUP	---	25	25	25	---
MALE MATING INDEX (%)	----	100.0	92.0	96.0	---
MALE FERTILITY INDEX (%)	----	87.5	80.0	92.0	---
NO. FEMALES IN CONTROL GROUP	25	25	25	25	25
FEMALE MATING INDEX (%)	---	100.0	92.0	96.0	---
FEMALE FERTILITY INDEX (%)	76.0	88.0	80.0	92.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	23
NO. THAT DELIVERED	19	---	20	---	23
NO. THAT DID NOT DELIVER	6	---	5	---	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	2
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	1
MEAN PRE-COITAL INTERVAL (DAYS)	----	3.8	2.7	2.2	---
MEAN GESTATION LENGTH (DAYS)	21.9	---	22.0	---	22.0
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
MEAN VIABLE LITTER SIZE ON PND 0	14.0	---	14.6	---	14.3
PUP SEX RATIO					
MEAN % MALE	46.9	---	51.9	---	51.2
MEAN % FEMALE	53.1	---	48.1	---	48.8
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.3	---	15.4	---	15.9
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.9	---	0.7	---	1.0
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	16.6	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.2	4.8	4.3	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	8/22/00	10/4/00	10/27/00	12/5/00	1/19/01
DATE OF LAST NECROPSY	10/8/00	1/23/01	3/3/01	1/31/01	3/6/01
ROUTE	Gavage	Untreated	Gavage	IV	Gavage
VEHICLE	Aqueous 10% Lactic Acid	Not Applicable	Sesame Oil	Saline	DI Water

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Modified: 1/24/2005

DATASET NO.	71	72	73	74	75
NO. MALES IN CONTROL GROUP	23	---	25	25	40
MALE MATING INDEX (%)	95.5	---	88.0	96.0	97.5
MALE FERTILITY INDEX (%)	90.9	---	84.0	87.5	90.0
NO. FEMALES IN CONTROL GROUP	23	25	25	25	40
FEMALE MATING INDEX (%)	95.7	---	92.0	100.0	97.5
FEMALE FERTILITY INDEX (%)	91.3	100.0	88.0	92.0	90.0
NO. FEMALES SELECTED TO DELIVER	23	25	---	---	---
NO. THAT DELIVERED	21	25	---	---	---
NO. THAT DID NOT DELIVER	2	0	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	0	0	---	---	---
NO. WITH DYSTOCIA	0	0	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.3	---	3.1	3.1	2.7
MEAN GESTATION LENGTH (DAYS)	21.9	21.6	---	---	---
MEAN NO. PUPS BORN	12.6	15.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	12.6	15.2	---	---	---
PUP SEX RATIO					
MEAN % MALE	47.6	50.5	---	---	---
MEAN % FEMALE	52.4	49.5	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.0	16.2	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.3	0.7	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.3	16.6	16.6
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.1	---	4.4	4.5	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	3/3/01	2/19/01	3/28/01	2/20/01	3/20/01
DATE OF LAST NECROPSY	7/2/01	4/2/01	7/10/01	4/26/01	7/5/01
ROUTE	Untreated	Gavage	Untreated	Gavage	Gavage
VEHICLE	Not Applicable	Reverse Osmosis-Purified Water	Not Applicable	Reverse Osmosis-Purified Water	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	76	77	78	79	80
NO. MALES IN CONTROL GROUP	---	30	29	---	30
MALE MATING INDEX (%)	---	100.0	96.6	---	100.0
MALE FERTILITY INDEX (%)	---	96.7	86.2	---	93.3
NO. FEMALES IN CONTROL GROUP	25	30	30	25	30
FEMALE MATING INDEX (%)	96.0	100.0	96.6	92.0	100.0
FEMALE FERTILITY INDEX (%)	92.0	96.7	86.2	92.0	93.3
NO. FEMALES SELECTED TO DELIVER	---	30	29	---	---
NO. THAT DELIVERED	---	29	25	---	---
NO. THAT DID NOT DELIVER	---	1	4	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	1	0	0
NO. WITH TOTAL LITTER LOSS	---	2	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.1	2.7	2.6	3.4	2.8
MEAN GESTATION LENGTH (DAYS)	---	21.6	21.8	---	---
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	14.2	13.9	---	---
PUP SEX RATIO					
MEAN % MALE	---	51.2	49.2	---	---
MEAN % FEMALE	---	48.8	50.8	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.6	15.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	0.9	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	14.6	---	---	14.9	16.2
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.5	4.9	5.5	5.1	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	132.9	---	---
EXPERIMENTAL START DATE	4/20/01	6/12/01	10/4/01	6/15/01	7/12/01
DATE OF LAST NECROPSY	6/11/01	10/22/01	3/8/02	7/30/01	10/5/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	2%Cremophor 0.15% Benzoic Acid 150 mM NaCl in DI Water	0.5% MC

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DATASET NO.	81	82	83	84	85
NO. MALES IN CONTROL GROUP	25	25	25	25	25
MALE MATING INDEX (%)	92.0	92.0	100.0	100.0	100.0
MALE FERTILITY INDEX (%)	84.0	92.0	100.0	91.7	100.0
NO. FEMALES IN CONTROL GROUP	25	25	25	24	25
FEMALE MATING INDEX (%)	100.0	96.0	100.0	100.0	100.0
FEMALE FERTILITY INDEX (%)	88.0	92.0	100.0	100.0	96.0
NO. FEMALES SELECTED TO DELIVER	25	25	---	---	---
NO. THAT DELIVERED	20	23	---	---	---
NO. THAT DID NOT DELIVER	5	2	---	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	1	1	0	0	0
NO. WITH TOTAL LITTER LOSS	1	1	---	---	---
NO. WITH DYSTOCIA	0	1	---	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.8	4.7	2.8	2.5	3.0
MEAN GESTATION LENGTH (DAYS)	21.9	22.0	---	---	---
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
MEAN VIABLE LITTER SIZE ON PND 0	14.3	12.7	---	---	---
PUP SEX RATIO					
MEAN % MALE	46.6	47.1	---	---	---
MEAN % FEMALE	53.4	52.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	14.3	---	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.9	---	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.8	15.1	15.1
MEAN ESTROUS CYCLE LENGTH (DAYS)	5.8	4.9	5.2	---	5.0
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	50.4	---	---	---
EXPERIMENTAL START DATE	8/6/01	11/28/01	8/6/01	9/7/01	7/17/01
DATE OF LAST NECROPSY	12/10/01	4/27/02	9/18/01	11/21/01	10/16/01
ROUTE	Inhalation/ Gavage	Inhalation/ Gavage	Gavage	Gavage	Gavage
VEHICLE	Filtered Air/ Olive Oil	Filtered Air/ Olive Oil	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	0.5%MC 0.1%Tween80 1% Sodium Dodecyl Sulfate in DI Water	PEG 1000/ Carbowax PEG 400 in DI Water

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	86	87	88	89	90
NO. MALES IN CONTROL GROUP	---	30	30	25	25
MALE MATING INDEX (%)	---	86.7	96.7	100.0	100.0
MALE FERTILITY INDEX (%)	---	73.3	73.3	96.0	100.0
NO. FEMALES IN CONTROL GROUP	25	30	30	25	25
FEMALE MATING INDEX (%)	100.0	86.7	96.7	100.0	100.0
FEMALE FERTILITY INDEX (%)	96.0	73.3	73.3	96.0	100.0
NO. FEMALES SELECTED TO DELIVER	---	30	30	---	---
NO. THAT DELIVERED	---	22	22	---	---
NO. THAT DID NOT DELIVER	---	8	8	---	---
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	0	0
NO. WITH TOTAL LITTER LOSS	---	0	0	---	---
NO. WITH DYSTOCIA	---	0	0	---	---
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	2.8	4.0	2.5	2.6
MEAN GESTATION LENGTH (DAYS)	---	22.0	22.0	---	---
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
MEAN VIABLE LITTER SIZE ON PND 0	---	13.6	13.0	---	---
PUP SEX RATIO					
MEAN % MALE	---	49.6	46.9	---	---
MEAN % FEMALE	---	50.4	53.1	---	---
MEAN NO. OF IMPLANTATION SITES AT WEANING	---	15.1	14.2	---	---
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	---	1.2	1.2	---	---
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	16.7	---	---	16.8	15.7
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	5.3	4.7	4.6	4.1
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	114.6	---	---
EXPERIMENTAL START DATE	8/26/01	9/2/01	1/2/02	10/12/01	10/19/01
DATE OF LAST NECROPSY	10/21/01	1/15/02	5/31/02	12/14/01	12/27/01
ROUTE	Gavage	Inhalation	Inhalation	Gavage	Gavage
VEHICLE	0.5% Aqueous CMC	Filtered Air	Filtered Air	DI Water	2.5%HPMC in 50mM Sodium Acetate

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WIL Reproductive Historical Control Data **Individual Study Data**
Crl:CD(SD) Rat*

DATASET NO.	91	92	93	94	95
NO. MALES IN CONTROL GROUP	---	25	30	30	30
MALE MATING INDEX (%)	---	95.5	96.7	96.7	100.0
MALE FERTILITY INDEX (%)	---	95.5	93.3	80.0	93.3
NO. FEMALES IN CONTROL GROUP	25	25	30	30	30
FEMALE MATING INDEX (%)	---	95.8	96.7	96.7	100.0
FEMALE FERTILITY INDEX (%)	100.0	95.8	93.3	80.0	93.3
NO. FEMALES SELECTED TO DELIVER	25	---	30	30	30
NO. THAT DELIVERED	25	---	28	24	27
NO. THAT DID NOT DELIVER	0	---	2	6	3
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	1	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	0	0
NO. WITH DYSTOCIA	0	---	0	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	3.0	3.5	3.1	1.8
MEAN GESTATION LENGTH (DAYS)	21.7	---	21.9	22.1	21.7
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
MEAN VIABLE LITTER SIZE ON PND 0	14.9	---	14.7	13.0	14.8
PUP SEX RATIO					
MEAN % MALE	49.1	---	42.7	56.6	45.9
MEAN % FEMALE	50.9	---	57.3	43.4	54.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	16.0	---	15.7	13.9	15.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	---	0.8	0.8	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	13.9	---	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	4.0	4.5	4.5	4.2
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	107.0	---
EXPERIMENTAL START DATE	12/3/01	1/8/02	2/15/02	6/21/02	12/26/01
DATE OF LAST NECROPSY	1/14/02	4/24/02	7/11/02	11/6/02	5/7/02
ROUTE	Gavage	Untreated	Diet	Diet	Drinking Water
VEHICLE	DI Water	Not Applicable	Basal Feed	Basal Feed	Drinking Water

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DATASET NO.	96	97	98	99	100
NO. MALES IN CONTROL GROUP	30	---	25	---	25
MALE MATING INDEX (%)	96.7	---	96.0	---	96.0
MALE FERTILITY INDEX (%)	86.7	---	92.0	---	96.0
NO. FEMALES IN CONTROL GROUP	30	25	25	25	25
FEMALE MATING INDEX (%)	96.7	---	100.0	---	100.0
FEMALE FERTILITY INDEX (%)	86.7	96.0	96.0	88.0	100.0
NO. FEMALES SELECTED TO DELIVER	30	25	---	25	25
NO. THAT DELIVERED	26	24	---	22	24
NO. THAT DID NOT DELIVER	4	1	---	3	1
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0	0	1	0
NO. WITH TOTAL LITTER LOSS	0	0	---	0	0
NO. WITH DYSTOCIA	0	0	---	1	0
MEAN PRE-COITAL INTERVAL (DAYS)	2.9	---	3.1	---	4.0
MEAN GESTATION LENGTH (DAYS)	22.0	21.7	---	21.8	21.8
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
MEAN VIABLE LITTER SIZE ON PND 0	14.3	15.0	---	15.3	14.2
PUP SEX RATIO					
MEAN % MALE	53.5	48.4	---	45.8	48.9
MEAN % FEMALE	46.5	51.6	---	54.2	51.1
MEAN NO. OF IMPLANTATION SITES AT WEANING	15.2	15.7	---	17.1	15.4
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.7	0.7	---	1.1	1.1
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	14.5	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.0	---	4.2	---	4.3
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	4/18/02	10/22/02	2/11/03	11/18/02	3/10/03
DATE OF LAST NECROPSY	9/12/02	12/9/02	3/20/03	12/30/02	5/8/03
ROUTE	Drinking Water	Gavage	Gavage	Gavage	Gavage
VEHICLE	Drinking Water	2.5%HPMC in 50mM Sodium Acetate	2.5%HPMC in 50mM Sodium Acetate	0.5% MC	0.5% MC

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DATASET NO.	101	102	103	104	105
NO. MALES IN CONTROL GROUP	25	---	---	25	25
MALE MATING INDEX (%)	96.0	---	---	96.0	96.0
MALE FERTILITY INDEX (%)	92.0	---	---	96.0	72.0
NO. FEMALES IN CONTROL GROUP	25	---	25	25	25
FEMALE MATING INDEX (%)	96.0	---	---	100.0	96.0
FEMALE FERTILITY INDEX (%)	92.0	---	96.0	100.0	72.0
NO. FEMALES SELECTED TO DELIVER	25	---	25	---	25
NO. THAT DELIVERED	23	---	24	---	18
NO. THAT DID NOT DELIVER	2	---	1	---	7
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	---	0	0	0
NO. WITH TOTAL LITTER LOSS	0	---	0	---	0
NO. WITH DYSTOCIA	0	---	0	---	0
MEAN PRE-COITAL INTERVAL (DAYS)	3.0	---	---	3.5	3.4
MEAN GESTATION LENGTH (DAYS)	22.0	---	21.9	---	21.9
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
MEAN VIABLE LITTER SIZE ON PND 0	13.9	---	15.3	---	13.4
PUP SEX RATIO					
MEAN % MALE	52.6	---	47.9	---	53.7
MEAN % FEMALE	47.4	---	52.1	---	46.3
MEAN NO. OF IMPLANTATION SITES AT WEANING	14.5	---	16.1	---	14.5
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	0.8	---	0.7	---	0.9
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---	---	15.4	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	4.2	---	---	4.2	4.7
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---	---	---	---
EXPERIMENTAL START DATE	1/7/03	1/7/03	7/22/03	11/10/03	6/10/03
DATE OF LAST NECROPSY	5/30/03	6/20/03	10/28/03	12/16/03	10/12/03
ROUTE	Gavage	Gavage	Gavage	Gavage	Gavage
VEHICLE	0.10% Sodium Phosphate Buffer	0.10% Sodium Phosphate Buffer	DI Water	DI Water	1.0% MC

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DATASET NO.	106	107
NO. MALES IN CONTROL GROUP	---	---
MALE MATING INDEX (%)	---	---
MALE FERTILITY INDEX (%)	---	---
NO. FEMALES IN CONTROL GROUP	25	25
FEMALE MATING INDEX (%)	---	---
FEMALE FERTILITY INDEX (%)	100.0	100.0
NO. FEMALES SELECTED TO DELIVER	25	25
NO. THAT DELIVERED	25	25
NO. THAT DID NOT DELIVER	0	0
NO. THAT DIED OR WERE EUTHANIZED MORIBUND	0	0
NO. WITH TOTAL LITTER LOSS	0	0
NO. WITH DYSTOCIA	0	0
MEAN PRE-COITAL INTERVAL (DAYS)	---	---
MEAN GESTATION LENGTH (DAYS)	21.6	21.7
MEAN NO. PUPS BORN	15.9	15.5
MEAN VIABLE LITTER SIZE ON PND 0	15.7	15.3
PUP SEX RATIO		
MEAN % MALE	49.4	46.3
MEAN % FEMALE	50.6	53.7
MEAN NO. OF IMPLANTATION SITES AT WEANING	17.0	16.0
MEAN NO. OF SITES UNACCOUNTED FOR AT WEANING	1.0	0.5
MEAN NO. OF IMPLANTATION SITES AT LAPAROHYSTERECTOMY	---	---
MEAN ESTROUS CYCLE LENGTH (DAYS)	---	---
MEAN PRIMORDIAL FOLLICLE COUNT/10 SECTIONS/DAM	---	---
EXPERIMENTAL START DATE	10/27/03	10/28/03
DATE OF LAST NECROPSY	2/2/04	2/3/04
ROUTE	Gavage	Gavage
VEHICLE	1.0% MC	1.0% MC

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DATASET NO.	1	2	3	4	5
MEAN NO. PUPS BORN	12.0	12.9	13.6	13.5	13.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	92.3	97.5	99.3	99.2	99.4
PND 0 TO PND 1	100.0	99.6	99.2	99.4	99.2
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	98.6	99.3	100.0	99.3
PND 4 (AFTER SELECTION) TO PND 7	99.5	100.0	100.0	99.1	100.0
PND 7 TO PND 14	100.0	100.0	100.0	100.0	100.0
PND 14 TO PND 21	100.0	98.5	100.0	100.0	99.6
BIRTH TO PND 4 (BEFORE SELECTION)	92.3	95.9	97.8	98.7	97.9
PND 4 (AFTER SELECTION) TO PND 21	99.5	98.5	100.0	99.1	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.4	7.1	7.2	7.0	7.2
PND 4 (BEFORE SELECTION)	10.6	10.6	10.1	10.2	10.4
PND 7	17.2	17.2	16.4	16.8	15.1
PND 14	33.7	35.8	29.9	35.0	27.8
PND 21	53.8	58.0	45.4	53.1	44.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.8	6.8	6.6	6.7
PND 4 (BEFORE SELECTION)	10.0	10.0	9.5	9.7	9.7
PND 7	16.1	16.3	15.5	16.2	14.1
PND 14	32.1	34.3	28.9	33.9	26.3
PND 21	51.6	54.8	44.1	51.0	42.2
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3915
SPLEEN	---	---	---	---	0.1698
THYMUS GLAND	---	---	---	---	0.1690
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3530
SPLEEN	---	---	---	---	0.1722
THYMUS GLAND	---	---	---	---	0.1743

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DATASET NO.	6	7	8	9	10
MEAN NO. PUPS BORN	13.4	15.0	13.2	13.2	13.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.3	96.6	97.7	98.2	97.7
PND 0 TO PND 1	99.8	94.5	99.4	99.7	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	97.8	99.4	97.8	99.7	100.0
PND 4 (AFTER SELECTION) TO PND 7	100.0	100.0	99.5	100.0	100.0
PND 7 TO PND 14	96.6	100.0	100.0	100.0	96.9
PND 14 TO PND 21	99.6	100.0	100.0	100.0	97.8
BIRTH TO PND 4 (BEFORE SELECTION)	96.0	91.3	95.2	97.7	97.4
PND 4 (AFTER SELECTION) TO PND 21	96.1	100.0	99.5	100.0	96.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	6.8	6.8	7.3	7.1
PND 4 (BEFORE SELECTION)	10.2	9.6	9.6	10.5	10.4
PND 7	15.3	15.3	15.4	16.4	16.6
PND 14	28.5	31.1	31.8	33.1	33.4
PND 21	45.3	51.0	49.5	50.6	52.1
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.5	6.3	6.9	6.7
PND 4 (BEFORE SELECTION)	9.5	9.1	9.0	10.0	9.7
PND 7	14.3	14.5	14.6	15.7	15.6
PND 14	27.5	29.7	30.8	32.2	31.2
PND 21	43.5	47.9	47.7	49.2	49.0
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4000	1.4926	1.4660	---	---
SPLEEN	0.1805	0.2106	0.1901	---	---
THYMUS GLAND	0.1790	0.2155	0.2076	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3682	1.4242	1.4214	---	---
SPLEEN	0.1846	0.1975	0.1929	---	---
THYMUS GLAND	0.1853	0.2113	0.2099	---	---

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Crl:CD(SD) Rat*

DATASET NO.	11	12	13	14	15
MEAN NO. PUPS BORN	13.7	13.4	13.5	14.9	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.4	97.6	97.8	97.0	95.7
PND 0 TO PND 1	99.3	98.9	99.4	99.6	95.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	99.6	99.2	98.8	100.0
PND 4 (AFTER SELECTION) TO PND 7	97.2	99.6	---	---	100.0
PND 7 TO PND 14	96.3	---	---	---	99.5
PND 14 TO PND 21	100.0	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.5	96.2	96.4	95.4	94.0
PND 4 (AFTER SELECTION) TO PND 21	95.4	98.5	---	---	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.9	6.6	7.0	6.9	7.1
PND 4 (BEFORE SELECTION)	9.1	8.9	9.3	9.5	10.0
PND 7	11.7	12.3	---	---	16.2
PND 14	22.5	24.6	---	---	32.5
PND 21	34.9	38.2	---	---	51.4
PND 28	65.4	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	6.2	6.5	6.4	6.7
PND 4 (BEFORE SELECTION)	8.5	8.4	8.8	9.0	9.5
PND 7	11.0	11.5	---	---	15.4
PND 14	21.2	23.4	---	---	31.7
PND 21	33.3	37.0	---	---	49.1
PND 28	59.8	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3616	1.4033	---	---	---
SPLEEN	0.1189	0.1544	---	---	---
THYMUS GLAND	0.1392	0.1640	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.2903	1.3390	---	---	---
SPLEEN	0.1182	0.1539	---	---	---
THYMUS GLAND	0.1338	0.1612	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN NO. PUPS BORN	14.3	15.5	14.8	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.5	97.3	99.0	---	---
PND 0 TO PND 1	100.0	98.5	98.8	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.4	99.0	99.6	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	94.9	97.5	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	100.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	6.7	7.1	---	---
PND 4 (BEFORE SELECTION)	10.3	9.2	10.2	---	---
PND 7	---	13.1	16.5	---	---
PND 14	---	25.1	34.9	---	---
PND 21	---	39.5	54.7	---	---
PND 28	---	70.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.3	6.7	---	---
PND 4 (BEFORE SELECTION)	9.8	8.7	9.7	---	---
PND 7	---	12.6	15.9	---	---
PND 14	---	24.1	33.7	---	---
PND 21	---	38.0	52.4	---	---
PND 28	---	66.8	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN NO. PUPS BORN	14.1	15.0	14.8	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.6	98.7	99.0	---	99.8
PND 0 TO PND 1	99.7	99.1	100.0	---	100.0
PND 1 TO PND 4 (BEFORE SELECTION)	100.0	99.8	98.8	---	99.5
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	---	100.0
PND 7 TO PND 14	99.5	---	100.0	---	100.0
PND 14 TO PND 21	100.0	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.4	97.5	97.8	---	99.3
PND 4 (AFTER SELECTION) TO PND 21	99.5	---	100.0	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.1	7.4	---	6.8
PND 4 (BEFORE SELECTION)	10.2	10.4	10.7	---	9.6
PND 7	16.7	---	17.8	---	15.7
PND 14	34.8	---	36.5	---	32.4
PND 21	53.3	---	55.3	---	52.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.7	6.9	---	6.5
PND 4 (BEFORE SELECTION)	9.7	9.7	10.0	---	9.1
PND 7	16.1	---	16.8	---	14.9
PND 14	33.5	---	34.7	---	31.2
PND 21	50.9	---	53.1	---	50.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN NO. PUPS BORN	---	15.2	16.3	14.8	15.1
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.9	97.7	98.9	99.5
PND 0 TO PND 1	---	94.3	96.7	98.2	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.6	98.8	98.8	99.4
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	99.5
PND 7 TO PND 14	---	99.3	100.0	---	98.5
PND 14 TO PND 21	---	100.0	100.0	---	98.8
BIRTH TO PND 4 (BEFORE SELECTION)	---	92.1	93.8	96.0	98.0
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	100.0	---	97.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	6.7	7.1	6.5
PND 4 (BEFORE SELECTION)	---	9.4	9.4	9.8	8.6
PND 7	---	15.1	15.1	---	13.0
PND 14	---	31.3	32.9	---	27.1
PND 21	---	48.1	50.9	---	41.3
PND 28	---	86.6	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.4	6.4	6.6	6.1
PND 4 (BEFORE SELECTION)	---	8.9	8.8	9.1	8.1
PND 7	---	14.1	14.3	---	12.2
PND 14	---	29.4	31.2	---	25.7
PND 21	---	45.0	48.0	---	39.4
PND 28	---	79.4	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN NO. PUPS BORN	---	15.4	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.3	---	---	---
PND 0 TO PND 1	---	99.3	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	99.7	---	---	---
PND 7 TO PND 14	---	99.7	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	97.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.3	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	---	---	---
PND 4 (BEFORE SELECTION)	---	10.1	---	---	---
PND 7	---	14.8	---	---	---
PND 14	---	27.2	---	---	---
PND 21	---	45.5	---	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	---	---	---
PND 4 (BEFORE SELECTION)	---	9.6	---	---	---
PND 7	---	14.0	---	---	---
PND 14	---	26.3	---	---	---
PND 21	---	43.8	---	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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WIL Reproductive Historical Control Data — Individual Study Data —
Crl:CD(SD) Rat*

DATASET NO.	36	37	38	39	40
MEAN NO. PUPS BORN	---	---	14.8	14.8	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	95.8	97.7	---
PND 0 TO PND 1	---	---	98.7	98.9	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	97.7	98.1	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	---	---
PND 7 TO PND 14	---	---	99.5	---	---
PND 14 TO PND 21	---	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	92.4	94.8	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.8	6.8	---
PND 4 (BEFORE SELECTION)	---	---	9.5	9.2	---
PND 7	---	---	15.0	---	---
PND 14	---	---	31.8	---	---
PND 21	---	---	48.9	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	6.4	6.3	---
PND 4 (BEFORE SELECTION)	---	---	8.9	8.8	---
PND 7	---	---	14.1	---	---
PND 14	---	---	30.5	---	---
PND 21	---	---	46.7	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN NO. PUPS BORN	15.6	15.2	---	---	14.8
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.5	98.6	---	---	99.1
PND 0 TO PND 1	99.7	99.6	---	---	98.6
PND 1 TO PND 4 (BEFORE SELECTION)	99.1	98.4	---	---	99.8
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.7	---	---	99.6
PND 7 TO PND 14	100.0	---	---	---	100.0
PND 14 TO PND 21	100.0	---	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	---	---	97.5
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	---	---	99.6
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	7.4	---	---	6.6
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	9.0
PND 7	15.3	15.2	---	---	14.9
PND 14	32.5	---	---	---	31.1
PND 21	51.4	---	---	---	45.7
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	6.9	---	---	6.2
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	8.5
PND 7	14.5	14.4	---	---	14.2
PND 14	31.3	---	---	---	30.0
PND 21	49.5	---	---	---	44.5
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.4163
SPLEEN	---	---	---	---	0.1822
THYMUS GLAND	---	---	---	---	0.1758
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	1.3876
SPLEEN	---	---	---	---	0.1915
THYMUS GLAND	---	---	---	---	0.1852

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DATASET NO.	46	47	48	49	50
MEAN NO. PUPS BORN	14.9	---	15.0	14.9	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.5	---	96.6	97.3	---
PND 0 TO PND 1	100.0	---	100.0	99.7	---
PND 1 TO PND 4 (BEFORE SELECTION)	98.4	---	99.5	99.7	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	---	100.0	100.0	---
PND 7 TO PND 14	100.0	---	99.5	100.0	---
PND 14 TO PND 21	100.0	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	96.9	---	96.1	96.8	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	---	99.5	100.0	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	---	7.3	7.1	---
PND 4 (BEFORE SELECTION)	9.3	---	10.7	10.3	---
PND 7	15.1	---	15.4	15.5	---
PND 14	32.1	---	28.8	29.2	---
PND 21	51.1	---	48.4	49.5	---
PND 28	---	---	88.1	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.2	---	6.9	6.7	---
PND 4 (BEFORE SELECTION)	8.7	---	10.1	9.6	---
PND 7	14.0	---	14.5	14.5	---
PND 14	30.4	---	27.4	27.6	---
PND 21	47.5	---	45.9	46.6	---
PND 28	---	---	79.5	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4763	---	1.4897	1.4728	---
SPLEEN	0.2176	---	0.2063	0.2189	---
THYMUS GLAND	0.1990	---	0.1951	0.1958	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4261	---	1.4332	1.3957	---
SPLEEN	0.2042	---	0.1977	0.2087	---
THYMUS GLAND	0.1986	---	0.2001	0.1895	---

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DATASET NO.	51	52	53	54	55
MEAN NO. PUPS BORN	---	---	13.2	14.3	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	---	98.7	97.6	---
PND 0 TO PND 1	---	---	100.0	99.5	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	---	99.3	99.2	---
PND 4 (AFTER SELECTION) TO PND 7	---	---	100.0	99.5	---
PND 7 TO PND 14	---	---	100.0	100.0	---
PND 14 TO PND 21	---	---	100.0	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	---	98.0	96.3	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	100.0	99.5	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.6	7.2	---
PND 4 (BEFORE SELECTION)	---	---	11.2	10.2	---
PND 7	---	---	17.7	16.9	---
PND 14	---	---	35.1	35.2	---
PND 21	---	---	57.6	55.2	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	---	7.2	6.8	---
PND 4 (BEFORE SELECTION)	---	---	10.7	9.7	---
PND 7	---	---	17.1	16.2	---
PND 14	---	---	35.1	33.7	---
PND 21	---	---	55.6	52.2	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.5175	1.4836	---
SPLEEN	---	---	0.2476	0.2227	---
THYMUS GLAND	---	---	0.2372	0.2446	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4597	1.4341	---
SPLEEN	---	---	0.2302	0.2200	---
THYMUS GLAND	---	---	0.2479	0.2407	---

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DATASET NO.	56	57	58	59	60
MEAN NO. PUPS BORN	---	15.1	---	---	16.5
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	98.9	---	---	97.3
PND 0 TO PND 1	---	98.6	---	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	---	93.5	---	---	100.0
PND 4 (AFTER SELECTION) TO PND 7	---	99.4	---	---	100.0
PND 7 TO PND 14	---	100.0	---	---	100.0
PND 14 TO PND 21	---	100.0	---	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	---	91.6	---	---	95.9
PND 4 (AFTER SELECTION) TO PND 21	---	99.4	---	---	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.0	---	---	7.1
PND 4 (BEFORE SELECTION)	---	9.6	---	---	9.7
PND 7	---	16.1	---	---	16.1
PND 14	---	33.9	---	---	34.4
PND 21	---	52.4		---	54.4
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.6	---	---	6.7
PND 4 (BEFORE SELECTION)	---	9.2	---	---	9.2
PND 7	---	15.1	---	---	15.2
PND 14	---	32.5	---	---	32.8
PND 21	---	49.2	---	---	52.1
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN NO. PUPS BORN	---	14.7	13.7	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	95.6	95.8	---	---
PND 0 TO PND 1	---	95.4	98.1	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	98.9	99.3	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	93.1	93.3	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	100.0	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	7.1	7.1	---	---
PND 4 (BEFORE SELECTION)	---	9.9	10.7	---	---
PND 7	---	15.7	---	---	---
PND 14	---	30.0	---	---	---
PND 21	---	48.4	---	---	---
PND 28	---	88.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.7	6.8	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.1	---	---
PND 7	---	14.9	---	---	---
PND 14	---	28.9	---	---	---
PND 21	---	46.6	---	---	---
PND 28	---	80.5	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN NO. PUPS BORN	14.4	---	14.8	---	14.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	97.0	---	98.8	---	97.8
PND 0 TO PND 1	99.0	---	98.1	---	99.7
PND 1 TO PND 4 (BEFORE SELECTION)	95.7	---	99.7	---	99.3
PND 4 (AFTER SELECTION) TO PND 7	95.8	---	100.0	---	98.4
PND 7 TO PND 14	100.0	---	100.0	---	99.4
PND 14 TO PND 21	99.2	---	100.0	---	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	91.9	---	96.6	---	96.7
PND 4 (AFTER SELECTION) TO PND 21	95.2	---	100.0	---	97.8
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	---	7.1	---	7.2
PND 4 (BEFORE SELECTION)	10.3	---	9.8	---	10.1
PND 7	16.3	---	15.3	---	15.1
PND 14	32.5	---	32.3	---	30.9
PND 21	49.4	---	52.1	---	48.2
PND 28	89.8	---	---	---	83.2
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	---	6.6	---	6.8
PND 4 (BEFORE SELECTION)	9.7	---	9.1	---	9.4
PND 7	15.8	---	14.5	---	14.1
PND 14	32.8	---	31.1	---	29.5
PND 21	50.2	---	49.7	---	46.3
PND 28	86.2	---	---	---	77.9
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	71	72	73	74	75
MEAN NO. PUPS BORN	12.6	15.5	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.6	97.4	---	---	---
PND 0 TO PND 1	98.5	99.8	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.0	99.0	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.4	99.5	---	---	---
PND 7 TO PND 14	---	100.0	---	---	---
PND 14 TO PND 21	---	100.0	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.1	96.2	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.5	7.0	---	---	---
PND 4 (BEFORE SELECTION)	10.8	9.7	---	---	---
PND 7	17.4	15.4	---	---	---
PND 14	---	32.4	---	---	---
PND 21	---	50.0	---	---	---
PND 28	---	87.8	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.6	---	---	---
PND 4 (BEFORE SELECTION)	10.4	9.1	---	---	---
PND 7	16.5	14.4	---	---	---
PND 14	---	30.9	---	---	---
PND 21	---	47.3	---	---	---
PND 28	---	82.1	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN NO. PUPS BORN	---	14.4	14.3	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.3	97.5	---	---
PND 0 TO PND 1	---	98.0	99.5	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	99.6	98.8	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	96.6	100.0	---	---
PND 7 TO PND 14	---	94.4	99.0	---	---
PND 14 TO PND 21	---	95.9	99.5	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	94.9	95.7	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	92.2	98.5	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.8	7.2	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.5	---	---
PND 7	---	12.8	15.0	---	---
PND 14	---	24.8	29.7	---	---
PND 21	---	39.1	45.1	---	---
PND 28	---	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	8.9	9.9	---	---
PND 7	---	11.8	14.3	---	---
PND 14	---	23.6	28.3	---	---
PND 21	---	39.1	42.9	---	---
PND 28	---	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3553	1.4080	---	---
SPLEEN	---	0.1471	0.1755	---	---
THYMUS GLAND	---	0.1723	0.1901	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	1.3241	1.3683	---	---
SPLEEN	---	0.1471	0.1850	---	---
THYMUS GLAND	---	0.1710	0.2032	---	---

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DATASET NO.	81	82	83	84	85
MEAN NO. PUPS BORN	14.5	13.6	---	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.0	93.3	---	---	---
PND 0 TO PND 1	100.0	100.0	---	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	99.6	99.3	---	---	---
PND 4 (AFTER SELECTION) TO PND 7	99.0	100.0	---	---	---
PND 7 TO PND 14	93.5	100.0	---	---	---
PND 14 TO PND 21	94.7	99.5	---	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.7	92.7	---	---	---
PND 4 (AFTER SELECTION) TO PND 21	91.1	99.5	---	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.1	7.4	---	---	---
PND 4 (BEFORE SELECTION)	9.7	10.7	---	---	---
PND 7	12.8	15.2	---	---	---
PND 14	23.3	---	---	---	---
PND 21	38.4	42.6	---	---	---
PND 28	74.0	79.2	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	7.1	---	---	---
PND 4 (BEFORE SELECTION)	9.2	10.1	---	---	---
PND 7	12.2	14.3	---	---	---
PND 14	22.7	---	---	---	---
PND 21	37.6	40.5	---	---	---
PND 28	69.3	73.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3451	1.4458	---	---	---
SPLEEN	0.1503	0.1817	---	---	---
THYMUS GLAND	0.1617	0.1971	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.3142	1.3833	---	---	---
SPLEEN	0.1515	0.1686	---	---	---
THYMUS GLAND	0.1669	0.1948	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN NO. PUPS BORN	---	13.9	13.1	---	---
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	---	97.8	98.8	---	---
PND 0 TO PND 1	---	100.0	99.4	---	---
PND 1 TO PND 4 (BEFORE SELECTION)	---	97.7	99.7	---	---
PND 4 (AFTER SELECTION) TO PND 7	---	100.0	100.0	---	---
PND 7 TO PND 14	---	100.0	100.0	---	---
PND 14 TO PND 21	---	100.0	99.4	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	---	95.5	97.9	---	---
PND 4 (AFTER SELECTION) TO PND 21	---	---	99.4	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.9	7.3	---	---
PND 4 (BEFORE SELECTION)	---	9.4	10.4	---	---
PND 7	---	12.9	14.6	---	---
PND 14	---	24.0	27.3	---	---
PND 21	---	38.5	43.9	---	---
PND 28	---	72.0	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	---	6.5	6.9	---	---
PND 4 (BEFORE SELECTION)	---	9.0	9.8	---	---
PND 7	---	12.5	13.9	---	---
PND 14	---	23.3	26.2	---	---
PND 21	---	36.9	41.9	---	---
PND 28	---	66.7	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3987	---	---
SPLEEN	---	---	0.1815	---	---
THYMUS GLAND	---	---	0.1678	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3623	---	---
SPLEEN	---	---	0.1905	---	---
THYMUS GLAND	---	---	0.1778	---	---

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DATASET NO.	91	92	93	94	95
MEAN NO. PUPS BORN	15.3	---	14.9	13.2	15.0
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	96.8	---	99.1	98.7	98.7
PND 0 TO PND 1	100.0	---	98.9	97.0	99.1
PND 1 TO PND 4 (BEFORE SELECTION)	99.8	---	99.0	99.2	99.8
PND 4 (AFTER SELECTION) TO PND 7	99.0	---	99.6	99.5	100.0
PND 7 TO PND 14	98.0	---	100.0	100.0	100.0
PND 14 TO PND 21	99.0	---	99.6	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	96.5	---	97.1	94.9	97.6
PND 4 (AFTER SELECTION) TO PND 21	96.0	---	99.1	99.5	100.0
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	7.1	7.5	6.9
PND 4 (BEFORE SELECTION)	9.2	---	9.9	10.8	9.5
PND 7	14.0	---	15.7	17.3	15.5
PND 14	24.6	---	32.2	35.3	32.6
PND 21	37.8	---	50.5	56.7	51.3
PND 28	69.8	---	---	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.4	---	6.7	7.0	6.4
PND 4 (BEFORE SELECTION)	8.8	---	9.4	10.1	8.9
PND 7	13.3	---	15.0	16.3	14.6
PND 14	24.2	---	31.3	33.9	31.2
PND 21	36.9	---	48.9	53.5	49.3
PND 28	67.4	---	---	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.4143	1.4899	1.4775
SPLEEN	---	---	0.2232	0.2480	0.2220
THYMUS GLAND	---	---	0.1943	0.2330	0.2081
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	1.3958	1.4378	1.4216
SPLEEN	---	---	0.2335	0.2408	0.2229
THYMUS GLAND	---	---	0.2120	0.2363	0.2265

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DATASET NO.	96	97	98	99	100
MEAN NO. PUPS BORN	14.5	15.0	---	15.9	14.3
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	98.9	100.0	---	96.1	99.0
PND 0 TO PND 1	99.5	99.5	---	99.7	98.8
PND 1 TO PND 4 (BEFORE SELECTION)	98.8	97.4	---	96.8	---
PND 4 (AFTER SELECTION) TO PND 7	100.0	97.3	---	96.9	---
PND 7 TO PND 14	100.0	99.4	---	99.3	---
PND 14 TO PND 21	100.0	100.0	---	100.0	---
BIRTH TO PND 4 (BEFORE SELECTION)	97.2	96.9	---	92.4	---
PND 4 (AFTER SELECTION) TO PND 21	100.0	96.8	---	96.3	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.0	6.9	---	7.0	7.3
PND 4 (BEFORE SELECTION)	9.9	9.3	---	9.5	---
PND 7	16.2	14.5	---	15.4	---
PND 14	33.0	30.7	---	32.7	---
PND 21	50.0	49.7	---	51.6	---
PND 28	---	83.5	---	87.1	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.7	6.6	---	6.6	6.9
PND 4 (BEFORE SELECTION)	9.4	8.9	---	9.0	---
PND 7	15.5	13.9	---	14.4	---
PND 14	31.9	29.5	---	30.7	---
PND 21	48.5	47.6	---	48.6	---
PND 28	---	77.7	---	78.4	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4605	---	---	---	---
SPLEEN	0.2211	---	---	---	---
THYMUS GLAND	0.2123	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	1.4199	---	---	---	---
SPLEEN	0.2261	---	---	---	---
THYMUS GLAND	0.2078	---	---	---	---

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Crl:CD(SD) Rat*

DATASET NO.	101	102	103	104	105
MEAN NO. PUPS BORN	13.9	---	15.4	---	13.7
PUP SURVIVAL INDICES (% PER LITTER)					
PND 0 (RELATIVE TO NO. BORN)	99.7	---	99.2	---	98.3
PND 0 TO PND 1	99.4	---	99.4	---	98.4
PND 1 TO PND 4 (BEFORE SELECTION)	99.2	---	99.2	---	99.2
PND 4 (AFTER SELECTION) TO PND 7	99.6	---	99.5	---	100.0
PND 7 TO PND 14	99.6	---	99.5	---	---
PND 14 TO PND 21	100.0	---	100.0	---	---
BIRTH TO PND 4 (BEFORE SELECTION)	98.4	---	97.8	---	---
PND 4 (AFTER SELECTION) TO PND 21	99.1	---	99.0	---	---
MEAN MALE OFFSPRING BODY WEIGHTS (G)					
PND 1	7.2	---	7.3	---	7.6
PND 4 (BEFORE SELECTION)	10.5	---	10.1	---	11.4
PND 7	16.1	---	16.4	---	16.4
PND 14	31.1	---	34.0	---	---
PND 21	49.0	---	53.8	---	---
PND 28	76.4	---	94.0	---	---
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)					
PND 1	6.8	---	6.9	---	7.2
PND 4 (BEFORE SELECTION)	9.9	---	9.6	---	10.9
PND 7	15.4	---	15.5	---	15.7
PND 14	29.9	---	32.8	---	---
PND 21	47.0	---	51.6	---	---
PND 28	68.9	---	85.3	---	---
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)					
BRAIN	---	---	---	---	---
SPLEEN	---	---	---	---	---
THYMUS GLAND	---	---	---	---	---

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DATASET NO.	106	107
MEAN NO. PUPS BORN	15.9	15.5
PUP SURVIVAL INDICES (% PER LITTER)		
PND 0 (RELATIVE TO NO. BORN)	98.6	98.6
PND 0 TO PND 1	99.2	99.5
PND 1 TO PND 4 (BEFORE SELECTION)	99.5	98.7
PND 4 (AFTER SELECTION) TO PND 7	100.0	99.5
PND 7 TO PND 14	100.0	100.0
PND 14 TO PND 21	100.0	100.0
BIRTH TO PND 4 (BEFORE SELECTION)	97.3	96.8
PND 4 (AFTER SELECTION) TO PND 21	100.0	99.5
MEAN MALE OFFSPRING BODY WEIGHTS (G)		
PND 1	7.0	6.8
PND 4 (BEFORE SELECTION)	9.5	9.4
PND 7	15.1	15.3
PND 14	31.8	31.6
PND 21	50.5	50.2
PND 28	86.6	85.3
MEAN FEMALE OFFSPRING BODY WEIGHTS (G)		
PND 1	6.5	6.3
PND 4 (BEFORE SELECTION)	8.9	8.8
PND 7	14.0	14.4
PND 14	30.0	30.4
PND 21	48.0	47.7
PND 28	79.1	77.0
MEAN MALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---
MEAN FEMALE PUP ORGAN WEIGHTS ON PND 21 (G)		
BRAIN	---	---
SPLEEN	---	---
THYMUS GLAND	---	---

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DATASET NO.	1	2	3	4	5
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	43.3	---	46.7	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	230.4	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.2	---	33.1	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	106.9	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	6	7	8	9	10
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	5.3	5.7	---	---
FEMALE	---	3.2	3.9	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.0	---	44.6	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	217.9	---	223.0	---	232.0
MEAN DAY OF VAGINAL PATENCY (PND)	33.4	---	34.4	---	32.6
MEAN BODY WEIGHT AT ACQUISITION (G)	105.1	---	118.9	---	112.2
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	11	12	13	14	15
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	5.3	5.3	---	---	---
FEMALE	3.3	3.1	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	47.0	47.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	38.8	32.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	5.2
FEMALE	---	---	---	---	5.2
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	4.8	---	---	---
FEMALE	---	2.7	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	41.6	---	41.8	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	210.5	---	212.2	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	32.5	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	107.4	---	117.7	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	4.0	---	---
FEMALE	---	---	4.0	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	16.1	---	---
FEMALE	---	---	16.1	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	21	22	23	24	25
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.0	---	42.4	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	227.1	---	229.0	---	226.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.4	---	31.9	---	33.2
MEAN BODY WEIGHT AT ACQUISITION (G)	115.2	---	109.9	---	119.1
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.0	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.2	---	---	---	---
FEMALE	14.8	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.1	---	43.8	49.0
MEAN BODY WEIGHT AT ACQUISITION (G)	---	247.9	---	229.2	248.0
MEAN DAY OF VAGINAL PATENCY (PND)	---	31.9	---	33.2	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	103.8	---	119.5	102.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	49.0	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	248.0	---	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	33.7	---	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	102.8	---	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	36	37	38	39	40
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.7	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	235.1	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	33.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	112.1	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	41	42	43	44	45
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.1	---	---	---	46.3
MEAN BODY WEIGHT AT ACQUISITION (G)	240.3	---	---	---	231.0
MEAN DAY OF VAGINAL PATENCY (PND)	32.7	---	---	---	31.7
MEAN BODY WEIGHT AT ACQUISITION (G)	114.7	---	---	---	99.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.1	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	---	---	---	---
FEMALE	4.0	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	18.7	---	---	---	---
FEMALE	18.6	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	46	47	48	49	50
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	44.2	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	228.9	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	36.0	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	130.3	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	51	52	53	54	55
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	---	42.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	227.0	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	---	34.4	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	---	133.0	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	56	57	58	59	60
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	42.0	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	---	215.7	---	---	248.6
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.9	---	---	33.7
MEAN BODY WEIGHT AT ACQUISITION (G)	---	112.6	---	---	125.0
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	61	62	63	64	65
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.7	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	238.3	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	32.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	107.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	5.1	---	---	---
FEMALE	---	5.2	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	4.2	---	---	---
FEMALE	---	4.2	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	15.5	---	---	---
FEMALE	---	15.5	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	66	67	68	69	70
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	43.7	---	---	---	44.3
MEAN BODY WEIGHT AT ACQUISITION (G)	224.7	---	---	---	220.6
MEAN DAY OF VAGINAL PATENCY (PND)	32.1	---	---	---	33.1
MEAN BODY WEIGHT AT ACQUISITION (G)	114.4	---	---	---	107.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	14.9
FEMALE	---	---	---	---	14.9
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	10.1
FEMALE	---	---	---	---	10.0

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WIL Reproductive Historical Control Data
Crl:CD(SD) Rat*

Individual Study Data

DATASET NO.	71	72	73	74	75
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.4	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	231.8	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.2	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	117.2	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	76	77	78	79	80
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	2.45	4.41	---	---
FEMALE	---	1.34	2.57	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	46.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	219.5	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	37.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	119.8	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	81	82	83	84	85
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.6	45.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	223.2	222.2	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	35.1	33.5	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	114.0	109.3	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	5.0	---	---	---	---
FEMALE	5.2	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	4.0	4.0	---	---	---
FEMALE	4.0	4.0	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	15.7	15.1	---	---	---
FEMALE	15.7	15.1	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	13.1	11.7	---	---	---
FEMALE	13.0	11.8	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	10.0	9.3	---	---	---
FEMALE	9.9	9.3	---	---	---

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DATASET NO.	86	87	88	89	90
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	49.0	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	236.1	---	---	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	35.3	---	---	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	109.0	---	---	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	91	92	93	94	95
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	4.34	4.32	---
FEMALE	---	---	2.41	2.37	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	45.8	---	46.1	---	44.4
MEAN BODY WEIGHT AT ACQUISITION (G)	213.8	---	236.6	---	212.8
MEAN DAY OF VAGINAL PATENCY (PND)	33.8	---	34.2	---	33.0
MEAN BODY WEIGHT AT ACQUISITION (G)	99.5	---	121.9	---	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	96	97	98	99	100
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	4.36	---	---	---	---
FEMALE	2.28	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	---	44.0	---	44.8	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	220.2	---	235.6	---
MEAN DAY OF VAGINAL PATENCY (PND)	---	33.9	---	33.5	---
MEAN BODY WEIGHT AT ACQUISITION (G)	---	115.1	---	111.5	---
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	---
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.7	---	42.3	---	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	221.8	---	223.8	---	225.2
MEAN DAY OF VAGINAL PATENCY (PND)	33.0	---	33.0	---	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	103.4	---	119.0	---	109.7
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF PINNAL DETACHMENT (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF EYE OPENING (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)	---	---	---	---	
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF HAIR GROWTH (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---
MEAN DAY OF INCISOR ERUPTION (PND)					
MALE	---	---	---	---	---
FEMALE	---	---	---	---	---

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DATASET NO.	106	107
MEAN ANOGENITAL DISTANCE ON PND 1 (MM)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF BALANOPREPUTIAL SEPARATION (PND)	44.4	44.6
MEAN BODY WEIGHT AT ACQUISITION (G)	238.2	228.2
MEAN DAY OF VAGINAL PATENCY (PND)	32.9	32.8
MEAN BODY WEIGHT AT ACQUISITION (G)	112.1	106.8
MEAN DAY OF SURFACE RIGHTING RESPONSE (PND)		
MALE	5.1	5.0
FEMALE	5.3	5.1
MEAN DAY OF PINNAL DETACHMENT (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF EYE OPENING (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF AIR DROP RIGHTING REFLEX (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF HAIR GROWTH (PND)		
MALE	---	---
FEMALE	---	---
MEAN DAY OF INCISOR ERUPTION (PND)		
MALE	---	---
FEMALE	---	---

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DATASET NO.	1	2	3	4	5
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.55	2.64	2.73	1.95	2.70
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.85	1.72	1.84	1.71
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.88	1.74	1.85	1.71
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.71	0.75	0.74	0.74	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.72	0.76	0.72	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3266	0.3293	0.3185	0.3164	0.3022
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3197	0.3423	0.3280	0.3295	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	85.2	89.1	99.3	87.0	87.3
LEFT EPIDIDYMIS	449.0	407.9	436.1	413.4	343.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.0	14.6	16.3	14.3	14.3
% MOTILE SPERM	84.9	82.4	85.5	87.6	80.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.6	99.4	99.9	99.6	99.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	0.5	0.0	0.3	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.1	0.0	0.1	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.2	198.8	199.9	199.1	198.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.4	0.9	0.1	0.6	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	1.3	0.3	0.1	0.3	0.9
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.1	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

187044 RAD

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DATASET NO.	6	7	8	9	10
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.05	1.88	1.82	2.80	1.76
MEAN RIGHT TESTIS WEIGHT (G)	1.70	1.72	1.72	1.73	1.79
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.73	1.75	1.75	1.81
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.75	0.68	0.71	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.70	0.69	0.74	0.76
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3269	0.3364	0.2812	0.3157	0.3210
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3225	0.3242	0.3057	0.3280	0.3271
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.6	81.7	104.8	90.8	95.8
LEFT EPIDIDYMIS	517.5	410.6	534.3	452.1	416.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.2	13.4	17.2	14.9	15.7
% MOTILE SPERM	80.8	85.3	82.3	87.6	85.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.7	99.8	99.0	99.8	96.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.8	0.1	0.7	0.2	2.0
HEAD ABSENT WITH NORMAL FLAGELLUM	0.5	0.1	0.3	0.1	1.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.4	199.6	198.0	199.5	192.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.6	0.3	1.5	0.3	4.0
HEAD ABSENT WITH NORMAL FLAGELLUM	1.0	0.1	0.5	0.2	3.2
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	0.0	0.0	0.0

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DATASET NO.	11	12	13	14	15
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.64	2.73	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.76	1.73	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.71	1.76	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	0.72	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.70	0.70	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3262	0.3174	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3064	0.2950	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	72.9	94.1	---	---	---
LEFT EPIDIDYMIS	456.0	467.9	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	11.9	15.4	---	---	---
% MOTILE SPERM	80.2	75.4	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.5	99.6	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.9	0.1	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.6	0.3	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.0	199.2	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.9	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	1.1	0.6	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.1	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	---	---

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DATASET NO.	16	17	18	19	20
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.65	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.67	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.64	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2807	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.2943	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	96.6	---	---	---
LEFT EPIDIDYMIS	---	438.8	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.8	---	---	---
% MOTILE SPERM	---	80.9	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.8	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.0	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.9	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.		22	23	24	25
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.45	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	1.86	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.73	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3160	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3293	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	91.7	---	---	---
LEFT EPIDIDYMIS	---	478.5	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.0	---	---	---
% MOTILE SPERM	---	86.2	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.7	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.1	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.3	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.2	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	---	---	---

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DATASET NO.	26	27	28	29	30
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

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DATASET NO.	31	32	33	34	35
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	---	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	---	1.77
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.68
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3092
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	---	0.3270
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	106.7
LEFT EPIDIDYMIS	---	---	---	---	442.7
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	17.5
% MOTILE SPERM	---	---	---	---	81.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	0.0

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DATASET NO.	36	37	38	39	40
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.80	1.76	---	---	1.93
MEAN LEFT TESTIS WEIGHT (G)	1.88	1.75	---	---	1.90
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.78	0.67	---	---	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.80	0.67	---	---	0.77
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3402	0.2857	---	---	0.3552
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3712	0.3061	---	---	0.3380
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	86.0	95.5	---	---	83.8
LEFT EPIDIDYMIS	393.1	556.7	---	---	418.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.1	15.7	---	---	13.7
% MOTILE SPERM	77.3	79.3	---	---	86.4
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	98.8	---	---	---	98.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.4	---	---	---	0.7
HEAD ABSENT WITH NORMAL FLAGELLUM	0.9	---	---	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	197.5	---	---	---	197.6
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.7	---	---	---	1.4
HEAD ABSENT WITH NORMAL FLAGELLUM	1.8	---	---	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	0.0

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DATASET NO.	41	42	43	44	45
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	1.79	1.87	1.83	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.90	1.82	1.76	1.79
MEAN LEFT TESTIS WEIGHT (G)	---	1.89	1.84	1.82	1.80
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.81	0.78	0.78	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.77	0.77	0.75	0.72
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3586	0.3495	0.3272	0.3338
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3374	0.3555	0.3487	0.3149
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	95.5	76.7	74.1	---
LEFT EPIDIDYMIS	---	476.1	421.3	407.1	477.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.7	12.6	12.1	---
% MOTILE SPERM	---	85.9	87.1	75.9	89.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.8	99.4	99.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.2	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.3	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	199.5	198.8	199.4	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.4	0.7	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.0	0.6	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	---

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DATASET NO.	46	47	48	49	50
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.15	2.14	---
MEAN RIGHT TESTIS WEIGHT (G)	1.83	1.70	1.79	1.84	1.69
MEAN LEFT TESTIS WEIGHT (G)	1.84	1.71	1.79	1.80	1.72
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.75	0.67	0.72	0.74	0.67
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.73	0.68	0.74	0.72	0.66
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3291	0.2817	0.3327	0.3178	0.3080
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3298	0.2967	0.3252	0.3304	0.3025
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	94.7	84.8	106.9	82.4
LEFT EPIDIDYMIS	539.2	500.8	471.9	640.1	503.2
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	15.5	13.9	17.5	13.5
% MOTILE SPERM	88.1	89.2	86.8	88.9	79.2
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	99.5	99.7	99.5	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.3	0.2	0.2	0.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.3	0.1	0.2	0.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	198.9	199.4	199.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	0.5	0.4	0.0	0.9
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.6	0.1	0.0	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

187044 RAD

= Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

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DATASET NO.	51	52	53	54	55
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.24	2.28
MEAN RIGHT TESTIS WEIGHT (G)	1.73	---	1.82	1.89	1.77
MEAN LEFT TESTIS WEIGHT (G)	1.69	---	1.80	1.92	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.70	---	0.81	0.75	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.69	---	0.76	0.78	0.75
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3121	---	0.3548	0.3431	0.3396
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3084	---	0.3387	0.3504	0.3475
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	90.5	---	105.4	83.8	---
LEFT EPIDIDYMIS	462.7	---	454.6	412.9	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	14.8	---	17.3	13.7	
% MOTILE SPERM	91.6	---	91.1	85.3	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.8	---	99.8	99.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.1	---	0.2	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	199.6	199.7	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	---	0.3	0.1	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	---	0.1	0.1	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	0.0	0.0	---

187044 RAD

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DATASET NO.	56	57	58	59	60
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---		---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.73	---
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.69	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.2962	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3168	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	91.0	---
LEFT EPIDIDYMIS	447.6	---	---	585.8	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	14.9	---
% MOTILE SPERM	86.3	---	---	84.2	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.3	---	---	99.5	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	---	---	0.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	0.3	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	198.6	---	---	199.1	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	1.1	---	---	0.4	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.3	---	---	0.5	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	0.0	---

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DATASET NO.	61	62	63	64	65
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	----	1.92	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	----	1.80	---	1.80
MEAN LEFT TESTIS WEIGHT (G)	---	----	1.79	---	1.75
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.73
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	----	0.74	---	0.67
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3189	---	0.3368
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	----	0.3449	---	0.3239
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	----	79.8	---	77.8
LEFT EPIDIDYMIS	---	----	506.2	---	417.4
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	----	13.1	---	12.8
% MOTILE SPERM	---	----	91.9	---	71.3
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	----	99.4	---	91.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.4	---	3.4
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.2	---	4.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	----	198.8	---	183.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	----	0.8	---	6.7
HEAD ABSENT WITH NORMAL FLAGELLUM	---	----	0.4	---	9.4
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	----	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	----	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	----	0.0	---	0.0

187044 RAD

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DATASET NO.	66	67	68	69	70
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	----	----	1.95	1.82	---
MEAN RIGHT TESTIS WEIGHT (G)	----	----	1.85	1.71	---
MEAN LEFT TESTIS WEIGHT (G)	----	----	1.83	1.71	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	----	----	0.71	0.64	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	----	----	0.70	0.62	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.2972	0.2629	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	----	----	0.3065	0.2714	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	----	----	81.0	---	---
LEFT EPIDIDYMIS	----	----	443.9	480.0	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	----	----	13.3	---	---
% MOTILE SPERM	----	----	87.3	82.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	----	----	98.9	97.9	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	0.7	1.2	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.4	0.9	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	----	----	197.9	195.8	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	----	----	1.4	1.7	---
HEAD ABSENT WITH NORMAL FLAGELLUM	----	----	0.8	2.4	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	----	----	0.0	0.1	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	----	----	0.0	0.0	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	----	----	0.0	0.0	---

187044 RAD

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DATASET NO.	71	72	73	74	75
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---	---	1.68	1.90
MEAN LEFT TESTIS WEIGHT (G)	---	---	---	1.69	1.91
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	---	0.70	0.78
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	---	0.68	0.78
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3057	0.3564
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	---	0.3143	0.3693
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	75.0	69.6
LEFT EPIDIDYMIS	---	---	---	458.8	466.3
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	12.3	11.4
% MOTILE SPERM	---	---	---	82.0	83.1
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	99.0	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	0.5	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	0.5	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	198.0	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	1.0	1.1
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	1.0	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	0.0	0.0

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DATASET NO.	76	77	78	79	80
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.26	2.29	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.84	---	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	1.84	1.87	---	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.74	---	0.74
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.76	---	0.74
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3354	0.3364	---	0.3397
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3460	0.3498	---	0.3377
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	77.7	90.8	---	74.3
LEFT EPIDIDYMIS	---	454.3	436.0	---	353.6
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	12.6	14.9	---	12.2
% MOTILE SPERM	---	87.5	87.0	---	84.6
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	96.1	99.2	---	98.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.6	0.4	---	0.6
HEAD ABSENT WITH NORMAL FLAGELLUM	---	2.3	0.5	---	0.5
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	192.2	198.3	---	197.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	3.1	0.7	---	1.2
HEAD ABSENT WITH NORMAL FLAGELLUM	---	4.6	0.9	---	1.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	---	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	---	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	---	0.0

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DATASET NO.	81	82	83	84	85
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.13	2.15	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.84	1.80	---	1.76	1.75
MEAN LEFT TESTIS WEIGHT (G)	1.81	1.80	---	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.80	0.73	---	0.79	0.70
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.76	0.73	---	0.78	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3686	0.3270	---	0.3682	0.3326
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3595	0.3243	---	0.3706	0.3286
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	79.1	96.6	---	79.2	84.6
LEFT EPIDIDYMIS	---	---	---	469.0	452.3
LEFT CAUDA EPIDIDYMIS	738.9	618.7	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	13.0	15.8	---	13.0	13.9
% MOTILE SPERM	88.6	84.3	---	89.7	78.9
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.5	99.3	---	99.3	97.9
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.3	0.4	---	0.5	1.8
HEAD ABSENT WITH NORMAL FLAGELLUM	0.2	0.2	---	0.3	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	199.0	198.7	---	198.6	195.8
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.6	0.9	---	0.9	3.5
HEAD ABSENT WITH NORMAL FLAGELLUM	0.4	0.4	---	0.5	0.6
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	0.0	---	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	0.0	---	0.0	0.0

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DATASET NO.	86	87	88	89	90
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	2.30	2.30		---
MEAN RIGHT TESTIS WEIGHT (G)	---	1.82	1.79	1.76	1.76
MEAN LEFT TESTIS WEIGHT (G)	---	1.83	1.80	1.76	1.76
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.69	0.71
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	0.74	0.73	0.71	0.70
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3055	0.3194	0.3257	0.3352
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	0.3306	0.3226	0.3384	0.3310
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	88.8	81.6	86.7	87.4
LEFT EPIDIDYMIS	---	476.2	434.0	475.8	461.0
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	14.5	13.4	14.2	14.3
% MOTILE SPERM	---	83.0	87.0	83.4	81.7
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	97.9	97.3	99.7	99.2
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	1.3	0.4	0.1	0.5
HEAD ABSENT WITH NORMAL FLAGELLUM	---	0.8	0.3	0.2	0.3
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	195.8	198.6	199.4	198.4
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	2.6	0.8	0.3	10.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	1.6	0.6	0.3	0.7
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	0.0	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	0.0	0.0	0.0	0.0

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DATASET NO.	91	92	93	94	95
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---	2.30	2.22	2.09
MEAN RIGHT TESTIS WEIGHT (G)	---	---	1.85	1.90	1.75
MEAN LEFT TESTIS WEIGHT (G)	---	---	1.82	1.91	1.74
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.76	0.72
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---	0.74	0.77	0.71
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3234	0.3424	0.3162
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---	0.3421	0.3460	0.3212
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	75.9	93.2	78.1
LEFT EPIDIDYMIS	---	---	---	---	406.0
LEFT CAUDA EPIDIDYMIS	---	---	689.5	662.8	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	12.4	15.3	12.8
% MOTILE SPERM	---	---	91.0	82.0	88.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	99.4	99.7	99.7
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.4	0.2	0.3
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.2	0.1	0.1
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	198.9	199.4	199.0
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	0.8	0.4	1.0
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	0.3	0.2	0.0
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	0.0	0.0	0.0
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	0.0	0.0	0.0
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	0.0	0.0	0.0

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DATASET NO.	96	97	98	99	100
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	1.98	---	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.86	---	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.82	---	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	---	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.63	---	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3264	---	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.3232	---	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	76.2	---	---	---	---
LEFT EPIDIDYMIS	548.6	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	12.5	---	---	---	---
% MOTILE SPERM	89.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	99.7	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.2	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.1	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	200.0	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	0.0	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	0.0	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	0.0	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	0.0	---	---	---	---

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DATASET NO.	101	102	103	104	105
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	2.23	2.04	---	---	---
MEAN RIGHT TESTIS WEIGHT (G)	1.87	1.92	---	---	---
MEAN LEFT TESTIS WEIGHT (G)	1.73	1.85	---	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	0.74	0.78	---	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	0.68	0.74	---	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	0.3336	0.3693	---	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	0.2858	0.3405	---	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)					
LEFT TESTIS	---	---	---	---	---
LEFT EPIDIDYMIS	---	---	---	---	---
LEFT CAUDA EPIDIDYMIS	---	---	---	---	---
MEAN SPERM PRODUCTION RATE					
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---	---	---	---
% MOTILE SPERM	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)					
NORMAL	---	---	---	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---	---	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---	---	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---	---	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---	---	---	---

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Modified: 1/24/2005

DATASET NO.	106	107
MEAN SEMINAL VESICLE/COAGULATING GLAND WEIGHTS (G)	---	---
MEAN RIGHT TESTIS WEIGHT (G)	---	---
MEAN LEFT TESTIS WEIGHT (G)	---	---
MEAN RIGHT EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT EPIDIDYMIS WEIGHT (G)	---	---
MEAN RIGHT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN LEFT CAUDA EPIDIDYMIS WEIGHT (G)	---	---
MEAN SPERM CONCENTRATION (NO. SPERM IN MILLIONS/GRAM OF TISSUE)		
LEFT TESTIS	---	---
LEFT EPIDIDYMIS	---	---
LEFT CAUDA EPIDIDYMIS	---	---
MEAN SPERM PRODUCTION RATE		
(NO. SPERM IN MILLIONS/GRAM OF TISSUE/DAY)	---	---
% MOTILE SPERM	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (%)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
SPERM MORPHOLOGY DIFFERENTIAL COUNT (ABSOLUTE NUMBER)		
NORMAL	---	---
NORMAL SHAPED HEAD SEPARATED FROM FLAGELLUM	---	---
HEAD ABSENT WITH NORMAL FLAGELLUM	---	---
HEAD ABSENT WITH ABNORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH NORMAL FLAGELLUM	---	---
MISSHAPEN HEAD WITH ABNORMAL FLAGELLUM	---	---
DEGENERATIVE FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---
OTHER FLAGELLAR DEFECTS WITH NORMAL HEAD	---	---

187044 RAD

* = Prior to January 1, 2005, this strain of rat was designated the Crl:CD®(SD)IGS BR rat.

APPENDIX G

Study Protocol

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Study Number: WIL-187044

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor Study Number: 05-003

A. Title of Study:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification:

1) **8.1** **Thyroid Hormones:**

In accordance with the Study Director Notification dated June 18, 2005, the Sponsor elected to collect additional serum for possible future serological evaluation. This serum was taken from the samples collected for TSH and T4 analysis from all animals following euthanasia. These samples are being stored frozen.

9.1 **Macroscopic Examination:**

2) In accordance with the Study Director Notification dated June 8, 2005, the following tissues were saved in 10% neutral-buffered formalin from animals found dead or euthanized *in extremis* beginning on June 8, 2005.

Lungs	Kidneys
Heart	Esophagus
Liver	GI Tract

3) In accordance with the Study Director Notification dated June 8, 2005, the animals euthanized *in extremis* and the animals which died following dosing had blood collected from the vena cava for evaluation of the following blood chemistry and complete blood count (with differential) parameters. These procedures were in effect beginning on June 8, 2005.

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Hematology:

Differential leukocyte count	MCHC
Erythrocyte count	MCV
Hematocrit	Platelet count
Hemoglobin	Reticulocyte count
MCH	Total leukocyte count

Serum Chemistry:

A/G ratio	Glucose
Alanine aminotransferase	Glutamyltransferase
Albumin	Phosphorus
Alkaline phosphatase	Potassium
Aspartate aminotransferase	Sodium
Calcium	Total bilirubin
Chloride	Total cholesterol
Creatinine	Total protein
Globulin	Urea nitrogen

C. Reason for Protocol Modification:

1) The Sponsor requested collection and processing of serum samples for possible serological evaluation.

2) Addition of tissues collected as per the request of the Sponsor.

[redacted]

[redacted]

3) Addition of hematology and serum chemistry parameters at the request of the Sponsor.

Approved By:

[redacted]
Team Leader, Toxicology Testing

29 July 2005
Date

Prepared By:

WIL Research Laboratories, LLC

[redacted]
Study Director

7/28/2005
Date

[redacted]
Director, Developmental and
Reproductive Toxicology

7/28/2005
Date

[redacted]

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PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 05-003

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

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1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]

2.2 WIL Study Director:

[redacted]

2.3 WIL Deputy Director:

[redacted]

2.4 WIL Departmental Responsibilities:

[redacted]

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[redacted]

3 STUDY SCHEDULE:

Proposed Animal Receipt Date:	May 17, 2005
Proposed Experimental Start Date (Experimental Starting Date):	May 31, 2005
Proposed Experimental Termination/ Completion Date:	June 22, 2005
Proposed Audited Report Date:	August 31, 2005

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

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4.1.1 Lot Number:

[redacted]

4.1.2 Purity:

100%.

4.1.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.1.4 Physical Description:

Viscous liquid.

4.1.5 Storage Conditions:

Store at ambient conditions under nitrogen.

4.1.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.1.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

4.2 Identification:

[redacted]

4.2.1 Lot Number:

[redacted]

4.2.2 Purity:

100%.

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4.2.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.2.4 Physical Description:

Viscous liquid.

4.2.5 Storage Conditions:

Store at ambient conditions under nitrogen.

4.2.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.2.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat.

5.2 Strain:

Sprague-Dawley Crl:CD®(SD)

5.3 Source:

Charles River Laboratories
Portage, Michigan

5.4 Number on Study:

105 Females (maximum of 130 females and 13 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 6-8 days old upon receipt. Animals not assigned to the study will be transferred to the stock animal colony

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or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and discarded.

5.5 Body Weight Range:

At randomization: 30-50 g. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal eartag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed-O'Cobs®). Following randomization, the juvenile female animals will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. Control animals (Group 1) will be housed on a separate rack from exposed animals. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL standard operating procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

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6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol-specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available ad libitum. Filters servicing the automatic watering system are changed regularly according to WIL standard operating procedures. The municipal water supplying the laboratory is analyzed according to WIL standard operating procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered ad libitum during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

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7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Each of 7 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[redacted]	60	12	5	15
3		250	50	5	15
4		1000	200	5	15
5		60	12	5	15
6		250	50	5	15
7		1000	200	5	15

7.4.2 Vehicle Control Article:

Corn oil

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7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 of age and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Article Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions under nitrogen. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

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7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The methods employed will be one or more of the following:

[redacted] SOP #ME-125

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature under nitrogen. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted]. This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will be observed also approximately one hour following dosing and the observations will be recorded. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded.

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7.6.2 Body Weights:

Daily body weights will be recorded individually (to the nearest 0.1 gram PND 22-42, with the exception of the weight collected the day prior to dosing and the final body weight) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized by carbon dioxide inhalation and necropsied as described in section 9.

8 HOROMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH) Thyroxine (T4)

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9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized in extremis. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. The following tissues will be collected and placed in 10% neutral-buffered formalin at study termination:

Cervix and Uterine Body (one longitudinal section)	Thyroid
Ovaries	Uterine horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized in extremis.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in the same sequence as which dosing occurred. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

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The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

9.2.2 Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Ovaries and oviducts
Liver	Pituitary gland
Kidneys	Thyroid (following fixation)

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 Microscopic Examination:

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination.

The vagina, ovaries, and thyroid from each animal will be similarly preserved with the uterus.

Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

Ovaries	Thyroid
Cervix and Uterine Body (one longitudinal section)	Uterine Horns (four sections per horn)

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10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age of first estrous and estrous cycle length will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL standard operating procedures and the appropriate provisions of EPA/TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Good Laboratory Practice Regulations [C (97) 186/Final]. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

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14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional paper copies of the final report may result in additional charges.

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

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17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via mail on March 24, 2005.

[redacted]
Team Leader, Toxicology Testing

15 April 2005
Date

WIL Research Laboratories, LLC

[redacted]
Study Director

4/14/2005
Date

[redacted]
Director, Developmental and
Reproductive Toxicology

4/14/2005
Date

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COMPANY SANITIZED

FINAL REPORT

Volume 1 of 3
(Text, Figures and Tables 1-43)

STUDY TITLE

A 28-DAY REPEATED DOSE ORAL (GAVAGE) TOXICITY STUDY OF [redacted] IN RATS (WITH FUNCTIONAL OBSERVATIONAL BATTERY AND MOTOR ACTIVITY DETERMINATIONS)

STUDY NUMBER

WIL-187051

DATA REQUIREMENT

OECD Guideline, Section 407

STUDY DIRECTOR

[redacted]

STUDY INITIATION DATE

21 September 2005

STUDY COMPLETION DATE

28 June 2006

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

05-087

SPONSOR

[redacted]

WIL-187051
Chevron

[redacted]-087

COMPLIANCE STATEMENT

This study, designated WIL-187051, was conducted in compliance with the OECD (Organisation for Economic Cooperation and Development) Principles of Good Laboratory Practice [C (97) 186/Final], 26 November 1997; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor with the following exception. Stability of the test article in the dosing formulations was not tested. However, in the professional judgment of the sponsor, the formulations were stable under the conditions of this study because the test article is intended for use at high temperatures and under oxidative conditions.

The protocol was designed to be in general accordance with the OECD Guidelines for Testing of Chemicals, Health Effects Test Guidelines, Section 407, July 27, 1995.

[redacted]
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology

28 June 2006
Date

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the possible toxic effects of [redacted] when administered orally by gavage to rats for 28 days and to assess recovery from such effects. This study included evaluation of potential neurotoxicity by functional observational battery (FOB) and motor activity (MA) assessment.

1.2. STUDY DESIGN

[redacted] in the vehicle, corn oil, was administered orally by gavage once daily for a minimum of 28 consecutive days to 3 groups (Groups 2-4) of Crl:CD(SD) rats. Dosage levels were 160, 400 and 1000 mg/kg/day. A concurrent control group (Group 1) received the vehicle on a comparable regimen. The dosage volume was 5 mL/kg for all groups. Groups 1 and 4 each consisted of 10 animals/sex, and Groups 2 and 3 each consisted of 5 animals/sex. Following 28 days of dose administration, 5 rats/sex/group were euthanized; the remaining 5 rats/sex in the control and high dose groups were euthanized following a 14-day nondosing (recovery) period.

For toxicology assessment, all animals were observed twice daily for mortality and moribundity. Clinical examinations were performed daily, and detailed physical examinations were performed weekly. Individual body weights and food consumption were recorded weekly. Functional observational battery and locomotor activity data were recorded for 5 animals/sex/group during study week 3. Clinical pathology evaluations (hematology and serum chemistry) were performed on all rats at the primary (study day 28) and recovery (study day 42) necropsies. Complete necropsies were conducted on all animals, and selected organs were weighed at the scheduled necropsies. Selected tissues were examined microscopically from all animals in the control (Group 1) and high dose (Group 4) groups at the primary necropsy. Gross lesions were examined from animals in the 160 and 400 mg/kg/day groups at the primary necropsy.

1.3. RESULTS

All animals survived to the scheduled necropsies. There were no test article-related effects on food consumption. Functional observational battery evaluations, including home cage, handling, open field, sensory, neuromuscular and physical observations and monitored locomotor activity patterns (total and ambulatory activity counts), during study week 3 were unaffected by test article administration. There were no test article-related macroscopic or microscopic changes observed. There were no test article-related effects in organ weights at the primary or recovery necropsy.

Test article-related clinical findings were generally limited to the 1000 mg/kg/day group males and females and consisted of high incidences of evidence of salivation, including clear material around the mouth, and also low incidences of red material around the mouth. These findings were most frequently observed at 1 hour post-dosing, usually not until the second or third week of dosing. These test article-related clinical findings were also noted in the 400 mg/kg/day group at a lower incidence, most frequently seen at 1 hour post-dosing during study weeks 1 to 3. None of these test article-related clinical findings were observed during the recovery period.

Test article-related decreased weekly and cumulative body weight gains, as well as slightly lower body weights, were observed in the 1000 mg/kg/day group males. This resulted in body weights and cumulative body weight gains that were 4.5% and 13% lower, respectively, than the control group males at the end of the dosing period.

At the end of the dosing period (study day 28), increases in mean prothrombin time in the 1000 mg/kg/day group males and females and mean activated partial thromboplastin time in the 1000 mg/kg/day group males compared to the control group were considered test article-related. These coagulation parameters were similar to the control group at the recovery evaluation.

Alanine aminotransferase in the 400 and 1000 mg/kg/day group males and females and aspartate aminotransferase in the 1000 mg/kg/day group males and females at study

day 28 were higher than the control group; these findings were dose-related and statistically significant. Also at study day 28, globulin and total protein were significantly lower in the 1000 mg/kg/day group males compared to the control group. Globulin and total protein were also numerically lower than the control group in the 1000 mg/kg/day group females, but the differences were not statistically significant. These differences were considered test article-related but not adverse as correlating macroscopic or microscopic changes in the liver were not observed, there was no effect on mean liver weight and a site of potential protein loss (kidney, gastrointestinal tract) was not identified.

1.4. CONCLUSIONS

Based on the results of this study, the no-observed-effect level (NOEL) for oral (gavage) administration of [redacted] to Crl:CD(SD) rats for 28 consecutive days was 160 mg/kg/day based on clinical observations and serum chemistry effects at 400 and 1000 mg/kg/day and body weight and coagulation parameter effects at 1000 mg/kg/day. The clinical observations and the effects upon serum chemistry were not considered to be adverse based on the absence of microscopic changes in the 400 and 1000 mg/kg/day groups. Effects at 1000 mg/kg/day were fully resolved after a 14-day recovery period. Based upon body weight and coagulation changes, the no-observed-adverse-effect level (NOAEL) for oral (gavage) administration of [redacted] to Crl:CD(SD) rats for 28 consecutive days was 400 mg/kg/day.

2. INTRODUCTION

2.1. GENERAL STUDY INFORMATION

This report presents the data from "A 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats (with Functional Observational Battery and Motor Activity Determinations)". Due to software spacing constraints, the study title appears as "A 28-Day Repeated Dose Toxicity Study of [redacted] in Rats" on the report tables.

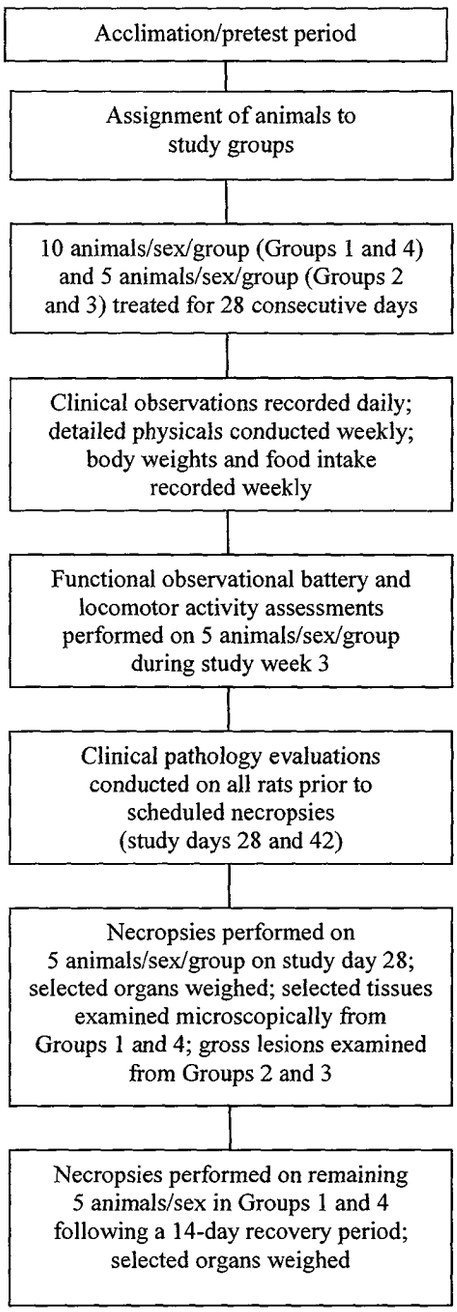
The following computer protocols were used for data collection during the study:

Computer Protocol	Type of Data Collected
WIL-187051	Main study data
WIL-187051P	Pretest data
WIL-187051U	Unscheduled clinical observations

2.2. KEY STUDY DATES

Date(s)	Event(s)
11 October 2005	Experimental starting date (animal receipt)
25 October 2005	Assignment to study groups
26 October 2005	Experimental start date (initiation of dose administration; study week 0)
23 November 2005	Primary necropsy (study week 4)
7 December 2005	Recovery necropsy (study week 6)
12 January 2006	Experimental termination (completion) date (last histopathological examination)

3. STUDY DESIGN



4. EXPERIMENTAL PROCEDURES - MATERIALS AND METHODS

4.1. TEST ARTICLE AND VEHICLE

4.1.1. TEST ARTICLE IDENTIFICATION

The test article, [redacted] was received from [redacted], on 27 July 2005, as follows:

Identification	Quantity Received	Physical Description
[redacted] Lot no [redacted] Exp. date: 1 August 2006 [WIL log no. 6578A]	1 can Gross weight: 3395.4 g	Dark brown viscous liquid

Data documenting the purity and stability of the test article are on file with the sponsor. A Certificate of Analysis for the test article was provided by the sponsor and is presented in Appendix A. The purity of the test article was 100%. The test article was stored at room temperature and was considered stable under this condition. A reserve sample of the test article (approximately 1 g) was collected on 28 July 2005 and stored in the Archives of WIL Research Laboratories, LLC.

4.1.2. VEHICLE IDENTIFICATION

The vehicle used in preparation of the test article formulations and for administration to the control group was 100% pure Mazola® corn oil (exp. date: 2 January 2007) distributed by ACH Food Companies, Inc., Memphis, Tennessee and purchased locally.

4.1.3. PREPARATION

For the control group (Group 1), a sufficient amount of corn oil was transferred to a glass container approximately weekly. The corn oil was stirred continuously using a magnetic stirrer throughout sampling and dosing. Aliquots of the vehicle were prepared for daily dispensation and stored at room temperature.

Dosing formulations were prepared at the concentrations indicated in the following table:

Group Number	Test Article[a]	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)
2	[redacted]	160	32
3		400	80
4		1000	200

[a] = The dosing formulations were not adjusted for purity.

The appropriate amount of the test article for each group was weighed into a tared, calibrated glass container. Vehicle was added to each container to bring the formulations nearly to the calibration mark. The formulations were mixed until uniform using a magnetic stirrer. Vehicle was then added to each container to bring the formulations to the calibration mark.

The test article formulations were prepared approximately weekly as single formulations for each dosage level, divided into aliquots for daily dispensation and stored at room temperature. The test article formulations were stirred continuously throughout the preparation, sampling and dose administration procedures. The test article formulations were visually inspected by the study director on 3 October 2005, and were found to be visibly homogeneous and acceptable for dose administration.

4.1.4. SAMPLING AND ANALYSES

Prior to the initiation of dose administration, triplicate samples (5 mL each) for homogeneity determination were collected on 3 October 2005 from the middle stratum of the vehicle and from the top, middle and bottom strata of the 32, 80 and 200 mg/mL formulations. In addition, triplicate samples (5 mL each) for stability and resuspension homogeneity determinations were collected from the top and bottom strata of the vehicle and from the top and bottom strata of these same suspensions on 13 October 2005 following 10 days of storage at room temperature. Duplicate samples (5 mL each) for concentration analyses were collected on the first and last day of each weekly preparation from the middle stratum of each dosing formulation (including the vehicle for the control

group). Two of the 3 sets of samples for resuspension homogeneity and stability and 1 set of samples for concentration analysis were shipped at ambient temperature to [redacted]. All remaining samples were retained at WIL Research Laboratories, LLC under normal laboratory conditions for possible future analysis. The methodology and results of these analyses are presented in Appendix B and are summarized in Section 6.1.

4.2. TEST SYSTEM

Crl:CD(SD) rats from Charles River Laboratories, Inc., Raleigh, North Carolina were used as the test system on this study. This species and strain of animal is recognized as appropriate for subchronic toxicity studies. The Sprague-Dawley rat was used because it is a widely used strain for which significant historical control data are available.

4.3. ORGANIZATION OF TEST GROUPS, DOSAGE LEVELS AND TREATMENT REGIMEN

The vehicle and test article formulations were administered orally by gastric intubation via appropriately sized flexible Teflon®-shafted, stainless steel ball-tipped dosing cannula (Natume, Japan) once daily for 28 consecutive days, through the day prior to the scheduled primary necropsy or recovery period. The dosage volume for all groups was 5 mL/kg. Individual doses were based on the most recently recorded body weights to provide the correct mg/kg/day dosage. Adjusted doses became effective the day of collection of the weekly body weights.

The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Volume (mL/kg)	Number of Animals[a] Males	Females
1	Vehicle	0	5	10	10
2	[redacted]	160	5	5	5
3		400	5	5	5
4		1000	5	10	10

[a] = 5 animals/sex/group were euthanized following a minimum of 28 days of dose administration; the remaining 5 animals/sex/group in Groups 1 and 4 were euthanized following a 14-day nondosing (recovery) period.

Dosage levels were selected based on results from a prior dose range-finding study (WIL-187047; [redacted] 2006) and were provided by the sponsor representative after consultation with the study director.

The selected route of administration for this study was oral (gavage) because this is an acceptable and standard method for administering test material per OECD Guideline 407. The number of animals selected for this study was the minimum required to yield statistically and scientifically meaningful data and was consistent with regulatory agency expectations.

4.4. ANIMAL RECEIPT AND ACCLIMATION/PRETEST PERIOD

Thirty-five male and 35 female Crl:CD(SD) rats were received in good health on 11 October 2005, from Charles River Laboratories, Inc., Raleigh, North Carolina. The animals were approximately 36 days old at receipt. Each animal was examined by a qualified technician on the day of receipt and weighed on the following day. Each animal was uniquely identified by a metal eartag displaying the permanent identification number. All animals were housed for a 15-day acclimation/pretest period. During this period, each animal was observed twice daily for mortality and changes in general appearance or behavior.

Pretest data collection began on 19 October 2005. Individual body weights were recorded, and detailed physical examinations were performed periodically during the

pretest period. Food consumption data were also recorded for pretest animals prior to the initiation of dose administration. Pretest clinical observations are presented in Appendix C.

4.5. ANIMAL HOUSING

Upon arrival, all animals were housed 2 or 3 per cage by sex for approximately 6 days. Thereafter, all animals were housed individually in clean, stainless steel, wire-mesh cages suspended above cage-board. Animals were maintained in accordance with the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 1996). The animal facilities at WIL Research Laboratories, LLC are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

4.6. DIET, DRINKING WATER AND MAINTENANCE

The basal diet used in this study, PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 (meal), is a certified feed with appropriate analyses performed by the manufacturer and provided to WIL Research Laboratories, LLC. Reverse osmosis-treated (on-site) drinking water, delivered by an automatic watering system, and the basal diet were provided ad libitum throughout the study, except during the period of fasting prior to blood collection when food, but not water, was withheld. Municipal water supplying the facility was sampled for contaminants according to the standard operating procedures. The results of the diet and water analyses are maintained at WIL Research Laboratories, LLC. No contaminants were present in animal feed or water at concentrations sufficient to interfere with the objectives of this study.

4.7. ENVIRONMENTAL CONDITIONS

All animals were housed throughout the acclimation period and during the study in an environmentally controlled room. The room temperature and humidity controls were set to maintain daily averages of $71 \pm 5°F$ ($22 \pm 3°C$) and $50 \pm 20\%$ relative humidity. Room temperature and relative humidity were controlled and monitored using the

Metasys® DDC Electronic Environmental control system. These data were recorded approximately hourly and are summarized in Appendix D. Actual mean daily temperature ranged from 70.2°F to 71.0°F (21.2°C to 21.7°C) and mean daily relative humidity ranged from 36.1% to 57.0% during the study. Light timers were set to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide a minimum of 10 fresh air changes per hour. The 12-hour light/12-hour dark photoperiod was interrupted as necessary to allow for the performance of protocol-specified activities.

4.8. ASSIGNMENT OF ANIMALS TO TREATMENT GROUPS

On 25 October 2005 (the day prior to the initiation of dose administration), all available rats were weighed and examined in detail for physical abnormalities. These data were collected using the WIL Toxicology Data Management System (WTDMS™) and reviewed by the study director. The animals judged suitable for assignment to the study were selected for use in a computerized randomization procedure. A printout containing the animal numbers, corresponding body weights and individual group assignments was generated based on body weight stratification in a block design. The animals were then arranged into groups according to the printout. Individual body weights at randomization were within ± 20% of the mean for each sex. The control and 1000 mg/kg/day groups (Groups 1 and 4, respectively) each consisted of 10 males and 10 females, and the 160 and 400 mg/kg/day groups (Groups 2 and 3, respectively) each consisted of 5 males and 5 females. These animals were then randomized into 2 study replicates to allow for the reasonable conduct of the functional observational battery and locomotor activity assessments. Each dose group and sex were approximately equally represented within each study replicate. The selected animals were approximately 7 weeks old at the initiation of dose administration; individual body weights ranged from 233 g to 272 g for males and from 146 g to 183 g for females.

5. PARAMETERS EVALUATED

5.1. CLINICAL OBSERVATIONS AND SURVIVAL

All animals were observed twice daily, once in the morning and once in the afternoon, for mortality and moribundity.

Clinical examinations were performed twice daily, at the time of dose administration and approximately 1 to 2 hours following dose administration (designated as 1 hour post-dosing for report presentation purposes). During the recovery period, the animals were observed once daily. All significant findings were recorded. Detailed physical examinations were conducted on all animals weekly, beginning 1 week prior to test article administration and prior to the scheduled necropsies. A separate computer protocol was used to record any observations noted outside of the above-specified intervals. These unscheduled clinical observations are presented in Appendix E.

5.2. BODY WEIGHTS

Individual body weights were recorded at least weekly, beginning 1 week prior to test article administration (study week -1). Mean body weights and mean body weight changes were calculated for the corresponding intervals. Final body weights (fasted) were recorded prior to the scheduled necropsies.

5.3. FOOD CONSUMPTION

Individual food consumption was recorded weekly, beginning 1 week prior to test article administration (study week -1). Food intake was calculated as g/animal/day for the corresponding body weight intervals. When food consumption could not be measured for a given interval (due to spillage, weighing error, obvious erroneous value, etc.), the appropriate interval was footnoted as "NA" (Not Applicable) on the individual tables.

5.4. FUNCTIONAL OBSERVATIONAL BATTERY [FOB]

Functional observational battery (FOB) assessments were recorded for 5 animals/sex/group during study week 3 (prior to dosing). Testing was performed by the same technicians,

whenever possible, without knowledge of the animals' group assignments. The FOB was performed in a sound-attenuated room equipped with a white-noise generator set to operate at 70 ± 10 dB. The FOB used at WIL Research Laboratories, LLC is based on previously developed protocols (Moser et al., 1991; Irwin, 1968; Gad, 1982; Moser et al., 1988; Haggerty, 1989; O'Donoghue, 1989). Refer to Appendix F for additional details on the functional observational battery methodology and validation.

All animals were observed for the following parameters as described below (refer to Appendix G for a detailed description of the scoring criteria used for each observation):

5.4.1. HOME CAGE OBSERVATIONS

Posture
Convulsions/tremors
Feces consistency
Biting
Palpebral (eyelid) closure

5.4.2. HANDLING OBSERVATIONS

Ease of removal from cage
Lacrimation/chromodacryorrhea
Piloerection
Palpebral closure
Eye prominence
Red/crusty deposits
Ease of handling animal in hand
Salivation
Fur appearance
Respiratory rate/character
Mucous membranes/eye/skin color
Muscle tone

5.4.3. OPEN FIELD OBSERVATIONS (EVALUATED OVER A 2-MINUTE OBSERVATION PERIOD)

Mobility
Rearing
Convulsions/tremors
Grooming
Bizarre/stereotypic behavior
Time to first step (seconds)
Gait
Arousal
Urination/defecation
Gait score
Backing

5.4.4. SENSORY OBSERVATIONS

Approach response	Touch response
Startle response	Tail pinch response
Pupil response	Eyeblink response
Forelimb extension	Hindlimb extension
Air righting reflex	Olfactory orientation

5.4.5. NEUROMUSCULAR OBSERVATIONS

Hindlimb extensor strength	Grip strength-hind and forelimb
Hindlimb foot splay	Rotarod performance

5.4.6. PHYSIOLOGICAL OBSERVATIONS

Catalepsy	Body weight
Body temperature	

5.5. LOCOMOTOR ACTIVITY

Locomotor activity was assessed for 5 animals/sex/group during study week 3. Locomotor activity, recorded after the completion of the FOB, was measured automatically using the SDI Photobeam Activity System (San Diego Instruments, Inc., San Diego, California). This personal computer-controlled system utilized a series of infrared photobeams surrounding a clear plastic, rectangular cage to quantify the motor activity of each animal. Four-sided black plastic enclosures were used to surround the clear plastic boxes and decrease the potential for distraction from extraneous environmental stimuli or activity by technicians or adjacent animals. The black enclosures rested on top of the photobeam frame and did not interfere with the path of the beams. The locomotor activity assessment was performed in a sound-attenuated room equipped with a white noise generator set to operate at 70±10 dB. The testing of treatment groups was conducted according to replicate sequence. Each animal was tested separately. Data were collected in 5-minute epochs and the test session duration was 60 minutes. These data were compiled as four 15-minute subsessions for tabulation.

Data for ambulatory and total motor activity were tabulated. Total motor activity was defined as a combination of fine motor skills (i.e., grooming, interruption of

1 photobeam) and ambulatory motor activity (interruption of 2 or more consecutive photobeams). Refer to Appendix F for additional details on the motor activity methodology and validation.

5.6. CLINICAL PATHOLOGY

Blood samples for clinical pathology evaluations (hematology and serum chemistry) were collected from all animals just prior to the scheduled necropsies (study weeks 4 and 6). The animals were fasted overnight prior to blood collection. Blood for hematology and serum chemistry evaluations was collected from the retro-orbital sinus of isoflurane-anesthetized animals prior to necropsy. Blood for coagulation parameters was collected from the vena cava at the time of necropsy. Blood was collected into tubes containing EDTA (hematology), sodium citrate (clotting determinations) or no anticoagulant (serum chemistry). Clinical pathology methods, procedures and references are presented in Appendix H. The following parameters were evaluated:

5.6.1. HEMATOLOGY

Total leukocyte count (White Cells)
Erythrocyte count (Red Cells)
Hemoglobin
Hematocrit
Mean corpuscular volume (MCV)
Mean corpuscular hemoglobin (MCH)
Mean corpuscular hemoglobin concentration (MCHC)
Platelet count (Platelet)
Prothrombin time (ProTime)
Activated partial thromboplastin time (APTT)
Reticulocyte count
  Percent (Reticulocyte)
  Absolute (Retic Absolute)

Differential leukocyte count -
  Percent and absolute
  -Neutrophil
  -Lymphocyte
  -Monocyte
  -Eosinophil
  -Basophil
  -Large unstained cell
Platelet estimate[a]
Red cell morphology (RBC Morphology)[a]

[a] - Presented on individual tables if the automated differential data were verified by manual review of slides
( ) - Designates tabular abbreviation

5.6.2. SERUM CHEMISTRY

Albumin
Total protein
Globulin [by calculation]
Albumin/globulin ratio (A/G Ratio) [by calculation]
Total bilirubin (Total Bili)
Urea nitrogen
Creatinine
Alkaline phosphatase (AlkalinePhos'tse)
Alanine aminotransferase (Alanine Transfer)
Aspartate aminotransferase (AspartatTransfer)
Glucose
Total cholesterol (Cholesterol)
Calcium
Chloride
Phosphorus
Potassium
Sodium
Triglycerides (Triglyceride)

( ) - Designates tabular abbreviation

5.7. ANATOMIC PATHOLOGY

5.7.1. MACROSCOPIC EXAMINATION

A complete necropsy was conducted on all animals. Animals were euthanized by carbon dioxide followed by exsanguination. The necropsies included, but were not limited to, examination of the external surface, all orifices, and the cranial, thoracic, abdominal and pelvic cavities, including viscera. Clinical findings that were confirmed macroscopically were designated CEO (correlates with externally observed) on the individual macroscopic data tables. The following tissues and organs were collected and placed in 10% neutral-buffered formalin (except as noted):

Adrenal glands (2)
Bone with marrow
  Femur
  Sternum
Bone marrow smear
  (from femur)[a]
Brain
  Cerebrum level 1
  Cerebrum level 2
  Cerebellum with medulla/pons
Epididymides (2)[b]
Gastrointestinal tract
  Stomach
  Duodenum
  Jejunum
  Ileum
  Cecum
  Colon
  Rectum
Heart
Kidneys (2)
Liver (sections of 2 lobes)
Lungs (including bronchi, fixed by
  inflation with fixative)
Lymph nodes
  Mandibular (2)
  Mesenteric
Mammary gland (females only)
Ovaries with oviducts (2)
Peripheral nerve (sciatic)
Prostate
Seminal vesicles (2)
Spinal cord (cervical, midthoracic,
  lumbar)
Spleen
Testes (2)[b]
Thymus
Thyroid [with parathyroids, if
  present (2)][c]
Trachea
Urinary bladder
Uterus
Cervix
Vagina
Gross lesions (when possible)

[a] - Bone marrow smears were obtained at necropsy but not placed in formalin; slides were examined only if scientifically warranted.
[b] - Fixed in Bouin's solution
[c] - Parathyroids were examined microscopically if in the plane of section, or if gross lesions were present.

5.7.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsies:

Adrenal glands	Prostate
Brain	Seminal vesicle/coagulating gland
Epididymides	Spleen
Heart	Testes
Kidneys	Thymus
Liver	Uterus
Ovaries with oviducts	

Paired organs were weighed together. Organ to final body weight and organ to brain weight ratios were calculated.

5.7.3. SLIDE PREPARATION AND MICROSCOPIC EXAMINATION

After fixation, protocol-specified tissues were trimmed according to standard operating procedures and the protocol. Trimmed tissues were processed into paraffin blocks, sectioned at 4 to 8 microns, mounted on glass microscope slides and stained with hematoxylin and eosin.

Microscopic examination was performed on all tissues listed in Section 5.7.1. from all animals in the control and 1000 mg/kg/day groups at the primary necropsy. Gross lesions were examined from animals in the 160 and 400 mg/kg/day groups. Microscopic examination was performed by [redacted], Consulting Pathologist, Regan Pathology/Toxicology Services.

5.8. STATISTICAL METHODS

All statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests (except as noted otherwise) for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group by sex. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. In addition, percent change from control is presented for body weights, clinical pathology parameters and organ weights.

Statistical analyses were not conducted if the number of animals was 2 or less. Due to the use of significant figures and the different rounding conventions inherent in the types of software used, the means and standard deviations on the summary and individual tables may differ slightly.

Body weight, body weight change, food consumption, continuous functional observational battery (FOB), clinical pathology and organ weight data were subjected to a parametric 1-way analysis of variance (ANOVA) (Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group. Functional observational battery parameters that yielded scalar or descriptive data were analyzed using Fisher's Exact Test (Steel and Torrie, 1980).

All RANOVA statistical analyses for total and ambulatory locomotor activity counts were conducted by BioSTAT Consultants, Inc. using SAS version 8.2 software (SAS Institute, Inc., 1999-2001). Each analysis endpoint was analyzed, by sex and session, with a repeated measure analysis of variance (RANOVA). Factors in the model included treatment group (TRT), time interval (TIME), and the interaction of time interval and treatment group (TRT*TIME). The SAS® procedure PROC MIXED was used for analysis with the random effect of animal included as the repeated measurement. The covariance structure across time was selected by comparing Akaike's Information Criterion (AIC) for first-order autoregressive homogeneous [AR(1)] and compound symmetric (CS) structures. The monotonic dose response relationship was evaluated using sequential linear trend tests based on ordinal spacing of dose levels. The linear dose by time interaction (LinTrt*Time) was evaluated and, if significant at the 0.05 level, trend tests on treatment means were performed at the 0.05 level for each time interval. If the linear dose by time interaction was not significant, the trend test was conducted across the pooled time intervals of the entire session only. Nonmonotonic dose responses were evaluated whenever no significant linear trends were detected but TRT and/or

TRT*TIME interaction was significant at the 0.01 level. Within the framework of the RANOVA, pairwise comparisons were made for each individual treated group with the control group through linear contrasts. If TRT*TIME was significant, the comparisons were conducted for each time interval. If only the TRT effect was significant, the comparisons were conducted across the pooled time intervals of the entire session. These nonmonotonic dose response comparisons were conducted at the 0.01 significance level. The results of these analyses are presented in Appendix J.

5.9. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

A reserve sample of the test article, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

6. RESULTS AND DISCUSSION

6.1. ANALYTICAL CHEMISTRY

Analytical Chemistry Report: Appendix B

The nominal concentrations for all dosing formulations analyzed were confirmed to be within ±15% of the target concentration. Initial bulk formulation and resuspension homogeneity after 10-day storage at room temperature were confirmed. Although the analytical method used for the 10-day resuspension analysis was not stability indicating, the test substance is formulated for use in the high temperature and oxidative environment found in internal combustion engines. Based on information provided by the sponsor, it is not expected to degrade under conditions used in this toxicology study.

6.2. CLINICAL OBSERVATIONS AND SURVIVAL

Summary Data: Tables 1, 2, 3, 4, 5, 6

Individual Data: Table 29; Appendices E, I

All animals survived to the scheduled necropsies. Test article-related clinical findings were generally limited to the 1000 mg/kg/day group males and females and consisted of high incidences of evidence of salivation, including clear material around the mouth, and much lower incidences of red material around the mouth. These findings were most frequently seen at 1 hour post-dosing, usually not until the second or third week of dosing. Evidence of salivation was noted for 8 males and 9 females in the 1000 mg/kg/day group. Red material around the mouth was noted for 5 males and 4 females in this group.

These test article-related clinical findings were also noted in the 400 mg/kg/day group at lower incidences, most frequently seen at 1 hour post-dosing during study weeks 1 to 3. Evidence of salivation was noted for 3 males and 4 females in the 400 mg/kg/day group. Red material around the mouth was noted for 2 males and 3 females in the 400 mg/kg/day group.

The aforementioned clinical findings were not noted during the recovery period. All other clinical findings in the test article-treated groups were noted with similar incidence in the control group, were limited to single animals, were not noted in a dose-related manner and/or were common findings for laboratory rats of this age and strain.

6.3. BODY WEIGHTS

Summary Data: Tables 7, 8, 9

Individual Data: Tables 30, 31, 32

Test article-related slightly lower body weights and weekly and cumulative body weight gains were observed in the 1000 mg/kg/day males compared to the control group. Although not statistically significant, these body weight parameters were consistently lower in the 1000 mg/kg/day group males than the control group throughout the study, resulting in mean body weights and cumulative mean body weight gains that were 4.5% and 13% lower, respectively, than the control group males at the end of the dosing period. Similar effects were not observed in the 1000 mg/kg/day group females.

Mean cumulative body weight gains for the test article-treated group males during treatment from study week 0 to 4 were lower, not statistically significant, than the control group males. Throughout test article administration, body weights for the 160 and 400 mg/kg/day group males and females were similar to the control group.

Mean body weight gains were slightly lower, not statistically significant, from study week 4 to 5 and study week 5 to 6 for 1000 mg/kg/day group males when compared to the control group. Statistically significantly ($p<0.05$) lower mean body weights were noted at study week 5 and 6 in the 1000 mg/kg/day males when compared to the control group males. These lower mean body weights were not considered test article-related as the animals assigned to the recovery control group by computer randomization were heavier than those animals assigned to the recovery 1000 mg/kg/day group. At study week 4, these control group males retained for recovery had a mean body weight of 396 g (versus 377g for the entire control group), and the 1000 mg/kg/day group males assigned

to recovery had a mean body weight of 360 g. There were no other statistically significant differences when the control and test article-treated groups were compared.

6.4. FOOD CONSUMPTION

Summary Data: Table 10

Individual Data: Table 33

There were no test article-related effects on food consumption. Mean food consumption in the 1000 mg/kg/day group males from study week 0 to 1 and study week 5 to 6 was statistically significantly ($p<0.05$) lower compared to the control group. For the 160 and 1000 mg/kg/day group females from study week 1 to 2, mean food consumption was statistically significantly ($p<0.05$) higher compared to the control group. However, these differences were not observed similarly in the opposite sex and/or in a time or dose-related manner, and therefore were not considered test article-related.

6.5. FUNCTIONAL OBSERVATIONAL BATTERY [FOB]

6.5.1. HOME CAGE OBSERVATIONS

Summary Data: Table 11

Individual Data: Table 34

Historical Control Data: Appendix K

Home cage observations were unaffected by test article administration. There were no statistically significant differences when the test article-treated males and females were compared to the control group at the study week 3 evaluation.

6.5.2. HANDLING OBSERVATIONS

Summary Data: Table 12

Individual Data: Table 35

Historical Control Data: Appendix K

Handling observations were unaffected by test article administration. There were no statistically significant differences when the test article-treated males and females were compared to the control group at the study week 3 evaluation.

6.5.3. OPEN FIELD OBSERVATIONS

Summary Data: Table 13

Individual Data: Table 36

Historical Control Data: Appendix K

Open field observations were unaffected by test article administration. There were no statistically significant differences when the test article-treated males and females were compared to the control group at the study week 3 evaluation.

6.5.4. SENSORY OBSERVATIONS

Summary Data: Table 14

Individual Data: Table 37

Historical Control Data: Appendix K

Sensory observations were unaffected by test article administration. There were no statistically significant differences when the test article-treated males and females were compared to the control group at the study week 3 evaluation.

6.5.5. NEUROMUSCULAR OBSERVATIONS

Summary Data: Table 15

Individual Data: Table 38

Historical Control Data: Appendix K

Neuromuscular observations were unaffected by test article administration. There were no statistically significant differences when the test article-treated males and females were compared to the control group at the study week 3 evaluation.

6.5.6. PHYSIOLOGICAL OBSERVATIONS

Summary Data: Table 16

Individual Data: Table 39

Historical Control Data: Appendix K

Physiological observations were unaffected by test article administration. There were no statistically significant differences when the test article-treated males and females were compared to the control group at the study week 3 evaluation.

6.6. LOCOMOTOR ACTIVITY

Summary Data: Table 17; Figures 1, 2, 3, 4

Individual Data: Table 40

Historical Control Data: Appendix L

Locomotor activity patterns (total and ambulatory activity counts) were unaffected by test article administration. There were no statistically significant changes for the test article-treated males and females when compared to the control group using a repeated measures analysis of variance at the study week 3 evaluation. Values obtained from the 4 epochs evaluated (0-15 minutes, 16-30 minutes, 31-45 minutes and 46-60 minutes) and the overall 60-minute test session were comparable to the concurrent control values. No remarkable shifts in the pattern of habituation occurred in any of the test article-treated groups when the animals were evaluated on study week 3.

6.7. CLINICAL PATHOLOGY

6.7.1. HEMATOLOGY

Summary Data: Table 18

Individual Data: Tables 41, 42

Historical Control Data: Appendix M

Hematology parameters affected by test article administration at 1000 mg/kg/day included activated partial thromboplastin times (APTT) and prothrombin times. At study day 28, statistically significant ($p<0.01$) increases in mean prothrombin time in the 1000 mg/kg/day group males and females and APTT in the 1000 mg/kg/day group males were observed compared to the control group. Increases in both prothrombin time and APTT suggest a deficiency in the common pathway of the coagulation cascade or multiple defects involving the intrinsic, extrinsic and common pathways. Mean values for prothrombin time and APTT in the 1000 mg/kg/day group males and females were similar to the control group after the 14-day recovery period.

Other statistically significant ($p<0.01$ or $p<0.05$) differences in hematology parameters were observed but were not considered test article-related. These differences included slightly lower mean hemoglobin and hematocrit in the 160 and/or 1000 mg/kg/day group males at study day 28, and lower mean hemoglobin, hematocrit and red blood cell count and higher mean corpuscular hemoglobin concentration (MCHC) in the 1000 mg/kg/day group females and higher mean corpuscular hemoglobin (MCH) in the 1000 mg/kg/day group males at study day 42. Also higher mean red blood cell count in the 160 mg/kg/day group females and higher mean percent monocytes in the 400 mg/kg/day group females were observed when compared to the control group at study day 28. All of these changes were considered spontaneous, incidental and unrelated to the administration of the test article as these hematology parameters were within WIL historical control data (version 2.1) ranges. There were no other statistically significant differences when the control and test article-treated groups were compared.

6.7.2. SERUM CHEMISTRY

Summary Data: Table 19

Individual Data: Tables 43, 44

Historical Control Data: Appendix M

Serum chemistry parameters affected by test article administration included alanine aminotransferase, aspartate aminotransferase, globulin and total protein in the 400 or 1000 mg/kg/day groups. However, these findings were not considered adverse as there were no correlating clinical signs, macroscopic or microscopic findings or weight changes, and the changes reversed quickly after a 2-week recovery period, and globulin and total protein levels were within WIL historical control data (version 2.1) ranges. Test article-related higher mean alanine aminotransferase in the 400 and 1000 mg/kg/day group males and females and mean aspartate aminotransferase in the 1000 mg/kg/day group males and females were observed at study day 28 when compared to the control group; these increases were dose-related and statistically significant ($p<0.05$ or $p<0.01$). There were no correlating macroscopic or microscopic changes in the liver. Also at study day 28, mean globulin and total protein were statistically significantly ($p<0.05$ and $p<0.01$, respectively) lower in the 1000 mg/kg/day group males when compared to the control group. Mean globulin and total protein were also numerically lower in the 1000 mg/kg/day group females, but the differences were not statistically significant. These differences were considered test article-related, although correlating microscopic changes in the liver were not observed, and a site of potential protein loss (kidney, gastrointestinal tract) was not identified microscopically. All other changes in serum chemistry parameters were considered spontaneous, incidental and unrelated to the administration of the test article. After the 14-day recovery period, changes observed at the primary necropsy were no longer apparent, suggesting recovery from these effects.

6.8. ANATOMIC PATHOLOGY

6.8.1. MACROSCOPIC EXAMINATION

Summary Data: Tables 20, 21

Individual Data: Tables 45, 46

There were no test article-related macroscopic changes observed.

6.8.2. ORGAN WEIGHTS

Summary Data: Tables 22, 23, 24, 25, 26, 27

Individual Data: Tables 47, 48, 49, 50, 51, 52

Historical Control Data: Appendix N

There were no test article-related changes in organ weights at the primary or recovery necropsy. At the study day 28 primary necropsy, mean absolute brain weight was statistically significantly ($p<0.01$ or $p<0.05$) lower in the 400 and 1000 mg/kg/day group males, and mean absolute testes weight was statistically significantly ($p<0.05$) lower in the 1000 mg/kg/day group males. These lower organ weights were not dose-related (brain) and were within WIL historical control data (version 2.1) ranges, and there were no correlating microscopic changes. Also at study day 28, mean relative (to brain weight) kidney weights in the 400 mg/kg/day group males were statistically significantly ($p<0.05$) higher compared to the control group. These organ weight differences were considered spontaneous and unrelated to the administration of the test article.

Mean absolute and relative (to final body and brain weight) heart, ovary (with oviducts) and adrenal gland weights for the 1000 mg/kg/day group females were higher than the control group at the study day 42 recovery necropsy. These increases were generally statistically significant ($p<0.05$). The relationship of these increases to test article administration is unclear. At the study day 28 necropsy, changes in mean heart, ovary and adrenal gland weights in females were not observed, and there were no microscopic test article-related changes in these organs. Mean relative (to final body weight) heart and adrenal gland weights were statistically significantly ($p<0.01$ or $p<0.05$) higher in the

1000 mg/kg/day group males; these increases resulted from a significantly ($p<0.05$) lower mean final body weight in the 1000 mg/kg/day group males at the recovery necropsy, and were not considered test article-related, because mean absolute and mean relative to brain weights were not changed.

No other statistically significant differences in organ weights were observed.

6.8.3. MICROSCOPIC EXAMINATION

Summary Data: Table 28

Individual Data: Table 45

There were no test article-related microscopic changes noted. Although lymph node hemorrhage was observed in the mandibular node for 4 males in the 1000 mg/kg/day group and 1 control group male, the hemorrhage was fresh in all animals, meaning the hemorrhage occurred around the time of death. Because of the mandibular node location on the ventral side of the neck, this node is easily squeezed at the time of necropsy, resulting in the hemorrhage that was noted microscopically. An effect on the immune system would more likely affect the lymphoid elements. The thymic epithelial hyperplasia noted in 2 females for the 1000 mg/kg/day group is a common change in the rodent thymus as the animal ages and the thymus starts to atrophy. This change appears in females first as was the case in this study. The thickness of the cortex and medulla were not noticeably changed indicating that there was no effect on the immune system. All microscopic observations were considered spontaneous, incidental and unrelated to the administration of the test article.

7. DISCUSSION

The objective of the study was to evaluate the possible toxic effects of [redacted] when administered orally by gavage to rats for 28 days and to assess recovery from such effects. This study included evaluation of potential neurotoxicity by functional observational battery (FOB) and motor activity (MA) assessment. Dosage levels of [redacted] were 160, 400 and 1000 mg/kg/day.

All animals survived to the scheduled necropsies. There were no test article-related effects on food consumption. Functional observational battery evaluations, including home cage, handling, open field, sensory, neuromuscular and physical observations and monitored locomotor activity patterns (total and ambulatory activity counts), during study week 3 were unaffected by test article administration. There were no test article-related macroscopic or microscopic changes observed. There were no test article-related effects in organ weights at the primary or recovery necropsy.

Test article-related clinical findings were generally limited to the 1000 mg/kg/day group males and females and consisted of high incidences of evidence of salivation, including clear material around the mouth, and also low incidences of red material around the mouth. These findings were most frequently observed at 1 hour post-dosing, usually not until the second or third week of dosing. These test article-related clinical findings were also noted in the 400 mg/kg/day group at a lower incidence, most frequently seen at 1 hour post-dosing during study weeks 1 to 3. None of these test article-related clinical findings were observed during the recovery period.

Test article-related slightly lower body weights and weekly and cumulative body weight gains were observed in the 1000 mg/kg/day group males than in the control group throughout the dosing period, resulting in body weights and cumulative body weight gains that were 4.5% and 13% lower, respectively, than the control group males at the end of the dosing period.

At the end of the dosing period (study day 28), increases in mean prothrombin time in the 1000 mg/kg/day group males and females and mean activated partial thromboplastin time in the 1000 mg/kg/day group males compared to the control group were considered test article-related. These coagulation parameters were similar to the control group at the recovery evaluation.

Alanine aminotransferase in the 400 and 1000 mg/kg/day group males and females and aspartate aminotransferase in the 1000 mg/kg/day group males and females at study day 28 were higher than the control group; these findings were dose-related and statistically significant. Also at study day 28, globulin and total protein were statistically significantly lower in the 1000 mg/kg/day group males compared to the control group. Globulin and total protein were also numerically lower than the control group in the 1000 mg/kg/day group females, but the differences were not statistically significant. These differences were considered test article-related but not adverse as correlating macroscopic or microscopic changes in the liver were not observed, there was no effect on liver weights and a site of potential protein loss (kidney, gastrointestinal tract) was not identified.

8. CONCLUSIONS

Based on the results of this study, the no-observed-effect level (NOEL) for oral (gavage) administration of [redacted] to Crl:CD(SD) rats for 28 consecutive days was 160 mg/kg/day based on clinical observations and serum chemistry effects at 400 and 1000 mg/kg/day and body weight and coagulation parameter effects at 1000 mg/kg/day. The clinical observations and the effects upon serum chemistry were not considered to be adverse based on the absence of microscopic changes in the 400 and 1000 mg/kg/day groups. Effects at 1000 mg/kg/day were fully resolved after a 14-day recovery period. Based upon body weight and coagulation changes, the no-observed-adverse-effect level (NOAEL) for oral (gavage) administration of [redacted] to Crl:CD(SD) rats for 28 consecutive days was 400 mg/kg/day.

WIL-187051 [redacted] [redacted] 05-087

9. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

[redacted]
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

28 June 2006
Date

Pathologist Of Record:

[redacted]

25 June 2006
Date

Report Prepared By:

[redacted]
Study Analyst

23 June 2006
Date

Report Reviewed By:

[redacted]

22 June 2006
Date

[redacted]
Assistant Director, Neurosciences

22 June 2006
Date

[redacted]
Director, Developmental and
Reproductive Toxicology

23 JUNE 2006
Date

[redacted]
Staff Toxicologist

23 June 2006
Date

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

[redacted]

23 June 2006
Date

Scheduling Coordinator, Regulatory Affairs and Services

Study Personnel:

[redacted]	Manager, Clinical Pathology
	Senior Operations Manager, Vivarium
	Manager, Gross Pathology and Developmental Toxicology Laboratory
[redacted]	Operations Manager, Toxicology
	Group Manager, Formulations Laboratory
	Manager, Histology
	Manager, Reporting and Regulatory Technical Services

10. QUALITY ASSURANCE UNIT STATEMENT

10.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
25-Oct-2005	Test Article Preparation	25-Oct-2005	19-Nov-2005	[redacted]
26-Oct-2005	Test Article Administration	26-Oct-2005	19-Nov-2005	
02-Nov-2005	Animal Care and Equipment	02-Nov-2005	21-Dec-2005	
16-Nov-2005	Functional Observational Battery	16-Nov-2005	21-Dec-2005	
23-Nov-2005	Blood Collection and Analysis	23-Nov-2005	21-Dec-2005	
23-Nov-2005	Necropsy	23-Nov-2005	21-Dec-2005	
16-Jan-2006	Study Records (I-1, I-2)	17-Jan-2006	20-Feb-2006	
10-Feb-2006, 21-Feb-2006	Study Records (C-1, C-2)	21-Feb-2006	24-Mar-2006	
15-Feb-2006, 21-Feb-2006, 22-Feb-2006	Draft Report	22-Feb-2006	24-Mar-2006	
15-Feb-2006, 22-Feb-2006	Study Records (Rx-1)	22-Feb-2006	24-Mar-2006	
15-Feb-2006, 22-Feb-2006	Study Records (N-1)	22-Feb-2006	24-Mar-2006	
22-Feb-2006	Study Records (P-1)	22-Feb-2006	24-Mar-2006	

This study was inspected in accordance with the OECD Principles of Good Laboratory Practice, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendments, with the following exceptions. The data located in Appendix B (Analyses of Formulations and Vehicle) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented

and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

10.2. APPROVAL

This study was inspected according to the criteria discussed in Section 10.1.

Report Audited By:

[redacted]

Sponsor Specialist, Quality Assurance

28 June 2006
Date

Report Released By:

[redacted]

Manager, Quality Assurance

28 June 2006
Date

BIOTECHNICS
FOCUSED EXPERTISE

A 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] In Rats (With Functional Observational Battery and Motor Activity Determinations)

Study Number: WIL-187051

QUALITY ASSURANCE STATEMENT

Phase Audited	Date of Audit	Date Reported To Principal Investigator	Date Reported To Management	Date Reported To Study Director
Tissue Processing	12 Dec 05	13 Dec 05	13 Dec 05	14 Mar 06
Embedding	13 Dec 05	13 Dec 05	13 Dec 05	14 Mar 06

[redacted]

Quality Assurance Unit

3/14/06
Date

310 Millstone Drive, Hillsborough, NC 27278 Phone: 919.245 3114 Fax 919.245.3115 www biotechnics-inc.com

11. REFERENCES

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

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12. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

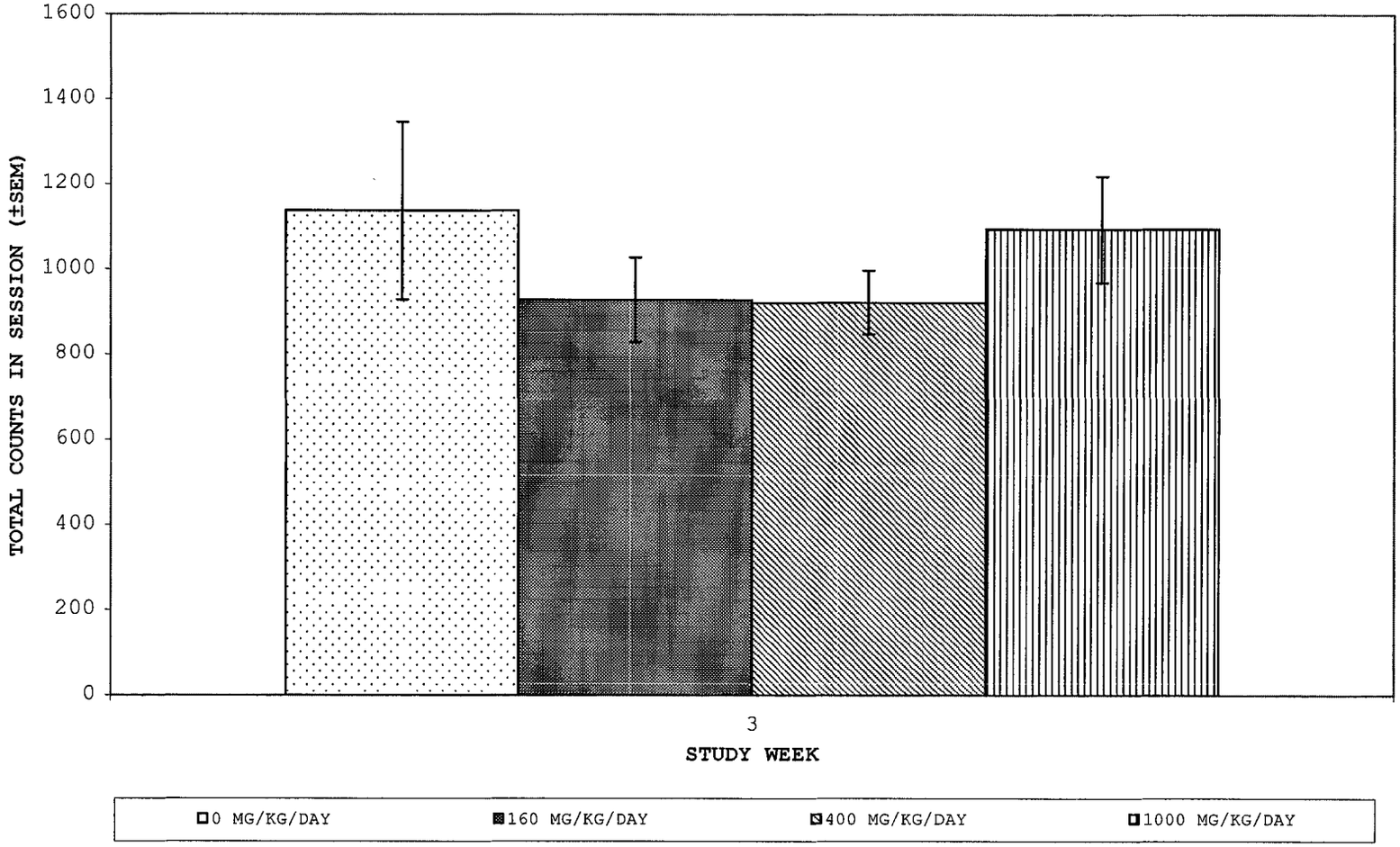
- **Protocol Section 5.5** states that the males will weigh approximately 160 to 260 g and the females approximately 110 to 180 g at initiation of dosing. On study day 0 the male weights ranged from 233 to 272 g with a mean weight of 251 g and the female weights from 146 to 183 g with a mean weight of 165 g. Therefore, several animals that were not within the specified weight range requirements were placed on study.
- **Protocol Section 7.5.2** states that 3 samples from the top and bottom of each formulation will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] for analysis of homogeneity and stability over a ten-day period. Stability of the dosing formulations was not addressed in the analytical method used.
- **Protocol Section 8.6** states that functional observational battery (FOB) evaluations may also be performed on the 5 recovery animals/sex from Groups 1 and 4 near the end of the 14 day recovery period (if added by protocol amendment). The same animals will be used for the appropriate time points. **Protocol Section 8.7** states that those animals not selected for recovery will be fasted overnight before taking blood samples just prior to necropsy. On 23 November 2005 (study day 28) prior to blood collection, it was noted that the animals in Groups 1 and 4 scheduled for blood collection and necropsy had not been fasted overnight. Instead the 5 animals/sex in Groups 1 and 4 selected for recovery FOB evaluations had been fasted overnight. The study director made a decision to draw the blood samples and perform necropsy on the animals that had been fasted overnight.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1 - 4

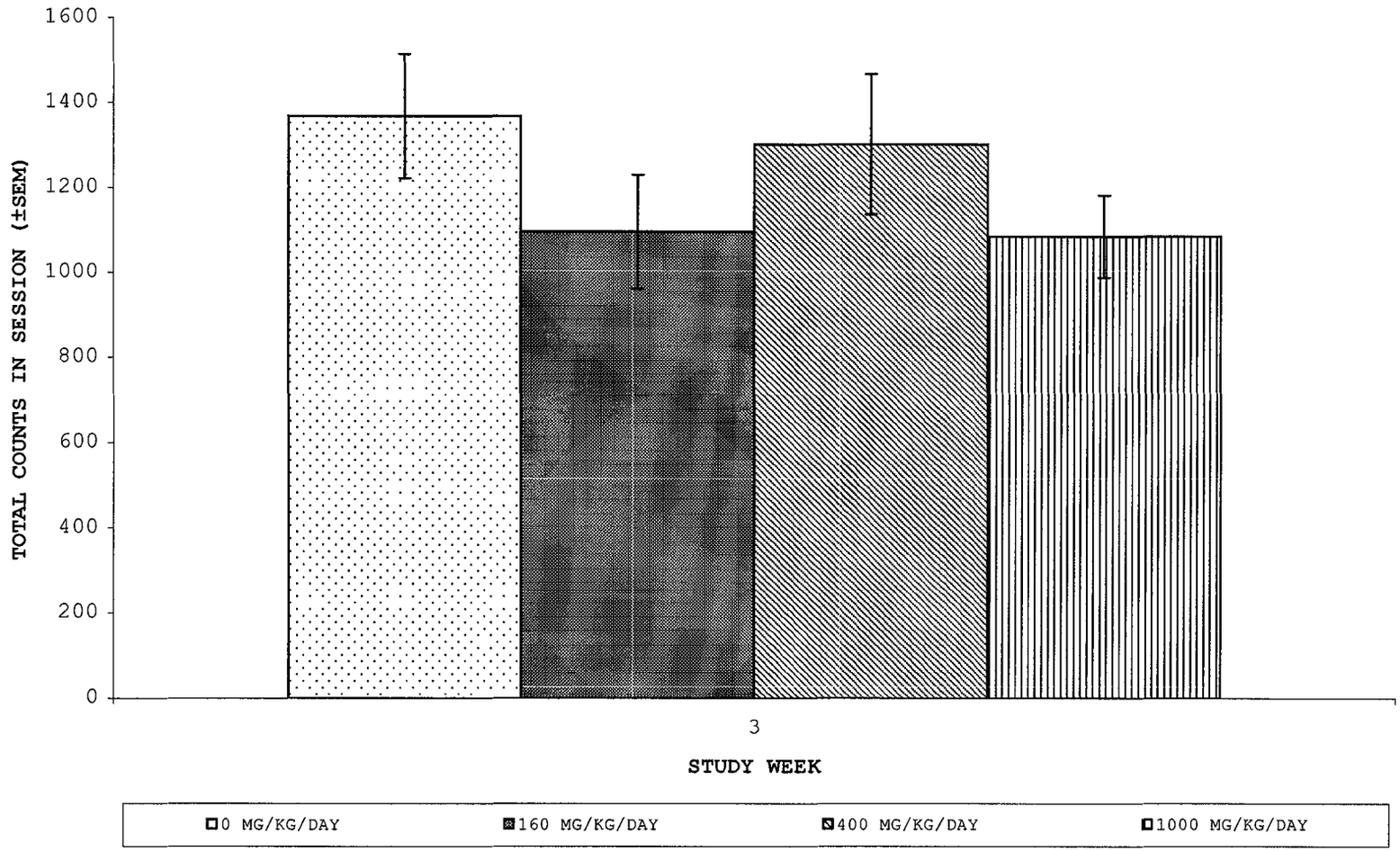
PROJECT [redacted]-187051
SPONSOR: [redacted]

FIGURE 1 (MALES - TOTAL COUNTS IN SES
A 28-DAY REPEATED DOSE ORAL TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS



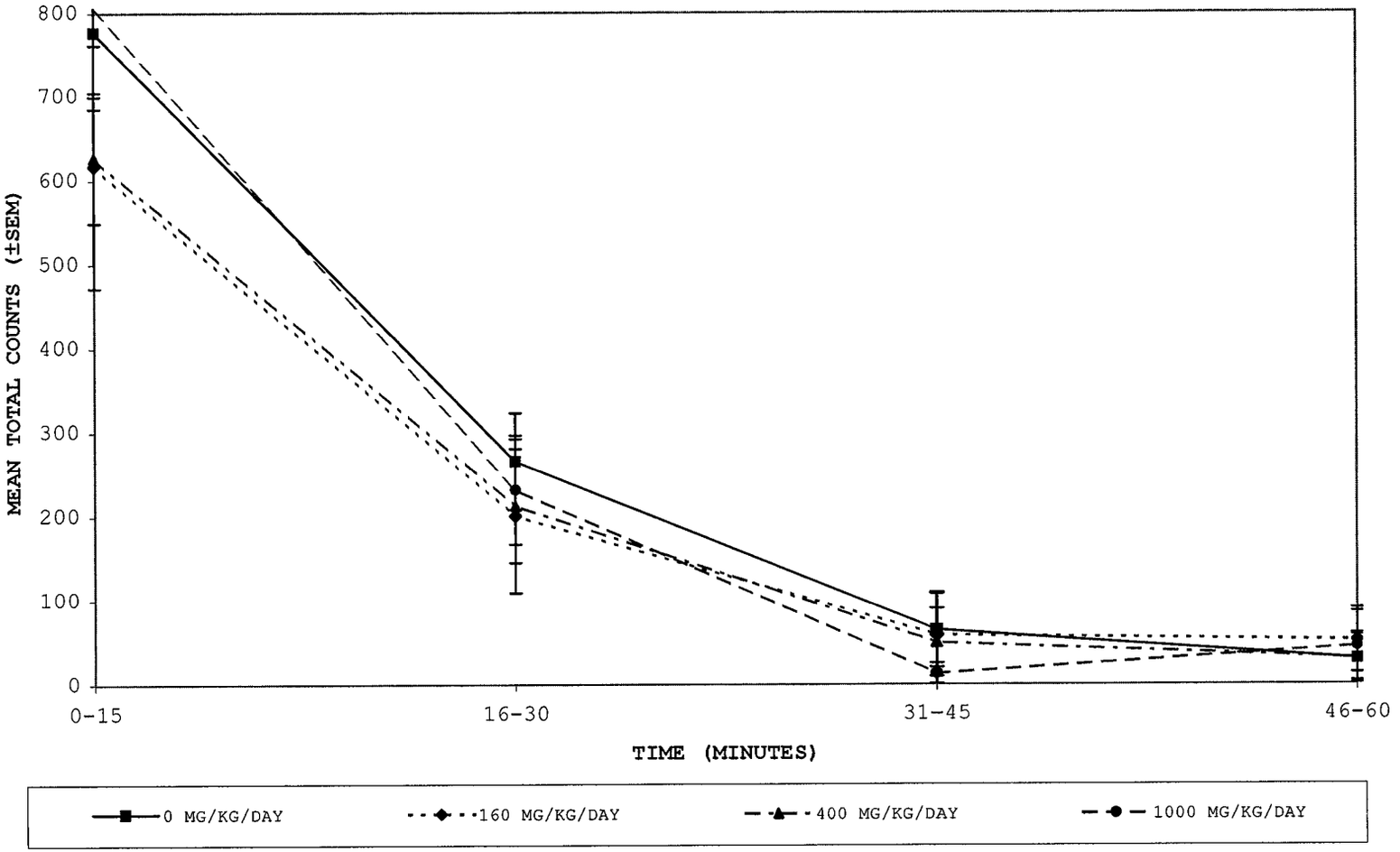
PROJECT [redacted]-187051
SPONSOR: [redacted]

FIGURE 2 (FEMALES - TOTAL COUNTS IN SE[redacted]
A 28-DAY REPEATED DOSE ORAL TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS



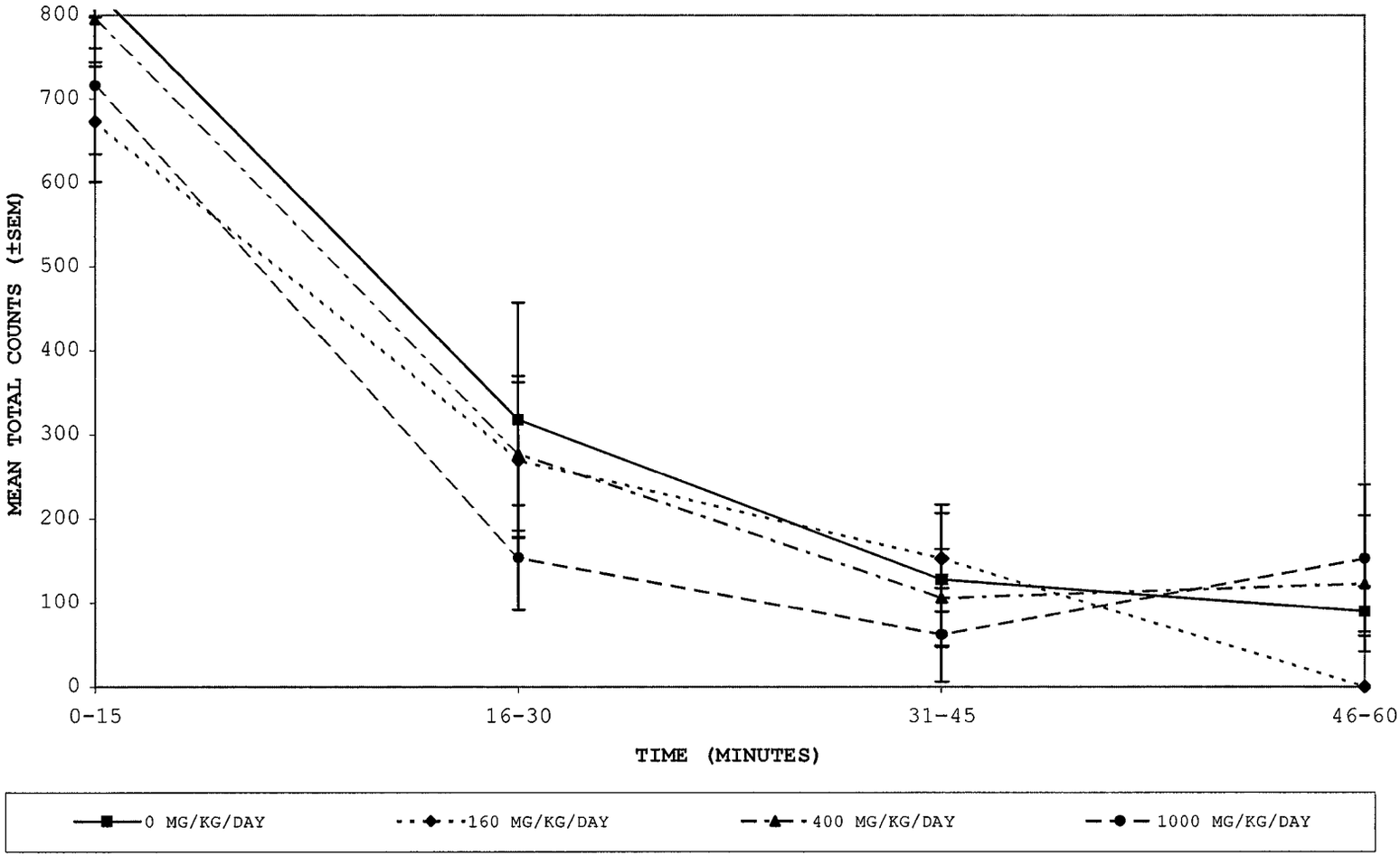
PROJECT [redacted]-187051
SPONSOR: [redacted]

FIGURE 3 (MALES)
A 28-DAY REPEATED DOSE ORAL TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS



PROJECT [redacted]-187051
SPONSOR: [redacted]

FIGURE 4 (FEMALES)
A 28-DAY REPEATED DOSE ORAL TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS



TABLES 1 - 43

TABLE 1

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF SURVIVAL AND DISPOSITION

MALES

GROUP :	1				2				3				4			
WEEK	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
0	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
1	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
2	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
3	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
4	5	0	0	5	0	0	0	5	0	0	0	5	5	0	0	5
5	5	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0
6	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	5

WEEK = WEEK OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 1

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	1				2				3				4			
WEEK	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
0	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
1	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
2	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
3	10	0	0	0	5	0	0	0	5	0	0	0	10	0	0	0
4	5	0	0	5	0	0	0	5	0	0	0	5	5	0	0	5
5	5	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0
6	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	5

WEEK = WEEK OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - DOSING PERIOD)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:05-087

----- M A L E -----

TABLE RANGE:	10-26-05 TO 11-27-05			
GROUP:	1	2	3	4
NORMAL				
-NO SIGNIFICANT CLINICAL OBSERVATIONS	47/10	21/ 5	21/ 5	48/10
DISPOSITION				
-SCHEDULED EUTHANASIA	5/ 5	5/ 5	5/ 5	5/ 5
BODY/INTEGUMENT				
-HAIR LOSS LEFT FORELIMB	0/ 0	2/ 1	0/ 0	0/ 0
-HAIR LOSS RIGHT FORELIMB	0/ 0	2/ 1	0/ 0	0/ 0
EYES/EARS/NOSE				
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	1/ 1	0/ 0
ORAL/DENTAL				
-UPPER INCISORS MALALIGNED	0/ 0	0/ 0	1/ 1	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - DOSING PERIOD)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:05-087

----- F E M A L E -----

TABLE RANGE:	10-26-05 TO 11-27-05			
GROUP:	1	2	3	4
NORMAL				
-NO SIGNIFICANT CLINICAL OBSERVATIONS	43/10	20/ 5	21/ 5	45/10
DISPOSITION				
-SCHEDULED EUTHANASIA	5/ 5	5/ 5	5/ 5	5/ 5
BODY/INTEGUMENT				
-HAIR LOSS LEFT FORELIMB	5/ 2	3/ 1	2/ 1	0/ 0
-HAIR LOSS RIGHT FORELIMB	4/ 1	3/ 1	2/ 1	2/ 1
-SCABBING LEFT FORELIMB	1/ 1	0/ 0	2/ 1	0/ 0
-SCABBING RIGHT FORELIMB	0/ 0	0/ 0	1/ 1	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 3 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - RECOVERY PERIOD)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	11-28-05 TO 12-07-05			
GROUP:	1	2	3	4
NORMAL				
-NO SIGNIFICANT CLINICAL OBSERVATIONS	9/ 5	0/ 0	0/ 0	10/ 5
DISPOSITION				
-SCHEDULED EUTHANASIA	5/ 5	0/ 0	0/ 0	5/ 5
ORAL/DENTAL				
-UPPER INCISORS MALALIGNED	1/ 1	0/ 0	0/ 0	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 3 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - RECOVERY PERIOD)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:05-087

----- F E M A L E -----

TABLE RANGE:	11-28-05 TO 12-07-05			
GROUP:	1	2	3	4
NORMAL				
-NO SIGNIFICANT CLINICAL OBSERVATIONS	6/ 3	0/ 0	0/ 0	8/ 4
DISPOSITION				
-SCHEDULED EUTHANASIA	5/ 5	0/ 0	0/ 0	5/ 5
BODY/INTEGUMENT				
-HAIR LOSS LEFT FORELIMB	4/ 2	0/ 0	0/ 0	2/ 1
-HAIR LOSS RIGHT FORELIMB	2/ 1	0/ 0	0/ 0	2/ 1
-SCABBING LEFT FORELIMB	0/ 0	0/ 0	0/ 0	1/ 1
-SCABBING RIGHT FORELIMB	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 4 (AT TIME OF DOSING)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	10-26-05 TO 11-27-05			
GROUP:	1	2	3	4
AT TIME OF DOSING				
ORAL/DENTAL				
-SALIVATION	0/ 0	0/ 0	2/ 1	10/ 4
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	5/ 3
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	3/ 3
-SALIVATION PRIOR TO DOSING	0/ 0	0/ 0	0/ 0	2/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 4 (AT TIME OF DOSING)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:05-087

----- F E M A L E -----

TABLE RANGE:	10-26-05 TO 11-27-05			
GROUP:	1	2	3	4
	AT TIME OF DOSING			
BODY/INTEGUMENT				
-HAIR LOSS LEFT INGUINAL AREA	1/ 1	0/ 0	0/ 0	0/ 0
-HAIR LOSS LEFT FORELIMB	4/ 3	0/ 0	0/ 0	2/ 1
-HAIR LOSS RIGHT FORELIMB	2/ 2	0/ 0	0/ 0	2/ 1
-SCABBING RIGHT FORELIMB	0/ 0	0/ 0	0/ 0	1/ 1
ORAL/DENTAL				
-SALIVATION	0/ 0	0/ 0	3/ 3	6/ 3
-WET CLEAR MATERIAL AROUND MOUTH	1/ 1	0/ 0	4/ 3	7/ 5
-SALIVATION PRIOR TO DOSING	0/ 0	0/ 0	1/ 1	4/ 2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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01/31/2006

TABLE 5 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	10-26-05 TO 11-27-05			
GROUP:	1	2	3	4
	1-HOUR POST-DOSE			
BODY/INTEGUMENT				
-WET CLEAR MATERIAL RIGHT FORELIMB	0/ 0	0/ 0	0/ 0	2/ 2
-WET CLEAR MATERIAL LEFT FORELIMB	0/ 0	0/ 0	0/ 0	2/ 2
EYES/EARS/NOSE				
-DRIED RED MATERIAL AROUND NOSE	1/ 1	1/ 1	2/ 1	1/ 1
ORAL/DENTAL				
-SALIVATION	0/ 0	0/ 0	0/ 0	44/ 6
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	48/ 8
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	1/ 1	6/ 2	10/ 5
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	5/ 2	10/ 5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 5 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:05-087
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	10-26-05 TO 11-27-05			
GROUP:	1	2	3	4
	1-HOUR POST-DOSE			
EYES/EARS/NOSE				
-DRIED RED MATERIAL AROUND NOSE	0/ 0	1/ 1	0/ 0	0/ 0
ORAL/DENTAL				
-SALIVATION	0/ 0	0/ 0	1/ 1	17/ 4
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	25/ 8
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	4/ 3	6/ 4
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	4/ 4
-WET RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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01/31/2006

TABLE 6 (DAILY OBSERVATIONS - RECOVERY PERIOD)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:05-087

----- M A L E -----

TABLE RANGE:	11-28-05 TO 12-06-05			
GROUP:	1	2	3	4
AT TIME OF DOSING				
ORAL/DENTAL				
-UPPER INCISORS MALALIGNED	1/ 1	0/ 0	0/ 0	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

----- F E M A L E -----

TABLE RANGE:	11-28-05 TO 12-06-05			
GROUP:	1	2	3	4
	AT TIME OF DOSING			
BODY/INTEGUMENT				
-HAIR LOSS LEFT INGUINAL AREA	1/ 1	0/ 0	0/ 0	0/ 0
-HAIR LOSS LEFT FORELIMB	3/ 2	0/ 0	0/ 0	2/ 1
-HAIR LOSS RIGHT FORELIMB	1/ 1	0/ 0	0/ 0	2/ 1
-SCABBING LEFT FORELIMB	0/ 0	0/ 0	0/ 0	2/ 1
-SCABBING RIGHT FORELIMB	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 7
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHTS [G]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -1				
MEAN	189.	187.	190.	190.
% CHANGE		-1.1	0.5	0.5
S.D.	9.4	8.3	9.1	6.5
N	10	5	5	10
0				
MEAN	252.	250.	251.	251.
% CHANGE		-0.8	-0.4	-0.4
S.D.	13.8	10.5	14.7	9.6
N	10	5	5	10
1				
MEAN	296.	291.	291.	286.
% CHANGE		-1.7	-1.7	-3.4
S.D.	23.5	19.5	17.0	11.5
N	10	5	5	10
2				
MEAN	326.	324.	323.	312.
% CHANGE		-0.6	-0.9	-4.3
S.D.	29.0	30.1	20.9	16.7
N	10	5	5	10
3				
MEAN	354.	347.	345.	337.
% CHANGE		-2.0	-2.5	-4.8
S.D.	34.0	35.8	13.4	20.4
N	10	5	5	10

None significantly different from control group

TABLE 7
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHTS [G]

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
WEEK 4				
MEAN	377.	369.	363.	360.
% CHANGE		-2.1	-3.7	-4.5
S.D.	36.2	45.4	17.7	21.5
N	10	5	5	10
5				
MEAN	427.	NA	NA	389.*
% CHANGE				-8.9
S.D.	25.9			22.4
N	5			5
6				
MEAN	443.	NA	NA	402.*
% CHANGE				-9.3
S.D.	24.3			25.9
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test
NA = NOT APPLICABLE

TABLE 7
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -1				
MEAN	139.	137.	138.	138.
% CHANGE		-1.4	-0.7	-0.7
S.D.	7.2	7.0	5.6	6.8
N	10	5	5	10
0				
MEAN	165.	166.	164.	165.
% CHANGE		0.6	-0.6	0.0
S.D.	8.3	9.6	13.5	9.6
N	10	5	5	10
1				
MEAN	186.	185.	188.	190.
% CHANGE		-0.5	1.1	2.2
S.D.	12.2	7.4	16.4	11.8
N	10	5	5	10
2				
MEAN	199.	204.	200.	205.
% CHANGE		2.5	0.5	3.0
S.D.	15.3	11.2	20.0	13.3
N	10	5	5	10
3				
MEAN	210.	215.	212.	217.
% CHANGE		2.4	1.0	3.3
S.D.	17.1	14.6	20.5	15.4
N	10	5	5	10

None significantly different from control group

TABLE 7

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 4				
MEAN	220.	224.	222.	229.
% CHANGE		1.8	0.9	4.1
S.D.	20.4	14.4	22.0	15.6
N	10	5	5	10
5				
MEAN	235.	NA	NA	242.
% CHANGE				3.0
S.D.	15.2			13.6
N	5			5
6				
MEAN	237.	NA	NA	243.
% CHANGE				2.5
S.D.	12.5			13.2
N	5			5

None significantly different from control group

NA = NOT APPLICABLE

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TABLE 8

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF BODY WEIGHT CHANGES [G]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -1 TO 0				
MEAN	63.	63.	61.	61.
S.D.	6.4	6.1	7.2	4.6
N	10	5	5	10
0 TO 1				
MEAN	44.	41.	40.	35.
S.D.	12.3	9.5	3.8	11.9
N	10	5	5	10
1 TO 2				
MEAN	30.	33.	33.	26.
S.D.	6.9	10.9	7.8	7.8
N	10	5	5	10
2 TO 3				
MEAN	28.	23.	21.	25.
S.D.	6.9	6.6	8.0	6.8
N	10	5	5	10
3 TO 4				
MEAN	23.	22.	19.	23.
S.D.	5.9	10.6	6.7	5.3
N	10	5	5	10

None significantly different from control group

TABLE 8

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:05-087 SUMMARY OF BODY WEIGHT CHANGES [G]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 4 TO 5				
MEAN	31.	NA	NA	28.
S.D.	2.8			12.9
N	5			5
5 TO 6				
MEAN	16.	NA	NA	14.
S.D.	2.2			4.8
N	5			5

None significantly different from control group

NA = NOT APPLICABLE

TABLE 8
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHT CHANGES [G]

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -1 TO 0				
MEAN	26.	29.	26.	27.
S.D.	3.6	3.8	9.4	6.2
N	10	5	5	10
0 TO 1				
MEAN	21.	19.	24.	26.
S.D.	4.8	6.8	3.2	4.9
N	10	5	5	10
1 TO 2				
MEAN	12.	19.	12.	15.
S.D.	5.1	5.6	4.2	7.0
N	10	5	5	10
2 TO 3				
MEAN	12.	11.	12.	12.
S.D.	5.7	6.1	6.7	5.0
N	10	5	5	10
3 TO 4				
MEAN	9.	9.	11.	12.
S.D.	4.6	6.6	4.2	4.1
N	10	5	5	10

None significantly different from control group

TABLE 8
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
WEEK 4 TO 5				
MEAN	17.	NA	NA	12.
S.D.	6.0			7.7
N	5			5
5 TO 6				
MEAN	2.	NA	NA	1.
S.D.	5.2			1.1
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

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TABLE 9

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-087 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

		MALES			
GROUP:		0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 1					
	MEAN	44.	41.	40.	35.
	S.D.	12.3	9.5	3.8	11.9
	N	10	5	5	10
0 TO 2					
	MEAN	74.	74.	72.	61.
	S.D.	17.6	20.2	10.9	16.9
	N	10	5	5	10
0 TO 3					
	MEAN	102.	97.	93.	85.
	S.D.	23.3	26.2	8.8	20.7
	N	10	5	5	10
0 TO 4					
	MEAN	126.	119.	112.	109.
	S.D.	26.5	36.4	14.2	20.6
	N	10	5	5	10
0 TO 5					
	MEAN	170.	NA	NA	134.*
	S.D.	23.0			25.2
	N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 9

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted] SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:05-087

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 6				
MEAN	186.	NA	NA	148.*
S.D.	21.0			27.6
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 9

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted] SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:05-087

		FEMALES			
GROUP:		0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 1					
	MEAN	21.	19.	24.	26.
	S.D.	4.8	6.8	3.2	4.9
	N	10	5	5	10
0 TO 2					
	MEAN	34.	38.	36.	41.
	S.D.	8.7	11.3	6.7	8.3
	N	10	5	5	10
0 TO 3					
	MEAN	45.	48.	48.	53.
	S.D.	11.4	16.7	8.9	11.3
	N	10	5	5	10
0 TO 4					
	MEAN	55.	58.	58.	64.
	S.D.	15.0	15.5	9.8	13.3
	N	10	5	5	10
0 TO 5					
	MEAN	71.	NA	NA	75.
	S.D.	11.4			19.1
	N	5			5

None significantly different from control group

NA = NOT APPLICABLE

TABLE 9

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 6				
MEAN	73.	NA	NA	76.
S.D.	9.3			19.2
N	5			5

None significantly different from control group

NA = NOT APPLICABLE

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TABLE 10

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -1 TO 0				
MEAN	26.	26.	26.	26.
S.D.	2.6	1.1	1.6	1.4
N	10	5	5	10
0 TO 1				
MEAN	25.	25.	22.	22.*
S.D.	2.4	1.3	1.6	2.0
N	10	5	5	10
1 TO 2				
MEAN	24.	23.	22.	23.
S.D.	1.8	1.1	1.6	2.0
N	10	5	5	10
2 TO 3				
MEAN	24.	23.	22.	24.
S.D.	2.4	1.6	1.9	2.1
N	10	5	5	10
3 TO 4				
MEAN	24.	24.	23.	24.
S.D.	2.2	2.5	1.2	3.4
N	10	5	5	10

* = Significantly different from the control group at 0.05 using Dunnett's test

TABLE 10

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 4 TO 5				
MEAN	29.	NA	NA	27.
S.D.	1.1			2.7
N	5			5
5 TO 6				
MEAN	31.	NA	NA	27.*
S.D.	1.6			2.9
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 10
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -1 TO 0				
MEAN	18.	19.	20.	19.
S.D.	2.9	0.5	1.6	1.8
N	10	5	5	10
0 TO 1				
MEAN	17.	17.	17.	17.
S.D.	1.1	1.5	2.1	1.8
N	7	3	5	7
1 TO 2				
MEAN	17.	19.*	19.	19.*
S.D.	1.4	2.5	1.5	1.3
N	10	5	5	10
2 TO 3				
MEAN	18.	18.	20.	19.
S.D.	1.6	2.7	1.5	1.5
N	10	5	5	10
3 TO 4				
MEAN	18.	16.	18.	20.
S.D.	2.1	3.3	2.6	2.2
N	10	5	4	8

* = Significantly different from the control group at 0.05 using Dunnett's test

TABLE 10

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 4 TO 5				
MEAN	20.	NA	NA	21.
S.D.	1.8			1.5
N	5			5
5 TO 6				
MEAN	21.	NA	NA	21.
S.D.	0.7			0.9
N	5			5

None significantly different from control group

NA = NOT APPLICABLE

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TABLE 11

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL

SPONSOR NO.:05-087

HOME CAGE OBSERVATIONS

MALES

NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
POSTURE				
SITTING OR STANDING NORMALLY	3	3	3	4
ASLEEP, LYING ON SIDE OR CURLED UP	1	0	0	1
ALERT, ORIENTED TOWARD OBSERVER	1	2	1	0
SITTING, HEAD HELD LOW	0	0	1	0
REARING	0	0	1	0
CONVULSIONS - CLONIC				
ABSENT	5	5	5	5
CONVULSIONS - TONIC				
ABSENT	5	5	5	5
TREMORS				
NONE	5	5	5	5
BITING				
NONE	5	5	5	5
PALPEBRAL CLOSURE				
EYELIDS WIDE OPEN	3	4	3	5
EYELIDS SLIGHTLY DROOPING	1	1	1	0
DROOPING EYELIDS (HALF-CLOSED)	1	0	1	0
FECES CONSISTENCY				
PELLETS	5	4	5	5
PELLETS ABSENT	0	1	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

HOME CAGE OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
POSTURE				
SITTING OR STANDING NORMALLY	3	2	2	3
ASLEEP, LYING ON SIDE OR CURLED UP	0	0	0	1
ALERT, ORIENTED TOWARD OBSERVER	2	3	3	1
REARING	2	3	2	0
CONVULSIONS - CLONIC				
ABSENT	5	5	5	5
CONVULSIONS - TONIC				
ABSENT	5	5	5	5
TREMORS				
NONE	5	5	5	5
BITING				
NONE	5	5	5	5
PALPEBRAL CLOSURE				
EYELIDS WIDE OPEN	5	5	5	5
FECES CONSISTENCY				
PELLETS	2	1	4	5
PELLETS ABSENT	3	4	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 12

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

HANDLING OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
EASE OF REMOVAL				
VERY EASY: ANIMAL SITS QUIETLY, ALLOWS INVESTIGATOR TO PICK IT UP	2	3	3	4
EASY: WITH/WITHOUT VOCALIZATION, WITHOUT RESISTANCE OR SLIGHT RESISTANCE	3	2	1	1
MODERATELY DIFFICULT: ANIMAL REARS, OFTEN FOLLOWING INVESTIGATOR'S HAND	0	0	1	0
EASE OF HANDLING IN HAND				
LOW: NO RESISTANCE, ANIMAL IS EASY TO HANDLE	5	5	5	5
LACRIMATION				
NONE	5	5	5	5
CHROMODACRYORRHEA				
ABSENT	5	5	5	5
SALIVATION				
NONE	5	5	5	5
PILOERECTION				
NONE	5	5	5	5
FUR APPEARANCE				
NORMAL: CLEAN AND GROOMED	5	5	5	5
PALPEBRAL CLOSURE				
EYELIDS WIDE OPEN	5	5	5	5
RESPIRATORY RATE				
NORMAL: BY OBSERVATION (80-110/MIN.)	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 12

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

HANDLING OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
RESPIRATORY CHARACTER				
NORMAL	5	5	5	5
RED DEPOSITS - eyes				
PRESENT	0	0	1	0
ABSENT	5	5	4	5
RED DEPOSITS - nose				
ABSENT	5	5	5	5
RED DEPOSITS - mouth				
ABSENT	5	5	5	5
CRUSTY DEPOSITS - eyes				
ABSENT	5	5	5	5
CRUSTY DEPOSITS - nose				
ABSENT	5	5	5	5
CRUSTY DEPOSITS - mouth				
ABSENT	5	5	5	5
MUCOUS MEMBRANES - color				
PINK	5	5	5	5
EYES - color				
PINK	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 12

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

HANDLING OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
SKIN - color				
PINK	5	5	5	5
EYE PROMINENCE				
NORMAL	5	5	5	5
MUSCLE TONE				
MUSCLE IS FIRM BUT NOT HARD (NORMAL)	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 12
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
EASE OF REMOVAL				
VERY EASY: ANIMAL SITS QUIETLY, ALLOWS INVESTIGATOR TO PICK IT UP	5	2	4	2
EASY: WITH/WITHOUT VOCALIZATION, WITHOUT RESISTANCE OR SLIGHT RESISTANCE	0	1	1	2
MODERATELY DIFFICULT: ANIMAL REARS, OFTEN FOLLOWING INVESTIGATOR'S HAND	0	1	0	1
DIFFICULT: RUNS AROUND CAGE, IS HARD TO GRAB, WITH/WITHOUT VOCALIZATION	0	1	0	0
EASE OF HANDLING IN HAND				
LOW: NO RESISTANCE, ANIMAL IS EASY TO HANDLE	5	5	5	5
LACRIMATION				
NONE	5	5	5	5
CHROMODACRYORRHEA				
ABSENT	5	5	5	5
SALIVATION				
NONE	5	5	5	5
PILOERECTION				
NONE	5	5	5	5
FUR APPEARANCE				
NORMAL: CLEAN AND GROOMED	5	5	5	5
PALPEBRAL CLOSURE				
EYELIDS WIDE OPEN	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 12
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
RESPIRATORY RATE				
NORMAL: BY OBSERVATION (80-110/MIN.)	5	5	5	5
RESPIRATORY CHARACTER				
NORMAL	5	5	5	5
RED DEPOSITS - eyes				
ABSENT	5	5	5	5
RED DEPOSITS - nose				
ABSENT	5	5	5	5
RED DEPOSITS - mouth				
ABSENT	5	5	5	5
CRUSTY DEPOSITS - eyes				
ABSENT	5	5	5	5
CRUSTY DEPOSITS - nose				
ABSENT	5	5	5	5
CRUSTY DEPOSITS - mouth				
ABSENT	5	5	5	5
MUCOUS MEMBRANES - color				
PINK	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 12

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL

SPONSOR NO.:05-087

HANDLING OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
EYES - color				
PINK	5	5	5	5
SKIN - color				
PINK	5	5	5	5
EYE PROMINENCE				
NORMAL	5	5	5	5
MUSCLE TONE				
MUSCLE IS FIRM BUT NOT HARD (NORMAL)	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

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TABLE 13

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

OPEN FIELD OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
TIME TO FIRST STEP (seconds)	: MEAN	0.3	0.3	0.3	0.3
	S.D.	0.08	0.11	0.14	0.10
MOBILITY					
NORMAL		5	5	5	5
GAIT					
NORMAL		5	5	5	5
CONVULSIONS - CLONIC					
ABSENT		5	5	5	5
CONVULSIONS - TONIC					
ABSENT		5	5	5	5
TREMORS					
NONE		5	5	5	5
GAIT SCORE					
NORMAL		5	5	5	5
AROUSAL					
NORMAL: ALERT, EXPLORATORY MOVEMENTS		5	5	5	5
BIZARRE/STEREOTYPIC BEHAVIOR					
NONE		5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

TABLE 13

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

OPEN FIELD OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
REARING	: MEAN	8.0	10.0	8.2	6.8
	S.D.	1.22	5.79	3.77	6.46
BACKING	: MEAN	0.0	0.0	0.0	0.0
	S.D.	0.00	0.00	0.00	0.00
GROOMING	: MEAN	0.4	0.2	0.4	0.2
	S.D.	0.89	0.45	0.89	0.45
URINATION	: MEAN	0.4	1.6	0.4	0.2
	S.D.	0.55	1.52	0.55	0.45
DEFECATION	: MEAN	0.6	1.4	1.4	0.4
	S.D.	0.89	2.19	1.95	0.89

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

TABLE 13

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

OPEN FIELD OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
TIME TO FIRST STEP (seconds)	: MEAN	0.3	0.3	0.3	0.3
	S.D.	0.00	0.12	0.12	0.13
MOBILITY					
NORMAL		5	5	5	5
GAIT					
NORMAL		5	5	5	5
CONVULSIONS - CLONIC					
ABSENT		5	5	5	5
CONVULSIONS - TONIC					
ABSENT		5	5	5	5
TREMORS					
NONE		5	5	5	5
GAIT SCORE					
NORMAL		5	5	5	5
AROUSAL					
NORMAL: ALERT, EXPLORATORY MOVEMENTS		5	5	5	5
BIZARRE/STEREOTYPIC BEHAVIOR					
NONE		5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

TABLE 13

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL

SPONSOR NO.:05-087

OPEN FIELD OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
REARING	: MEAN	12.6	14.4	11.0	11.0
	S.D.	2.61	2.41	5.79	5.10
BACKING	: MEAN	0.0	0.0	0.4	0.0
	S.D.	0.00	0.00	0.89	0.00
GROOMING	: MEAN	0.2	0.4	0.2	0.2
	S.D.	0.45	0.55	0.45	0.45
URINATION	: MEAN	0.0	0.0	0.0	0.0
	S.D.	0.00	0.00	0.00	0.00
DEFECATION	: MEAN	0.0	0.0	0.0	0.0
	S.D.	0.00	0.00	0.00	0.00

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

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TABLE 14

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

SENSORY OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
APPROACH RESPONSE				
SLOW APPROACH, SNIFFING OR TURNING AWAY	5	5	5	5
TOUCH RESPONSE				
NO REACTION	0	1	1	0
ANIMAL MAY SLOWLY TURN, WALK AWAY	5	3	4	5
MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION	0	1	0	0
STARTLE RESPONSE				
SLIGHT REACTION, EAR FLICK OR SOME EVIDENCE THAT SNAP WAS HEARD	5	5	5	5
TAIL PINCH RESPONSE				
ANIMAL MAY SLOWLY TURN, WALK AWAY	5	4	5	5
MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION	0	1	0	0
OLFACTORY ORIENTATION				
REACTION PRESENT: ANIMAL APPROACHES SWAB MAKING SNIFFING MOVEMENTS WITH NOSE	5	5	5	5
PUPIL RESPONSE				
PUPIL RESPONSE PRESENT	5	5	5	5
EYEBLINK RESPONSE				
EYEBLINK RESPONSE PRESENT	5	5	5	5
FORELIMB EXTENSION				
FORELIMB EXTENSION PRESENT	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
COMPLETE SCORING CRITERIA PRESENTED AS AN APPENDIX
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 14

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

SENSORY OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
HINDLIMB EXTENSION				
HINDLIMB EXTENSION PRESENT	5	5	5	5
AIR RIGHTING REFLEX				
NORMAL	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
COMPLETE SCORING CRITERIA PRESENTED AS AN APPENDIX
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 14

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

SENSORY OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
APPROACH RESPONSE				
SLOW APPROACH, SNIFFING OR TURNING AWAY	5	5	5	5
TOUCH RESPONSE				
NO REACTION	0	0	1	0
ANIMAL MAY SLOWLY TURN, WALK AWAY	5	5	4	5
STARTLE RESPONSE				
SLIGHT REACTION, EAR FLICK OR SOME EVIDENCE THAT SNAP WAS HEARD	4	5	5	4
MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION	1	0	0	1
TAIL PINCH RESPONSE				
ANIMAL MAY SLOWLY TURN, WALK AWAY	5	5	5	5
OLFACTORY ORIENTATION				
REACTION PRESENT: ANIMAL APPROACHES SWAB MAKING SNIFFING MOVEMENTS WITH NOSE	5	5	5	5
PUPIL RESPONSE				
PUPIL RESPONSE PRESENT	5	5	5	5
EYEBLINK RESPONSE				
EYEBLINK RESPONSE PRESENT	5	5	5	5
FORELIMB EXTENSION				
FORELIMB EXTENSION PRESENT	5	5	5	5
HINDLIMB EXTENSION				
HINDLIMB EXTENSION PRESENT	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
COMPLETE SCORING CRITERIA PRESENTED AS AN APPENDIX
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

TABLE 14

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

SENSORY OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:	1	2	3	4
NUMBER TESTED:	5	5	5	5
AIR RIGHTING REFLEX				
NORMAL	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
COMPLETE SCORING CRITERIA PRESENTED AS AN APPENDIX
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST

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TABLE 15

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

NEUROMUSCULAR OBSERVATIONS
MALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:			1	2	3	4
NUMBER TESTED:			5	5	5	5
HINDLIMB EXTENSOR STRENGTH						
HINDLIMB RESISTANCE PRESENT			5	5	5	5
GRIP STRENGTH (g) - FORE/HINDLIMB	FORE:	MEAN	840.0	731.4	889.2	667.8
		S.D.	264.85	113.66	191.42	182.22
	HIND:	MEAN	404.0	431.8	407.8	351.2
		S.D.	135.90	73.28	88.15	28.15
ROTAROD PERFORMANCE (seconds)	:	MEAN	70.9	93.0	76.1	57.9
		S.D.	45.50	37.84	31.34	36.66
HINDLIMB FOOTSPLAY (mm)	:	MEAN	63.6	70.8	55.8	61.2
		S.D.	17.60	14.24	25.37	18.66

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

TABLE 15

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2
SPONSOR:[redacted] SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA ALL
SPONSOR NO.:05-087

NEUROMUSCULAR OBSERVATIONS
FEMALES
NUMBER OF ANIMALS SHOWING EACH OBSERVATION

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
HINDLIMB EXTENSOR STRENGTH HINDLIMB RESISTANCE PRESENT		5	5	5	5
GRIP STRENGTH (g) - FORE/HINDLIMB	FORE: MEAN	728.2	601.6	613.0	749.4
	S.D.	180.11	151.54	117.51	261.66
	HIND: MEAN	341.2	363.2	308.8	402.2
	S.D.	31.20	150.70	43.16	123.65
ROTAROD PERFORMANCE (seconds)	: MEAN	76.6	35.4	37.3	68.9
	S.D.	59.41	24.52	18.54	47.97
HINDLIMB FOOTSPLAY (mm)	: MEAN	52.4	38.2	52.6	45.2
	S.D.	17.39	8.38	11.59	17.20

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS AT THE 0.05 LEVEL USING FISHER'S EXACT TEST
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

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TABLE 16

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA

ALL

PHYSIOLOGICAL OBSERVATIONS
MALES

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
CATALEPSY (seconds)	: MEAN	0.4	0.8	0.6	0.3
	S.D.	0.13	1.00	0.43	0.10
	N	5	5	5	5
BODY TEMPERATURE (degrees C)	: MEAN	38.6	39.0	38.8	38.9
	S.D.	0.88	0.95	0.73	0.91
	N	5	5	5	5
BODY WEIGHT (g)	: MEAN	331.0	341.7	339.9	332.1
	S.D.	36.83	35.06	13.28	26.06
	N	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

TABLE 16
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF FUNCTIONAL OBSERVATIONAL BATTERY DATA

PHYSIOLOGICAL OBSERVATIONS
FEMALES

GROUP:		1	2	3	4
NUMBER TESTED:		5	5	5	5
CATALEPSY (seconds)	: MEAN	0.3	0.5	0.3	0.4
	S.D.	0.13	0.37	0.18	0.15
	N	5	5	5	5
BODY TEMPERATURE (degrees C)	: MEAN	39.5	39.4	39.3	39.1
	S.D.	0.50	0.66	0.63	0.55
	N	5	5	5	5
BODY WEIGHT (g)	: MEAN	211.4	214.0	208.4	211.2
	S.D.	21.19	15.04	20.21	18.97
	N	5	5	5	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NONE SIGNIFICANTLY DIFFERENT FROM THE CONTROLS USING DUNNETT'S TEST

PROJECT NO.:WIL-187051
SPONSOR: [redacted]

TABLE 17
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS

Period	Sex	Variable		Statistic	Minutes 0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	M	TOTAL	1	Mean	777.20	265.60	64.800	29.800	284.35	1137.40
				S.D.	205.823	129.094	99.6980	63.3340	NA	466.163
				N	5	5	5	5	5	5
				LSMean	777.20	265.60	64.800	29.800	284.35	NA
				Linear Trend p-value#						NA
			2	Mean	616.60	200.60	58.800	52.000	232.00	928.00
				S.D.	323.986	204.659	110.5111	85.9447	NA	222.588
				N	5	5	5	5	5	5
				LSMean	616.60	200.60	58.800	52.000	232.00	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	627.00	213.40	50.400	31.200	230.50	922.00
				S.D.	143.854	151.299	90.1127	65.9219	NA	166.741
				N	5	5	5	5	5	5
				LSMean	627.00	213.40	50.400	31.200	230.50	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	804.00	232.00	13.000	45.000	273.50	1094.00
				S.D.	233.256	144.907	27.4044	92.3363	NA	277.965
				N	5	5	5	5	5	5
				LSMean	804.00	232.00	13.000	45.000	273.50	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.860	NA
			ALL	Trt F-test p-value++					0.732	
			INTN	Trt*Time p-value++					0.815	
				LinTrt*Time p-value#					0.920	
				Covariance Structure					AR1	

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

TABLE 17
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS

					Minutes					
Period	Sex	Variable		Statistic	0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	M	AMBULATORY	1	Mean	260.80	71.600	15.400	10.200	89.500	358.00
				S.D.	87.004	40.9060	30.1048	21.7071	NA	171.213
				N	5	5	5	5	5	5
				LSMean	260.80	71.600	15.400	10.200	89.500	NA
				Linear Trend p-value#						NA
			2	Mean	186.20	41.800	15.000	11.400	63.600	254.40
				S.D.	131.570	59.9725	30.2985	22.7991	NA	118.018
				N	5	5	5	5	5	5
				LSMean	186.20	41.800	15.000	11.400	63.600	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	191.00	63.800	11.200	6.4000	68.100	272.40
				S.D.	81.511	44.4826	16.7541	14.31084	NA	85.019
				N	5	5	5	5	5	5
				LSMean	191.00	63.800	11.200	6.4000	68.100	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	288.80	49.000	0.0000	12.800	87.650	350.60
				S.D.	84.942	34.7347	0.00000	28.6217	NA	99.896
				N	5	5	5	5	5	5
				LSMean	288.80	49.000	-0.0000	12.800	87.650	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.989	NA
			ALL	Trt F-test p-value++					0.613	
			INTN	Trt*Time p-value++					0.266	
				LinTrt*Time p-value#					0.745	
				Covariance Structure					AR1	

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

TABLE 17
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS

					Minutes					
Period	Sex	Variable		Statistic	0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	F	TOTAL	1	Mean	831.40	318.40	127.80	90.200	341.95	1367.80
				S.D.	156.439	311.781	176.503	65.8232	NA	327.447
				N	5	5	5	5	5	5
				LSMean	831.40	318.40	127.80	90.200	341.95	NA
				Linear Trend p-value#						NA
			2	Mean	673.00	270.00	152.80	0.0000	273.95	1095.80
				S.D.	160.075	207.030	142.670	0.00000	NA	299.951
				N	5	5	5	5	5	5
				LSMean	673.00	270.00	152.80	0.0000	273.95	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	795.00	278.20	105.60	123.00	325.45	1301.80
				S.D.	124.619	205.504	130.722	181.693	NA	369.891
				N	5	5	5	5	5	5
				LSMean	795.00	278.20	105.60	123.00	325.45	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	716.00	154.40	61.600	153.20	271.30	1085.20
				S.D.	182.872	139.715	124.5685	195.661	NA	216.368
				N	5	5	5	5	5	5
				LSMean	716.00	154.40	61.600	153.20	271.30	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.386	NA
			ALL	Trt F-test p-value++					0.513	
			INTN	Trt*Time p-value++					0.752	
				LinTrt*Time p-value#					0.407	
				Covariance Structure					AR1	

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

: Level of Significance tested = .05. ++ : Level of Significance tested = .01.
* : Statistically Significant. NT : Not tested. NA : Not applicable.

TABLE 17
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MOTOR ACTIVITY COUNTS

					Minutes					
Period	Sex	Variable		Statistic	0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	F	AMBULATORY	1	Mean	332.60	105.40	47.000	21.800	126.70	506.80
				S.D.	63.865	115.578	69.3506	22.7200	NA	116.446
				N	5	5	5	5	5	5
				LSMean	332.60	105.40	47.000	21.800	126.70	NA
				Linear Trend p-value#						NA
			2	Mean	284.40	81.200	35.800	0.0000	100.35	401.40
				S.D.	69.291	60.3796	39.3472	0.00000	NA	92.533
				N	5	5	5	5	5	5
				LSMean	284.40	81.200	35.800	0.0000	100.35	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	316.00	73.800	17.800	52.200	114.95	459.80
				S.D.	51.015	73.1997	27.2066	83.6672	NA	114.205
				N	5	5	5	5	5	5
				LSMean	316.00	73.800	17.800	52.200	114.95	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	294.00	40.400	21.400	47.000	100.70	402.80
				S.D.	97.645	35.6553	47.2948	65.7723	NA	24.773
				N	5	5	5	5	5	5
				LSMean	294.00	40.400	21.400	47.000	100.70	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.199	NA
			ALL	Trt F-test p-value++					0.270	
			INTN	Trt*Time p-value++					0.892	
				LinTrt*Time p-value#					0.398	
				Covariance Structure					CS	

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:05-087

		MALES			
ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WHITE CELLS (thous/uL)					
DAY 28	MEAN	8.91	9.13	11.34	13.38
	% CHANGE		2.5	27.3	50.2
	S.D.	1.132	1.416	1.409	6.082
	N	5	5	5	5
DAY 42	MEAN	8.15	NA	NA	8.30
	% CHANGE				1.8
	S.D.	1.020			2.253
	N	5			5
RED CELLS (mil/uL)					
DAY 28	MEAN	8.61	8.15	8.22	8.15
	% CHANGE		-5.3	-4.5	-5.3
	S.D.	0.257	0.404	0.307	0.335
	N	5	5	5	5
DAY 42	MEAN	8.06	NA	NA	8.14
	% CHANGE				1.0
	S.D.	0.156			0.533
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
HEMOGLOBIN (g/dL)					
DAY 28	MEAN	16.2	15.1**	15.6	15.3*
	% CHANGE		-6.8	-3.7	-5.6
	S.D.	0.60	0.50	0.13	0.44
	N	5	5	5	5
DAY 42	MEAN	14.4	NA	NA	15.1
	% CHANGE				4.9
	S.D.	0.30			0.93
	N	5			5
HEMATOCRIT (%)					
DAY 28	MEAN	51.7	49.2	50.9	48.2*
	% CHANGE		-4.8	-1.5	-6.8
	S.D.	2.44	1.37	0.43	2.23
	N	5	5	5	5
DAY 42	MEAN	45.0	NA	NA	46.5
	% CHANGE				3.3
	S.D.	1.30			3.57
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test
NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

		MALES			
ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MCV (fL)					
DAY 28	MEAN	60.1	60.5	61.9	59.1
	% CHANGE		0.7	3.0	-1.7
	S.D.	2.19	2.32	2.11	1.77
	N	5	5	5	5
DAY 42	MEAN	55.9	NA	NA	57.2
	% CHANGE				2.3
	S.D.	1.03			1.08
	N	5			5
MCH (pg)					
DAY 28	MEAN	18.8	18.6	19.0	18.8
	% CHANGE		-1.1	1.1	0.0
	S.D.	0.60	0.80	0.66	0.46
	N	5	5	5	5
DAY 42	MEAN	17.8	NA	NA	18.6**
	% CHANGE				4.5
	S.D.	0.11			0.22
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

** = Significantly different from the control group at 0.01 using Dunnett's test

NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MCHC (g/dL)					
DAY 28	MEAN	31.4	30.8	30.7	31.8
	% CHANGE		-1.9	-2.2	1.3
	S.D.	0.38	0.24	0.26	0.70
	N	5	5	5	5
DAY 42	MEAN	31.9	NA	NA	32.5
	% CHANGE				1.9
	S.D.	0.60			0.68
	N	5			5
PLATELET (thous/uL)					
DAY 28	MEAN	995.	1135.	1064.	1102.
	% CHANGE		14.1	6.9	10.8
	S.D.	82.5	250.8	196.2	306.0
	N	5	5	5	5
DAY 42	MEAN	1163.	NA	NA	1252.
	% CHANGE				7.7
	S.D.	207.0			196.0
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group
NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
PROTIME (seconds)					
DAY 28	MEAN	19.9	19.6	21.0	33.3**
	% CHANGE		-1.5	5.5	67.3
	S.D.	1.46	3.18	2.87	4.80
	N	5	5	5	5
DAY 42	MEAN	17.7	NA	NA	18.5
	% CHANGE				4.5
	S.D.	1.53			3.63
	N	4			3
APTT (seconds)					
DAY 28	MEAN	21.7	23.5	22.8	29.3**
	% CHANGE		8.3	5.1	35.0
	S.D.	3.48	2.40	1.79	2.99
	N	5	5	5	5
DAY 42	MEAN	21.6	NA	NA	21.4
	% CHANGE				-0.9
	S.D.	2.89			2.80
	N	4			3

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

** = Significantly different from the control group at 0.01 using Dunnett's test

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
RETICULOCYTE (%)					
DAY 28	MEAN	1.5	1.5	1.6	1.4
	% CHANGE		0.0	6.7	-6.7
	S.D.	0.23	0.54	0.41	0.37
	N	5	5	5	5
DAY 42	MEAN	1.9	NA	NA	2.1
	% CHANGE				10.5
	S.D.	0.24			0.28
	N	5			5
RETIC ABSOLUTE (thous/uL)					
DAY 28	MEAN	133.4	123.8	127.1	112.0
	% CHANGE		-7.2	-4.7	-16.0
	S.D.	15.14	36.53	30.42	28.94
	N	5	5	5	5
DAY 42	MEAN	152.7	NA	NA	171.2
	% CHANGE				12.1
	S.D.	21.49			13.39
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 7

SPONSOR:[redacted]

SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:05-087

MALES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
NEUTROPHIL (%)					
DAY 28	MEAN	14.3	11.1	10.0	12.6
	% CHANGE		-22.4	-30.1	-11.9
	S.D.	3.54	3.84	5.51	5.81
	N	5	5	5	5
DAY 42	MEAN	18.7	NA	NA	18.1
	% CHANGE				-3.2
	S.D.	11.10			10.80
	N	5			5
LYMPHOCYTE (%)					
DAY 28	MEAN	82.6	85.9	86.7	84.3
	% CHANGE		4.0	5.0	2.1
	S.D.	4.12	5.01	6.24	6.41
	N	5	5	5	5
DAY 42	MEAN	78.2	NA	NA	78.5
	% CHANGE				0.4
	S.D.	11.34			12.06
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MONOCYTE (%)					
DAY 28	MEAN	1.3	0.9	0.8	1.0
	% CHANGE		-30.8	-38.5	-23.1
	S.D.	0.99	0.18	0.39	0.34
	N	5	5	5	5
DAY 42	MEAN	1.2	NA	NA	1.5
	% CHANGE				25.0
	S.D.	0.45			0.78
	N	5			5
EOSINOPHIL (%)					
DAY 28	MEAN	1.2	1.3	1.5	1.2
	% CHANGE		8.3	25.0	0.0
	S.D.	0.48	1.17	0.73	1.09
	N	5	5	5	5
DAY 42	MEAN	1.1	NA	NA	0.9
	% CHANGE				-18.2
	S.D.	0.38			0.44
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group
NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 9

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BASOPHIL (%)					
DAY 28	MEAN	0.2	0.2	0.3	0.3
	% CHANGE		0.0	50.0	50.0
	S.D.	0.13	0.08	0.13	0.08
	N	5	5	5	5
DAY 42	MEAN	0.2	NA	NA	0.2
	% CHANGE				0.0
	S.D.	0.07			0.04
	N	5			5
LG UNSTAIN CELL (%)					
DAY 28	MEAN	0.4	0.5	0.6	0.7
	% CHANGE		25.0	50.0	75.0
	S.D.	0.27	0.15	0.15	0.23
	N	5	5	5	5
DAY 42	MEAN	0.6	NA	NA	0.7
	% CHANGE				16.7
	S.D.	0.23			0.30
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES			
NEU ABSOLUTE (thous/uL)					
DAY 28	MEAN	1.26	1.02	1.16	1.59
	% CHANGE		-19.0	-7.9	26.2
	S.D.	0.318	0.390	0.698	0.604
	N	5	5	5	5
DAY 42	MEAN	1.55	NA	NA	1.68
	% CHANGE				8.4
	S.D.	0.938			1.338
	N	5			5
LYMPH ABSOLUTE (thous/uL)					
DAY 28	MEAN	7.37	7.83	9.81	11.40
	% CHANGE		6.2	33.1	54.7
	S.D.	1.099	1.250	1.218	5.627
	N	5	5	5	5
DAY 42	MEAN	6.35	NA	NA	6.32
	% CHANGE				-0.5
	S.D.	1.038			0.983
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 11

SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MONO ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.11	0.09	0.09	0.12
	% CHANGE		-18.2	-18.2	9.1
	S.D.	0.068	0.024	0.049	0.035
	N	5	5	5	5
DAY 42	MEAN	0.10	NA	NA	0.13
	% CHANGE				30.0
	S.D.	0.031			0.102
	N	5			5
EOS ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.11	0.12	0.17	0.13
	% CHANGE		9.1	54.5	18.2
	S.D.	0.050	0.101	0.085	0.085
	N	5	5	5	5
DAY 42	MEAN	0.09	NA	NA	0.08
	% CHANGE				-11.1
	S.D.	0.037			0.044
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 12

SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:05-087

		MALES			
ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BASO ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.02	0.02	0.04	0.04
	% CHANGE		0.0	100.0	100.0
	S.D.	0.014	0.011	0.019	0.025
	N	5	5	5	5
DAY 42	MEAN	0.01	NA	NA	0.01
	% CHANGE				0.0
	S.D.	0.005			0.005
	N	5			5
LUC ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.04	0.05	0.07	0.10
	% CHANGE		25.0	75.0	150.0
	S.D.	0.026	0.018	0.026	0.069
	N	5	5	5	5
DAY 42	MEAN	0.05	NA	NA	0.07
	% CHANGE				40.0
	S.D.	0.019			0.037
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WHITE CELLS (thous/uL)					
DAY 28	MEAN	7.45	7.59	7.97	8.37
	% CHANGE		1.9	7.0	12.3
	S.D.	4.105	0.662	2.357	2.747
	N	5	5	5	5
DAY 42	MEAN	7.02	NA	NA	5.96
	% CHANGE				-15.1
	S.D.	2.067			1.505
	N	4			5
RED CELLS (mil/uL)					
DAY 28	MEAN	7.50	8.14*	7.58	7.67
	% CHANGE		8.5	1.1	2.3
	S.D.	0.401	0.277	0.445	0.204
	N	5	5	5	5
DAY 42	MEAN	7.82	NA	NA	6.63*
	% CHANGE				-15.2
	S.D.	0.296			0.873
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

* = Significantly different from the control group at 0.05 using Dunnett's test
NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 14

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
HEMOGLOBIN (g/dL)					
DAY 28	MEAN	14.2	15.5*	14.4	14.7
	% CHANGE		9.2	1.4	3.5
	S.D.	0.89	0.31	0.90	0.35
	N	5	5	5	5
DAY 42	MEAN	14.4	NA	NA	12.3*
	% CHANGE				-14.6
	S.D.	0.41			1.60
	N	4			5
HEMATOCRIT (%)					
DAY 28	MEAN	44.5	48.8	45.6	45.4
	% CHANGE		9.7	2.5	2.0
	S.D.	3.41	1.99	4.02	1.65
	N	5	5	5	5
DAY 42	MEAN	45.3	NA	NA	37.4*
	% CHANGE				-17.4
	S.D.	2.07			5.37
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 15

SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MCV (fL)					
DAY 28	MEAN	59.3	60.0	60.0	59.2
	% CHANGE		1.2	1.2	-0.2
	S.D.	2.25	1.20	2.53	3.16
	N	5	5	5	5
DAY 42	MEAN	57.9	NA	NA	56.4
	% CHANGE				-2.6
	S.D.	1.37			0.95
	N	4			5
MCH (pg)					
DAY 28	MEAN	18.9	19.1	19.0	19.2
	% CHANGE		1.1	0.5	1.6
	S.D.	0.40	0.58	0.45	0.63
	N	5	5	5	5
DAY 42	MEAN	18.5	NA	NA	18.5
	% CHANGE				0.0
	S.D.	0.26			0.29
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MCHC (g/dL)					
DAY 28	MEAN	31.9	31.8	31.7	32.4
	% CHANGE		-0.3	-0.6	1.6
	S.D.	0.64	0.92	0.95	0.81
	N	5	5	5	5
DAY 42	MEAN	31.9	NA	NA	32.9*
	% CHANGE				3.1
	S.D.	0.62			0.54
	N	4			5
PLATELET (thous/uL)					
DAY 28	MEAN	841.	1090.	1115.	1122.
	% CHANGE		29.6	32.6	33.4
	S.D.	134.9	150.3	33.1	351.6
	N	5	5	5	5
DAY 42	MEAN	1184.	NA	NA	1161.
	% CHANGE				-1.9
	S.D.	263.6			44.3
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

* = Significantly different from the control group at 0.05 using Dunnett's test
NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
PROTIME (seconds)					
DAY 28	MEAN	12.1	12.1	12.6	13.4**
	% CHANGE		0.0	4.1	10.7
	S.D.	0.75	0.54	0.40	0.53
	N	5	5	5	5
DAY 42	MEAN	13.2	NA	NA	13.4
	% CHANGE				1.5
	S.D.	0.41			0.20
	N	5			5
APTT (seconds)					
DAY 28	MEAN	17.0	15.4	18.7	18.5
	% CHANGE		-9.4	10.0	8.8
	S.D.	3.19	2.11	1.04	2.53
	N	5	5	5	5
DAY 42	MEAN	18.1	NA	NA	18.2
	% CHANGE				0.6
	S.D.	1.75			1.12
	N	5			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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NA = NOT APPLICABLE

FEMALES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
RETICULOCYTE (%)					
DAY 28	MEAN	1.7	1.4	1.8	1.8
	% CHANGE		-17.6	5.9	5.9
	S.D.	0.45	0.09	0.55	0.74
	N	5	5	5	5
DAY 42	MEAN	2.0	NA	NA	2.1
	% CHANGE				5.0
	S.D.	0.59			0.29
	N	4			5
RETIC ABSOLUTE (thous/uL)					
DAY 28	MEAN	129.6	110.8	137.6	136.6
	% CHANGE		-14.5	6.2	5.4
	S.D.	30.95	6.82	47.28	56.05
	N	5	5	5	5
DAY 42	MEAN	151.3	NA	NA	141.2
	% CHANGE				-6.7
	S.D.	42.29			29.18
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group
NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
NEUTROPHIL (%)					
DAY 28	MEAN	17.8	16.5	16.7	16.2
	% CHANGE		-7.3	-6.2	-9.0
	S.D.	7.74	7.38	13.74	10.12
	N	5	5	5	5
DAY 42	MEAN	18.5	NA	NA	26.3
	% CHANGE				42.2
	S.D.	13.56			12.21
	N	4			5
LYMPHOCYTE (%)					
DAY 28	MEAN	78.5	79.1	79.7	81.0
	% CHANGE		0.8	1.5	3.2
	S.D.	8.71	8.38	14.00	10.71
	N	5	5	5	5
DAY 42	MEAN	78.2	NA	NA	70.2
	% CHANGE				-10.2
	S.D.	14.01			13.30
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group
NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 20

SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES			
MONOCYTE (%)					
DAY 28	MEAN	0.9	1.2	1.4**	1.0
	% CHANGE		33.3	55.6	11.1
	S.D.	0.19	0.25	0.26	0.15
	N	5	5	5	5
DAY 42	MEAN	1.3	NA	NA	1.6
	% CHANGE				23.1
	S.D.	0.29			0.97
	N	4			5
EOSINOPHIL (%)					
DAY 28	MEAN	1.9	2.3	1.5	1.1
	% CHANGE		21.1	-21.1	-42.1
	S.D.	1.37	1.74	0.78	0.75
	N	5	5	5	5
DAY 42	MEAN	1.1	NA	NA	1.1
	% CHANGE				0.0
	S.D.	0.29			0.46
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

** = Significantly different from the control group at 0.01 using Dunnett's test

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 21

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES			
BASOPHIL (%)					
DAY 28	MEAN	0.1	0.3	0.2	0.2
	% CHANGE		200.0	100.0	100.0
	S.D.	0.05	0.05	0.08	0.09
	N	5	5	5	5
DAY 42	MEAN	0.2	NA	NA	0.1
	% CHANGE				-50.0
	S.D.	0.05			0.05
	N	4			5
LG UNSTAIN CELL (%)					
DAY 28	MEAN	0.6	0.5	0.5	0.5
	% CHANGE		-16.7	-16.7	-16.7
	S.D.	0.24	0.13	0.25	0.28
	N	5	5	5	5
DAY 42	MEAN	0.9	NA	NA	0.7
	% CHANGE				-22.2
	S.D.	0.25			0.16
	N	4			5

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None significantly different from control group

NA = NOT APPLICABLE

TABLE 18

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 22

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
NEU ABSOLUTE (thous/uL)					
DAY 28	MEAN	1.20	1.25	1.20	1.51
	% CHANGE		4.2	0.0	25.8
	S.D.	0.555	0.515	0.791	1.459
	N	5	5	5	5
DAY 42	MEAN	1.32	NA	NA	1.67
	% CHANGE				26.5
	S.D.	1.193			1.161
	N	4			5
LYMPH ABSOLUTE (thous/uL)					
DAY 28	MEAN	6.00	6.01	6.47	6.61
	% CHANGE		0.2	7.8	10.2
	S.D.	3.942	0.826	2.596	1.651
	N	5	5	5	5
DAY 42	MEAN	5.46	NA	NA	4.08
	% CHANGE				-25.3
	S.D.	1.834			0.934
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MONO ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.07	0.10	0.11	0.08
	% CHANGE		42.9	57.1	14.3
	S.D.	0.038	0.021	0.038	0.030
	N	5	5	5	5
DAY 42	MEAN	0.09	NA	NA	0.10
	% CHANGE				11.1
	S.D.	0.036			0.090
	N	4			5
EOS ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.12	0.18	0.11	0.11
	% CHANGE		50.0	-8.3	-8.3
	S.D.	0.093	0.142	0.046	0.104
	N	5	5	5	5
DAY 42	MEAN	0.07	NA	NA	0.06
	% CHANGE				-14.3
	S.D.	0.014			0.018
	N	4			5

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None significantly different from control group
NA = NOT APPLICABLE

TABLE 18
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES			
BASO ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.01	0.02	0.02	0.01
	% CHANGE		100.0	100.0	0.0
	S.D.	0.012	0.004	0.008	0.009
	N	5	5	5	5
DAY 42	MEAN	0.02	NA	NA	0.01
	% CHANGE				-50.0
	S.D.	0.006			0.008
	N	4			5
LUC ABSOLUTE (thous/uL)					
DAY 28	MEAN	0.06	0.04	0.04	0.04
	% CHANGE		-33.3	-33.3	-33.3
	S.D.	0.048	0.010	0.031	0.027
	N	5	5	5	5
DAY 42	MEAN	0.07	NA	NA	0.04
	% CHANGE				-42.9
	S.D.	0.037			0.019
	N	4			5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group
NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
ALBUMIN (g/dL)					
DAY 28	MEAN	4.4	4.5	4.4	4.2
	% CHANGE		2.3	0.0	-4.5
	S.D.	0.16	0.09	0.09	0.11
	N	5	5	5	5
DAY 42	MEAN	4.2	NA	NA	4.4
	% CHANGE				4.8
	S.D.	0.23			0.18
	N	5			5
TOTAL PROTEIN (g/dL)					
DAY 28	MEAN	6.8	6.8	6.6	6.2**
	% CHANGE		0.0	-2.9	-8.8
	S.D.	0.16	0.16	0.23	0.15
	N	5	5	5	5
DAY 42	MEAN	6.7	NA	NA	6.7
	% CHANGE				0.0
	S.D.	0.45			0.34
	N	5			5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

** = Significantly different from the control group at 0.01 using Dunnett's test

NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
GLOBULIN (g/dL)					
DAY 28	MEAN	2.4	2.4	2.3	2.0*
	% CHANGE		0.0	-4.2	-16.7
	S.D.	0.13	0.25	0.20	0.14
	N	5	5	5	5
DAY 42	MEAN	2.5	NA	NA	2.4
	% CHANGE				-4.0
	S.D.	0.28			0.16
	N	5			5
A/G RATIO					
DAY 28	MEAN	1.87	1.87	1.95	2.14
	% CHANGE		0.0	4.3	14.4
	S.D.	0.173	0.239	0.176	0.194
	N	5	5	5	5
DAY 42	MEAN	1.69	NA	NA	1.85
	% CHANGE				9.5
	S.D.	0.181			0.091
	N	5			5

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NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
TOTAL BILI (mg/dL)					
DAY 28	MEAN	0.1	0.1	0.0	0.1
	% CHANGE		0.0	-100.0	0.0
	S.D.	0.00	0.00	0.04	0.08
	N	5	5	5	5
DAY 42	MEAN	0.1	NA	NA	0.1
	% CHANGE				0.0
	S.D.	0.00			0.00
	N	5			5
UREA NITROGEN (mg/dL)					
DAY 28	MEAN	15.2	14.3	14.6	13.4
	% CHANGE		-5.9	-3.9	-11.8
	S.D.	3.43	1.15	0.88	1.36
	N	5	5	5	5
DAY 42	MEAN	15.5	NA	NA	14.0
	% CHANGE				-9.7
	S.D.	2.33			1.84
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
CREATININE (mg/dL)					
DAY 28	MEAN	0.2	0.3	0.3	0.2
	% CHANGE		50.0	50.0	0.0
	S.D.	0.08	0.00	0.04	0.08
	N	5	5	5	5
DAY 42	MEAN	0.3	NA	NA	0.3
	% CHANGE				0.0
	S.D.	0.05			0.00
	N	5			5
ALKALINEPHOS'TSE (U/L)					
DAY 28	MEAN	209.	295.	268.	270.
	% CHANGE		41.1	28.2	29.2
	S.D.	50.1	50.9	60.0	55.3
	N	5	5	5	5
DAY 42	MEAN	135.	NA	NA	161.
	% CHANGE				19.3
	S.D.	29.5			22.1
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES			
ALANINE TRANSFER (U/L)					
DAY 28	MEAN	39.	58.	106.*	389.**
	% CHANGE		48.7	171.8	897.4
	S.D.	6.2	9.2	39.6	52.9
	N	5	5	5	5
DAY 42	MEAN	43.	NA	NA	38.
	% CHANGE				-11.6
	S.D.	3.8			4.1
	N	5			5
ASPARTATTRANSFER (U/L)					
DAY 28	MEAN	102.	115.	110.	198.**
	% CHANGE		12.7	7.8	94.1
	S.D.	8.4	16.3	13.2	8.7
	N	5	5	5	5
DAY 42	MEAN	128.	NA	NA	99.*
	% CHANGE				-22.7
	S.D.	19.9			4.3
	N	5			5

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* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
GLUCOSE (mg/dL)					
DAY 28	MEAN	108.	118.	114.	104.
	% CHANGE		9.3	5.6	-3.7
	S.D.	20.5	18.0	9.0	19.7
	N	5	5	5	5
DAY 42	MEAN	125.	NA	NA	126.
	% CHANGE				0.8
	S.D.	11.3			19.8
	N	5			5
CHOLESTEROL (mg/dL)					
DAY 28	MEAN	42.	50.	52.	43.
	% CHANGE		19.0	23.8	2.4
	S.D.	5.1	7.9	10.5	11.3
	N	5	5	5	5
DAY 42	MEAN	57.	NA	NA	47.
	% CHANGE				-17.5
	S.D.	14.1			12.6
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
CALCIUM (mg/dL)					
DAY 28	MEAN	10.7	10.7	10.9	10.5
	% CHANGE		0.0	1.9	-1.9
	S.D.	0.19	0.34	0.35	0.27
	N	5	5	5	5
DAY 42	MEAN	10.2	NA	NA	10.3
	% CHANGE				1.0
	S.D.	0.38			0.20
	N	5			5
CHLORIDE (mEq/L)					
DAY 28	MEAN	102.	104.	104.*	104.
	% CHANGE		2.0	2.0	2.0
	S.D.	1.3	1.6	1.1	1.1
	N	5	5	5	5
DAY 42	MEAN	102.	NA	NA	103.
	% CHANGE				1.0
	S.D.	1.6			2.0
	N	5			5

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NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 8

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
PHOSPHORUS (mg/dL)					
DAY 28	MEAN	8.5	8.4	8.7	8.5
	% CHANGE		-1.2	2.4	0.0
	S.D.	0.51	0.78	0.61	0.35
	N	5	5	5	5
DAY 42	MEAN	7.0	NA	NA	6.9
	% CHANGE				-1.4
	S.D.	0.32			0.59
	N	5			5
POTASSIUM (mEq/L)					
DAY 28	MEAN	4.52	4.87	4.75	4.70
	% CHANGE		7.7	5.1	4.0
	S.D.	0.229	0.269	0.197	0.125
	N	5	5	5	5
DAY 42	MEAN	4.97	NA	NA	4.98
	% CHANGE				0.2
	S.D.	0.160			0.216
	N	5			5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 9

SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SODIUM (mEq/L)					
DAY 28	MEAN	145.	147.	148.	145.
	% CHANGE		1.4	2.1	0.0
	S.D.	2.2	1.1	2.3	1.9
	N	5	5	5	5
DAY 42	MEAN	143.	NA	NA	143.
	% CHANGE				0.0
	S.D.	1.3			0.4
	N	5			5
TRIGLYCERIDE (mg/dL)					
DAY 28	MEAN	36.	53.	52.	62.
	% CHANGE		47.2	44.4	72.2
	S.D.	10.9	12.2	22.3	20.1
	N	5	5	5	5
DAY 42	MEAN	53.	NA	NA	38.
	% CHANGE				-28.3
	S.D.	25.8			9.9
	N	5			5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

None significantly different from control group

NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 10

SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES			
ALBUMIN (g/dL)					
DAY 28	MEAN	4.8	4.8	4.6	4.5
	% CHANGE		0.0	-4.2	-6.3
	S.D.	0.23	0.15	0.27	0.22
	N	5	5	5	5
DAY 42	MEAN	4.9	NA	NA	4.6
	% CHANGE				-6.1
	S.D.	0.21			0.13
	N	5			5
TOTAL PROTEIN (g/dL)					
DAY 28	MEAN	7.0	7.0	6.8	6.6
	% CHANGE		0.0	-2.9	-5.7
	S.D.	0.44	0.09	0.37	0.34
	N	5	5	5	5
DAY 42	MEAN	7.4	NA	NA	7.1
	% CHANGE				-4.1
	S.D.	0.11			0.34
	N	5			5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

None significantly different from control group
NA = NOT APPLICABLE

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
GLOBULIN (g/dL)					
DAY 28	MEAN	2.3	2.2	2.2	2.1
	% CHANGE		-4.3	-4.3	-8.7
	S.D.	0.24	0.13	0.19	0.22
	N	5	5	5	5
DAY 42	MEAN	2.5	NA	NA	2.5
	% CHANGE				0.0
	S.D.	0.22			0.29
	N	5			5
A/G RATIO					
DAY 28	MEAN	2.13	2.20	2.09	2.15
	% CHANGE		3.3	-1.9	0.9
	S.D.	0.230	0.190	0.202	0.222
	N	5	5	5	5
DAY 42	MEAN	1.94	NA	NA	1.88
	% CHANGE				-3.1
	S.D.	0.254			0.263
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
TOTAL BILI (mg/dL)					
DAY 28	MEAN	0.0	0.1	0.1	0.1
	% CHANGE		NA	NA	NA
	S.D.	0.04	0.05	0.08	0.07
	N	5	5	5	5
DAY 42	MEAN	0.1	NA	NA	0.1
	% CHANGE				0.0
	S.D.	0.04			0.04
	N	5			5
UREA NITROGEN (mg/dL)					
DAY 28	MEAN	16.5	16.7	16.4	15.3
	% CHANGE		1.2	-0.6	-7.3
	S.D.	2.32	2.29	2.15	1.25
	N	5	5	5	5
DAY 42	MEAN	20.5	NA	NA	19.1
	% CHANGE				-6.8
	S.D.	6.87			1.05
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
CREATININE (mg/dL)					
DAY 28	MEAN	0.3	0.3	0.3	0.3
	% CHANGE		0.0	0.0	0.0
	S.D.	0.05	0.04	0.04	0.05
	N	5	5	5	5
DAY 42	MEAN	0.4	NA	NA	0.3
	% CHANGE				-25.0
	S.D.	0.04			0.05
	N	5			5
ALKALINEPHOS'TSE (U/L)					
DAY 28	MEAN	133.	121.	148.	171.
	% CHANGE		-9.0	11.3	28.6
	S.D.	20.5	9.5	17.9	40.1
	N	5	5	5	5
DAY 42	MEAN	87.	NA	NA	96.
	% CHANGE				10.3
	S.D.	21.0			21.2
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

TABLE 19

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
ALANINE TRANSFER (U/L)					
DAY 28	MEAN	34.	41.	76.**	138.**
	% CHANGE		20.6	123.5	305.9
	S.D.	5.1	4.3	11.6	27.0
	N	5	5	5	5
DAY 42	MEAN	35.	NA	NA	37.
	% CHANGE				5.7
	S.D.	7.3			7.8
	N	5			5
ASPARTATTRANSFER (U/L)					
DAY 28	MEAN	93.	97.	109.	132.**
	% CHANGE		4.3	17.2	41.9
	S.D.	6.2	8.8	9.1	15.3
	N	5	5	5	5
DAY 42	MEAN	95.	NA	NA	113.
	% CHANGE				18.9
	S.D.	14.4			28.4
	N	5			5

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** = Significantly different from the control group at 0.01 using Dunnett's test
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
GLUCOSE (mg/dL)					
DAY 28	MEAN	108.	113.	111.	99.
	% CHANGE		4.6	2.8	-8.3
	S.D.	10.6	10.9	7.9	11.3
	N	5	5	5	5
DAY 42	MEAN	112.	NA	NA	105.
	% CHANGE				-6.3
	S.D.	8.0			9.9
	N	5			5
CHOLESTEROL (mg/dL)					
DAY 28	MEAN	69.	66.	63.	63.
	% CHANGE		-4.3	-8.7	-8.7
	S.D.	7.4	10.6	7.7	12.5
	N	5	5	5	5
DAY 42	MEAN	74.	NA	NA	64.
	% CHANGE				-13.5
	S.D.	16.6			14.8
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
CALCIUM (mg/dL)					
DAY 28	MEAN	10.7	11.0	10.8	10.7
	% CHANGE		2.8	0.9	0.0
	S.D.	0.27	0.33	0.23	0.33
	N	5	5	5	5
DAY 42	MEAN	10.5	NA	NA	10.3
	% CHANGE				-1.9
	S.D.	0.24			0.29
	N	5			5
CHLORIDE (mEq/L)					
DAY 28	MEAN	103.	102.	104.	104.
	% CHANGE		-1.0	1.0	1.0
	S.D.	0.7	0.7	1.2	1.7
	N	5	5	5	5
DAY 42	MEAN	103.	NA	NA	103.
	% CHANGE				0.0
	S.D.	1.3			1.9
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
PHOSPHORUS (mg/dL)					
DAY 28	MEAN	7.9	8.0	7.5	8.9
	% CHANGE		1.3	-5.1	12.7
	S.D.	1.32	0.57	0.67	0.76
	N	5	5	5	5
DAY 42	MEAN	6.1	NA	NA	6.3
	% CHANGE				3.3
	S.D.	0.72			0.84
	N	5			5
POTASSIUM (mEq/L)					
DAY 28	MEAN	4.45	4.63	4.54	4.67
	% CHANGE		4.0	2.0	4.9
	S.D.	0.376	0.340	0.472	0.305
	N	5	5	5	5
DAY 42	MEAN	4.40	NA	NA	4.70
	% CHANGE				6.8
	S.D.	0.401			0.536
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 19
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SODIUM (mEq/L)					
DAY 28	MEAN	144.	145.	146.	145.
	% CHANGE		0.7	1.4	0.7
	S.D.	2.3	0.7	1.4	2.6
	N	5	5	5	5
DAY 42	MEAN	143.	NA	NA	143.
	% CHANGE				0.0
	S.D.	1.5			1.5
	N	5			5
TRIGLYCERIDE (mg/dL)					
DAY 28	MEAN	39.	46.	48.	61.
	% CHANGE		17.9	23.1	56.4
	S.D.	5.3	11.2	7.7	23.0
	N	5	5	5	5
DAY 42	MEAN	40.	NA	NA	38.
	% CHANGE				-5.0
	S.D.	8.0			15.5
	N	5			5

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None significantly different from control group
NA = NOT APPLICABLE

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PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 20 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MACROSCOPIC FINDINGS

SCHEDULED NECROPSY

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	5	5	5
JEJUNUM				
-DIVERTICULUM	0	0	1	0
TEETH				
-MALALIGNED	0	0	1	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	5	5	3	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 20 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MACROSCOPIC FINDINGS

SCHEDULED NECROPSY

	----- FEMALE -----			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	5	5	5
KIDNEYS				
-CYST(S)	1	0	0	0
LYMPH NODE, ILI				
-ENLARGED	1	0	0	0
OVARIES				
-CYST(S)	1	0	0	0
UTERUS				
-CONTENTS, CLEAR FLUID	0	0	1	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	2	5	4	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 21 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF MACROSCOPIC FINDINGS

SCHEDULED NECROPSY

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 6	5	0	0	5
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	5	0	0	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 21 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MACROSCOPIC FINDINGS

SCHEDULED NECROPSY

	----- FEMALE -----			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 6	5	0	0	5
KIDNEYS				
-DILATED PELVIS	1	0	0	0
-AREA(S), DEPRESSED	0	0	0	1
LUNGS				
-AREA(S), DARK RED	0	0	0	1
URINARY BLADDER				
-THICKENED	1	0	0	0
-CALCULUS(I)	1	0	0	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	3	0	0	3

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

TABLE 22 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
BRAIN (G)				
MEAN	2.04	1.94	1.85**	1.93*
% CHANGE		-4.9	-9.3	-5.4
S.D.	0.092	0.083	0.020	0.056
N	5	5	5	5
LIVER (G)				
MEAN	10.50	10.81	11.77	11.71
% CHANGE		3.0	12.1	11.5
S.D.	1.144	2.116	1.274	1.584
N	5	5	5	5
KIDNEYS (G)				
MEAN	2.95	2.87	3.02	3.00
% CHANGE		-2.7	2.4	1.7
S.D.	0.216	0.226	0.203	0.230
N	5	5	5	5
HEART (G)				
MEAN	1.22	1.28	1.24	1.22
% CHANGE		4.9	1.6	0.0
S.D.	0.129	0.137	0.073	0.170
N	5	5	5	5
SPLEEN (G)				
MEAN	0.69	0.69	0.60	0.66
% CHANGE		0.0	-13.0	-4.3
S.D.	0.096	0.136	0.051	0.092
N	5	5	5	5

* = Significantly different from the control group at 0.05 using Dunnett's test

** = Significantly different from the control group at 0.01 using Dunnett's test

TABLE 22 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
SEMINAL VES/COAG (G)				
MEAN	1.49	1.47	1.35	1.57
% CHANGE		-1.3	-9.4	5.4
S.D.	0.329	0.265	0.413	0.181
N	5	5	5	5
PROSTATE (G)				
MEAN	0.63	0.63	0.63	0.67
% CHANGE		0.0	0.0	6.3
S.D.	0.100	0.212	0.128	0.082
N	5	5	5	5
TESTES (G)				
MEAN	3.35	3.40	3.18	2.97*
% CHANGE		1.5	-5.1	-11.3
S.D.	0.245	0.235	0.233	0.167
N	5	5	5	5
EPIDIDYMIDES (G)				
MEAN	1.03	1.01	0.95	0.99
% CHANGE		-1.9	-7.8	-3.9
S.D.	0.068	0.086	0.063	0.025
N	5	5	5	5
THYMUS (G)				
MEAN	0.3603	0.4116	0.4597	0.4071
% CHANGE		14.2	27.6	13.0
S.D.	0.06847	0.13085	0.12286	0.09348
N	5	5	5	5

* = Significantly different from the control group at 0.05 using Dunnett's test

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 22 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF ORGAN WEIGHTS [G]

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
ADRENAL GLANDS (G)				
MEAN	0.0747	0.0750	0.0593	0.0666
% CHANGE		0.4	-20.6	-10.8
S.D.	0.02467	0.02684	0.00981	0.01160
N	5	5	5	5

None significantly different from control group

TABLE 22 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
BRAIN (G)				
MEAN	1.85	1.84	1.79	1.81
% CHANGE		-0.5	-3.2	-2.2
S.D.	0.069	0.093	0.058	0.040
N	5	5	5	5
LIVER (G)				
MEAN	7.52	7.75	7.83	7.99
% CHANGE		3.1	4.1	6.3
S.D.	1.025	0.938	0.726	0.679
N	5	5	5	5
KIDNEYS (G)				
MEAN	1.92	1.87	1.96	1.88
% CHANGE		-2.6	2.1	-2.1
S.D.	0.193	0.239	0.207	0.157
N	5	5	5	5
HEART (G)				
MEAN	0.90	0.86	0.88	0.90
% CHANGE		-4.4	-2.2	0.0
S.D.	0.042	0.092	0.092	0.129
N	5	5	5	5
SPLEEN (G)				
MEAN	0.47	0.46	0.47	0.52
% CHANGE		-2.1	0.0	10.6
S.D.	0.078	0.038	0.073	0.102
N	5	5	5	5

None significantly different from control group

TABLE 22 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
UTERUS (G)				
MEAN	0.49	0.37	0.72	0.54
% CHANGE		-24.5	46.9	10.2
S.D.	0.046	0.065	0.283	0.155
N	5	5	5	5
OVARIES/OVIDUCTS (G)				
MEAN	0.1388	0.1277	0.1322	0.1179
% CHANGE		-8.0	-4.8	-15.1
S.D.	0.01718	0.01984	0.02367	0.01117
N	5	5	5	5
THYMUS (G)				
MEAN	0.4551	0.3786	0.3877	0.3444
% CHANGE		-16.8	-14.8	-24.3
S.D.	0.13154	0.07803	0.10493	0.04630
N	5	5	5	5
ADRENAL GLANDS (G)				
MEAN	0.0655	0.0699	0.0727	0.0784
% CHANGE		6.7	11.0	19.7
S.D.	0.00633	0.00830	0.01600	0.00965
N	5	5	5	5

None significantly different from control group

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PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 23 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF ORGAN WEIGHTS [G]

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BRAIN (G)				
MEAN	2.03	NA	NA	1.99
% CHANGE				-2.0
S.D.	0.070			0.130
N	5			5
LIVER (G)				
MEAN	13.06	NA	NA	11.36
% CHANGE				-13.0
S.D.	1.474			0.996
N	5			5
KIDNEYS (G)				
MEAN	3.45	NA	NA	3.24
% CHANGE				-6.1
S.D.	0.222			0.371
N	5			5
HEART (G)				
MEAN	1.40	NA	NA	1.40
% CHANGE				0.0
S.D.	0.093			0.058
N	5			5
SPLEEN (G)				
MEAN	0.78	NA	NA	0.66
% CHANGE				-15.4
S.D.	0.098			0.070
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 23 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF ORGAN WEIGHTS [G]

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SEMINAL VES/COAG (G)				
MEAN	1.90	NA	NA	1.66
% CHANGE				-12.6
S.D.	0.190			0.404
N	5			5
PROSTATE (G)				
MEAN	0.83	NA	NA	0.72
% CHANGE				-13.3
S.D.	0.173			0.146
N	5			5
TESTES (G)				
MEAN	3.41	NA	NA	3.29
% CHANGE				-3.5
S.D.	0.275			0.082
N	5			5
EPIDIDYMIDES (G)				
MEAN	1.25	NA	NA	1.16
% CHANGE				-7.2
S.D.	0.118			0.100
N	5			5
THYMUS (G)				
MEAN	0.5077	NA	NA	0.3694
% CHANGE				-27.2
S.D.	0.12606			0.07759
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 23 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF ORGAN WEIGHTS [G]

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
ADRENAL GLANDS (G)				
MEAN	0.0667	NA	NA	0.0724
% CHANGE				8.5
S.D.	0.01108			0.00744
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

TABLE 23 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS [G] — WEEK 6

SPONSOR NO.:05-087

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BRAIN (G)				
MEAN	1.92	NA	NA	1.89
% CHANGE				-1.6
S.D.	0.068			0.028
N	5			5
LIVER (G)				
MEAN	7.36	NA	NA	7.48
% CHANGE				1.6
S.D.	0.347			0.523
N	5			5
KIDNEYS (G)				
MEAN	2.01	NA	NA	2.07
% CHANGE				3.0
S.D.	0.135			0.155
N	5			5
HEART (G)				
MEAN	0.88	NA	NA	1.01*
% CHANGE				14.8
S.D.	0.061			0.096
N	5			5
SPLEEN (G)				
MEAN	0.48	NA	NA	0.44
% CHANGE				-8.3
S.D.	0.047			0.070
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 23 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF ORGAN WEIGHTS [G]

GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
UTERUS (G)				
MEAN	0.52	NA	NA	0.44
% CHANGE				-15.4
S.D.	0.117			0.028
N	5			5
OVARIES/OVIDUCTS (G)				
MEAN	0.1262	NA	NA	0.1564*
% CHANGE				23.9
S.D.	0.01720			0.02156
N	5			5
THYMUS (G)				
MEAN	0.3735	NA	NA	0.4042
% CHANGE				8.2
S.D.	0.06964			0.08364
N	5			5
ADRENAL GLANDS (G)				
MEAN	0.0600	NA	NA	0.0800*
% CHANGE				33.3
S.D.	0.00951			0.00958
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test
NA = NOT APPLICABLE

TABLE 24 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
FINAL BODY WT (G)				
MEAN	329.	338.	335.	330.
% CHANGE		2.7	1.8	0.3
S.D.	35.2	43.2	17.0	27.4
N	5	5	5	5
BRAIN				
MEAN	0.626	0.580	0.554	0.589
% CHANGE		-7.3	-11.5	-5.9
S.D.	0.0635	0.0539	0.0296	0.0672
N	5	5	5	5
LIVER				
MEAN	3.198	3.179	3.515	3.544
% CHANGE		-0.6	9.9	10.8
S.D.	0.1857	0.3044	0.3291	0.2671
N	5	5	5	5
KIDNEYS				
MEAN	0.900	0.854	0.901	0.912
% CHANGE		-5.1	0.1	1.3
S.D.	0.0646	0.0698	0.0453	0.0774
N	5	5	5	5
HEART				
MEAN	0.372	0.379	0.371	0.370
% CHANGE		1.9	-0.3	-0.5
S.D.	0.0165	0.0100	0.0158	0.0395
N	5	5	5	5

None significantly different from control group

TABLE 24 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
SPLEEN				
MEAN	0.211	0.203	0.179	0.199
% CHANGE		-3.8	-15.2	-5.7
S.D.	0.0330	0.0214	0.0129	0.0169
N	5	5	5	5
SEMINAL VES/COAG				
MEAN	0.452	0.432	0.402	0.474
% CHANGE		-4.4	-11.1	4.9
S.D.	0.0886	0.0471	0.1116	0.0235
N	5	5	5	5
PROSTATE				
MEAN	0.195	0.186	0.189	0.207
% CHANGE		-4.6	-3.1	6.2
S.D.	0.0472	0.0492	0.0316	0.0364
N	5	5	5	5
TESTES				
MEAN	1.028	1.015	0.951	0.909
% CHANGE		-1.3	-7.5	-11.6
S.D.	0.1242	0.1057	0.0887	0.1058
N	5	5	5	5
EPIDIDYMIDES				
MEAN	0.317	0.302	0.284	0.302
% CHANGE		-4.7	-10.4	-4.7
S.D.	0.0297	0.0378	0.0262	0.0323
N	5	5	5	5

None significantly different from control group

TABLE 24 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
THYMUS				
MEAN	0.110	0.121	0.138	0.124
% CHANGE		10.0	25.5	12.7
S.D.	0.0219	0.0332	0.0389	0.0315
N	5	5	5	5
ADRENAL GLANDS				
MEAN	0.023	0.022	0.018	0.020
% CHANGE		-4.3	-21.7	-13.0
S.D.	0.0070	0.0068	0.0030	0.0022
N	5	5	5	5

None significantly different from control group

TABLE 24 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
FINAL BODY WT (G)				
MEAN	202.	206.	202.	205.
% CHANGE		2.0	0.0	1.5
S.D.	22.0	15.2	19.0	21.5
N	5	5	5	5
BRAIN				
MEAN	0.923	0.894	0.890	0.890
% CHANGE		-3.1	-3.6	-3.6
S.D.	0.0877	0.0701	0.0623	0.0954
N	5	5	5	5
LIVER				
MEAN	3.709	3.750	3.873	3.909
% CHANGE		1.1	4.4	5.4
S.D.	0.1177	0.2564	0.1717	0.2081
N	5	5	5	5
KIDNEYS				
MEAN	0.953	0.903	0.970	0.919
% CHANGE		-5.2	1.8	-3.6
S.D.	0.0787	0.0516	0.0387	0.0671
N	5	5	5	5
HEART				
MEAN	0.446	0.419	0.436	0.439
% CHANGE		-6.1	-2.2	-1.6
S.D.	0.0435	0.0317	0.0351	0.0567
N	5	5	5	5

None significantly different from control group

TABLE 24 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SPLEEN				
MEAN	0.232	0.221	0.234	0.252
% CHANGE		-4.7	0.9	8.6
S.D.	0.0255	0.0079	0.0277	0.0216
N	5	5	5	5
UTERUS				
MEAN	0.243	0.180	0.348	0.269
% CHANGE		-25.9	43.2	10.7
S.D.	0.0317	0.0303	0.1158	0.0965
N	5	5	5	5
OVARIES/OVIDUCTS				
MEAN	0.069	0.062	0.065	0.058
% CHANGE		-10.1	-5.8	-15.9
S.D.	0.0070	0.0097	0.0100	0.0072
N	5	5	5	5
THYMUS				
MEAN	0.225	0.184	0.193	0.170
% CHANGE		-18.2	-14.2	-24.4
S.D.	0.0621	0.0404	0.0567	0.0290
N	5	5	5	5
ADRENAL GLANDS				
MEAN	0.032	0.034	0.036	0.038
% CHANGE		6.3	12.5	18.8
S.D.	0.0029	0.0034	0.0058	0.0018
N	5	5	5	5

None significantly different from control group

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TABLE 25 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

	MALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
FINAL BODY WT (G)				
MEAN	416.	NA	NA	375.*
% CHANGE				-9.9
S.D.	21.4			25.2
N	5			5
BRAIN				
MEAN	0.489	NA	NA	0.532
% CHANGE				8.8
S.D.	0.0386			0.0360
N	5			5
LIVER				
MEAN	3.132	NA	NA	3.033
% CHANGE				-3.2
S.D.	0.2299			0.1952
N	5			5
KIDNEYS				
MEAN	0.830	NA	NA	0.862
% CHANGE				3.9
S.D.	0.0406			0.0492
N	5			5
HEART				
MEAN	0.337	NA	NA	0.374**
% CHANGE				11.0
S.D.	0.0103			0.0173
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test
NA = NOT APPLICABLE

TABLE 25 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
SPLEEN				
MEAN	0.188	NA	NA	0.176
% CHANGE				-6.4
S.D.	0.0186			0.0147
N	5			5
SEMINAL VES/COAG				
MEAN	0.458	NA	NA	0.442
% CHANGE				-3.5
S.D.	0.0585			0.0948
N	5			5
PROSTATE				
MEAN	0.199	NA	NA	0.192
% CHANGE				-3.5
S.D.	0.0380			0.0260
N	5			5
TESTES				
MEAN	0.820	NA	NA	0.880
% CHANGE				7.3
S.D.	0.0430			0.0432
N	5			5
EPIDIDYMIDES				
MEAN	0.301	NA	NA	0.309
% CHANGE				2.7
S.D.	0.0220			0.0231
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

TABLE 25 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

	MALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
THYMUS				
MEAN	0.122	NA	NA	0.099
% CHANGE				-18.9
S.D.	0.0289			0.0225
N	5			5
ADRENAL GLANDS				
MEAN	0.016	NA	NA	0.020*
% CHANGE				25.0
S.D.	0.0023			0.0026
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 25 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
FINAL BODY WT (G)				
MEAN	220.	NA	NA	225.
% CHANGE				2.3
S.D.	12.4			12.2
N	5			5
BRAIN				
MEAN	0.874	NA	NA	0.843
% CHANGE				-3.5
S.D.	0.0340			0.0392
N	5			5
LIVER				
MEAN	3.356	NA	NA	3.323
% CHANGE				-1.0
S.D.	0.2435			0.1459
N	5			5
KIDNEYS				
MEAN	0.917	NA	NA	0.920
% CHANGE				0.3
S.D.	0.0761			0.0819
N	5			5
HEART				
MEAN	0.402	NA	NA	0.449*
% CHANGE				11.7
S.D.	0.0350			0.0258
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 25 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR:[redacted] — SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SPLEEN				
MEAN	0.218	NA	NA	0.197
% CHANGE				-9.6
S.D.	0.0272			0.0326
N	5			5
UTERUS				
MEAN	0.235	NA	NA	0.196
% CHANGE				-16.6
S.D.	0.0482			0.0187
N	5			5
OVARIES/OVIDUCTS				
MEAN	0.057	NA	NA	0.070
% CHANGE				22.8
S.D.	0.0070			0.0115
N	5			5
THYMUS				
MEAN	0.170	NA	NA	0.179
% CHANGE				5.3
S.D.	0.0285			0.0331
N	5			5
ADRENAL GLANDS				
MEAN	0.027	NA	NA	0.036
% CHANGE				33.3
S.D.	0.0056			0.0065
N	5			5

None significantly different from control group

NA = NOT APPLICABLE

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TABLE 26 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
BRAIN WT (G)				
MEAN	2.04	1.94	1.85**	1.93*
% CHANGE		-4.9	-9.3	-5.4
S.D.	0.092	0.083	0.020	0.056
N	5	5	5	5
LIVER				
MEAN	514.195	553.924	635.759	609.080
% CHANGE		7.7	23.6	18.5
S.D.	52.1360	90.2947	64.4437	94.6524
N	5	5	5	5
KIDNEYS				
MEAN	144.224	147.470	163.042*	155.810
% CHANGE		2.3	13.0	8.0
S.D.	7.1106	5.6368	11.1227	15.3907
N	5	5	5	5
HEART				
MEAN	59.924	65.721	67.033	63.474
% CHANGE		9.7	11.9	5.9
S.D.	6.7746	4.6642	4.0077	10.0673
N	5	5	5	5
SPLEEN				
MEAN	33.656	35.312	32.332	34.223
% CHANGE		4.9	-3.9	1.7
S.D.	4.1110	6.3483	2.8583	5.3982
N	5	5	5	5

* = Significantly different from the control group at 0.05 using Dunnett's test

** = Significantly different from the control group at 0.01 using Dunnett's test

TABLE 26 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
SEMINAL VES/COAG				
MEAN	72.430	75.125	72.973	81.429
% CHANGE		3.7	0.7	12.4
S.D.	13.7266	11.3025	22.3341	11.1245
N	5	5	5	5
PROSTATE				
MEAN	30.822	32.394	34.237	34.939
% CHANGE		5.1	11.1	13.4
S.D.	4.5241	9.5908	6.6910	3.9431
N	5	5	5	5
TESTES				
MEAN	164.442	175.069	171.605	154.276
% CHANGE		6.5	4.4	-6.2
S.D.	15.7570	10.8356	11.1999	7.9902
N	5	5	5	5
EPIDIDYMIDES				
MEAN	50.749	51.950	51.333	51.367
% CHANGE		2.4	1.2	1.2
S.D.	4.4731	3.8292	3.0016	1.3703
N	5	5	5	5
THYMUS				
MEAN	17.675	21.061	24.890	21.108
% CHANGE		19.2	40.8	19.4
S.D.	3.5472	6.2814	6.8471	4.8035
N	5	5	5	5

None significantly different from control group

TABLE 26 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
ADRENAL GLANDS				
MEAN	3.636	3.840	3.206	3.471
% CHANGE		5.6	-11.8	-4.5
S.D.	1.0981	1.2762	0.5299	0.6876
N	5	5	5	5

None significantly different from control group

TABLE 26 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BRAIN WT (G)				
MEAN	1.85	1.84	1.79	1.81
% CHANGE		-0.5	-3.2	-2.2
S.D.	0.069	0.093	0.058	0.040
N	5	5	5	5
LIVER				
MEAN	405.456	422.118	436.907	442.933
% CHANGE		4.1	7.8	9.2
S.D.	49.0398	47.4560	35.4722	46.9919
N	5	5	5	5
KIDNEYS				
MEAN	103.512	101.852	109.555	103.979
% CHANGE		-1.6	5.8	0.5
S.D.	7.3020	13.5538	10.3380	10.0181
N	5	5	5	5
HEART				
MEAN	48.333	47.161	49.146	49.719
% CHANGE		-2.4	1.7	2.9
S.D.	1.5529	5.6773	5.2754	6.9943
N	5	5	5	5
SPLEEN				
MEAN	25.388	24.899	26.387	28.877
% CHANGE		-1.9	3.9	13.7
S.D.	4.4597	2.6478	3.4636	6.2754
N	5	5	5	5

None significantly different from control group

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
UTERUS				
MEAN	26.310	20.232	39.691	29.924
% CHANGE		-23.1	50.9	13.7
S.D.	2.0347	3.9448	15.1056	8.7323
N	5	5	5	5
OVARIES/OVIDUCTS				
MEAN	7.501	6.984	7.381	6.538
% CHANGE		-6.9	-1.6	-12.8
S.D.	1.0453	1.2497	1.2921	0.6987
N	5	5	5	5
THYMUS				
MEAN	24.678	20.698	21.591	19.104
% CHANGE		-16.1	-12.5	-22.6
S.D.	7.8718	4.6059	5.6125	2.8129
N	5	5	5	5
ADRENAL GLANDS				
MEAN	3.535	3.813	4.050	4.350
% CHANGE		7.9	14.6	23.1
S.D.	0.3482	0.4561	0.8366	0.6108
N	5	5	5	5

None significantly different from control group

TABLE 27 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 6

SPONSOR NO.:05-087

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BRAIN WT (G)				
MEAN	2.03	NA	NA	1.99
% CHANGE				-2.0
S.D.	0.070			0.130
N	5			5
LIVER				
MEAN	645.504	NA	NA	570.621
% CHANGE				-11.6
S.D.	86.1696			24.7403
N	5			5
KIDNEYS				
MEAN	170.656	NA	NA	163.002
% CHANGE				-4.5
S.D.	14.9937			17.1972
N	5			5
HEART				
MEAN	69.228	NA	NA	70.626
% CHANGE				2.0
S.D.	5.6783			5.9859
N	5			5
SPLEEN				
MEAN	38.666	NA	NA	33.147
% CHANGE				-14.3
S.D.	5.5844			2.4342
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
SEMINAL VES/COAG				
MEAN	93.469	NA	NA	83.537
% CHANGE				-10.6
S.D.	6.7856			20.0320
N	5			5
PROSTATE				
MEAN	40.880	NA	NA	36.152
% CHANGE				-11.6
S.D.	8.8442			5.5692
N	5			5
TESTES				
MEAN	168.443	NA	NA	165.770
% CHANGE				-1.6
S.D.	15.5573			9.1499
N	5			5
EPIDIDYMIDES				
MEAN	61.780	NA	NA	58.150
% CHANGE				-5.9
S.D.	6.1328			2.0556
N	5			5
THYMUS				
MEAN	25.174	NA	NA	18.689
% CHANGE				-25.8
S.D.	6.6739			4.5092
N	5			5

None significantly different from control group
NA = NOT APPLICABLE

TABLE 27 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 6

SPONSOR NO.:05-087

	MALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
ADRENAL GLANDS				
MEAN	3.294	NA	NA	3.645
% CHANGE				10.7
S.D.	0.5749			0.3705
N	5			5

None significantly different from control group

NA = NOT APPLICABLE

TABLE 27 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 6

SPONSOR NO.:05-087

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
BRAIN WT (G)				
MEAN	1.92	NA	NA	1.89
% CHANGE				-1.6
S.D.	0.068			0.028
N	5			5
LIVER				
MEAN	384.115	NA	NA	394.751
% CHANGE				2.8
S.D.	24.3155			27.7919
N	5			5
KIDNEYS				
MEAN	105.109	NA	NA	109.137
% CHANGE				3.8
S.D.	9.6141			8.9565
N	5			5
HEART				
MEAN	46.084	NA	NA	53.418*
% CHANGE				15.9
S.D.	4.3822			4.8317
N	5			5
SPLEEN				
MEAN	24.994	NA	NA	23.350
% CHANGE				-6.6
S.D.	3.1653			3.7963
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

TABLE 27 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR:[redacted] — SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 6

SPONSOR NO.:05-087

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
UTERUS				
MEAN	26.900	NA	NA	23.144
% CHANGE				-14.0
S.D.	5.9705			1.7369
N	5			5
OVARIES/OVIDUCTS				
MEAN	6.567	NA	NA	8.260*
% CHANGE				25.8
S.D.	0.7028			1.1727
N	5			5
THYMUS				
MEAN	19.409	NA	NA	21.359
% CHANGE				10.0
S.D.	3.0975			4.5386
N	5			5
ADRENAL GLANDS				
MEAN	3.135	NA	NA	4.229*
% CHANGE				34.9
S.D.	0.5506			0.5400
N	5			5

* = Significantly different from the control group at 0.05 using Dunnett's test

NA = NOT APPLICABLE

POFBSTv5.05
02/13/2006

TABLE 28 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
BRAIN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
CECUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	4	NA	NA	5
-INFILTRATE, MONONUCLEAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
COLON				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
DUODENUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
EPIDIDYMIDES				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	3	NA	NA	1
-INFILTRATE, MONONUCLEAR	2	NA	NA	4
MINIMAL	2	NA	NA	4
-LUMINAL DEBRIS, CELLULAR	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
FEMUR				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
HEART				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	1	NA	NA	5
-CARDIOMYOPATHY	4	NA	NA	0
MINIMAL	4	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
ILEUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
JEJUNUM				
TOTAL NUMBER EXAMINED	5	NA	1	5
EXAMINED, UNREMARKABLE	5	NA	0	5
-DIVERTICULUM	0	NA	1	0
PRESENT	NONE	NA	1	NONE
KIDNEYS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	2	NA	NA	2
-NEPHROPATHY, CHRONIC PROGRESSIVE	3	NA	NA	3
MINIMAL	3	NA	NA	3
-CYST, MEDULLARY	1	NA	NA	1
MINIMAL	1	NA	NA	1
LIVER				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	2	NA	NA	0
-INFLAMMATION, SUBACUTE	3	NA	NA	5
MINIMAL	3	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

TABLE 28 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
LUNGS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	1	NA	NA	1
-MINERALIZATION, VASCULAR	4	NA	NA	4
MINIMAL	4	NA	NA	4
-MACROPHAGES, ALVEOLAR	1	NA	NA	1
MINIMAL	1	NA	NA	1
-INFILTRATE, MONONUCLEAR, PERIVASCULAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	2	NA	NA	0
-PLASMACYTOSIS, MEDULLARY	3	NA	NA	2
MINIMAL	NONE	NA	NA	1
MILD	3	NA	NA	1
-HEMORRHAGE	1	NA	NA	4
MINIMAL	1	NA	NA	3
MODERATE	NONE	NA	NA	1
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	4
-INFLAMMATION, GRANULOMATOUS	0	NA	NA	1
MINIMAL	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
MARROW, FEMUR				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
MARROW, STERN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	4	NA	NA	5
EXAMINED, UNREMARKABLE	4	NA	NA	5
NOT EXAMINED	1	NA	NA	0
PARATHYROIDS				
TOTAL NUMBER EXAMINED	3	NA	NA	0
EXAMINED, UNREMARKABLE	3	NA	NA	0
NOT EXAMINED	2	NA	NA	5
PROSTATE				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

TABLE 28 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:05-087

SUMMARY OF MICROSCOPIC FINDINGS

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
RECTUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
SEMINAL VESICLES				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
SPINAL CORD				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
SPLEEN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	2	NA	NA	4
-HEMATOPOIESIS, EXTRAMEDULLARY	3	NA	NA	1
MINIMAL	3	NA	NA	1
STERNUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
STOMACH, NON				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
TEETH				
TOTAL NUMBER EXAMINED	NA	NA	1	NA
EXAMINED, UNREMARKABLE	NA	NA	1	NA
TESTES				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	3	NA	NA	3
-DEGENERATION, SEMINIFEROUS TUBULES	2	NA	NA	2
MINIMAL	2	NA	NA	1
MILD	NONE	NA	NA	1
THYMUS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	4	NA	NA	4
-HEMORRHAGE	1	NA	NA	1
MINIMAL	1	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

TABLE 28 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MICROSCOPIC FINDINGS

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	2	5
THYROID GLANDS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	3	NA	NA	2
-CYST, ULTIMOBRANCHIAL	2	NA	NA	3
MINIMAL	2	NA	NA	3
TRACHEA				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
URINARY BLADDER				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
BRAIN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
CECUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	4	NA	NA	5
-INFILTRATE, MONONUCLEAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
CERVIX				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

TABLE 28 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 10

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
COLON				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
DUODENUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
FEMUR				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
HEART				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	4	NA	NA	5
-CARDIOMYOPATHY	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
ILEUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
JEJUNUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
KIDNEYS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	1	NA	NA	1
-NEPHROPATHY, CHRONIC PROGRESSIVE	3	NA	NA	2
MINIMAL	3	NA	NA	2
-MINERALIZATION, TUBULAR	2	NA	NA	2
MINIMAL	2	NA	NA	2
-CAST, HYALINE	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
LIVER				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	0	NA	NA	0
-INFLAMMATION, SUBACUTE	5	NA	NA	5
MINIMAL	5	NA	NA	5
-VACUOLATION, HEPATOCELLULAR, PERIPORTAL	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
-HEMATOPOIESIS, EXTRAMEDULLARY	0	NA	NA	1
MINIMAL	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
LUNGS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	2	NA	NA	1
-MINERALIZATION, VASCULAR	2	NA	NA	2
MINIMAL	2	NA	NA	2
-MACROPHAGES, ALVEOLAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
-INFLAMMATION, SUBACUTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
-INFILTRATE, EOSINOPHIL, PERIVASCULAR	1	NA	NA	4
MINIMAL	1	NA	NA	4
LYMPH NODE, ILI				
TOTAL NUMBER EXAMINED	1	NA	NA	NA
EXAMINED, UNREMARKABLE	1	NA	NA	NA
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	1	NA	NA	0
-PLASMACYTOSIS, MEDULLARY	4	NA	NA	5
MINIMAL	3	NA	NA	1
MILD	1	NA	NA	4
-HEMORRHAGE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	4
-HISTIOCYTOSIS, SINUS	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
MAMMARY GLAND				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
MARROW, FEMUR				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
MARROW, STERN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	5	NA	NA	4
EXAMINED, UNREMARKABLE	5	NA	NA	4
NOT EXAMINED	0	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
OVARIES				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
OVIDUCTS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
PARATHYROIDS				
TOTAL NUMBER EXAMINED	0	NA	NA	2
EXAMINED, UNREMARKABLE	0	NA	NA	2
NOT EXAMINED	5	NA	NA	3
RECTUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
SPINAL CORD				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
SPLEEN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	0	NA	NA	1
-HEMATOPOIESIS, EXTRAMEDULLARY	5	NA	NA	4
MINIMAL	5	NA	NA	4

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
STERNUM				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	3
-INFILTRATE, EOSINOPHIL	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
-DILATATION, GLANDULAR	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
STOMACH, NON				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
THYMUS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	3
-HEMORRHAGE	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
-HYPERPLASIA, EPITHELIAL	0	NA	NA	2
MINIMAL	NONE	NA	NA	2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
THYROID GLANDS				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	3
-CYST, ULTIMOBRANCHIAL	0	NA	NA	2
MINIMAL	NONE	NA	NA	2
TRACHEA				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	4	NA	NA	5
-INFILTRATE, MONONUCLEAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
URINARY BLADDER				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5
UTERUS				
TOTAL NUMBER EXAMINED	5	NA	1	5
EXAMINED, UNREMARKABLE	5	NA	0	4
-DILATATION	0	NA	1	1
MILD	NONE	NA	1	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

TABLE 28 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	5	5	10
NUMBER OF ANIMALS EXAMINED WEEK 4	5	0	1	5
VAGINA				
TOTAL NUMBER EXAMINED	5	NA	NA	5
EXAMINED, UNREMARKABLE	5	NA	NA	5

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

TABLE 29

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted] INDIVIDUAL SURVIVAL AND DISPOSITION

SPONSOR NO.:05-087

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
96223	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96226	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96229	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96230	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96232	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96235	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96244	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96247	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96249	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96251	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96228	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96233	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96236	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96238	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96254	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96241	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96245	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96248	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96250	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96256	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96224	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96225	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96231	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96234	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96237	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96242	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96246	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

TABLE 29
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SURVIVAL AND DISPOSITION

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
96252	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96253	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96255	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

TABLE 29

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted] INDIVIDUAL SURVIVAL AND DISPOSITION

SPONSOR NO.:05-087

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
96261	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96262	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96266	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96267	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96269	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96270	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96275	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96278	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96283	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96284	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96280	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96285	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96289	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96290	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96291	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96263	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96265	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96268	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96272	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96276	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96259	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96260	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96264	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96271	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96273	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96277	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96279	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 29
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SURVIVAL AND DISPOSITION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
96281	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	11	23-NOV-05	28
96282	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42
96287	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	13	07-DEC-05	42

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

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02/13/2006

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6	
ANIMAL									
96223	192.	254.	291.	323.	355.	371.	399.	418.	SCHEDULED EUTH WEEK 6
96226	180.	245.	290.	325.	357.	382.	SCHEDULED EUTH WEEK 4		
96229	205.	271.	329.	366.	394.	410.	SCHEDULED EUTH WEEK 4		
96230	178.	243.	303.	338.	376.	409.	441.	454.	SCHEDULED EUTH WEEK 6
96232	192.	250.	280.	308.	331.	348.	SCHEDULED EUTH WEEK 4		
96235	201.	271.	333.	367.	395.	425.	453.	469.	SCHEDULED EUTH WEEK 6
96244	180.	234.	262.	286.	304.	326.	SCHEDULED EUTH WEEK 4		
96247	189.	252.	295.	317.	342.	367.	400.	417.	SCHEDULED EUTH WEEK 6
96249	192.	265.	311.	347.	383.	410.	444.	459.	SCHEDULED EUTH WEEK 6
96251	180.	233.	268.	285.	303.	325.	SCHEDULED EUTH WEEK 4		
MEAN	189.	252.	296.	326.	354.	377.	427.	443.	
S.D.	9.4	13.8	23.5	29.0	34.0	36.2	25.9	24.3	
N	10	10	10	10	10	10	5	5	

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 160 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6
ANIMAL								
96228	194.	248.	283.	306.	324.	333.	SCHEDULED EUTH WEEK 4	
96233	182.	248.	287.	321.	345.	367.	SCHEDULED EUTH WEEK 4	
96236	190.	254.	305.	346.	378.	413.	SCHEDULED EUTH WEEK 4	
96238	194.	264.	315.	361.	386.	416.	SCHEDULED EUTH WEEK 4	
96254	175.	235.	265.	286.	301.	316.	SCHEDULED EUTH WEEK 4	
MEAN	187.	250.	291.	324.	347.	369.	NA	NA
S.D.	8.3	10.5	19.5	30.1	35.8	45.4		
N	5	5	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 400 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6
ANIMAL								
96241	202.	272.	316.	349.	358.	373.	SCHEDULED EUTH WEEK 4	
96245	177.	234.	272.	300.	329.	340.	SCHEDULED EUTH WEEK 4	
96248	188.	250.	284.	306.	333.	349.	SCHEDULED EUTH WEEK 4	
96250	191.	242.	283.	323.	346.	373.	SCHEDULED EUTH WEEK 4	
96256	194.	258.	299.	339.	357.	381.	SCHEDULED EUTH WEEK 4	
MEAN	190.	251.	291.	323.	345.	363.	NA	NA
S.D.	9.1	14.7	17.0	20.9	13.4	17.7		
N	5	5	5	5	5	5		

NA = NOT APPLICABLE

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6	
ANIMAL									
96224	182.	239.	272.	303.	324.	346.	368.	376.	SCHEDULED EUTH WEEK 6
96225	187.	240.	272.	283.	305.	326.	SCHEDULED EUTH WEEK 4		
96231	196.	264.	304.	328.	347.	384.	393.	404.	SCHEDULED EUTH WEEK 6
96234	189.	250.	288.	321.	361.	384.	425.	445.	SCHEDULED EUTH WEEK 6
96237	183.	243.	289.	310.	328.	348.	SCHEDULED EUTH WEEK 4		
96242	192.	252.	290.	313.	340.	360.	SCHEDULED EUTH WEEK 4		
96246	182.	248.	300.	338.	364.	383.	SCHEDULED EUTH WEEK 4		
96252	195.	256.	295.	326.	358.	380.	SCHEDULED EUTH WEEK 4		
96253	192.	253.	277.	299.	321.	348.	383.	396.	SCHEDULED EUTH WEEK 6
96255	201.	268.	277.	298.	318.	339.	374.	391.	SCHEDULED EUTH WEEK 6
MEAN	190.	251.	286.	312.	337.	360.	389.	402.	
S.D.	6.5	9.6	11.5	16.7	20.4	21.5	22.4	25.9	
N	10	10	10	10	10	10	5	5	

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 0 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6
ANIMAL								
96261	134.	156.	168.	180.	183.	185.	SCHEDULED EUTH WEEK 4	
96262	141.	171.	195.	213.	215.	229.	245.	240. SCHEDULED EUTH WEEK 6
96266	126.	154.	174.	191.	207.	216.	SCHEDULED EUTH WEEK 4	
96267	132.	155.	175.	181.	193.	203.	214.	218. SCHEDULED EUTH WEEK 6
96269	147.	178.	209.	229.	246.	262.	SCHEDULED EUTH WEEK 4	
96270	140.	164.	182.	188.	204.	215.	SCHEDULED EUTH WEEK 4	
96275	145.	166.	187.	193.	203.	207.	224.	233. SCHEDULED EUTH WEEK 6
96278	144.	167.	190.	203.	215.	220.	247.	247. SCHEDULED EUTH WEEK 6
96283	135.	164.	187.	200.	219.	232.	246.	249. SCHEDULED EUTH WEEK 6
96284	148.	175.	196.	208.	219.	226.	SCHEDULED EUTH WEEK 4	
MEAN	139.	165.	186.	199.	210.	220.	235.	237.
S.D.	7.2	8.3	12.2	15.3	17.1	20.4	15.2	12.5
N	10	10	10	10	10	10	5	5

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 160 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6
ANIMAL								
96280	143.	174.	185.	195.	195.	210.	SCHEDULED EUTH WEEK 4	
96285	129.	152.	173.	190.	204.	212.	SCHEDULED EUTH WEEK 4	
96289	143.	175.	188.	208.	221.	225.	SCHEDULED EUTH WEEK 4	
96290	140.	169.	192.	217.	229.	246.	SCHEDULED EUTH WEEK 4	
96291	130.	162.	189.	210.	225.	227.	SCHEDULED EUTH WEEK 4	
MEAN	137.	166.	185.	204.	215.	224.	NA	NA
S.D.	7.0	9.6	7.4	11.2	14.6	14.4		
N	5	5	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6
ANIMAL								
96263	131.	146.	168.	175.	190.	199.	SCHEDULED EUTH WEEK 4	
96265	135.	167.	192.	201.	211.	218.	SCHEDULED EUTH WEEK 4	
96268	140.	158.	179.	192.	195.	209.	SCHEDULED EUTH WEEK 4	
96272	146.	183.	212.	230.	240.	256.	SCHEDULED EUTH WEEK 4	
96276	137.	166.	189.	202.	223.	230.	SCHEDULED EUTH WEEK 4	
MEAN	138.	164.	188.	200.	212.	222.	NA	NA
S.D.	5.6	13.5	16.4	20.0	20.5	22.0		
N	5	5	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 30
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	-1	0	1	2	3	4	5	6	
ANIMAL									
96259	134.	160.	186.	187.	204.	213.	SCHEDULED EUTH WEEK 4		
96260	137.	157.	185.	199.	204.	223.	SCHEDULED EUTH WEEK 4		
96264	144.	178.	208.	220.	232.	240.	258.	257.	SCHEDULED EUTH WEEK 6
96271	140.	166.	181.	200.	212.	223.	236.	237.	SCHEDULED EUTH WEEK 6
96273	142.	174.	207.	229.	249.	265.	SCHEDULED EUTH WEEK 4		
96277	141.	162.	189.	211.	227.	237.	253.	255.	SCHEDULED EUTH WEEK 6
96279	144.	163.	185.	207.	219.	229.	SCHEDULED EUTH WEEK 4		
96281	128.	157.	180.	191.	198.	210.	SCHEDULED EUTH WEEK 4		
96282	124.	150.	177.	196.	209.	225.	241.	242.	SCHEDULED EUTH WEEK 6
96287	141.	179.	205.	214.	219.	225.	224.	225.	SCHEDULED EUTH WEEK 6
MEAN	138.	165.	190.	205.	217.	229.	242.	243.	
S.D.	6.8	9.6	11.8	13.3	15.4	15.6	13.6	13.2	
N	10	10	10	10	10	10	5	5	

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02/13/2006

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 31
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96223	62.	37.	32.	32.	16.	28.	19. SCHEDULED EUTH WEEK 6
96226	65.	45.	35.	32.	25.	SCHEDULED EUTH WEEK 4	
96229	66.	58.	37.	28.	16.	SCHEDULED EUTH WEEK 4	
96230	65.	60.	35.	38.	33.	32.	13. SCHEDULED EUTH WEEK 6
96232	58.	30.	28.	23.	17.	SCHEDULED EUTH WEEK 4	
96235	70.	62.	34.	28.	30.	28.	16. SCHEDULED EUTH WEEK 6
96244	54.	28.	24.	18.	22.	SCHEDULED EUTH WEEK 4	
96247	63.	43.	22.	25.	25.	33.	17. SCHEDULED EUTH WEEK 6
96249	73.	46.	36.	36.	27.	34.	15. SCHEDULED EUTH WEEK 6
96251	53.	35.	17.	18.	22.	SCHEDULED EUTH WEEK 4	
MEAN	63.	44.	30.	28.	23.	31.	16.
S.D.	6.4	12.3	6.9	6.9	5.9	2.8	2.2
N	10	10	10	10	10	5	5

TABLE 31

PROJECT NO.:WIL-187051
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96228	54.	35.	23.	18.	9.	SCHEDULED EUTH WEEK 4	
96233	66.	39.	34.	24.	22.	SCHEDULED EUTH WEEK 4	
96236	64.	51.	41.	32.	35.	SCHEDULED EUTH WEEK 4	
96238	70.	51.	46.	25.	30.	SCHEDULED EUTH WEEK 4	
96254	60.	30.	21.	15.	15.	SCHEDULED EUTH WEEK 4	
MEAN	63.	41.	33.	23.	22.	NA	NA
S.D.	6.1	9.5	10.9	6.6	10.6		
N	5	5	5	5	5		

NA = NOT APPLICABLE

TABLE 31

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:05-087 INDIVIDUAL BODY WEIGHT CHANGES [G]

MALE GROUP: 400 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96241	70.	44.	33.	9.	15.	SCHEDULED EUTH WEEK 4	
96245	57.	38.	28.	29.	11.	SCHEDULED EUTH WEEK 4	
96248	62.	34.	22.	27.	16.	SCHEDULED EUTH WEEK 4	
96250	51.	41.	40.	23.	27.	SCHEDULED EUTH WEEK 4	
96256	64.	41.	40.	18.	24.	SCHEDULED EUTH WEEK 4	
MEAN	61.	40.	33.	21.	19.	NA	NA
S.D.	7.2	3.8	7.8	8.0	6.7		
N	5	5	5	5	5		

NA = NOT APPLICABLE

TABLE 31
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	
ANIMAL								
96224	57.	33.	31.	21.	22.	22.	8.	SCHEDULED EUTH WEEK 6
96225	53.	32.	11.	22.	21.	SCHEDULED EUTH WEEK 4		
96231	68.	40.	24.	19.	37.	9.	11.	SCHEDULED EUTH WEEK 6
96234	61.	38.	33.	40.	23.	41.	20.	SCHEDULED EUTH WEEK 6
96237	60.	46.	21.	18.	20.	SCHEDULED EUTH WEEK 4		
96242	60.	38.	23.	27.	20.	SCHEDULED EUTH WEEK 4		
96246	66.	52.	38.	26.	19.	SCHEDULED EUTH WEEK 4		
96252	61.	39.	31.	32.	22.	SCHEDULED EUTH WEEK 4		
96253	61.	24.	22.	22.	27.	35.	13.	SCHEDULED EUTH WEEK 6
96255	67.	9.	21.	20.	21.	35.	17.	SCHEDULED EUTH WEEK 6
MEAN	61.	35.	26.	25.	23.	28.	14.	
S.D.	4.6	11.9	7.8	6.8	5.3	12.9	4.8	
N	10	10	10	10	10	5	5	

TABLE 31
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 0 MG/KG/DAY

WEEK / ANIMAL	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
96261	22.	12.	12.	3.	2.	SCHEDULED EUTH WEEK 4	
96262	30.	24.	18.	2.	14.	16.	-5. SCHEDULED EUTH WEEK 6
96266	28.	20.	17.	16.	9.	SCHEDULED EUTH WEEK 4	
96267	23.	20.	6.	12.	10.	11.	4. SCHEDULED EUTH WEEK 6
96269	31.	31.	20.	17.	16.	SCHEDULED EUTH WEEK 4	
96270	24.	18.	6.	16.	11.	SCHEDULED EUTH WEEK 4	
96275	21.	21.	6.	10.	4.	17.	9. SCHEDULED EUTH WEEK 6
96278	23.	23.	13.	12.	5.	27.	0. SCHEDULED EUTH WEEK 6
96283	29.	23.	13.	19.	13.	14.	3. SCHEDULED EUTH WEEK 6
96284	27.	21.	12.	11.	7.	SCHEDULED EUTH WEEK 4	
MEAN	26.	21.	12.	12.	9.	17.	2.
S.D.	3.6	4.8	5.1	5.7	4.6	6.0	5.2
N	10	10	10	10	10	5	5

TABLE 31
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 160 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96280	31.	11.	10.	0.	15.	SCHEDULED EUTH WEEK 4	
96285	23.	21.	17.	14.	8.	SCHEDULED EUTH WEEK 4	
96289	32.	13.	20.	13.	4.	SCHEDULED EUTH WEEK 4	
96290	29.	23.	25.	12.	17.	SCHEDULED EUTH WEEK 4	
96291	32.	27.	21.	15.	2.	SCHEDULED EUTH WEEK 4	
MEAN	29.	19.	19.	11.	9.	NA	NA
S.D.	3.8	6.8	5.6	6.1	6.6		
N	5	5	5	5	5		

NA = NOT APPLICABLE

TABLE 31
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 400 MG/KG/DAY

WEEK / ANIMAL	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
96263	15.	22.	7.	15.	9.	SCHEDULED EUTH WEEK 4	
96265	32.	25.	9.	10.	7.	SCHEDULED EUTH WEEK 4	
96268	18.	21.	13.	3.	14.	SCHEDULED EUTH WEEK 4	
96272	37.	29.	18.	10.	16.	SCHEDULED EUTH WEEK 4	
96276	29.	23.	13.	21.	7.	SCHEDULED EUTH WEEK 4	
MEAN	26.	24.	12.	12.	11.	NA	NA
S.D.	9.4	3.2	4.2	6.7	4.2		
N	5	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 31
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	
ANIMAL								
96259	26.	26.	1.	17.	9.	SCHEDULED EUTH WEEK 4		
96260	20.	28.	14.	5.	19.	SCHEDULED EUTH WEEK 4		
96264	34.	30.	12.	12.	8.	18.	-1.	SCHEDULED EUTH WEEK 6
96271	26.	15.	19.	12.	11.	13.	1.	SCHEDULED EUTH WEEK 6
96273	32.	33.	22.	20.	16.	SCHEDULED EUTH WEEK 4		
96277	21.	27.	22.	16.	10.	16.	2.	SCHEDULED EUTH WEEK 6
96279	19.	22.	22.	12.	10.	SCHEDULED EUTH WEEK 4		
96281	29.	23.	11.	7.	12.	SCHEDULED EUTH WEEK 4		
96282	26.	27.	19.	13.	16.	16.	1.	SCHEDULED EUTH WEEK 6
96287	38.	26.	9.	5.	6.	-1.	1.	SCHEDULED EUTH WEEK 6
MEAN	27.	26.	15.	12.	12.	12.	1.	
S.D.	6.2	4.9	7.0	5.0	4.1	7.7	1.1	
N	10	10	10	10	10	5	5	

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	
ANIMAL							
96223	37.	69.	101.	117.	145.	164.	SCHEDULED EUTH WEEK 6
96226	45.	80.	112.	137.	SCHEDULED EUTH WEEK 4		
96229	58.	95.	123.	139.	SCHEDULED EUTH WEEK 4		
96230	60.	95.	133.	166.	198.	211.	SCHEDULED EUTH WEEK 6
96232	30.	58.	81.	98.	SCHEDULED EUTH WEEK 4		
96235	62.	96.	124.	154.	182.	198.	SCHEDULED EUTH WEEK 6
96244	28.	52.	70.	92.	SCHEDULED EUTH WEEK 4		
96247	43.	65.	90.	115.	148.	165.	SCHEDULED EUTH WEEK 6
96249	46.	82.	118.	145.	179.	194.	SCHEDULED EUTH WEEK 6
96251	35.	52.	70.	92.	SCHEDULED EUTH WEEK 4		
MEAN	44.	74.	102.	126.	170.	186.	
S.D.	12.3	17.6	23.3	26.5	23.0	21.0	
N	10	10	10	10	5	5	

TABLE 32

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 160 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6
ANIMAL						
96228	35.	58.	76.	85.	SCHEDULED EUTH WEEK 4	
96233	39.	73.	97.	119.	SCHEDULED EUTH WEEK 4	
96236	51.	92.	124.	159.	SCHEDULED EUTH WEEK 4	
96238	51.	97.	122.	152.	SCHEDULED EUTH WEEK 4	
96254	30.	51.	66.	81.	SCHEDULED EUTH WEEK 4	
MEAN	41.	74.	97.	119.	NA	NA
S.D.	9.5	20.2	26.2	36.4		
N	5	5	5	5		

NA = NOT APPLICABLE

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

MALE GROUP: 400 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6
ANIMAL						
96241	44.	77.	86.	101.	SCHEDULED EUTH WEEK 4	
96245	38.	66.	95.	106.	SCHEDULED EUTH WEEK 4	
96248	34.	56.	83.	99.	SCHEDULED EUTH WEEK 4	
96250	41.	81.	104.	131.	SCHEDULED EUTH WEEK 4	
96256	41.	81.	99.	123.	SCHEDULED EUTH WEEK 4	
MEAN	40.	72.	93.	112.	NA	NA
S.D.	3.8	10.9	8.8	14.2		
N	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 1000 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	
ANIMAL							
96224	33.	64.	85.	107.	129.	137.	SCHEDULED EUTH WEEK 6
96225	32.	43.	65.	86.	SCHEDULED EUTH WEEK 4		
96231	40.	64.	83.	120.	129.	140.	SCHEDULED EUTH WEEK 6
96234	38.	71.	111.	134.	175.	195.	SCHEDULED EUTH WEEK 6
96237	46.	67.	85.	105.	SCHEDULED EUTH WEEK 4		
96242	38.	61.	88.	108.	SCHEDULED EUTH WEEK 4		
96246	52.	90.	116.	135.	SCHEDULED EUTH WEEK 4		
96252	39.	70.	102.	124.	SCHEDULED EUTH WEEK 4		
96253	24.	46.	68.	95.	130.	143.	SCHEDULED EUTH WEEK 6
96255	9.	30.	50.	71.	106.	123.	SCHEDULED EUTH WEEK 6
MEAN	35.	61.	85.	109.	134.	148.	
S.D.	11.9	16.9	20.7	20.6	25.2	27.6	
N	10	10	10	10	5	5	

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 0 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6
ANIMAL						
96261	12.	24.	27.	29.	SCHEDULED EUTH WEEK 4	
96262	24.	42.	44.	58.	74.	69. SCHEDULED EUTH WEEK 6
96266	20.	37.	53.	62.	SCHEDULED EUTH WEEK 4	
96267	20.	26.	38.	48.	59.	63. SCHEDULED EUTH WEEK 6
96269	31.	51.	68.	84.	SCHEDULED EUTH WEEK 4	
96270	18.	24.	40.	51.	SCHEDULED EUTH WEEK 4	
96275	21.	27.	37.	41.	58.	67. SCHEDULED EUTH WEEK 6
96278	23.	36.	48.	53.	80.	80. SCHEDULED EUTH WEEK 6
96283	23.	36.	55.	68.	82.	85. SCHEDULED EUTH WEEK 6
96284	21.	33.	44.	51.	SCHEDULED EUTH WEEK 4	
MEAN	21.	34.	45.	55.	71.	73.
S.D.	4.8	8.7	11.4	15.0	11.4	9.3
N	10	10	10	10	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6
ANIMAL						
96280	11.	21.	21.	36.	SCHEDULED EUTH WEEK 4	
96285	21.	38.	52.	60.	SCHEDULED EUTH WEEK 4	
96289	13.	33.	46.	50.	SCHEDULED EUTH WEEK 4	
96290	23.	48.	60.	77.	SCHEDULED EUTH WEEK 4	
96291	27.	48.	63.	65.	SCHEDULED EUTH WEEK 4	
MEAN	19.	38.	48.	58.	NA	NA
S.D.	6.8	11.3	16.7	15.5		
N	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6
ANIMAL						
96263	22.	29.	44.	53.	SCHEDULED EUTH WEEK 4	
96265	25.	34.	44.	51.	SCHEDULED EUTH WEEK 4	
96268	21.	34.	37.	51.	SCHEDULED EUTH WEEK 4	
96272	29.	47.	57.	73.	SCHEDULED EUTH WEEK 4	
96276	23.	36.	57.	64.	SCHEDULED EUTH WEEK 4	
MEAN	24.	36.	48.	58.	NA	NA
S.D.	3.2	6.7	8.9	9.8		
N	5	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 32
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	
ANIMAL							
96259	26.	27.	44.	53.	SCHEDULED EUTH WEEK 4		
96260	28.	42.	47.	66.	SCHEDULED EUTH WEEK 4		
96264	30.	42.	54.	62.	80.	79.	SCHEDULED EUTH WEEK 6
96271	15.	34.	46.	57.	70.	71.	SCHEDULED EUTH WEEK 6
96273	33.	55.	75.	91.	SCHEDULED EUTH WEEK 4		
96277	27.	49.	65.	75.	91.	93.	SCHEDULED EUTH WEEK 6
96279	22.	44.	56.	66.	SCHEDULED EUTH WEEK 4		
96281	23.	34.	41.	53.	SCHEDULED EUTH WEEK 4		
96282	27.	46.	59.	75.	91.	92.	SCHEDULED EUTH WEEK 6
96287	26.	35.	40.	46.	45.	46.	SCHEDULED EUTH WEEK 6
MEAN	26.	41.	53.	64.	75.	76.	
S.D.	4.9	8.3	11.3	13.3	19.1	19.2	
N	10	10	10	10	5	5	

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PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 33
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 0 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	
ANIMAL								
96223	27.	25.	23.	23.	24.	28.	29.	SCHEDULED EUTH WEEK 6
96226	32.	25.	25.	25.	26.	SCHEDULED EUTH WEEK 4		
96229	22.	27.	25.	25.	24.	SCHEDULED EUTH WEEK 4		
96230	25.	26.	25.	27.	27.	30.	32.	SCHEDULED EUTH WEEK 6
96232	25.	23.	22.	22.	22.	SCHEDULED EUTH WEEK 4		
96235	27.	28.	26.	25.	27.	29.	33.	SCHEDULED EUTH WEEK 6
96244	24.	20.	20.	19.	22.	SCHEDULED EUTH WEEK 4		
96247	26.	24.	22.	23.	25.	29.	30.	SCHEDULED EUTH WEEK 6
96249	27.	26.	24.	26.	26.	31.	31.	SCHEDULED EUTH WEEK 6
96251	25.	22.	23.	22.	21.	SCHEDULED EUTH WEEK 4		
MEAN	26.	25.	24.	24.	24.	29.	31.	
S.D.	2.6	2.4	1.8	2.4	2.2	1.1	1.6	
N	10	10	10	10	10	5	5	

TABLE 33

PROJECT NO.:WIL-187051
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]
SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96228	24.	27.	23.	21.	21.	SCHEDULED EUTH WEEK 4	
96233	26.	24.	23.	24.	24.	SCHEDULED EUTH WEEK 4	
96236	25.	25.	23.	25.	28.	SCHEDULED EUTH WEEK 4	
96238	27.	26.	24.	24.	25.	SCHEDULED EUTH WEEK 4	
96254	26.	24.	21.	22.	24.	SCHEDULED EUTH WEEK 4	
MEAN	26.	25.	23.	23.	24.	NA	NA
S.D.	1.1	1.3	1.1	1.6	2.5		
N	5	5	5	5	5		

NA = NOT APPLICABLE

TABLE 33

PROJECT NO.:WIL-187051
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]
SPONSOR NO.:05-087

MALE GROUP: 400 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96241	28.	24.	22.	21.	23.	SCHEDULED EUTH WEEK 4	
96245	24.	21.	20.	21.	22.	SCHEDULED EUTH WEEK 4	
96248	27.	23.	21.	20.	22.	SCHEDULED EUTH WEEK 4	
96250	25.	20.	23.	24.	25.	SCHEDULED EUTH WEEK 4	
96256	25.	22.	24.	24.	23.	SCHEDULED EUTH WEEK 4	
MEAN	26.	22.	22.	22.	23.	NA	NA
S.D.	1.6	1.6	1.6	1.9	1.2		
N	5	5	5	5	5		

NA = NOT APPLICABLE

TABLE 33
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

WEEK / ANIMAL	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	
96224	23.	21.	21.	23.	23.	24.	25.	SCHEDULED EUTH WEEK 6
96225	25.	21.	20.	20.	22.	SCHEDULED EUTH WEEK 4		
96231	27.	22.	22.	24.	27.	25.	25.	SCHEDULED EUTH WEEK 6
96234	26.	21.	23.	25.	26.	31.	32.	SCHEDULED EUTH WEEK 6
96237	26.	23.	22.	23.	25.	SCHEDULED EUTH WEEK 4		
96242	27.	24.	25.	27.	28.	SCHEDULED EUTH WEEK 4		
96246	27.	25.	26.	27.	16.	SCHEDULED EUTH WEEK 4		
96252	26.	23.	24.	26.	24.	SCHEDULED EUTH WEEK 4		
96253	27.	19.	23.	24.	24.	27.	27.	SCHEDULED EUTH WEEK 6
96255	28.	19.	20.	23.	21.	27.	27.	SCHEDULED EUTH WEEK 6
MEAN	26.	22.	23.	24.	24.	27.	27.	
S.D.	1.4	2.0	2.0	2.1	3.4	2.7	2.9	
N	10	10	10	10	10	5	5	

TABLE 33
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 0 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96261	19.	16.	15.	15.	15.	SCHEDULED EUTH WEEK 4	
96262	19.	18.	19.	19.	20.	21.	21. SCHEDULED EUTH WEEK 6
96266	19.	16.	16.	17.	17.	SCHEDULED EUTH WEEK 4	
96267	19.	NA	15.	16.	16.	17.	21. SCHEDULED EUTH WEEK 6
96269	19.	19.	18.	19.	19.	SCHEDULED EUTH WEEK 4	
96270	21.	NA	17.	19.	21.	SCHEDULED EUTH WEEK 4	
96275	11.	17.	15.	16.	15.	19.	20. SCHEDULED EUTH WEEK 6
96278	16.	17.	17.	18.	18.	21.	21. SCHEDULED EUTH WEEK 6
96283	20.	NA	18.	19.	20.	21.	22. SCHEDULED EUTH WEEK 6
96284	20.	17.	16.	19.	17.	SCHEDULED EUTH WEEK 4	
MEAN	18.	17.	17.	18.	18.	20.	21.
S.D.	2.9	1.1	1.4	1.6	2.1	1.8	0.7
N	10	7	10	10	10	5	5

NA = NOT APPLICABLE

TABLE 33
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 160 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96280	19.	15.	15.	14.	15.	SCHEDULED EUTH WEEK 4	
96285	18.	NA	21.	19.	18.	SCHEDULED EUTH WEEK 4	
96289	19.	17.	18.	18.	19.	SCHEDULED EUTH WEEK 4	
96290	19.	NA	21.	21.	11.	SCHEDULED EUTH WEEK 4	
96291	18.	18.	19.	20.	18.	SCHEDULED EUTH WEEK 4	
MEAN	19.	17.	19.	18.	16.	NA	NA
S.D.	0.5	1.5	2.5	2.7	3.3		
N	5	3	5	5	5		

NA = NOT APPLICABLE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 33
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96263	19.	15.	17.	19.	17.	SCHEDULED EUTH WEEK 4	
96265	19.	17.	18.	18.	16.	SCHEDULED EUTH WEEK 4	
96268	19.	15.	19.	20.	18.	SCHEDULED EUTH WEEK 4	
96272	22.	20.	21.	22.	22.	SCHEDULED EUTH WEEK 4	
96276	22.	18.	18.	20.	NA	SCHEDULED EUTH WEEK 4	
MEAN	20.	17.	19.	20.	18.	NA	NA
S.D.	1.6	2.1	1.5	1.5	2.6		
N	5	5	5	5	4		

NA = NOT APPLICABLE

TABLE 33
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL							
96259	19.	NA	18.	19.	21.	SCHEDULED EUTH WEEK 4	
96260	20.	NA	20.	17.	20.	SCHEDULED EUTH WEEK 4	
96264	20.	17.	18.	19.	19.	21.	21. SCHEDULED EUTH WEEK 6
96271	19.	NA	17.	18.	18.	20.	20. SCHEDULED EUTH WEEK 6
96273	20.	19.	21.	22.	21.	SCHEDULED EUTH WEEK 4	
96277	15.	17.	19.	20.	NA	24.	22. SCHEDULED EUTH WEEK 6
96279	17.	14.	17.	17.	16.	SCHEDULED EUTH WEEK 4	
96281	20.	19.	19.	20.	NA	SCHEDULED EUTH WEEK 4	
96282	18.	17.	19.	19.	23.	21.	22. SCHEDULED EUTH WEEK 6
96287	21.	19.	19.	20.	21.	21.	22. SCHEDULED EUTH WEEK 6
MEAN	19.	17.	19.	19.	20.	21.	21.
S.D.	1.8	1.8	1.3	1.5	2.2	1.5	0.9
N	10	7	10	10	8	5	5

NA = NOT APPLICABLE

PBFTSv4.44
02/13/2006

TABLE 34
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HOME CAGE OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96226	3	1	1	1	1	1	1
96229	1	1	1	1	1	2	1
96232	1	1	1	1	1	1	1
96244	1	1	1	1	1	1	1
96251	2	1	1	1	1	3	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HOME CAGE OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96228	3	1	1	1	1	1	1
96233	1	1	1	1	1	1	1
96236	1	1	1	1	1	1	4
96238	1	1	1	1	1	2	1
96254	3	1	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HOME CAGE OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96241	4	1	1	1	1	3	1
96245	1	1	1	1	1	1	1
96248	3,8	1	1	1	1	1	1
96250	1	1	1	1	1	2	1
96256	1	1	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HOME CAGE OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96225	1	1	1	1	1	1	1
96237	1	1	1	1	1	1	1
96242	1	1	1	1	1	1	1
96246	2	1	1	1	1	1	1
96252	1	1	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 5

SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

HOME CAGE OBSERVATIONS

DOSE GROUP: 1

DOSE LEVEL: 0 MG/KG/DAY SEX: FEMALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96261	1	1	1	1	1	1	1
96266	1	1	1	1	1	1	4
96269	1	1	1	1	1	1	1
96270	3,8	1	1	1	1	1	4
96284	3,8	1	1	1	1	1	4

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HOME CAGE OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96280	1	1	1	1	1	1	4
96285	1	1	1	1	1	1	1
96289	3,8	1	1	1	1	1	4
96290	3,8	1	1	1	1	1	4
96291	3,8	1	1	1	1	1	4

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HOME CAGE OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96263	3	1	1	1	1	1	1
96265	3,8	1	1	1	1	1	1
96268	1	1	1	1	1	1	1
96272	3,8	1	1	1	1	1	4
96276	1	1	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 34

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

HOME CAGE OBSERVATIONS

DOSE GROUP: 4

DOSE LEVEL: 1000 MG/KG/DAY SEX: FEMALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	POSTURE	CONVULSIONS		TREMORS	BITING	PALPEBRAL CLOSURE	FECES CONSISTENCY
		CLONIC	TONIC				
96259	3	1	1	1	1	1	1
96260	1	1	1	1	1	1	1
96273	1	1	1	1	1	1	1
96279	2	1	1	1	1	1	1
96281	1	1	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

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02/13/2006

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96226	1	1	1	1	1
96229	2	1	1	1	1
96232	2	1	1	1	1
96244	1	1	1	1	1
96251	2	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96226	1	1	1	1	1	2	2	2
96229	1	1	1	1	1	2	2	2
96232	1	1	1	1	1	2	2	2
96244	1	1	1	1	1	2	2	2
96251	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96226	2	2	2	1	1	1	1	1
96229	2	2	2	1	1	1	1	1
96232	2	2	2	1	1	1	1	1
96244	2	2	2	1	1	1	1	1
96251	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

HANDLING OBSERVATIONS

DOSE GROUP: 2

DOSE LEVEL: 160 MG/KG/DAY SEX: MALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96228	2	1	1	1	1
96233	1	1	1	1	1
96236	1	1	1	1	1
96238	1	1	1	1	1
96254	2	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96228	1	1	1	1	1	2	2	2
96233	1	1	1	1	1	2	2	2
96236	1	1	1	1	1	2	2	2
96238	1	1	1	1	1	2	2	2
96254	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96228	2	2	2	1	1	1	1	1
96233	2	2	2	1	1	1	1	1
96236	2	2	2	1	1	1	1	1
96238	2	2	2	1	1	1	1	1
96254	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96241	1	1	1	1	1
96245	1	1	1	1	1
96248	1	1	1	1	1
96250	2	1	1	1	1
96256	3	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 8

SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

HANDLING OBSERVATIONS

DOSE GROUP: 3

DOSE LEVEL: 400 MG/KG/DAY SEX: MALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96241	1	1	1	1	1	1	2	2
96245	1	1	1	1	1	2	2	2
96248	1	1	1	1	1	2	2	2
96250	1	1	1	1	1	2	2	2
96256	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96241	2	2	2	1	1	1	1	1
96245	2	2	2	1	1	1	1	1
96248	2	2	2	1	1	1	1	1
96250	2	2	2	1	1	1	1	1
96256	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96225	1	1	1	1	1
96237	1	1	1	1	1
96242	1	1	1	1	1
96246	1	1	1	1	1
96252	2	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96225	1	1	1	1	1	2	2	2
96237	1	1	1	1	1	2	2	2
96242	1	1	1	1	1	2	2	2
96246	1	1	1	1	1	2	2	2
96252	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR				
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN	EYE PROMINENCE	MUSCLE TONE
96225	2	2	2	1	1	1	1	1
96237	2	2	2	1	1	1	1	1
96242	2	2	2	1	1	1	1	1
96246	2	2	2	1	1	1	1	1
96252	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96261	1	1	1	1	1
96266	1	1	1	1	1
96269	1	1	1	1	1
96270	1	1	1	1	1
96284	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96261	1	1	1	1	1	2	2	2
96266	1	1	1	1	1	2	2	2
96269	1	1	1	1	1	2	2	2
96270	1	1	1	1	1	2	2	2
96284	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96261	2	2	2	1	1	1	1	1
96266	2	2	2	1	1	1	1	1
96269	2	2	2	1	1	1	1	1
96270	2	2	2	1	1	1	1	1
96284	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96280	3	1	1	1	1
96285	5	1	1	1	1
96289	1	1	1	1	1
96290	1	1	1	1	1
96291	2	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96280	1	1	1	1	1	2	2	2
96285	1	1	1	1	1	2	2	2
96289	1	1	1	1	1	2	2	2
96290	1	1	1	1	1	2	2	2
96291	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96280	2	2	2	1	1	1	1	1
96285	2	2	2	1	1	1	1	1
96289	2	2	2	1	1	1	1	1
96290	2	2	2	1	1	1	1	1
96291	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96263	1	1	1	1	1
96265	2	1	1	1	1
96268	1	1	1	1	1
96272	1	1	1	1	1
96276	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96263	1	1	1	1	1	2	2	2
96265	1	1	1	1	1	2	2	2
96268	1	1	1	1	1	2	2	2
96272	1	1	1	1	1	2	2	2
96276	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96263	2	2	2	1	1	1	1	1
96265	2	2	2	1	1	1	1	1
96268	2	2	2	1	1	1	1	1
96272	2	2	2	1	1	1	1	1
96276	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	EASE OF REMOVAL FROM CAGE	EASE OF HANDLING ANIMAL IN HAND	LACRIMATION	CHROMODACRYORRHEA	SALIVATION
96259	1	1	1	1	1
96260	1	1	1	1	1
96273	3	1	1	1	1
96279	2*	1	1	1	1
96281	2	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE
* = ANIMAL VOCALIZED

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
HANDLING OBSERVATIONS

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PILOERECTION	FUR APPEARANCE	PALPEBRAL CLOSURE	RESPIRATORY RATE	RESPIRATORY CHARACTER	RED DEPOSITS		
						EYES	NOSE	MOUTH
96259	1	1	1	1	1	2	2	2
96260	1	1	1	1	1	2	2	2
96273	1	1	1	1	1	2	2	2
96279	1	1	1	1	1	2	2	2
96281	1	1	1	1	1	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 35
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

HANDLING OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CRUSTY DEPOSITS			COLOR			EYE PROMINENCE	MUSCLE TONE
	EYES	NOSE	MOUTH	MUCOUS MEMBRANES	EYES	SKIN		
96259	2	2	2	1	1	1	1	1
96260	2	2	2	1	1	1	1	1
96273	2	2	2	1	1	1	1	1
96279	2	2	2	1	1	1	1	1
96281	2	2	2	1	1	1	1	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

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TABLE 36

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

OPEN FIELD OBSERVATIONS

DOSE GROUP: 1

DOSE LEVEL: 0 MG/KG/DAY SEX: MALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96226	0.4	1	1	1	1	1	1	3
96229	0.3	1	1	1	1	1	1	3
96232	0.2	1	1	1	1	1	1	3
96244	0.3	1	1	1	1	1	1	3
96251	0.2	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.08							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96226	1	8.0	0.0	0.0	0.0	0.0
96229	1	9.0	0.0	0.0	0.0	0.0
96232	1	9.0	0.0	2.0	0.0	2.0
96244	1	6.0	0.0	0.0	1.0	1.0
96251	1	8.0	0.0	0.0	1.0	0.0
MEAN		8.0	0.0	0.4	0.4	0.6
S.D.		1.22	0.00	0.89	0.55	0.89
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96228	0.4	1	1	1	1	1	1	3
96233	0.5	1	1	1	1	1	1	3
96236	0.3	1	1	1	1	1	1	3
96238	0.3	1	1	1	1	1	1	3
96254	0.2	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.11							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96228	1	2.0	0.0	0.0	3.0	2.0
96233	1	7.0	0.0	1.0	0.0	0.0
96236	1	15.0	0.0	0.0	3.0	5.0
96238	1	16.0	0.0	0.0	0.0	0.0
96254	1	10.0	0.0	0.0	2.0	0.0
MEAN		10.0	0.0	0.2	1.6	1.4
S.D.		5.79	0.00	0.45	1.52	2.19
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96241	0.2	1	1	1	1	1	1	3
96245	0.5	1	1	1	1	1	1	3
96248	0.4	1	1	1	1	1	1	3
96250	0.2	1	1	1	1	1	1	3
96256	0.2	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.14							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

OPEN FIELD OBSERVATIONS

DOSE GROUP: 3

DOSE LEVEL: 400 MG/KG/DAY SEX: MALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96241	1	5.0	0.0	2.0	0.0	0.0
96245	1	8.0	0.0	0.0	0.0	0.0
96248	1	4.0	0.0	0.0	0.0	4.0
96250	1	12.0	0.0	0.0	1.0	0.0
96256	1	12.0	0.0	0.0	1.0	3.0
MEAN		8.2	0.0	0.4	0.4	1.4
S.D.		3.77	0.00	0.89	0.55	1.95
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

OPEN FIELD OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96225	0.2	1	1	1	1	1	1	3
96237	0.3	1	1	1	1	1	1	3
96242	0.4	1	1	1	1	1	1	3
96246	0.4	1	1	1	1	1	1	3
96252	0.2	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.10							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96225	1	1.0	0.0	0.0	1.0	2.0
96237	1	11.0	0.0	0.0	0.0	0.0
96242	1	2.0	0.0	0.0	0.0	0.0
96246	1	4.0	0.0	0.0	0.0	0.0
96252	1	16.0	0.0	1.0	0.0	0.0
MEAN		6.8	0.0	0.2	0.2	0.4
S.D.		6.46	0.00	0.45	0.45	0.89
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
OPEN FIELD OBSERVATIONS

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96261	0.3	1	1	1	1	1	1	3
96266	0.3	1	1	1	1	1	1	3
96269	0.3	1	1	1	1	1	1	3
96270	0.3	1	1	1	1	1	1	3
96284	0.3	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.00							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96261	1	14.0	0.0	1.0	0.0	0.0
96266	1	16.0	0.0	0.0	0.0	0.0
96269	1	10.0	0.0	0.0	0.0	0.0
96270	1	10.0	0.0	0.0	0.0	0.0
96284	1	13.0	0.0	0.0	0.0	0.0
MEAN		12.6	0.0	0.2	0.0	0.0
S.D.		2.61	0.00	0.45	0.00	0.00
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96280	0.2	1	1	1	1	1	1	3
96285	0.3	1	1	1	1	1	1	3
96289	0.3	1	1	1	1	1	1	3
96290	0.5	1	1	1	1	1	1	3
96291	0.2	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.12							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96280	1	16.0	0.0	1.0	0.0	0.0
96285	1	11.0	0.0	0.0	0.0	0.0
96289	1	13.0	0.0	1.0	0.0	0.0
96290	1	15.0	0.0	0.0	0.0	0.0
96291	1	17.0	0.0	0.0	0.0	0.0
MEAN		14.4	0.0	0.4	0.0	0.0
S.D.		2.41	0.00	0.55	0.00	0.00
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96263	0.5	1	1	1	1	1	1	3
96265	0.2	1	1	1	1	1	1	3
96268	0.3	1	1	1	1	1	1	3
96272	0.2	1	1	1	1	1	1	3
96276	0.3	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.12							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96263	1	18.0	0.0	0.0	0.0	0.0
96265	1	11.0	0.0	1.0	0.0	0.0
96268	1	2.0	2.0	0.0	0.0	0.0
96272	1	11.0	0.0	0.0	0.0	0.0
96276	1	13.0	0.0	0.0	0.0	0.0
MEAN		11.0	0.4	0.2	0.0	0.0
S.D.		5.79	0.89	0.45	0.00	0.00
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 36
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

OPEN FIELD OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	TIME TO 1ST STEP (seconds)	MOBILITY	GAIT	CONVULSIONS		TREMORS	GAIT SCORE	AROUSAL
				CLONIC	TONIC			
96259	0.5	1	1	1	1	1	1	3
96260	0.3	1	1	1	1	1	1	3
96273	0.2	1	1	1	1	1	1	3
96279	0.2	1	1	1	1	1	1	3
96281	0.2	1	1	1	1	1	1	3
MEAN	0.3							
S.D.	0.13							
N	5							

OBSERVATION SCORE, UNLESS STATED OTHERWISE

OPEN FIELD OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	BIZARRE/STEREO-TYPIC BEHAVIOR	REARING (counts)	BACKING (counts)	GROOMING (counts)	URINATION (counts)	DEFECATION (counts)
96259	1	16.0	0.0	0.0	0.0	0.0
96260	1	5.0	0.0	1.0	0.0	0.0
96273	1	14.0	0.0	0.0	0.0	0.0
96279	1	6.0	0.0	0.0	0.0	0.0
96281	1	14.0	0.0	0.0	0.0	0.0
MEAN		11.0	0.0	0.2	0.0	0.0
S.D.		5.10	0.00	0.45	0.00	0.00
N		5	5	5	5	5

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted] INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SPONSOR NO.:05-087

SENSORY OBSERVATIONS

DOSE GROUP: 1

DOSE LEVEL: 0 MG/KG/DAY SEX: MALES

TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96226	2	2	2	2	2
96229	2	2	2	2	2
96232	2	2	2	2	2
96244	2	2	2	2	2
96251	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

SENSORY OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96226	2	2	2	2	1
96229	2	2	2	2	1
96232	2	2	2	2	1
96244	2	2	2	2	1
96251	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
SENSORY OBSERVATIONS

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96228	2	1	2	2	2
96233	2	3	2	2	2
96236	2	2	2	2	2
96238	2	2	2	2	2
96254	2	2	2	3*	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE
* = ANIMAL VOCALIZED

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
SENSORY OBSERVATIONS

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96228	2	2	2	2	1
96233	2	2	2	2	1
96236	2	2	2	2	1
96238	2	2	2	2	1
96254	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96241	2	2	2	2	2
96245	2	2	2	2	2
96248	2	1	2	2	2
96250	2	2	2	2	2
96256	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96241	2	2	2	2	1
96245	2	2	2	2	1
96248	2	2	2	2	1
96250	2	2	2	2	1
96256	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
SENSORY OBSERVATIONS

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96225	2	2	2	2	2
96237	2	2	2	2	2
96242	2	2	2	2	2
96246	2	2	2	2	2
96252	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96225	2	2	2	2	1
96237	2	2	2	2	1
96242	2	2	2	2	1
96246	2	2	2	2	1
96252	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
SENSORY OBSERVATIONS

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96261	2	2	2	2	2
96266	2	2	3	2	2
96269	2	2	2	2	2
96270	2	2	2	2	2
96284	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
SENSORY OBSERVATIONS

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96261	2	2	2	2	1
96266	2	2	2	2	1
96269	2	2	2	2	1
96270	2	2	2	2	1
96284	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96280	2	2	2	2	2
96285	2	2	2	2	2
96289	2	2	2	2	2
96290	2	2	2	2	2
96291	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96280	2	2	2	2	1
96285	2	2	2	2	1
96289	2	2	2	2	1
96290	2	2	2	2	1
96291	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96263	2	2	2	2	2
96265	2	2	2	2	2
96268	2	1	2	2	2
96272	2	2	2	2	2
96276	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96263	2	2	2	2	1
96265	2	2	2	2	1
96268	2	2	2	2	1
96272	2	2	2	2	1
96276	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	APPROACH RESPONSE	TOUCH RESPONSE	STARTLE RESPONSE	TAIL PINCH RESPONSE	OLFACTORY ORIENTATION
96259	2	2	2	2	2
96260	2	2	3	2	2
96273	2	2	2	2	2
96279	2	2	2	2	2
96281	2	2	2	2	2

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 37
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

SENSORY OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	PUPIL RESPONSE	EYEBLINK RESPONSE	FORELIMB EXTENSION	HINDLIMB EXTENSION	AIR RIGHTING REFLEX
96259	2	2	2	2	1
96260	2	2	2	2	1
96273	2	2	2	2	1
96279	2	2	2	2	1
96281	2	2	2	2	1

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
NEUROMUSCULAR OBSERVATIONS

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96226	3	630.	700.	650.	660.	36.1	450.	365.	425.	413.	43.7
96229	3	1295.	1135.	1460.	1297.	162.5	560.	535.	805.	633.	149.2
96232	3	1115.	595.	795.	835.	262.3	440.	220.	395.	352.	116.2
96244	3	510.	650.	850.	670.	170.9	235.	355.	265.	285.	62.4
96251	3	1020.	510.	685.	738.	259.1	470.	270.	270.	337.	115.5
MEAN					840.0					404.0	
S.D.					264.85					135.90	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96226	32.2	88.	86.	87.	1.4
96229	51.1	55.	47.	51.	5.7
96232	120.0	60.	53.	57.	4.9
96244	120.0	79.	74.	77.	3.5
96251	31.3	41.	51.	46.	7.1
MEAN	70.9			63.6	
S.D.	45.50			17.60	
N	5			5	

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96228	3	850.	750.	455.	685.	205.4	315.	375.	315.	335.	34.6
96233	3	735.	675.	660.	690.	39.7	450.	450.	445.	448.	2.9
96236	3	995.	910.	845.	917.	75.2	690.	530.	395.	538.	147.7
96238	3	645.	670.	535.	617.	71.8	480.	320.	425.	408.	81.3
96254	3	645.	1050.	550.	748.	265.5	440.	415.	435.	430.	13.2
MEAN					731.4					431.8	
S.D.					113.66					73.28	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96228	120.0	81.	65.	73.	11.3
96233	120.0	89.	82.	86.	4.9
96236	95.8	58.	45.	52.	9.2
96238	28.2	62.	59.	61.	2.1
96254	101.0	79.	84.	82.	3.5
MEAN	93.0			70.8	
S.D.	37.84			14.24	
N	5			5	

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96241	3	840.	830.	840.	837.	5.8	395.	165.	275.	278.	115.0
96245	3	895.	735.	565.	732.	165.0	450.	420.	375.	415.	37.7
96248	3	880.	865.	680.	808.	111.4	560.	400.	580.	513.	98.7
96250	3	1480.	1100.	1085.	1222.	223.8	460.	380.	295.	378.	82.5
96256	3	1035.	805.	700.	847.	171.3	640.	330.	395.	455.	163.5
MEAN					889.2					407.8	
S.D.					191.42					88.15	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
NEUROMUSCULAR OBSERVATIONS

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96241	93.3	57.	62.	60.	3.5
96245	71.5	88.	91.	90.	2.1
96248	120.0	61.	73.	67.	8.5
96250	40.9	36.	34.	35.	1.4
96256	55.0	23.	30.	27.	4.9
MEAN	76.1			55.8	
S.D.	31.34			25.37	
N	5			5	

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96225	3	895.	920.	880.	898.	20.2	310.	345.	365.	340.	27.8
96237	3	680.	565.	295.	513.	197.6	240.	555.	295.	363.	168.3
96242	3	510.	640.	525.	558.	71.1	365.	355.	270.	330.	52.2
96246	3	535.	585.	495.	538.	45.1	330.	480.	375.	395.	77.0
96252	3	980.	785.	730.	832.	131.4	345.	295.	345.	328.	28.9
MEAN					667.8					351.2	
S.D.					182.22					28.15	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96225	24.6	48.	41.	45.	4.9
96237	42.9	64.	69.	67.	3.5
96242	44.3	88.	85.	87.	2.1
96246	120.0	59.	73.	66.	9.9
96252	57.7	42.	39.	41.	2.1
MEAN	57.9			61.2	
S.D.	36.66			18.66	
N	5			5	

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96261	3	945.	405.	955.	768.	314.7	225.	485.	150.	287.	175.8
96266	3	925.	1070.	1065.	1020.	82.3	205.	415.	465.	362.	138.0
96269	3	875.	525.	530.	643.	200.6	430.	325.	295.	350.	70.9
96270	3	700.	450.	510.	553.	130.5	240.	395.	400.	345.	91.0
96284	3	610.	855.	505.	657.	179.6	430.	320.	335.	362.	59.7
MEAN					728.2					341.2	
S.D.					180.11					31.20	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
NEUROMUSCULAR OBSERVATIONS

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96261	10.3	31.	28.	30.	2.1
96266	12.8	39.	37.	38.	1.4
96269	120.0	63.	70.	67.	4.9
96270	120.0	65.	71.	68.	4.2
96284	120.0	51.	67.	59.	11.3
MEAN	76.6			52.4	
S.D.	59.41			17.39	
N	5			5	

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96280	3	900.	915.	710.	842.	114.3	430.	330.	540.	433.	105.0
96285	3	545.	510.	780.	612.	146.8	420.	640.	470.	510.	115.3
96289	3	655.	515.	320.	497.	168.3	150.	160.	180.	163.	15.3
96290	3	560.	615.	645.	607.	43.1	170.	315.	250.	245.	72.6
96291	3	620.	355.	375.	450.	147.6	515.	555.	325.	465.	122.9
MEAN					601.6					363.2	
S.D.					151.54					150.70	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96280	14.5	54.	49.	52.	3.5
96285	28.6	38.	37.	38.	0.7
96289	21.3	38.	38.	38.	0.0
96290	76.9	33.	31.	32.	1.4
96291	35.6	30.	31.	31.	0.7
MEAN	35.4			38.2	
S.D.	24.52			8.38	
N	5			5	

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
NEUROMUSCULAR OBSERVATIONS

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96263	3	610.	265.	705.	527.	231.5	345.	310.	365.	340.	27.8
96265	3	840.	560.	395.	598.	225.0	305.	480.	205.	330.	139.2
96268	3	505.	630.	740.	625.	117.6	310.	315.	385.	337.	41.9
96272	3	970.	460.	985.	805.	298.9	210.	245.	255.	237.	23.6
96276	3	420.	595.	515.	510.	87.6	245.	360.	295.	300.	57.7
MEAN					613.0					308.8	
S.D.					117.51					43.16	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
NEUROMUSCULAR OBSERVATIONS

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96263	62.1	43.	48.	46.	3.5
96265	40.8	72.	62.	67.	7.1
96268	19.0	59.	64.	62.	3.5
96272	45.7	33.	44.	39.	7.8
96276	18.8	46.	51.	49.	3.5
MEAN	37.3			52.6	
S.D.	18.54			11.59	
N	5			5	

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

NEUROMUSCULAR OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: FEMALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	HINDLIMB EXTENSOR STRENGTH	FORELIMB GRIP STRENGTH (grams)					HINDLIMB GRIP STRENGTH (grams)				
		1	2	3	MEAN	S.D.	1	2	3	MEAN	S.D.
96259	3	490.	285.	540.	438.	135.1	260.	295.	315.	290.	27.8
96260	3	1100.	1010.	680.	930.	221.1	380.	475.	510.	455.	67.3
96273	3	1185.	720.	815.	907.	245.7	495.	370.	730.	532.	182.8
96279	3	470.	620.	385.	492.	119.0	365.	200.	190.	252.	98.3
96281	3	980.	1025.	935.	980.	45.0	510.	555.	380.	482.	90.9
MEAN					749.4					402.2	
S.D.					261.66					123.65	
N					5					5	

OBSERVATION SCORE, UNLESS STATED OTHERWISE

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
NEUROMUSCULAR OBSERVATIONS

TABLE 38
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	ROTAROD PERFORMANCE (seconds)	HINDLIMB FOOTSPLAY (mm)			
		1	2	MEAN	S.D.
96259	19.8	64.	66.	65.	1.4
96260	120.0	41.	36.	39.	3.5
96273	33.3	31.	25.	28.	4.2
96279	120.0	58.	65.	62.	4.9
96281	51.5	38.	26.	32.	8.5
MEAN	68.9			45.2	
S.D.	47.97			17.20	
N	5			5	

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PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
PHYSIOLOGICAL OBSERVATIONS

TABLE 39
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96226	0.2	39.5	351.0
96229	0.4	38.1	383.8
96232	0.5	37.9	324.2
96244	0.3	39.7	297.6
96251	0.5	38.0	298.2
MEAN	0.4	38.6	331.0
S.D.	0.13	0.88	36.83
N	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
PHYSIOLOGICAL OBSERVATIONS

TABLE 39
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96228	0.2	39.4	315.8
96233	0.2	39.8	341.2
96236	0.8	37.6	369.7
96238	2.5	38.5	382.5
96254	0.2	39.8	299.3
MEAN	0.8	39.0	341.7
S.D.	1.00	0.95	35.06
N	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
PHYSIOLOGICAL OBSERVATIONS

TABLE 39
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: MALES

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96241	0.8	38.6	356.4
96245	0.2	39.4	322.7
96248	0.2	39.8	331.3
96250	1.2	38.1	341.1
96256	0.4	38.3	347.8
MEAN	0.6	38.8	339.9
S.D.	0.43	0.73	13.28
N	5	5	5

TABLE 39

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA
PAGE 4

PHYSIOLOGICAL OBSERVATIONS

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
SEX: MALES
TEST PERIOD: WEEK 3

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96225	0.4	38.0	293.7
96237	0.2	39.8	321.2
96242	0.3	39.1	334.6
96246	0.2	39.7	359.3
96252	0.4	37.9	351.5
MEAN	0.3	38.9	332.1
S.D.	0.10	0.91	26.06
N	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
PHYSIOLOGICAL OBSERVATIONS

TABLE 39
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 1
DOSE LEVEL: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96261	0.5	38.8	184.0
96266	0.4	39.1	209.6
96269	0.2	39.7	239.9
96270	0.3	39.9	201.0
96284	0.2	39.9	222.4
MEAN	0.3	39.5	211.4
S.D.	0.13	0.50	21.19
N	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
PHYSIOLOGICAL OBSERVATIONS

TABLE 39
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 2
DOSE LEVEL: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96280	0.5	39.2	195.4
96285	0.5	39.3	202.8
96289	0.2	40.0	216.0
96290	0.2	40.0	232.7
96291	1.1	38.4	222.9
MEAN	0.5	39.4	214.0
S.D.	0.37	0.66	15.04
N	5	5	5

TABLE 39

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

PHYSIOLOGICAL OBSERVATIONS

DOSE GROUP: 3
DOSE LEVEL: 400 MG/KG/DAY
TEST PERIOD: WEEK 3
SEX: FEMALES

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96263	0.2	39.6	183.3
96265	0.6	38.3	209.0
96268	0.2	39.3	195.7
96272	0.4	39.4	235.6
96276	0.2	40.0	218.5
MEAN	0.3	39.3	208.4
S.D.	0.18	0.63	20.21
N	5	5	5

TABLE 39
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL FUNCTIONAL OBSERVATIONAL BATTERY DATA

DOSE GROUP: 4
DOSE LEVEL: 1000 MG/KG/DAY
TEST PERIOD: WEEK 3

SEX: FEMALES

ANIMAL NUMBER	CATALEPSY (seconds)	BODY TEMPERATURE (degrees C)	BODY WEIGHT (grams)
96259	0.2	39.8	201.9
96260	0.5	39.3	201.6
96273	0.4	38.9	243.7
96279	0.2	39.2	212.1
96281	0.5	38.3	196.9
MEAN	0.4	39.1	211.2
S.D.	0.15	0.55	18.97
N	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

MALE GROUP: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96226	827	278	258	84	6	0	6	2	1097	364
96229	771	235	163	32	1	0	0	0	935	267
96232	712	261	330	77	70	7	0	0	1112	345
96244	503	144	129	34	11	1	0	0	643	179
96251	1073	386	448	131	236	69	143	49	1900	635
MEAN	777.	261.	266.	72.	65.	15.	30.	10.	1137.	358.
S.D.	205.8	87.0	129.1	40.9	99.7	30.1	63.3	21.7	466.2	171.2
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

MALE GROUP: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96228	168	47	2	0	256	69	201	52	627	168
96233	572	160	497	139	19	6	0	0	1088	305
96236	548	91	153	0	0	0	51	5	752	96
96238	1062	372	40	9	4	0	0	0	1106	381
96254	733	261	311	61	15	0	8	0	1067	322
MEAN	617.	186.	201.	42.	59.	15.	52.	11.	928.	254.
S.D.	324.0	131.6	204.7	60.0	110.5	30.3	85.9	22.8	222.6	118.0
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

MALE GROUP: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96241	683	212	23	6	0	0	0	0	706	218
96245	387	60	122	31	210	39	149	32	868	162
96248	717	209	424	114	11	2	0	0	1152	325
96250	743	284	255	93	0	0	7	0	1005	377
96256	605	190	243	75	31	15	0	0	879	280
MEAN	627.	191.	213.	64.	50.	11.	31.	6.	922.	272.
S.D.	143.9	81.5	151.3	44.5	90.1	16.8	65.9	14.3	166.7	85.0
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

MALE GROUP: 1000 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96225	737	239	87	23	62	0	2	0	888	262
96237	732	257	83	18	1	0	210	64	1026	339
96242	810	311	411	104	2	0	2	0	1225	415
96246	555	211	257	41	0	0	11	0	823	252
96252	1186	426	322	59	0	0	0	0	1508	485
MEAN	804.	289.	232.	49.	13.	0.	45.	13.	1094.	351.
S.D.	233.3	84.9	144.9	34.7	27.4	0.0	92.3	28.6	278.0	99.9
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

FEMALE GROUP: 0 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96261	895	291	23	3	0	0	183	52	1101	346
96266	857	329	730	258	234	75	104	0	1925	662
96269	1039	435	42	5	14	3	96	36	1191	479
96270	738	339	252	66	389	157	1	0	1380	562
96284	628	269	545	195	2	0	67	21	1242	485
MEAN	831.	333.	318.	105.	128.	47.	90.	22.	1368.	507.
S.D.	156.4	63.9	311.8	115.6	176.5	69.4	65.8	22.7	327.4	116.4
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

FEMALE GROUP: 160 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96280	644	279	44	0	314	80	0	0	1002	359
96285	844	370	335	107	14	0	0	0	1193	477
96289	558	214	167	49	290	75	0	0	1015	338
96290	488	221	214	90	25	0	0	0	727	311
96291	831	338	590	160	121	24	0	0	1542	522
MEAN	673.	284.	270.	81.	153.	36.	0.	0.	1096.	401.
S.D.	160.1	69.3	207.0	60.4	142.7	39.3	0.0	0.0	300.0	92.5
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

FEMALE GROUP: 400 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96263	790	296	379	108	8	0	0	0	1177	404
96265	582	238	155	4	182	65	3	0	922	307
96268	869	367	326	84	39	8	2	0	1236	459
96272	888	350	531	173	299	16	201	69	1919	608
96276	846	329	0	0	0	0	409	192	1255	521
MEAN	795.	316.	278.	74.	106.	18.	123.	52.	1302.	460.
S.D.	124.6	51.0	205.5	73.2	130.7	27.2	181.7	83.7	369.9	114.2
N	5									

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 40
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MOTOR ACTIVITY COUNTS

FEMALE GROUP: 1000 MG/KG/DAY
TEST PERIOD: WEEK 3

ANIMAL	0 TO 15 MINS TOTAL	0 TO 15 MINS AMB	16 TO 30 MINS TOTAL	16 TO 30 MINS AMB	31 TO 45 MINS TOTAL	31 TO 45 MINS AMB	46 TO 60 MINS TOTAL	46 TO 60 MINS AMB	COMBINED TOTAL	COMBINED AMB
96259	855	392	0	0	0	0	0	0	855	392
96260	831	360	247	57	5	0	0	0	1083	417
96273	773	282	308	75	19	1	328	78	1428	436
96279	403	139	14	4	284	106	402	149	1103	398
96281	718	297	203	66	0	0	36	8	957	371
MEAN	716.	294.	154.	40.	62.	21.	153.	47.	1085.	403.
S.D.	182.9	97.6	139.7	35.7	124.6	47.3	195.7	65.8	216.4	24.8
N	5									

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PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 0 MG/KG/DAY		MALES								
96226	7.49	8.96	16.0	51.6	57.6	17.9	31.1	874.	21.6	24.7
96229	9.41	8.50	16.3	52.1	61.3	19.2	31.3	1064.	18.1	24.0
96232	8.01	8.80	17.2	55.6	63.2	19.5	30.9	1079.	21.1	21.1
96244	9.39	8.37	15.7	49.4	59.0	18.8	31.8	988.	18.9	16.0
96251	10.26	8.42	15.8	49.9	59.3	18.8	31.7	968.	19.8	22.8
MEAN	8.91	8.61	16.2	51.7	60.1	18.8	31.4	995.	19.9	21.7
S.D.	1.132	0.257	0.60	2.44	2.19	0.60	0.38	82.5	1.46	3.48
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 0 MG/KG/DAY MALES								
96226	1.3	118.4	17.0	79.0	3.0	1.0	0.0	0.0
96229	1.5	126.9	18.8	77.5	1.1	2.0	0.3	0.3
96232	1.4	126.8	12.9	84.8	0.5	1.2	0.2	0.4
96244	1.6	137.4	10.1	87.0	0.8	1.3	0.3	0.6
96251	1.9	157.7	12.6	84.8	1.0	0.7	0.3	0.7
MEAN	1.5	133.4	14.3	82.6	1.3	1.2	0.2	0.4
S.D.	0.23	15.14	3.54	4.12	0.99	0.48	0.13	0.27
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 0 MG/KG/DAY	MALES							
96226	1.27	5.92	0.22	0.07	0.00	0.00	INCREASE 3-PLT CLUM	2-POL, 1-GPL
96229	1.77	7.29	0.10	0.19	0.03	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96232	1.04	6.79	0.04	0.09	0.01	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96244	0.95	8.17	0.07	0.12	0.03	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96251	1.29	8.69	0.10	0.07	0.03	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.26	7.37	0.11	0.11	0.02	0.04		
S.D.	0.318	1.099	0.068	0.050	0.014	0.026		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 160 MG/KG/DAY		MALES								
96228	7.94	8.60	16.0	51.5	59.8	18.6	31.1	1263.	22.6	23.8
96233	8.82	8.13	15.1	49.5	60.9	18.6	30.6	755.	19.6	25.0
96236	9.03	7.69	15.0	48.4	63.0	19.5	30.9	1173.	16.5	21.2
96238	11.54	7.82	14.8	48.3	61.8	18.9	30.7	1424.	16.4	21.1
96254	8.30	8.51	14.8	48.4	56.9	17.3	30.5	1058.	23.0	26.6
MEAN	9.13	8.15	15.1	49.2	60.5	18.6	30.8	1135.	19.6	23.5
S.D.	1.416	0.404	0.50	1.37	2.32	0.80	0.24	250.8	3.18	2.40
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 160 MG/KG/DAY MALES								
96228	1.0	89.7	8.0	89.3	0.9	0.8	0.2	0.7
96233	1.5	122.4	16.5	78.2	1.2	3.4	0.3	0.4
96236	2.2	171.9	12.9	84.2	0.9	1.0	0.2	0.7
96238	1.9	147.2	10.9	86.6	1.0	0.6	0.3	0.5
96254	1.0	87.6	7.0	91.0	0.7	0.8	0.1	0.4
MEAN	1.5	123.8	11.1	85.9	0.9	1.3	0.2	0.5
S.D.	0.54	36.53	3.84	5.01	0.18	1.17	0.08	0.15
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 160 MG/KG/DAY MALES								
96228	0.64	7.09	0.07	0.07	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96233	1.46	6.90	0.10	0.30	0.03	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96236	1.16	7.61	0.09	0.09	0.02	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96238	1.26	10.00	0.12	0.07	0.04	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96254	0.58	7.55	0.06	0.07	0.01	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.02	7.83	0.09	0.12	0.02	0.05		
S.D.	0.390	1.250	0.024	0.101	0.011	0.018		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 400 MG/KG/DAY MALES										
96241	12.35	7.89	15.5	51.1	64.7	19.7	30.4	808.	20.7	20.4
96245	9.54	8.15	15.5	50.6	62.1	19.1	30.7	1267.	25.8	25.2
96248	13.12	8.55	15.6	50.8	59.4	18.2	30.6	1098.	20.5	23.3
96250	10.92	7.98	15.7	50.4	63.1	19.6	31.1	1224.	18.1	23.1
96256	10.76	8.53	15.8	51.5	60.4	18.5	30.6	921.	19.9	21.8
MEAN	11.34	8.22	15.6	50.9	61.9	19.0	30.7	1064.	21.0	22.8
S.D.	1.409	0.307	0.13	0.43	2.11	0.66	0.26	196.2	2.87	1.79
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 400 MG/KG/DAY MALES								
96241	1.9	147.3	18.1	78.5	1.1	1.3	0.3	0.7
96245	1.3	102.4	6.4	91.7	0.5	0.8	0.2	0.4
96248	1.3	112.1	7.1	89.4	0.6	1.6	0.5	0.8
96250	2.1	170.5	5.2	92.3	0.6	1.1	0.2	0.6
96256	1.2	103.1	13.4	81.7	1.4	2.7	0.2	0.6
MEAN	1.6	127.1	10.0	86.7	0.8	1.5	0.3	0.6
S.D.	0.41	30.42	5.51	6.24	0.39	0.73	0.13	0.15
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 400 MG/KG/DAY	MALES							
96241	2.24	9.70	0.14	0.16	0.04	0.08	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96245	0.61	8.75	0.04	0.07	0.02	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96248	0.93	11.73	0.08	0.21	0.07	0.11	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96250	0.57	10.08	0.06	0.12	0.03	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96256	1.44	8.79	0.15	0.29	0.03	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.16	9.81	0.09	0.17	0.04	0.07		
S.D.	0.698	1.218	0.049	0.085	0.019	0.026		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

TABLE 41 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 10

SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES DAY 28

SPONSOR NO.:05-087

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 1000 MG/KG/DAY MALES										
96225	7.92	8.71	16.0	51.2	58.8	18.4	31.3	1150.	34.1	30.5
96237	8.42	8.00	15.5	48.6	60.8	19.4	31.8	692.	30.1	27.2
96242	12.40	7.82	15.0	46.5	59.4	19.2	32.3	1152.	32.3	29.0
96246	22.80	8.09	14.9	45.6	56.3	18.4	32.6	1535.	41.1	33.8
96252	15.34	8.15	15.2	49.2	60.4	18.7	30.9	983.	28.9	26.2
MEAN	13.38	8.15	15.3	48.2	59.1	18.8	31.8	1102.	33.3	29.3
S.D.	6.082	0.335	0.44	2.23	1.77	0.46	0.70	306.0	4.80	2.99
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 1000 MG/KG/DAY MALES								
96225	1.3	111.1	6.9	89.8	1.5	0.7	0.3	0.8
96237	0.8	64.0	21.9	73.7	0.8	3.1	0.2	0.3
96242	1.8	140.6	14.1	83.3	0.9	0.9	0.2	0.7
96246	1.5	118.9	9.3	88.5	0.6	0.3	0.4	0.9
96252	1.5	125.4	10.9	86.1	1.0	1.1	0.3	0.7
MEAN	1.4	112.0	12.6	84.3	1.0	1.2	0.3	0.7
S.D.	0.37	28.94	5.81	6.41	0.34	1.09	0.08	0.23
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 1000 MG/KG/DAY MALES								
96225	0.55	7.11	0.12	0.05	0.03	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96237	1.84	6.21	0.06	0.26	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96242	1.75	10.33	0.11	0.11	0.02	0.08	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96246	2.12	20.17	0.14	0.07	0.08	0.21	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96252	1.67	13.20	0.15	0.17	0.04	0.11	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.59	11.40	0.12	0.13	0.04	0.10		
S.D.	0.604	5.627	0.035	0.085	0.025	0.069		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 0 MG/KG/DAY		FEMALES								
96261	5.45	7.78	14.4	45.0	57.9	18.5	31.9	876.	11.1	11.4
96266	14.58	7.04	13.4	42.6	60.5	19.0	31.5	998.	12.1	18.9
96269	7.20	7.84	15.1	48.4	61.7	19.3	31.2	662.	12.0	18.1
96270	5.50	7.08	13.1	39.7	56.1	18.5	32.9	748.	12.2	17.7
96284	4.50	7.75	14.9	46.6	60.2	19.3	32.0	920.	13.2	19.0
MEAN	7.45	7.50	14.2	44.5	59.3	18.9	31.9	841.	12.1	17.0
S.D.	4.105	0.401	0.89	3.41	2.25	0.40	0.64	134.9	0.75	3.19
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 0 MG/KG/DAY FEMALES								
96261	1.0	79.9	16.0	81.2	1.0	1.0	0.1	0.5
96266	2.2	153.5	8.2	89.2	0.9	0.5	0.2	0.9
96269	2.0	156.7	29.7	65.1	0.7	3.9	0.1	0.5
96270	1.7	123.7	18.8	77.6	1.2	1.4	0.1	0.9
96284	1.7	134.3	16.5	79.6	0.8	2.6	0.2	0.4
MEAN	1.7	129.6	17.8	78.5	0.9	1.9	0.1	0.6
S.D.	0.45	30.95	7.74	8.71	0.19	1.37	0.05	0.24
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 0 MG/KG/DAY	FEMALES							
96261	0.87	4.42	0.06	0.05	0.01	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96266	1.20	13.01	0.13	0.07	0.03	0.14	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96269	2.14	4.69	0.05	0.28	0.00	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96270	1.03	4.27	0.07	0.08	0.00	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96284	0.74	3.59	0.03	0.12	0.01	0.02	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.20	6.00	0.07	0.12	0.01	0.06		
S.D.	0.555	3.942	0.038	0.093	0.012	0.048		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 160 MG/KG/DAY FEMALES										
96280	7.27	8.19	15.1	48.0	58.7	18.5	31.5	1252.	12.1	13.2
96285	8.61	7.74	15.3	45.9	59.3	19.7	33.3	1004.	11.3	13.2
96289	7.87	7.99	15.8	49.2	61.6	19.7	32.0	1113.	12.3	16.1
96290	7.26	8.44	15.8	51.3	60.8	18.7	30.8	1200.	12.8	17.1
96291	6.94	8.32	15.6	49.4	59.4	18.8	31.6	880.	12.2	17.6
MEAN	7.59	8.14	15.5	48.8	60.0	19.1	31.8	1090.	12.1	15.4
S.D.	0.662	0.277	0.31	1.99	1.20	0.58	0.92	150.3	0.54	2.11
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 160 MG/KG/DAY FEMALES								
96280	1.3	105.6	7.8	89.3	1.4	0.8	0.3	0.4
96285	1.5	118.7	17.3	76.3	1.3	4.5	0.2	0.5
96289	1.3	103.1	14.3	82.7	1.4	0.7	0.3	0.6
96290	1.3	109.7	15.1	80.7	1.3	1.9	0.2	0.7
96291	1.4	116.8	28.1	66.7	0.8	3.8	0.3	0.4
MEAN	1.4	110.8	16.5	79.1	1.2	2.3	0.3	0.5
S.D.	0.09	6.82	7.38	8.38	0.25	1.74	0.05	0.13
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 160 MG/KG/DAY FEMALES								
96280	0.56	6.50	0.10	0.06	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96285	1.49	6.57	0.11	0.39	0.01	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96289	1.13	6.51	0.11	0.06	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96290	1.10	5.86	0.10	0.14	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96291	1.95	4.63	0.06	0.26	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.25	6.01	0.10	0.18	0.02	0.04		
S.D.	0.515	0.826	0.021	0.142	0.004	0.010		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 400 MG/KG/DAY FEMALES										
96263	5.15	7.25	14.0	43.3	59.7	19.3	32.4	1125.	13.2	20.1
96265	8.74	7.98	14.7	46.9	58.7	18.4	31.4	1087.	12.6	17.8
96268	8.45	7.54	14.7	47.1	62.5	19.4	31.1	1114.	12.4	18.9
96272	6.27	7.05	13.1	40.0	56.7	18.6	32.9	1085.	12.1	19.0
96276	11.22	8.07	15.5	50.5	62.6	19.2	30.6	1166.	12.5	17.5
MEAN	7.97	7.58	14.4	45.6	60.0	19.0	31.7	1115.	12.6	18.7
S.D.	2.357	0.445	0.90	4.02	2.53	0.45	0.95	33.1	0.40	1.04
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 400 MG/KG/DAY	FEMALES							
96263	1.1	82.2	11.5	84.2	1.3	2.5	0.3	0.2
96265	1.5	121.5	13.8	83.4	1.0	1.0	0.2	0.5
96268	1.9	142.8	9.4	87.6	1.5	0.6	0.2	0.7
96272	1.8	129.6	40.9	54.9	1.7	2.1	0.1	0.3
96276	2.6	211.9	7.7	88.2	1.5	1.5	0.3	0.8
MEAN	1.8	137.6	16.7	79.7	1.4	1.5	0.2	0.5
S.D.	0.55	47.28	13.74	14.00	0.26	0.78	0.08	0.25
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 400 MG/KG/DAY FEMALES								
96263	0.59	4.34	0.07	0.13	0.01	0.01	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96265	1.21	7.29	0.09	0.09	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96268	0.79	7.40	0.12	0.05	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96272	2.56	3.44	0.10	0.13	0.01	0.02	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96276	0.86	9.89	0.17	0.17	0.03	0.09	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.20	6.47	0.11	0.11	0.02	0.04		
S.D.	0.791	2.596	0.038	0.046	0.008	0.031		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 1000 MG/KG/DAY FEMALES										
96259	5.93	7.60	14.4	44.9	59.1	19.0	32.1	868.	13.9	21.5
96260	12.13	7.74	14.3	44.0	56.9	18.5	32.5	781.	12.8	15.8
96273	10.01	7.66	14.7	43.9	57.4	19.2	33.5	997.	13.4	18.5
96279	8.11	7.96	15.1	46.2	58.1	19.0	32.7	1622.	14.0	20.4
96281	5.66	7.40	15.0	47.8	64.7	20.2	31.3	1341.	13.0	16.1
MEAN	8.37	7.67	14.7	45.4	59.2	19.2	32.4	1122.	13.4	18.5
S.D.	2.747	0.204	0.35	1.65	3.16	0.63	0.81	351.6	0.53	2.53
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 1000 MG/KG/DAY	FEMALES							
96259	1.5	117.3	16.0	82.0	1.0	1.0	0.0	0.0
96260	3.0	232.4	33.7	62.4	0.9	2.3	0.2	0.6
96273	1.4	107.1	11.5	85.2	1.2	1.2	0.2	0.6
96279	1.1	90.3	9.0	88.8	0.8	0.7	0.2	0.6
96281	1.8	135.8	10.8	86.8	1.0	0.3	0.2	0.7
MEAN	1.8	136.6	16.2	81.0	1.0	1.1	0.2	0.5
S.D.	0.74	56.05	10.12	10.71	0.15	0.75	0.09	0.28
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 41 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 1000 MG/KG/DAY FEMALES								
96259	0.95	4.86	0.06	0.06	0.00	0.00	INCREASE 3-PLT CLUM	
	2-CRE, 1-POL							
96260	4.09	7.57	0.11	0.28	0.02	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96273	1.15	8.53	0.12	0.12	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96279	0.73	7.20	0.06	0.05	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
96281	0.61	4.91	0.06	0.02	0.01	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.51	6.61	0.08	0.11	0.01	0.04		
S.D.	1.459	1.651	0.030	0.104	0.009	0.027		
N	5	5	5	5	5	5		

thous/uL = THOUSANDS/MICROLITER

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PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 0 MG/KG/DAY MALES										
96223	7.02	8.14	14.5	46.7	57.4	17.8	31.0	1186.	16.2	19.5
96230	9.70	8.08	14.5	44.5	55.1	18.0	32.6	1360.	CLT	CLT
96235	7.48	8.09	14.3	44.3	54.8	17.7	32.3	907.	16.6	19.9
96247	8.26	7.79	13.9	43.6	56.0	17.8	31.9	999.	19.3	25.8
96249	8.30	8.19	14.7	46.1	56.3	17.9	31.9	1362.	18.7	21.2
MEAN	8.15	8.06	14.4	45.0	55.9	17.8	31.9	1163.	17.7	21.6
S.D.	1.020	0.156	0.30	1.30	1.03	0.11	0.60	207.0	1.53	2.89
N	5	5	5	5	5	5	5	5	4	4

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 0 MG/KG/DAY	MALES							
96223	2.0	163.8	6.0	91.6	0.9	0.6	0.2	0.8
96230	1.6	126.5	18.3	78.4	1.0	1.4	0.2	0.6
96235	2.2	181.8	21.6	74.2	1.9	1.5	0.2	0.6
96247	2.0	152.4	35.5	61.7	1.4	1.0	0.1	0.3
96249	1.7	138.9	12.3	85.0	0.8	0.8	0.3	0.9
MEAN	1.9	152.7	18.7	78.2	1.2	1.1	0.2	0.6
S.D.	0.24	21.49	11.10	11.34	0.45	0.38	0.07	0.23
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: 0 MG/KG/DAY MALES						
96223	0.42	6.43	0.07	0.04	0.01	0.05
96230	1.78	7.61	0.10	0.13	0.02	0.06
96235	1.61	5.55	0.14	0.12	0.01	0.05
96247	2.93	5.09	0.12	0.08	0.01	0.02
96249	1.02	7.05	0.07	0.07	0.02	0.07
MEAN	1.55	6.35	0.10	0.09	0.01	0.05
S.D.	0.938	1.038	0.031	0.037	0.005	0.019
N	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 1000 MG/KG/DAY MALES										
96224	7.42	8.83	16.4	52.1	59.0	18.5	31.4	1466.	22.6	24.2
96231	7.55	8.26	15.1	46.7	56.6	18.3	32.3	1376.	17.0	21.4
96234	9.74	7.60	14.4	43.5	57.2	18.9	33.0	964.	15.8	18.6
96253	5.48	8.39	15.6	47.1	56.2	18.6	33.1	1290.	CLT	CLT
96255	11.29	7.60	14.1	43.3	57.0	18.5	32.5	1162.	CLT	CLT
MEAN	8.30	8.14	15.1	46.5	57.2	18.6	32.5	1252.	18.5	21.4
S.D.	2.253	0.533	0.93	3.57	1.08	0.22	0.68	196.0	3.63	2.80
N	5	5	5	5	5	5	5	5	3	3

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 1000 MG/KG/DAY MALES								
96224	1.9	169.6	10.1	87.2	1.0	0.7	0.2	0.8
96231	2.0	162.7	11.6	86.1	0.9	0.5	0.2	0.6
96234	2.6	194.7	31.1	63.5	2.5	1.6	0.3	1.0
96253	2.0	164.3	9.2	88.4	0.8	1.1	0.2	0.3
96255	2.2	164.7	28.7	67.3	2.1	0.7	0.2	1.0
MEAN	2.1	171.2	18.1	78.5	1.5	0.9	0.2	0.7
S.D.	0.28	13.39	10.80	12.06	0.78	0.44	0.04	0.30
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: 1000 MG/KG/DAY MALES						
96224	0.75	6.46	0.07	0.05	0.01	0.06
96231	0.88	6.50	0.07	0.04	0.01	0.05
96234	3.03	6.19	0.25	0.15	0.02	0.10
96253	0.51	4.85	0.04	0.06	0.01	0.02
96255	3.25	7.60	0.24	0.08	0.02	0.11
MEAN	1.68	6.32	0.13	0.08	0.01	0.07
S.D.	1.338	0.983	0.102	0.044	0.005	0.037
N	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 0 MG/KG/DAY FEMALES										
96262	4.62	7.48	13.9	42.6	56.9	18.6	32.7	862.	13.7	20.9
96267	8.95	7.86	14.7	47.1	59.9	18.7	31.2	1481.	13.3	16.8
96275	8.52	7.73	14.3	44.7	57.8	18.4	31.9	1286.	12.6	18.0
96278	5.98	8.19	14.8	46.7	57.1	18.1	31.7	1106.	13.3	16.5
96283	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	13.0	18.4
MEAN	7.02	7.82	14.4	45.3	57.9	18.5	31.9	1184.	13.2	18.1
S.D.	2.067	0.296	0.41	2.07	1.37	0.26	0.62	263.6	0.41	1.75
N	4	4	4	4	4	4	4	4	5	5

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 0 MG/KG/DAY	FEMALES							
96262	1.6	121.0	22.2	74.0	1.5	1.4	0.1	0.8
96267	2.5	193.0	8.9	88.0	1.1	0.7	0.2	1.2
96275	2.4	181.9	36.0	60.2	1.6	1.1	0.2	0.9
96278	1.3	109.2	6.7	90.5	1.0	1.1	0.2	0.6
96283	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
MEAN	2.0	151.3	18.5	78.2	1.3	1.1	0.2	0.9
S.D.	0.59	42.29	13.56	14.01	0.29	0.29	0.05	0.25
N	4	4	4	4	4	4	4	4

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: 0 MG/KG/DAY	FEMALES					
96262	1.02	3.42	0.07	0.07	0.01	0.04
96267	0.80	7.87	0.10	0.06	0.02	0.11
96275	3.07	5.12	0.14	0.09	0.02	0.08
96278	0.40	5.41	0.06	0.06	0.01	0.03
96283	CLT	CLT	CLT	CLT	CLT	CLT
MEAN	1.32	5.46	0.09	0.07	0.02	0.07
S.D.	1.193	1.834	0.036	0.014	0.006	0.037
N	4	4	4	4	4	4

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 1000 MG/KG/DAY	FEMALES									
96264	7.84	7.31	13.4	40.9	55.9	18.3	32.6	1112.	13.3	17.0
96271	6.16	5.62	10.4	31.5	56.1	18.5	33.0	1209.	13.2	18.6
96277	6.85	6.45	12.3	36.6	56.7	19.0	33.5	1186.	13.6	19.2
96282	4.85	6.04	11.1	33.4	55.3	18.3	33.2	1181.	13.2	17.0
96287	4.10	7.72	14.3	44.6	57.8	18.6	32.1	1115.	13.6	19.2
MEAN	5.96	6.63	12.3	37.4	56.4	18.5	32.9	1161.	13.4	18.2
S.D.	1.505	0.873	1.60	5.37	0.95	0.29	0.54	44.3	0.20	1.12
N	5	5	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 1000 MG/KG/DAY	FEMALES							
96264	2.1	154.1	46.5	48.0	3.3	1.0	0.2	0.9
96271	2.0	114.9	27.6	69.7	1.3	0.6	0.2	0.7
96277	2.5	162.3	15.8	81.8	1.0	0.8	0.1	0.5
96282	1.7	105.2	23.6	72.6	1.3	1.6	0.1	0.8
96287	2.2	169.6	18.0	78.8	1.0	1.6	0.1	0.6
MEAN	2.1	141.2	26.3	70.2	1.6	1.1	0.1	0.7
S.D.	0.29	29.18	12.21	13.30	0.97	0.46	0.05	0.16
N	5	5	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

TABLE 42 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL
GROUP: 1000 MG/KG/DAY FEMALES						
96264	3.65	3.77	0.26	0.08	0.02	0.07
96271	1.70	4.29	0.08	0.04	0.01	0.04
96277	1.09	5.60	0.07	0.05	0.01	0.03
96282	1.15	3.52	0.06	0.08	0.00	0.04
96287	0.74	3.23	0.04	0.06	0.00	0.02
MEAN	1.67	4.08	0.10	0.06	0.01	0.04
S.D.	1.161	0.934	0.090	0.018	0.008	0.019
N	5	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 0 MG/KG/DAY	MALES									
96226	4.3	6.8	2.5	1.71	0.1	17.2	0.2	196.	43.	102.
96229	4.4	6.9	2.5	1.74	0.1	14.3	0.3	168.	39.	98.
96232	4.7	7.0	2.2	2.14	0.1	20.1	0.3	285.	47.	116.
96244	4.3	6.6	2.3	1.84	0.1	11.6	0.2	231.	31.	96.
96251	4.4	6.7	2.3	1.93	0.1	12.9	0.1	165.	36.	96.
MEAN	4.4	6.8	2.4	1.87	0.1	15.2	0.2	209.	39.	102.
S.D.	0.16	0.16	0.13	0.173	0.00	3.43	0.08	50.1	6.2	8.4
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 0 MG/KG/DAY		MALES						
96226	107.	43.	10.6	100.	8.3	4.85	142.	27.
96229	129.	44.	10.7	101.	7.9	4.63	144.	43.
96232	127.	36.	10.4	102.	8.4	4.49	146.	23.
96244	96.	38.	10.9	103.	9.3	4.40	147.	49.
96251	81.	49.	10.8	103.	8.6	4.25	147.	38.
MEAN	108.	42.	10.7	102.	8.5	4.52	145.	36.
S.D.	20.5	5.1	0.19	1.3	0.51	0.229	2.2	10.9
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

TABLE 43 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 160 MG/KG/DAY		MALES								
96228	4.4	7.0	2.6	1.69	0.1	15.4	0.3	266.	65.	118.
96233	4.6	6.7	2.2	2.12	0.1	14.3	0.3	380.	62.	112.
96236	4.4	6.9	2.6	1.71	0.1	12.5	0.3	260.	59.	119.
96238	4.4	6.9	2.6	1.70	0.1	14.1	0.3	264.	42.	90.
96254	4.5	6.6	2.1	2.15	0.1	15.2	0.3	306.	62.	135.
MEAN	4.5	6.8	2.4	1.87	0.1	14.3	0.3	295.	58.	115.
S.D.	0.09	0.16	0.25	0.239	0.00	1.15	0.00	50.9	9.2	16.3
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 160 MG/KG/DAY		MALES						
96228	148.	55.	10.6	102.	7.9	4.97	145.	49.
96233	106.	58.	10.9	105.	7.6	4.47	148.	46.
96236	102.	46.	11.1	102.	9.6	5.20	147.	74.
96238	118.	38.	10.8	105.	8.2	4.78	147.	44.
96254	117.	52.	10.2	105.	8.7	4.92	146.	50.
MEAN	118.	50.	10.7	104.	8.4	4.87	147.	53.
S.D.	18.0	7.9	0.34	1.6	0.78	0.269	1.1	12.2
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 400 MG/KG/DAY		MALES								
96241	4.4	6.9	2.5	1.78	0.0	13.8	0.3	309.	95.	104.
96245	4.3	6.4	2.1	2.06	0.0	15.9	0.2	180.	86.	106.
96248	4.3	6.8	2.5	1.73	0.0	13.9	0.3	336.	78.	103.
96250	4.3	6.4	2.1	2.06	0.1	15.0	0.3	265.	176.	133.
96256	4.5	6.7	2.2	2.10	0.0	14.2	0.3	249.	97.	102.
MEAN	4.4	6.6	2.3	1.95	0.0	14.6	0.3	268.	106.	110.
S.D.	0.09	0.23	0.20	0.176	0.04	0.88	0.04	60.0	39.6	13.2
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 400 MG/KG/DAY		MALES						
96241	128.	57.	11.1	104.	9.3	4.47	149.	50.
96245	111.	47.	10.7	106.	8.4	4.96	149.	36.
96248	115.	68.	10.8	104.	8.3	4.92	147.	53.
96250	114.	48.	10.5	103.	8.2	4.69	145.	33.
96256	103.	41.	11.4	104.	9.5	4.72	151.	89.
MEAN	114.	52.	10.9	104.	8.7	4.75	148.	52.
S.D.	9.0	10.5	0.35	1.1	0.61	0.197	2.3	22.3
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

TABLE 43 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — DAY 28

SPONSOR NO.:05-087

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 1000 MG/KG/DAY	MALES									
96225	4.4	6.3	1.9	2.33	0.1	13.0	0.1	206.	384.	196.
96237	4.3	6.2	1.9	2.28	0.0	12.6	0.2	241.	314.	189.
96242	4.2	6.3	2.1	1.97	0.1	15.0	0.3	354.	463.	209.
96246	4.2	6.4	2.2	1.90	0.2	14.5	0.2	284.	396.	204.
96252	4.1	6.0	1.9	2.23	0.0	11.7	0.3	263.	386.	190.
MEAN	4.2	6.2	2.0	2.14	0.1	13.4	0.2	270.	389.	198.
S.D.	0.11	0.15	0.14	0.194	0.08	1.36	0.08	55.3	52.9	8.7
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 1000 MG/KG/DAY MALES								
96225	81.	58.	10.7	103.	8.8	4.53	147.	72.
96237	96.	33.	10.2	105.	7.9	4.87	145.	41.
96242	100.	36.	10.5	102.	8.5	4.65	142.	41.
96246	134.	53.	10.4	104.	8.6	4.74	144.	74.
96252	111.	37.	10.9	104.	8.7	4.73	146.	84.
MEAN	104.	43.	10.5	104.	8.5	4.70	145.	62.
S.D.	19.7	11.3	0.27	1.1	0.35	0.125	1.9	20.1
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

TABLE 43 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 9

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — DAY 28

SPONSOR NO.:05-087

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 0 MG/KG/DAY FEMALES										
96261	4.5	6.8	2.4	1.89	0.0	12.9	0.2	149.	31.	89.
96266	4.7	6.9	2.2	2.20	0.0	17.5	0.3	131.	42.	103.
96269	4.9	7.5	2.5	1.95	0.0	19.1	0.3	98.	29.	93.
96270	4.7	6.5	1.9	2.47	0.1	17.1	0.2	145.	35.	87.
96284	5.1	7.5	2.4	2.16	0.0	15.9	0.3	140.	32.	94.
MEAN	4.8	7.0	2.3	2.13	0.0	16.5	0.3	133.	34.	93.
S.D.	0.23	0.44	0.24	0.230	0.04	2.32	0.05	20.5	5.1	6.2
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 0 MG/KG/DAY	FEMALES							
96261	102.	76.	10.4	103.	5.9	4.00	141.	41.
96266	117.	74.	10.9	102.	8.1	4.47	144.	37.
96269	122.	61.	11.0	104.	9.1	4.89	146.	36.
96270	102.	61.	10.5	103.	7.4	4.15	144.	48.
96284	98.	73.	10.9	103.	9.0	4.73	147.	35.
MEAN	108.	69.	10.7	103.	7.9	4.45	144.	39.
S.D.	10.6	7.4	0.27	0.7	1.32	0.376	2.3	5.3
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 160 MG/KG/DAY FEMALES										
96280	5.0	7.1	2.1	2.43	0.1	17.5	0.3	123.	40.	94.
96285	4.7	6.9	2.1	2.21	0.0	20.1	0.4	128.	35.	102.
96289	4.8	6.9	2.1	2.28	0.1	15.9	0.3	104.	41.	94.
96290	4.6	7.0	2.4	1.91	0.1	13.9	0.3	123.	41.	85.
96291	4.7	6.9	2.2	2.18	0.0	16.1	0.3	125.	47.	108.
MEAN	4.8	7.0	2.2	2.20	0.1	16.7	0.3	121.	41.	97.
S.D.	0.15	0.09	0.13	0.190	0.05	2.29	0.04	9.5	4.3	8.8
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 160 MG/KG/DAY FEMALES								
96280	128.	53.	11.4	101.	8.4	4.55	146.	55.
96285	104.	75.	10.6	103.	7.4	4.30	144.	58.
96289	113.	66.	11.0	102.	7.4	4.75	145.	47.
96290	120.	77.	10.8	102.	8.2	5.15	145.	31.
96291	102.	57.	11.3	102.	8.6	4.38	145.	39.
MEAN	113.	66.	11.0	102.	8.0	4.63	145.	46.
S.D.	10.9	10.6	0.33	0.7	0.57	0.340	0.7	11.2
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 400 MG/KG/DAY FEMALES										
96263	4.7	6.7	2.0	2.34	0.1	18.8	0.2	152.	71.	102.
96265	4.2	6.4	2.3	1.86	0.0	13.5	0.3	144.	73.	112.
96268	4.4	6.5	2.1	2.07	0.1	16.6	0.3	149.	64.	122.
96272	4.8	7.3	2.5	1.93	0.0	15.0	0.3	123.	78.	99.
96276	4.8	7.0	2.2	2.24	0.2	17.9	0.3	173.	95.	110.
MEAN	4.6	6.8	2.2	2.09	0.1	16.4	0.3	148.	76.	109.
S.D.	0.27	0.37	0.19	0.202	0.08	2.15	0.04	17.9	11.6	9.1
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES

SPONSOR NO.:05-087

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 400 MG/KG/DAY FEMALES								
96263	107.	58.	10.6	106.	7.8	4.37	147.	61.
96265	117.	68.	10.6	103.	7.0	4.67	144.	44.
96268	103.	64.	11.0	104.	7.6	4.58	147.	46.
96272	122.	71.	10.8	103.	6.6	3.88	145.	41.
96276	107.	52.	11.1	104.	8.3	5.18	147.	49.
MEAN	111.	63.	10.8	104.	7.5	4.54	146.	48.
S.D.	7.9	7.7	0.23	1.2	0.67	0.472	1.4	7.7
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 1000 MG/KG/DAY FEMALES										
96259	4.4	6.6	2.3	1.91	0.2	14.0	0.2	176.	133.	134.
96260	4.7	6.7	2.0	2.33	0.1	15.5	0.3	228.	154.	135.
96273	4.2	6.2	2.0	2.14	0.1	14.8	0.3	151.	108.	149.
96279	4.6	6.4	1.9	2.41	0.0	17.3	0.3	179.	176.	134.
96281	4.7	7.1	2.4	1.95	0.1	14.8	0.2	119.	121.	107.
MEAN	4.5	6.6	2.1	2.15	0.1	15.3	0.3	171.	138.	132.
S.D.	0.22	0.34	0.22	0.222	0.07	1.25	0.05	40.1	27.0	15.3
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

TABLE 43 (DAY 28 EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 1000 MG/KG/DAY FEMALES								
96259	92.	72.	10.4	105.	8.3	4.43	145.	51.
96260	119.	56.	10.7	103.	8.4	4.32	144.	38.
96273	94.	54.	10.3	101.	8.8	4.79	142.	54.
96279	93.	52.	11.0	104.	10.2	4.70	148.	62.
96281	99.	80.	11.0	105.	8.8	5.09	148.	99.
MEAN	99.	63.	10.7	104.	8.9	4.67	145.	61.
S.D.	11.3	12.5	0.33	1.7	0.76	0.305	2.6	23.0
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

FINAL REPORT

Volume 2 of 3
(Tables 44-52 and Appendices A-M)

STUDY TITLE

A 28-DAY REPEATED DOSE ORAL (GAVAGE)
TOXICITY STUDY OF [redacted] IN RATS (WITH FUNCTIONAL
OBSERVATIONAL BATTERY AND MOTOR ACTIVITY DETERMINATIONS)

STUDY NUMBER

WIL-187051

STUDY DIRECTOR

[redacted]

STUDY INITIATION DATE

21 September 2005

STUDY COMPLETION DATE

28 June 2006

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

05-087

SPONSOR

[redacted]

TABLES 44 - 52

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 0 MG/KG/DAY		MALES								
96223	4.0	6.6	2.6	1.55	0.1	16.9	0.4	137.	42.	103.
96230	4.2	6.9	2.7	1.57	0.1	13.1	0.3	128.	46.	142.
96235	4.6	7.4	2.8	1.67	0.1	13.1	0.3	184.	40.	123.
96247	4.1	6.5	2.4	1.68	0.1	16.2	0.4	115.	38.	153.
96249	4.1	6.2	2.1	2.00	0.1	18.3	0.3	110.	47.	117.
MEAN	4.2	6.7	2.5	1.69	0.1	15.5	0.3	135.	43.	128.
S.D.	0.23	0.45	0.28	0.181	0.00	2.33	0.05	29.5	3.8	19.9
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 0 MG/KG/DAY		MALES						
96223	115.	55.	10.3	101.	6.7	4.72	142.	39.
96230	134.	72.	10.1	100.	7.0	5.14	141.	54.
96235	115.	71.	10.8	102.	7.5	4.93	144.	98.
96247	123.	40.	9.8	104.	6.8	5.07	143.	38.
96249	140.	48.	10.0	103.	7.2	4.97	144.	38.
MEAN	125.	57.	10.2	102.	7.0	4.97	143.	53.
S.D.	11.3	14.1	0.38	1.6	0.32	0.160	1.3	25.8
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 160 MG/KG/DAY MALES										

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 160 MG/KG/DAY MALES								

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 400 MG/KG/DAY MALES										

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 400 MG/KG/DAY		MALES						

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 1000 MG/KG/DAY MALES										
96224	4.4	6.8	2.4	1.82	0.1	11.2	0.3	150.	41.	97.
96231	4.1	6.2	2.1	1.99	0.1	13.8	0.3	128.	33.	103.
96234	4.4	6.9	2.5	1.74	0.1	13.8	0.3	179.	43.	93.
96253	4.4	6.7	2.4	1.84	0.1	15.4	0.3	179.	36.	97.
96255	4.6	7.1	2.5	1.87	0.1	15.9	0.3	171.	36.	103.
MEAN	4.4	6.7	2.4	1.85	0.1	14.0	0.3	161.	38.	99.
S.D.	0.18	0.34	0.16	0.091	0.00	1.84	0.00	22.1	4.1	4.3
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 1000 MG/KG/DAY MALES								
96224	126.	47.	10.5	101.	6.9	4.71	143.	41.
96231	107.	34.	10.0	105.	7.1	5.18	144.	29.
96234	120.	58.	10.4	102.	7.7	4.99	143.	40.
96253	117.	36.	10.4	105.	6.3	4.81	143.	28.
96255	159.	62.	10.2	101.	6.3	5.19	143.	52.
MEAN	126.	47.	10.3	103.	6.9	4.98	143.	38.
S.D.	19.8	12.6	0.20	2.0	0.59	0.216	0.4	9.9
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 0 MG/KG/DAY FEMALES										
96262	4.7	7.4	2.7	1.73	0.2	16.6	0.4	60.	46.	111.
96267	5.1	7.5	2.3	2.19	0.1	17.1	0.3	71.	31.	88.
96275	4.6	7.4	2.8	1.61	0.1	32.2	0.4	92.	32.	96.
96278	5.0	7.4	2.4	2.11	0.1	21.0	0.4	107.	37.	106.
96283	4.9	7.2	2.4	2.06	0.1	15.5	0.4	106.	27.	75.
MEAN	4.9	7.4	2.5	1.94	0.1	20.5	0.4	87.	35.	95.
S.D.	0.21	0.11	0.22	0.254	0.04	6.87	0.04	21.0	7.3	14.4
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 0 MG/KG/DAY FEMALES								
96262	117.	87.	10.6	102.	6.0	4.86	141.	42.
96267	105.	66.	10.8	104.	5.7	4.68	143.	51.
96275	106.	81.	10.2	101.	6.4	4.09	142.	37.
96278	107.	49.	10.5	104.	7.1	4.48	145.	29.
96283	123.	88.	10.3	102.	5.2	3.90	143.	40.
MEAN	112.	74.	10.5	103.	6.1	4.40	143.	40.
S.D.	8.0	16.6	0.24	1.3	0.72	0.401	1.5	8.0
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 160 MG/KG/DAY FEMALES										

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 160 MG/KG/DAY FEMALES								

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 400 MG/KG/DAY FEMALES										

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 400 MG/KG/DAY FEMALES								

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 1000 MG/KG/DAY FEMALES										
96264	4.7	7.4	2.7	1.74	0.1	19.6	0.4	104.	47.	153.
96271	4.6	7.4	2.7	1.69	0.2	19.6	0.3	63.	38.	99.
96277	4.7	6.7	2.0	2.34	0.1	17.4	0.3	112.	33.	101.
96282	4.4	6.8	2.4	1.86	0.1	18.9	0.3	88.	26.	81.
96287	4.7	7.3	2.6	1.79	0.1	20.1	0.4	114.	39.	129.
MEAN	4.6	7.1	2.5	1.88	0.1	19.1	0.3	96.	37.	113.
S.D.	0.13	0.34	0.29	0.263	0.04	1.05	0.05	21.2	7.8	28.4
N	5	5	5	5	5	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 44 (DAY 42 RECOVERY EVALUATION)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL SERUM CHEMISTRY VALUES

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 1000 MG/KG/DAY FEMALES								
96264	100.	87.	10.8	102.	7.8	5.47	145.	29.
96271	101.	48.	10.3	103.	6.2	5.02	142.	37.
96277	103.	62.	10.4	101.	5.8	4.22	143.	65.
96282	100.	69.	10.1	102.	6.0	4.56	142.	33.
96287	123.	56.	10.1	106.	5.8	4.25	145.	27.
MEAN	105.	64.	10.3	103.	6.3	4.70	143.	38.
S.D.	9.9	14.8	0.29	1.9	0.84	0.536	1.5	15.5
N	5	5	5	5	5	5	5	5

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

PCHEv4.03
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TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96226 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.96	0.563
LIVER	11.40	3.276
KIDNEYS	2.99	0.859
HEART	1.38	0.397
SPLEEN	0.73	0.210
SEMINAL VES/COAG	1.54	0.443
PROSTATE	0.48	0.138
TESTES	3.53	1.014
EPIDIDYMIDES	1.08	0.310
THYMUS	0.4509	0.130
ADRENAL GLANDS	0.0562	0.016
FINAL BODY WT(G)	348.	

NO SIGNIFICANT CHANGES OBSERVED

EPIDIDYMIDES
HEART
LUNGS
SPLEEN
PARATHYROIDS

		GRADE
EPIDIDYMIDES	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL, BILATERAL	1
HEART	MICRO: CARDIOMYOPATHY FOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION	

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	ILEUM	JEJUNUM
	KIDNEYS	LYMPH NODE, MAND	LIVER	LYMPH NODE, MES
	NERVE, SCIATIC	PROSTATE	RECTUM	SPINAL CORD
	STOMACH, GLAN	STOMACH, NON	SEMINAL VESICLES	TESTES
	THYROID GLANDS	PARATHYROIDS	THYMUS	TRACHEA
	URINARY BLADDER			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96229 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.18	0.575
LIVER	11.90	3.140
KIDNEYS	3.28	0.865
HEART	1.34	0.354
SPLEEN	0.76	0.201
SEMINAL VES/COAG	1.90	0.501
PROSTATE	0.62	0.164
TESTES	3.28	0.865
EPIDIDYMIDES	1.05	0.277
THYMUS	0.3564	0.094
ADRENAL GLANDS	0.1046	0.028
FINAL BODY WT(G)	379.	

		GRADE
CECUM	MICRO: INFILTRATE, MONONUCLEAR DIFFUSE, MUCOSA	1
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
TESTES	MICRO: DEGENERATION, SEMINIFEROUS TUBULES MULTIFOCAL, BILATERAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL FOCAL, UNILATERAL	1
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION	
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96229 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	COLON
	DUODENUM	EPIDIDYMIDES	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	NERVE, SCIATIC	PROSTATE
	RECTUM	SPINAL CORD	STOMACH, GLAN	STOMACH, NON
	SPLEEN	SEMINAL VESICLES	PARATHYROIDS	THYMUS
	TRACHEA	URINARY BLADDER		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96232 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.96	0.611
LIVER	9.98	3.109
KIDNEYS	2.76	0.860
HEART	1.16	0.361
SPLEEN	0.59	0.184
SEMINAL VES/COAG	0.99	0.308
PROSTATE	0.61	0.190
TESTES	3.20	0.997
EPIDIDYMIDES	1.03	0.321
THYMUS	0.2986	0.093
ADRENAL GLANDS	0.0616	0.019
FINAL BODY WT(G)	321.	

			GRADE
HEART	MICRO:	CARDIOMYOPATHY FOCAL	1
KIDNEYS	MICRO:	NEPHROPATHY, CHRONIC PROGRESSIVE MULTIFOCAL, UNILATERAL	1
		CYST, MEDULLARY FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO:	PLASMACYTOSIS, MEDULLARY	2
		HEMORRHAGE	1
LUNGS	MICRO:	MINERALIZATION, VASCULAR MULTIFOCAL	1
		MACROPHAGES, ALVEOLAR MULTIFOCAL	1
		INFILTRATE, MONONUCLEAR, PERIVASCULAR MULTIFOCAL	1
SPLEEN	MICRO:	HEMATOPOIESIS, EXTRAMEDULLARY	1
PARATHYROIDS	MICRO:	NOT EXAMINED NOT IN PLANE OF SECTION	
THYMUS	MICRO:	HEMORRHAGE	1
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS, AORTA, STERNUM, FEMUR BRAIN, CECUM, COLON, DUODENUM EPIDIDYMIDES, ESOPHAGUS, EYES, HEART ILEUM, JEJUNUM, KIDNEYS, LYMPH NODE, MAND LIVER, LYMPH NODE, MES, LUNGS, NERVE, SCIATIC PANCREAS, PITUITARY, PROSTATE, RECTUM	

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:05-087 INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96232 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

GRADE

	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	EPIDIDYMIDES	ILEUM
	JEJUNUM	LIVER	LYMPH NODE, MES	NERVE, SCIATIC
	PROSTATE	RECTUM	SPINAL CORD	STOMACH, GLAN
	STOMACH, NON	SEMINAL VESICLES	TESTES	THYROID GLANDS
	TRACHEA	URINARY BLADDER		

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96244 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.03	0.670
LIVER	9.06	2.990
KIDNEYS	2.75	0.908
HEART	1.14	0.376
SPLEEN	0.58	0.191
SEMINAL VES/COAG	1.42	0.469
PROSTATE	0.70	0.231
TESTES	3.67	1.211
EPIDIDYMIDES	1.09	0.360
THYMUS	0.2912	0.096
ADRENAL GLANDS	0.0981	0.032
FINAL BODY WT(G)	303.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
HEART	MICRO: CARDIOMYOPATHY FOCAL	1
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE MULTIFOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
NERVE, SCIATIC	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION; RECUT EXAMINED	
TESTES	MICRO: DEGENERATION, SEMINIFEROUS TUBULES MULTIFOCAL, BILATERAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL MULTIFOCAL, UNILATERAL	1

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	EPIDIDYMIDES	ILEUM

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 7

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96244 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

GRADE

JEJUNUM	LYMPH NODE, MES	LUNGS	PROSTATE
RECTUM	SPINAL CORD	STOMACH, GLAN	STOMACH, NON
SPLEEN	SEMINAL VESICLES	PARATHYROIDS	THYMUS
TRACHEA	URINARY BLADDER		

NOT EXAMINED

MICRO:NERVE, SCIATIC

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96251 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.08	0.712
LIVER	10.15	3.476
KIDNEYS	2.95	1.010
HEART	1.09	0.373
SPLEEN	0.78	0.267
SEMINAL VES/COAG	1.58	0.541
PROSTATE	0.74	0.253
TESTES	3.07	1.051
EPIDIDYMIDES	0.92	0.315
THYMUS	0.4044	0.138
ADRENAL GLANDS	0.0528	0.018
FINAL BODY WT(G)	292.	

NO SIGNIFICANT CHANGES OBSERVED

			GRADE
ADRENAL MEDULLA	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE MEDULLA NOT IN PLANE OF SECTION; RECUT EXAMINED		
EPIDIDYMIDES	MICRO: INFILTRATE, MONONUCLEAR FOCAL, UNILATERAL		1
HEART	MICRO: CARDIOMYOPATHY MULTIFOCAL		1
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL		1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL		1
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY		1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION		

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	ILEUM	JEJUNUM

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96251 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
KIDNEYS	LYMPH NODE, MAND	LYMPH NODE, MES	NERVE, SCIATIC	
PROSTATE	RECTUM	SPINAL CORD	STOMACH, GLAN	
STOMACH, NON	SEMINAL VESICLES	TESTES	THYROID GLANDS	
THYMUS	TRACHEA	URINARY BLADDER		

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96228 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.85	0.605
LIVER	9.97	3.258
KIDNEYS	2.63	0.859
HEART	1.19	0.389
SPLEEN	0.67	0.219
SEMINAL VES/COAG	1.08	0.353
PROSTATE	0.48	0.157
TESTES	3.14	1.026
EPIDIDYMIDES	0.88	0.288
THYMUS	0.2588	0.085
ADRENAL GLANDS	0.0846	0.028
FINAL BODY WT(G)	306.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96233 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.97	0.586
LIVER	9.28	2.762
KIDNEYS	2.88	0.857
HEART	1.29	0.384
SPLEEN	0.63	0.188
SEMINAL VES/COAG	1.56	0.464
PROSTATE	0.47	0.140
TESTES	3.53	1.051
EPIDIDYMIDES	1.11	0.330
THYMUS	0.5767	0.172
ADRENAL GLANDS	0.0641	0.019
FINAL BODY WT(G)	336.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96236 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.05	0.544
LIVER	13.50	3.581
KIDNEYS	3.22	0.854
HEART	1.42	0.377
SPLEEN	0.73	0.194
SEMINAL VES/COAG	1.60	0.424
PROSTATE	0.99	0.263
TESTES	3.28	0.870
EPIDIDYMIDES	0.99	0.263
THYMUS	0.3893	0.103
ADRENAL GLANDS	0.1169	0.031
FINAL BODY WT(G)	377.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96238 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.98	0.513
LIVER	12.59	3.262
KIDNEYS	2.90	0.751
HEART	1.40	0.363
SPLEEN	0.89	0.231
SEMINAL VES/COAG	1.76	0.456
PROSTATE	0.64	0.166
TESTES	3.74	0.969
EPIDIDYMIDES	1.06	0.275
THYMUS	0.5098	0.132
ADRENAL GLANDS	0.0616	0.016
FINAL BODY WT(G)	386.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96254 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.87	0.652
LIVER	8.70	3.031
KIDNEYS	2.72	0.948
HEART	1.10	0.383
SPLEEN	0.52	0.181
SEMINAL VES/COAG	1.33	0.463
PROSTATE	0.59	0.206
TESTES	3.32	1.157
EPIDIDYMIDES	1.01	0.352
THYMUS	0.3236	0.113
ADRENAL GLANDS	0.0479	0.017
FINAL BODY WT(G)	287.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96241 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.85	0.535
LIVER	12.94	3.740
KIDNEYS	3.34	0.965
HEART	1.36	0.393
SPLEEN	0.59	0.171
SEMINAL VES/COAG	2.06	0.595
PROSTATE	0.70	0.202
TESTES	3.36	0.971
EPIDIDYMIDES	0.99	0.286
THYMUS	0.5069	0.147
ADRENAL GLANDS	0.0618	0.018
FINAL BODY WT(G)	346.	

TEETH
NO SIGNIFICANT
CHANGES OBSERVED

				GRADE
GROSS: MALALIGNED				P
UPPER INCISOR, BILATERAL; CEO MALALIGNED				
MICRO: NO SIGNIFICANT CHANGES OBSERVED				
MACROSCOPIC MALALIGNMENT UNCONFIRMED				
GROSS: ADRENAL GLANDS	AORTA	STERNUM	FEMUR	
BRAIN	CECUM	COLON	DUODENUM	
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART	
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC	
PANCREAS	PITUITARY	PROSTATE	RECTUM	
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	
SKIN	SPLEEN	SEMINAL VESICLES	TESTES	
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER	
MICRO: TEETH				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96245 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.87	0.597
LIVER	11.46	3.661
KIDNEYS	2.90	0.927
HEART	1.17	0.374
SPLEEN	0.59	0.188
SEMINAL VES/COAG	1.17	0.374
PROSTATE	0.56	0.179
TESTES	3.43	1.096
EPIDIDYMIDES	1.03	0.329
THYMUS	0.3111	0.099
ADRENAL GLANDS	0.0663	0.021
FINAL BODY WT(G)	313.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 17

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96248 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.83	0.572
LIVER	10.91	3.409
KIDNEYS	2.81	0.878
HEART	1.20	0.375
SPLEEN	0.54	0.169
SEMINAL VES/COAG	1.00	0.312
PROSTATE	0.54	0.169
TESTES	2.87	0.897
EPIDIDYMIDES	0.87	0.272
THYMUS	0.6404	0.200
ADRENAL GLANDS	0.0452	0.014
FINAL BODY WT(G)	320.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE				
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96250 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.87	0.534
LIVER	13.23	3.780
KIDNEYS	2.97	0.849
HEART	1.25	0.357
SPLEEN	0.59	0.169
SEMINAL VES/COAG	1.20	0.343
PROSTATE	0.83	0.237
TESTES	3.20	0.914
EPIDIDYMIDES	0.95	0.271
THYMUS	0.4086	0.117
ADRENAL GLANDS	0.0539	0.015
FINAL BODY WT(G)	350.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE				
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96256 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.83	0.530
LIVER	10.30	2.986
KIDNEYS	3.06	0.887
HEART	1.22	0.354
SPLEEN	0.68	0.197
SEMINAL VES/COAG	1.32	0.383
PROSTATE	0.54	0.157
TESTES	3.02	0.875
EPIDIDYMIDES	0.91	0.264
THYMUS	0.4313	0.125
ADRENAL GLANDS	0.0694	0.020
FINAL BODY WT(G)	345.	

		GRADE
JEJUNUM	GROSS: DIVERTICULUM ONE, 5 X 3 X 3 MM	P
JEJUNUM	MICRO: DIVERTICULUM CORRESPONDS TO THE MACROSCOPIC DIVERTICULUM	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS: ADRENAL GLANDS, AORTA, STERNUM, FEMUR; BRAIN, CECUM, COLON, DUODENUM; EPIDIDYMIDES, ESOPHAGUS, EYES, HEART; ILEUM, KIDNEYS, LYMPH NODE, MAND, LIVER; LYMPH NODE, MES, LUNGS, NERVE, SCIATIC, PANCREAS; PITUITARY, PROSTATE, RECTUM, SPINAL CORD; SAL. GLAND MAND, STOMACH, SKELETAL MUSCLE, SKIN; SPLEEN, SEMINAL VESICLES, TESTES, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96225 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.02	0.692
LIVER	9.55	3.271
KIDNEYS	2.70	0.925
HEART	0.96	0.329
SPLEEN	0.54	0.185
SEMINAL VES/COAG	1.39	0.476
PROSTATE	0.70	0.240
TESTES	3.01	1.031
EPIDIDYMIDES	1.02	0.349
THYMUS	0.4778	0.164
ADRENAL GLANDS	0.0490	0.017
FINAL BODY WT(G)	292.	

		GRADE
EPIDIDYMIDES	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL, UNILATERAL	1
	LUMINAL DEBRIS, CELLULAR UNILATERAL	1
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
TESTES	MICRO: DEGENERATION, SEMINIFEROUS TUBULES MULTIFOCAL, UNILATERAL	2
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL FOCAL, UNILATERAL	1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION	

NO SIGNIFICANT CHANGES OBSERVED

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM

ANIMAL NO. 96225 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	NERVE, SCIATIC	PROSTATE
	RECTUM	SPINAL CORD	STOMACH, GLAN	STOMACH, NON
	SPLEEN	SEMINAL VESICLES	THYMUS	TRACHEA
	URINARY BLADDER			

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96237 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.92	0.611
LIVER	11.30	3.599
KIDNEYS	3.27	1.041
HEART	1.22	0.389
SPLEEN	0.62	0.197
SEMINAL VES/COAG	1.40	0.446
PROSTATE	0.68	0.217
TESTES	2.94	0.936
EPIDIDYMIDES	1.01	0.322
THYMUS	0.2918	0.093
ADRENAL GLANDS	0.0690	0.022
FINAL BODY WT(G)	314.	

EPIDIDYMIDES
LYMPH NODE, MAND
LIVER
PARATHYROIDS
THYMUS
NO SIGNIFICANT
CHANGES OBSERVED

					GRADE
MICRO:	INFILTRATE, MONONUCLEAR FOCAL, UNILATERAL				1
MICRO:	HEMORRHAGE				1
MICRO:	INFLAMMATION, SUBACUTE MULTIFOCAL				1
MICRO:	NOT EXAMINED NOT IN PLANE OF SECTION				
MICRO:	HEMORRHAGE				1
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR	
	BRAIN	CECUM	COLON	DUODENUM	
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART	
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC	
	PANCREAS	PITUITARY	PROSTATE	RECTUM	
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES	
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN	
	FEMUR	MARROW, FEMUR	BRAIN	CECUM	
	COLON	DUODENUM	HEART	ILEUM	
	JEJUNUM	KIDNEYS	LYMPH NODE, MES	LUNGS	
	NERVE, SCIATIC	PROSTATE	RECTUM	SPINAL CORD	
	STOMACH, GLAN	STOMACH, NON	SPLEEN	SEMINAL VESICLES	
	TESTES	THYROID GLANDS	TRACHEA	URINARY BLADDER	

NOT EXAMINED
MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96242 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.93	0.583
LIVER	11.80	3.565
KIDNEYS	2.85	0.861
HEART	1.40	0.423
SPLEEN	0.69	0.208
SEMINAL VES/COAG	1.55	0.468
PROSTATE	0.79	0.239
TESTES	3.24	0.979
EPIDIDYMIDES	0.96	0.290
THYMUS	0.4447	0.134
ADRENAL GLANDS	0.0620	0.019
FINAL BODY WT(G)	331.	

LYMPH NODE, MAND
LIVER
LUNGS
SPLEEN
PARATHYROIDS
NO SIGNIFICANT CHANGES OBSERVED

		GRADE
MICRO:	PLASMACYTOSIS, MEDULLARY	1
	HEMORRHAGE	1
MICRO:	INFLAMMATION, SUBACUTE MULTIFOCAL	1
MICRO:	MINERALIZATION, VASCULAR MULTIFOCAL	1
MICRO:	HEMATOPOIESIS, EXTRAMEDULLARY	1
MICRO:	NOT EXAMINED NOT IN PLANE OF SECTION	

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	EPIDIDYMIDES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MES
	NERVE, SCIATIC	PROSTATE	RECTUM	SPINAL CORD
	STOMACH, GLAN	STOMACH, NON	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

NOT EXAMINED
MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 24

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96246 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.90	0.537
LIVER	13.98	3.949
KIDNEYS	3.01	0.850
HEART	1.18	0.333
SPLEEN	0.79	0.223
SEMINAL VES/COAG	1.81	0.511
PROSTATE	0.57	0.161
TESTES	2.81	0.794
EPIDIDYMIDES	0.97	0.274
THYMUS	0.3234	0.091
ADRENAL GLANDS	0.0753	0.021
FINAL BODY WT(G)	354.	

		GRADE
EPIDIDYMIDES	MICRO: INFILTRATE, MONONUCLEAR FOCAL, UNILATERAL	1
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE FOCAL, UNILATERAL	1
	CYST, MEDULLARY FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: HEMORRHAGE	3
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL FOCAL, UNILATERAL	1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION	
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 25

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96246 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

GRADE

MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	NERVE, SCIATIC	PROSTATE
	RECTUM	SPINAL CORD	STOMACH, GLAN	STOMACH, NON
	SPLEEN	SEMINAL VESICLES	TESTES	THYMUS
	TRACHEA	URINARY BLADDER		

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 26

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96252 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.87	0.524
LIVER	11.91	3.336
KIDNEYS	3.16	0.885
HEART	1.34	0.375
SPLEEN	0.65	0.182
SEMINAL VES/COAG	1.68	0.471
PROSTATE	0.63	0.176
TESTES	2.87	0.804
EPIDIDYMIDES	0.99	0.277
THYMUS	0.4979	0.139
ADRENAL GLANDS	0.0778	0.022
FINAL BODY WT(G)	357.	

		GRADE
EPIDIDYMIDES	MICRO: INFILTRATE, MONONUCLEAR FOCAL, UNILATERAL	1
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE MULTIFOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: HEMORRHAGE	1
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
LYMPH NODE, MES	MICRO: INFLAMMATION, GRANULOMATOUS MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
	MACROPHAGES, ALVEOLAR FOCAL	1
TESTES	MICRO: DEGENERATION, SEMINIFEROUS TUBULES MULTIFOCAL, BILATERAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL MULTIFOCAL, UNILATERAL	1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION	
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, AORTA, STERNUM, FEMUR BRAIN, CECUM, COLON, DUODENUM EPIDIDYMIDES, ESOPHAGUS, EYES, HEART	

ANIMAL NO. 96252 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	NERVE, SCIATIC	PROSTATE	RECTUM
	SPINAL CORD	STOMACH, GLAN	STOMACH, NON	SPLEEN
	SEMINAL VESICLES	THYMUS	TRACHEA	URINARY BLADDER

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96261 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.82	1.052
LIVER	6.31	3.647
KIDNEYS	1.69	0.977
HEART	0.90	0.520
SPLEEN	0.36	0.208
UTERUS	0.47	0.272
OVARIES/OVIDUCTS	0.1221	0.071
THYMUS	0.3068	0.177
ADRENAL GLANDS	0.0648	0.037
FINAL BODY WT(G)	173.	

			GRADE
CECUM	MICRO:	INFILTRATE, MONONUCLEAR	1
		DIFFUSE, MUCOSA	
KIDNEYS	GROSS:	CYST(S)	P
		FEW, PINPOINT TO 1 MM IN DIAMETER, IN CORTEX, LEFT	
KIDNEYS	MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
		MACROSCOPIC CYSTS UNCONFIRMED	
LIVER	MICRO:	INFLAMMATION, SUBACUTE	1
		MULTIFOCAL	
LUNGS	MICRO:	MACROPHAGES, ALVEOLAR	1
		MULTIFOCAL	
		INFLAMMATION, SUBACUTE	1
		FOCAL	
		INFILTRATE, EOSINOPHIL, PERIVASCULAR	1
		MULTIFOCAL	
SPLEEN	MICRO:	HEMATOPOIESIS, EXTRAMEDULLARY	1
THYROID GLANDS	MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
		ONE LOBE NOT IN PLANE OF SECTION; RECUT EXAMINED	
PARATHYROIDS	MICRO:	NOT EXAMINED	
		NOT IN PLANE OF SECTION	

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LYMPH NODE, MAND	LIVER	LYMPH NODE, MES

ANIMAL NO. 96261 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
	LUNGS	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	THYROID GLANDS	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	COLON
	DUODENUM	HEART	ILEUM	JEJUNUM
	KIDNEYS	LYMPH NODE, MAND	LYMPH NODE, MES	MAMMARY GLAND
	NERVE, SCIATIC	OVIDUCTS	OVARIES	RECTUM
	SPINAL CORD	STOMACH, GLAN	STOMACH, NON	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		

NOT EXAMINED

MICRO: PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96266 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.76	0.876
LIVER	7.54	3.751
KIDNEYS	1.75	0.871
HEART	0.86	0.428
SPLEEN	0.55	0.274
UTERUS	0.47	0.234
OVARIES/OVIDUCTS	0.1600	0.080
THYMUS	0.6682	0.332
ADRENAL GLANDS	0.0671	0.033
FINAL BODY WT(G)	201.	

		GRADE
ADRENAL MEDULLA	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE MEDULLA NOT IN PLANE OF SECTION; RECUT EXAMINED	
HEART	MICRO: CARDIOMYOPATHY	1
	FOCAL	
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE	1
	MULTIFOCAL, UNILATERAL	
	MINERALIZATION, TUBULAR	1
	MULTIFOCAL, UNILATERAL	
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	1
LIVER	MICRO: INFLAMMATION, SUBACUTE	1
	MULTIFOCAL	
LUNGS	MICRO: MINERALIZATION, VASCULAR	1
	MULTIFOCAL	
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
PARATHYROIDS	MICRO: NOT EXAMINED	
	NOT IN PLANE OF SECTION	
LYMPH NODE, ILI	GROSS: ENLARGED	P
	BILATERAL	
LYMPH NODE, ILI	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	MACROSCOPIC OBSERVATION, ENLARGED, UNCONFIRMED	
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM

ANIMAL NO. 96266 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	ILEUM	JEJUNUM
	LYMPH NODE, MES	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	RECTUM	SPINAL CORD	STOMACH, GLAN
	STOMACH, NON	THYROID GLANDS	THYMUS	TRACHEA
	URINARY BLADDER	UTERUS	VAGINA	CERVIX
	LYMPH NODE, ILI			

NOT EXAMINED
MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96269 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.91	0.816
LIVER	9.07	3.876
KIDNEYS	2.03	0.868
HEART	0.95	0.406
SPLEEN	0.54	0.231
UTERUS	0.46	0.197
OVARIES/OVIDUCTS	0.1536	0.066
THYMUS	0.4405	0.188
ADRENAL GLANDS	0.0751	0.032
FINAL BODY WT(G)	234.	

		GRADE
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE MULTIFOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	1
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
	VACUOLATION, HEPATOCELLULAR, PERIPORTAL MULTIFOCAL	1
OVARIES	GROSS: CYST(S) ONE, 3 MM IN DIAMETER, RED FLUID FILLED, LEFT; ONE, 2 MM IN DIAMETER, RED FLUID FILLED, RIGHT	P
OVARIES	MICRO: NO SIGNIFICANT CHANGES OBSERVED MACROSCOPIC CYSTS UNCONFIRMED	
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION	
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	PANCREAS	PITUITARY	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	THYROID GLANDS	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96269 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
FEMUR	MARROW, FEMUR	BRAIN	CECUM	
COLON	DUODENUM	HEART	ILEUM	
JEJUNUM	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	
NERVE, SCIATIC	OVIDUCTS	OVARIES	RECTUM	
SPINAL CORD	STOMACH, GLAN	STOMACH, NON	THYROID GLANDS	
THYMUS	TRACHEA	URINARY BLADDER	UTERUS	
VAGINA	CERVIX			

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 34

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96270 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.85	0.944
LIVER	6.98	3.561
KIDNEYS	2.00	1.020
HEART	0.85	0.434
SPLEEN	0.45	0.230
UTERUS	0.47	0.240
OVARIES/OVIDUCTS	0.1243	0.063
THYMUS	0.4169	0.213
ADRENAL GLANDS	0.0581	0.030
FINAL BODY WT(G)	196.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
	HEMORRHAGE	1
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION	
TRACHEA	MICRO: INFILTRATE, MONONUCLEAR DIFFUSE, SUBMUCOSA	1

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	LUNGS	MAMMARY GLAND
	NERVE, SCIATIC	OVIDUCTS	OVARIES	RECTUM
	SPINAL CORD	STOMACH, GLAN	STOMACH, NON	THYROID GLANDS

ANIMAL NO. 96270 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

	GRADE
THYMUS	
CERVIX	
URINARY BLADDER	
UTERUS	
VAGINA	

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96284 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.93	0.928
LIVER	7.72	3.712
KIDNEYS	2.14	1.029
HEART	0.92	0.442
SPLEEN	0.45	0.216
UTERUS	0.57	0.274
OVARIES/OVIDUCTS	0.1340	0.064
THYMUS	0.4433	0.213
ADRENAL GLANDS	0.0623	0.030
FINAL BODY WT(G)	208.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
KIDNEYS	MICRO: MINERALIZATION, TUBULAR MULTIFOCAL, BILATERAL	1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	1
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION	

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	RECTUM	SPINAL CORD
	STOMACH, GLAN	STOMACH, NON	THYROID GLANDS	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA

ANIMAL NO. 96284 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

	GRADE
CERVIX	
NOT EXAMINED	
MICRO:PARATHYROIDS	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96280 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.83	0.958
LIVER	6.68	3.497
KIDNEYS	1.70	0.890
HEART	0.71	0.372
SPLEEN	0.44	0.230
UTERUS	0.29	0.152
OVARIES/OVIDUCTS	0.0969	0.051
THYMUS	0.2981	0.156
ADRENAL GLANDS	0.0562	0.029
FINAL BODY WT(G)	191.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96285 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.73	0.901
LIVER	7.10	3.698
KIDNEYS	1.59	0.828
HEART	0.88	0.458
SPLEEN	0.42	0.219
UTERUS	0.42	0.219
OVARIES/OVIDUCTS	0.1477	0.077
THYMUS	0.4632	0.241
ADRENAL GLANDS	0.0706	0.037
FINAL BODY WT(G)	192.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, STERNUM, FEMUR; BRAIN, CECUM, COLON, DUODENUM; ESOPHAGUS, EYES, HEART, ILEUM; JEJUNUM, KIDNEYS, LYMPH NODE, MAND, LIVER; LYMPH NODE, MES, LUNGS, MAMMARY GLAND, NERVE, SCIATIC; OVIDUCTS, OVARIES, PANCREAS, PITUITARY; RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH; SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER, UTERUS; VAGINA, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96289 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.94	0.907
LIVER	8.95	4.182
KIDNEYS	1.98	0.925
HEART	0.93	0.435
SPLEEN	0.46	0.215
UTERUS	0.43	0.201
OVARIES/OVIDUCTS	0.1389	0.065
THYMUS	0.4549	0.213
ADRENAL GLANDS	0.0784	0.037
FINAL BODY WT(G)	214.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, STERNUM, FEMUR; BRAIN, CECUM, COLON, DUODENUM; ESOPHAGUS, EYES, HEART, ILEUM; JEJUNUM, KIDNEYS, LYMPH NODE, MAND, LIVER; LYMPH NODE, MES, LUNGS, MAMMARY GLAND, NERVE, SCIATIC; OVIDUCTS, OVARIES, PANCREAS, PITUITARY; RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH; SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER, UTERUS; VAGINA, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96290 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	1.76	0.775	
LIVER	8.44	3.718	
KIDNEYS	2.20	0.969	
HEART	0.94	0.414	
SPLEEN	0.52	0.229	
UTERUS	0.40	0.176	
OVARIES/OVIDUCTS	0.1347	0.059	
THYMUS	0.3670	0.162	
ADRENAL GLANDS	0.0737	0.032	
FINAL BODY WT(G)	227.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96291 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.92	0.928
LIVER	7.57	3.657
KIDNEYS	1.87	0.903
HEART	0.86	0.415
SPLEEN	0.44	0.213
UTERUS	0.31	0.150
OVARIES/OVIDUCTS	0.1205	0.058
THYMUS	0.3096	0.150
ADRENAL GLANDS	0.0707	0.034
FINAL BODY WT(G)	207.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, STERNUM, FEMUR; BRAIN, CECUM, COLON, DUODENUM; ESOPHAGUS, EYES, HEART, ILEUM; JEJUNUM, KIDNEYS, LYMPH NODE, MAND, LIVER; LYMPH NODE, MES, LUNGS, MAMMARY GLAND, NERVE, SCIATIC; OVIDUCTS, OVARIES, PANCREAS, PITUITARY; RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH; SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER, UTERUS; VAGINA, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96263 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	1.69	0.939	
LIVER	7.35	4.083	
KIDNEYS	1.83	1.017	
HEART	0.88	0.489	
SPLEEN	0.38	0.211	
UTERUS	0.35	0.194	
OVARIES/OVIDUCTS	0.1275	0.071	
THYMUS	0.2949	0.164	
ADRENAL GLANDS	0.0625	0.035	
FINAL BODY WT(G)	180.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96265 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.83	0.906
LIVER	7.98	3.950
KIDNEYS	1.95	0.965
HEART	0.80	0.396
SPLEEN	0.51	0.252
UTERUS	0.74	0.366
OVARIES/OVIDUCTS	0.1060	0.052
THYMUS	0.3678	0.182
ADRENAL GLANDS	0.0831	0.041
FINAL BODY WT(G)	202.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, STERNUM, FEMUR; BRAIN, CECUM, COLON, DUODENUM; ESOPHAGUS, EYES, HEART, ILEUM; JEJUNUM, KIDNEYS, LYMPH NODE, MAND, LIVER; LYMPH NODE, MES, LUNGS, MAMMARY GLAND, NERVE, SCIATIC; OVIDUCTS, OVARIES, PANCREAS, PITUITARY; RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH; SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER, UTERUS; VAGINA, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96268 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.80	0.942
LIVER	6.91	3.618
KIDNEYS	1.75	0.916
HEART	0.81	0.424
SPLEEN	0.43	0.225
UTERUS	0.81	0.424
OVARIES/OVIDUCTS	0.1150	0.060
THYMUS	0.5116	0.268
ADRENAL GLANDS	0.0670	0.035
FINAL BODY WT(G)	191.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96272 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.82	0.791
LIVER	8.79	3.822
KIDNEYS	2.29	0.996
HEART	1.03	0.448
SPLEEN	0.48	0.209
UTERUS	1.11	0.483
OVARIES/OVIDUCTS	0.1504	0.065
THYMUS	0.2830	0.123
ADRENAL GLANDS	0.0950	0.041
FINAL BODY WT(G)	230.	

		GRADE
UTERUS	GROSS: CONTENTS, CLEAR FLUID BOTH HORNS	P
UTERUS	MICRO: DILATATION CORRESPONDS TO THE MACROSCOPIC CLEAR FLUID CONTENTS	2
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	VAGINA
CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96276 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.82	0.871
LIVER	8.13	3.890
KIDNEYS	2.00	0.957
HEART	0.88	0.421
SPLEEN	0.57	0.273
UTERUS	0.57	0.273
OVARIES/OVIDUCTS	0.1623	0.078
THYMUS	0.4811	0.230
ADRENAL GLANDS	0.0559	0.027
FINAL BODY WT(G)	209.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

ANIMAL NO. 96259 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.84	0.953
LIVER	7.57	3.922
KIDNEYS	1.96	1.016
HEART	0.85	0.440
SPLEEN	0.47	0.244
UTERUS	0.57	0.295
OVARIES/OVIDUCTS	0.1086	0.056
THYMUS	0.3147	0.163
ADRENAL GLANDS	0.0753	0.039
FINAL BODY WT(G)	193.	

NO SIGNIFICANT CHANGES OBSERVED

				GRADE
KIDNEYS	MICRO: MINERALIZATION, TUBULAR MULTIFOCAL, BILATERAL			1
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY			2
LIVER	MICRO: INFLAMMATION, SUBACUTE MULTIFOCAL			1
LUNGS	MICRO: INFILTRATE, EOSINOPHIL, PERIVASCULAR MULTIFOCAL			1
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY			1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL MULTIFOCAL, BILATERAL			1
PARATHYROIDS	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION			

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	MAMMARY GLAND	NERVE, SCIATIC

ANIMAL NO. 96259 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
OVIDUCTS	OVARIES	RECTUM	SPINAL CORD	
STOMACH, GLAN	STOMACH, NON	THYMUS	TRACHEA	
URINARY BLADDER	UTERUS	VAGINA	CERVIX	

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96260 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.84	0.906
LIVER	7.79	3.837
KIDNEYS	1.85	0.911
HEART	1.09	0.537
SPLEEN	0.48	0.236
UTERUS	0.57	0.281
OVARIES/OVIDUCTS	0.1266	0.062
THYMUS	0.2793	0.138
ADRENAL GLANDS	0.0794	0.039
FINAL BODY WT(G)	203.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
KIDNEYS	MICRO: MINERALIZATION, TUBULAR	1
	MULTIFOCAL, BILATERAL	
	NEPHROPATHY, CHRONIC PROGRESSIVE	1
	MULTIFOCAL, BILATERAL	
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
LIVER	MICRO: INFLAMMATION, SUBACUTE	1
	MULTIFOCAL	
SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	1
	FOCAL, BILATERAL	
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION	

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	LUNGS	MAMMARY GLAND

TABLE 45 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96260 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

GRADE

NERVE, SCIATIC	OVIDUCTS	OVARIES	RECTUM	
SPINAL CORD	STOMACH, GLAN	STOMACH, NON	PARATHYROIDS	
THYMUS	TRACHEA	URINARY BLADDER	UTERUS	
VAGINA	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 52

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96273 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.75	0.726	KIDNEYS	MICRO: NEPHROPATHY, CHRONIC PROGRESSIVE	1
LIVER	9.17	3.805		FOCAL, UNILATERAL	
KIDNEYS	2.10	0.871	LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
HEART	0.96	0.398	LIVER	MICRO: INFLAMMATION, SUBACUTE	1
SPLEEN	0.70	0.290		MULTIFOCAL	
UTERUS	0.46	0.191		HEMATOPOIESIS, EXTRAMEDULLARY	1
OVARIES/OVIDUCTS	0.1252	0.052		FOCAL	
THYMUS	0.3587	0.149	LUNGS	MICRO: INFILTRATE, EOSINOPHIL, PERIVASCULAR	1
ADRENAL GLANDS	0.0946	0.039		MULTIFOCAL	
FINAL BODY WT(G)	241.			MINERALIZATION, VASCULAR	1
				FOCAL	
			STOMACH, GLAN	MICRO: INFILTRATE, EOSINOPHIL	1
				FOCALLY EXTENSIVE, MUCOSA AND SUBMUCOSA	
			SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
			THYROID GLANDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
				ONE LOBE NOT IN PLANE OF SECTION; RECUT EXAMINED	
			PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
				ONE NOT IN PLANE OF SECTION	
			THYMUS	MICRO: HEMORRHAGE	1
				HYPERPLASIA, EPITHELIAL	1
				FOCAL	
			NO SIGNIFICANT CHANGES OBSERVED	GROSS:ADRENAL GLANDS AORTA STERNUM FEMUR	

ANIMAL NO. 96273 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MES	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	RECTUM	SPINAL CORD
	STOMACH, NON	THYROID GLANDS	PARATHYROIDS	TRACHEA
	URINARY BLADDER	UTERUS	VAGINA	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96279 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.82	0.901	KIDNEYS	MICRO: CAST, HYALINE	1
LIVER	7.52	3.723		FOCAL, UNILATERAL	
KIDNEYS	1.71	0.847	LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	1
HEART	0.83	0.411	LIVER	MICRO: INFLAMMATION, SUBACUTE	1
SPLEEN	0.50	0.248		MULTIFOCAL	
UTERUS	0.34	0.168	LYMPH NODE, MES	MICRO: HISTIOCYTOSIS, SINUS	1
OVARIES/OVIDUCTS	0.1032	0.051	LUNGS	MICRO: MINERALIZATION, VASCULAR	1
THYMUS	0.3869	0.192		MULTIFOCAL	
ADRENAL GLANDS	0.0705	0.035		INFILTRATE, EOSINOPHIL, PERIVASCULAR	1
FINAL BODY WT(G)	202.			MULTIFOCAL	
			SPLEEN	MICRO: HEMATOPOIESIS, EXTRAMEDULLARY	1
			PARATHYROIDS	MICRO: NOT EXAMINED	
				NOT IN PLANE OF SECTION	
			THYMUS	MICRO: HYPERPLASIA, EPITHELIAL	1
				FOCAL	
			NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

TABLE 45 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 96279 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

				GRADE
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	RECTUM	SPINAL CORD	STOMACH, GLAN
	STOMACH, NON	THYROID GLANDS	TRACHEA	URINARY BLADDER
	UTERUS	VAGINA	CERVIX	

NOT EXAMINED

MICRO: PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

TABLE 45 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96281 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.78	0.962
LIVER	7.88	4.259
KIDNEYS	1.76	0.951
HEART	0.76	0.411
SPLEEN	0.45	0.243
UTERUS	0.76	0.411
OVARIES/OVIDUCTS	0.1261	0.068
THYMUS	0.3824	0.207
ADRENAL GLANDS	0.0723	0.039
FINAL BODY WT(G)	185.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
LYMPH NODE, MAND	MICRO: PLASMACYTOSIS, MEDULLARY	2
LIVER	MICRO: INFLAMMATION, SUBACUTE	1
	MULTIFOCAL	
LUNGS	MICRO: INFILTRATE, EOSINOPHIL, PERIVASCULAR	1
	MULTIFOCAL	
NERVE, SCIATIC	MICRO: NOT EXAMINED	
	SECTION INADEQUATE; RECUT EXAMINED	
STOMACH, GLAN	MICRO: DILATATION, GLANDULAR	1
	MULTIFOCAL	
PARATHYROIDS	MICRO: NOT EXAMINED	
	NOT IN PLANE OF SECTION	
UTERUS	MICRO: DILATATION	2

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	ESOPHAGUS	EYES	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	STERNUM	MARROW, STERN
	FEMUR	MARROW, FEMUR	BRAIN	CECUM
	COLON	DUODENUM	HEART	ILEUM
	JEJUNUM	KIDNEYS	LYMPH NODE, MES	MAMMARY GLAND

ANIMAL NO. 96281 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 11/23/05 DATE OF DEATH: 11/23/05 STUDY DAY: 28

GRADE

OVIDUCTS	OVARIES	RECTUM	SPINAL CORD	
STOMACH, NON	SPLEEN	THYROID GLANDS	THYMUS	
TRACHEA	URINARY BLADDER	VAGINA	CERVIX	

NOT EXAMINED

MICRO:NERVE, SCIATIC PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.52
02/13/2006

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 46 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96223 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.99	0.503
LIVER	11.94	3.015
KIDNEYS	3.37	0.851
HEART	1.27	0.321
SPLEEN	0.73	0.184
SEMINAL VES/COAG	1.69	0.427
PROSTATE	0.65	0.164
TESTES	3.06	0.773
EPIDIDYMIDES	1.08	0.273
THYMUS	0.5457	0.138
ADRENAL GLANDS	0.0491	0.012
FINAL BODY WT(G)	396.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

ANIMAL NO. 96230 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.00	0.468
LIVER	14.38	3.368
KIDNEYS	3.80	0.890
HEART	1.46	0.342
SPLEEN	0.94	0.220
SEMINAL VES/COAG	1.95	0.457
PROSTATE	1.11	0.260
TESTES	3.36	0.787
EPIDIDYMIDES	1.24	0.290
THYMUS	0.6519	0.153
ADRENAL GLANDS	0.0778	0.018
FINAL BODY WT(G)	427.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

ANIMAL NO. 96235 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.98	0.448
LIVER	14.93	3.378
KIDNEYS	3.48	0.787
HEART	1.51	0.342
SPLEEN	0.79	0.179
SEMINAL VES/COAG	1.87	0.423
PROSTATE	0.75	0.170
TESTES	3.83	0.867
EPIDIDYMIDES	1.41	0.319
THYMUS	0.4451	0.101
ADRENAL GLANDS	0.0737	0.017
FINAL BODY WT(G)	442.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 46 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96247 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.15	0.548
LIVER	11.90	3.036
KIDNEYS	3.19	0.814
HEART	1.36	0.347
SPLEEN	0.68	0.173
SEMINAL VES/COAG	2.19	0.559
PROSTATE	0.78	0.199
TESTES	3.38	0.862
EPIDIDYMIDES	1.28	0.327
THYMUS	0.3249	0.083
ADRENAL GLANDS	0.0644	0.016
FINAL BODY WT(G)	392.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 46 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96249 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.02	0.476
LIVER	12.14	2.863
KIDNEYS	3.43	0.809
HEART	1.41	0.333
SPLEEN	0.77	0.182
SEMINAL VES/COAG	1.79	0.422
PROSTATE	0.85	0.200
TESTES	3.43	0.809
EPIDIDYMIDES	1.25	0.295
THYMUS	0.5709	0.135
ADRENAL GLANDS	0.0686	0.016
FINAL BODY WT(G)	424.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 46 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96224 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.07	0.590
LIVER	11.17	3.182
KIDNEYS	2.91	0.829
HEART	1.30	0.370
SPLEEN	0.69	0.197
SEMINAL VES/COAG	1.41	0.402
PROSTATE	0.64	0.182
TESTES	3.22	0.917
EPIDIDYMIDES	1.21	0.345
THYMUS	0.3097	0.088
ADRENAL GLANDS	0.0825	0.024
FINAL BODY WT(G)	351.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 46 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96231 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.95	0.515
LIVER	11.07	2.921
KIDNEYS	3.50	0.923
HEART	1.44	0.380
SPLEEN	0.64	0.169
SEMINAL VES/COAG	2.29	0.604
PROSTATE	0.64	0.169
TESTES	3.25	0.858
EPIDIDYMIDES	1.08	0.285
THYMUS	0.2830	0.075
ADRENAL GLANDS	0.0669	0.018
FINAL BODY WT(G)	379.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 8

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96234 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	2.16	0.519	
LIVER	12.84	3.087	
KIDNEYS	3.74	0.899	
HEART	1.44	0.346	
SPLEEN	0.76	0.183	
SEMINAL VES/COAG	1.85	0.445	
PROSTATE	0.98	0.236	
TESTES	3.41	0.820	
EPIDIDYMIDES	1.31	0.315	
THYMUS	0.3686	0.089	
ADRENAL GLANDS	0.0747	0.018	
FINAL BODY WT(G)	416.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:				
ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 9

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96253 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.82	0.496
LIVER	10.10	2.752
KIDNEYS	3.15	0.858
HEART	1.42	0.387
SPLEEN	0.64	0.174
SEMINAL VES/COAG	1.35	0.368
PROSTATE	0.66	0.180
TESTES	3.23	0.880
EPIDIDYMIDES	1.08	0.294
THYMUS	0.4089	0.111
ADRENAL GLANDS	0.0745	0.020
FINAL BODY WT(G)	367.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	AORTA	STERNUM	FEMUR
	BRAIN	CECUM	COLON	DUODENUM
	EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96255 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.95	0.540
LIVER	11.63	3.222
KIDNEYS	2.90	0.803
HEART	1.40	0.388
SPLEEN	0.57	0.158
SEMINAL VES/COAG	1.41	0.391
PROSTATE	0.69	0.191
TESTES	3.34	0.925
EPIDIDYMIDES	1.11	0.307
THYMUS	0.4766	0.132
ADRENAL GLANDS	0.0635	0.018
FINAL BODY WT(G)	361.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
PANCREAS	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96262 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.89	0.848
LIVER	7.68	3.444
KIDNEYS	2.08	0.933
HEART	0.93	0.417
SPLEEN	0.47	0.211
UTERUS	0.41	0.184
OVARIES/OVIDUCTS	0.1133	0.051
THYMUS	0.3110	0.139
ADRENAL GLANDS	0.0681	0.031
FINAL BODY WT(G)	223.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96267 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.87	0.930
LIVER	7.42	3.692
KIDNEYS	1.88	0.935
HEART	0.83	0.413
SPLEEN	0.46	0.229
UTERUS	0.43	0.214
OVARIES/OVIDUCTS	0.1231	0.061
THYMUS	0.3788	0.188
ADRENAL GLANDS	0.0704	0.035
FINAL BODY WT(G)	201.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96275 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.85	0.860
LIVER	7.17	3.335
KIDNEYS	2.21	1.028
HEART	0.96	0.447
SPLEEN	0.56	0.260
UTERUS	0.61	0.284
OVARIES/OVIDUCTS	0.1131	0.053
THYMUS	0.3012	0.140
ADRENAL GLANDS	0.0524	0.024
FINAL BODY WT(G)	215.	

		GRADE
URINARY BLADDER	GROSS: THICKENED	P
URINARY BLADDER	GROSS: CALCULUS(I) MULTIPLE, 3 TO 12 MM IN DIAMETER	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	UTERUS	VAGINA
CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96278 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.00	0.881
LIVER	6.86	3.022
KIDNEYS	1.91	0.841
HEART	0.82	0.361
SPLEEN	0.44	0.194
UTERUS	0.46	0.203
OVARIES/OVIDUCTS	0.1551	0.068
THYMUS	0.4075	0.180
ADRENAL GLANDS	0.0486	0.021
FINAL BODY WT(G)	227.	

GENERAL COMMENT: NO SIGNIFICANT CHANGES OBSERVED

					GRADE
GROSS: ORGAN DAMAGED AT NECROPSY					P
VAGINA					
KIDNEYS GROSS: DILATED PELVIS					1
BILATERAL					
GROSS: ADRENAL GLANDS	AORTA	STERNUM	FEMUR		
BRAIN	CECUM	COLON	DUODENUM		
ESOPHAGUS	EYES	HEART	ILEUM		
JEJUNUM	LYMPH NODE, MAND	LIVER	LYMPH NODE, MES		
LUNGS	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS		
OVARIES	PANCREAS	PITUITARY	RECTUM		
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE		
SKIN	SPLEEN	THYROID GLANDS	THYMUS		
TRACHEA	URINARY BLADDER	UTERUS	VAGINA		
CERVIX					

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO. 96283 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.98	0.850
LIVER	7.66	3.288
KIDNEYS	1.98	0.850
HEART	0.87	0.373
SPLEEN	0.46	0.197
UTERUS	0.67	0.288
OVARIES/OVIDUCTS	0.1265	0.054
THYMUS	0.4688	0.201
ADRENAL GLANDS	0.0603	0.026
FINAL BODY WT(G)	233.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96264 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.94	0.815
LIVER	7.56	3.176
KIDNEYS	1.94	0.815
HEART	1.09	0.458
SPLEEN	0.44	0.185
UTERUS	0.39	0.164
OVARIES/OVIDUCTS	0.1367	0.057
THYMUS	0.3441	0.145
ADRENAL GLANDS	0.0752	0.032
FINAL BODY WT(G)	238.	

LUNGS — NO SIGNIFICANT CHANGES OBSERVED

GRADE P

GROSS: AREA(S), DARK RED
FEW, PINPOINT TO 2 MM IN DIAMETER, LEFT LOBE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	THYROID GLANDS	THYMUS
TRACHEA	URINARY BLADDER	UTERUS	VAGINA
CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96271 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.88	0.855
LIVER	7.34	3.336
KIDNEYS	1.89	0.859
HEART	0.95	0.432
SPLEEN	0.36	0.164
UTERUS	0.45	0.205
OVARIES/OVIDUCTS	0.1769	0.080
THYMUS	0.4164	0.189
ADRENAL GLANDS	0.0746	0.034
FINAL BODY WT(G)	220.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96277 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.88	0.803
LIVER	8.31	3.551
KIDNEYS	2.28	0.974
HEART	1.14	0.487
SPLEEN	0.53	0.226
UTERUS	0.46	0.197
OVARIES/OVIDUCTS	0.1352	0.058
THYMUS	0.5373	0.230
ADRENAL GLANDS	0.0737	0.031
FINAL BODY WT(G)	234.	

KIDNEYS: NO SIGNIFICANT CHANGES OBSERVED

				GRADE
GROSS: AREA(S), DEPRESSED FEW, PINPOINT TO 1 MM IN DIAMETER, IN CORTEX, BILATERAL				P
GROSS: ADRENAL GLANDS	AORTA	STERNUM	FEMUR	
BRAIN	CECUM	COLON	DUODENUM	
ESOPHAGUS	EYES	HEART	ILEUM	
JEJUNUM	LYMPH NODE, MAND	LIVER	LYMPH NODE, MES	
LUNGS	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	RECTUM	
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	
SKIN	SPLEEN	THYROID GLANDS	THYMUS	
TRACHEA	URINARY BLADDER	UTERUS	VAGINA	
CERVIX				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96282 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.90	0.841
LIVER	7.27	3.217
KIDNEYS	2.12	0.938
HEART	0.95	0.420
SPLEEN	0.39	0.173
UTERUS	0.45	0.199
OVARIES/OVIDUCTS	0.1806	0.080
THYMUS	0.3994	0.177
ADRENAL GLANDS	0.0801	0.035
FINAL BODY WT(G)	226.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

TABLE 46 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:05-087

ANIMAL NO. 96287 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 12/07/05 DATE OF DEATH: 12/07/05 STUDY DAY: 42

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.87	0.903
LIVER	6.90	3.333
KIDNEYS	2.10	1.014
HEART	0.93	0.449
SPLEEN	0.49	0.237
UTERUS	0.44	0.213
OVARIES/OVIDUCTS	0.1524	0.074
THYMUS	0.3237	0.156
ADRENAL GLANDS	0.0966	0.047
FINAL BODY WT(G)	207.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	FEMUR
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
OVIDUCTS	OVARIES	PANCREAS	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.52
02/28/2006

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96226	348.	1.96	11.40	2.99	1.38	0.73
96229	379.	2.18	11.90	3.28	1.34	0.76
96232	321.	1.96	9.98	2.76	1.16	0.59
96244	303.	2.03	9.06	2.75	1.14	0.58
96251	292.	2.08	10.15	2.95	1.09	0.78
MEAN	329.	2.04	10.50	2.95	1.22	0.69
S.D.	35.2	0.092	1.144	0.216	0.129	0.096
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96228	306.	1.85	9.97	2.63	1.19	0.67
96233	336.	1.97	9.28	2.88	1.29	0.63
96236	377.	2.05	13.50	3.22	1.42	0.73
96238	386.	1.98	12.59	2.90	1.40	0.89
96254	287.	1.87	8.70	2.72	1.10	0.52
MEAN	338.	1.94	10.81	2.87	1.28	0.69
S.D.	43.2	0.083	2.116	0.226	0.137	0.136
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 47 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96241	346.	1.85	12.94	3.34	1.36	0.59
96245	313.	1.87	11.46	2.90	1.17	0.59
96248	320.	1.83	10.91	2.81	1.20	0.54
96250	350.	1.87	13.23	2.97	1.25	0.59
96256	345.	1.83	10.30	3.06	1.22	0.68
MEAN	335.	1.85	11.77	3.02	1.24	0.60
S.D.	17.0	0.020	1.274	0.203	0.073	0.051
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 47 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96225	292.	2.02	9.55	2.70	0.96	0.54
96237	314.	1.92	11.30	3.27	1.22	0.62
96242	331.	1.93	11.80	2.85	1.40	0.69
96246	354.	1.90	13.98	3.01	1.18	0.79
96252	357.	1.87	11.91	3.16	1.34	0.65
MEAN	330.	1.93	11.71	3.00	1.22	0.66
S.D.	27.4	0.056	1.584	0.230	0.170	0.092
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 47 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 0 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96226	1.54	0.48	3.53	1.08	0.4509	0.0562
96229	1.90	0.62	3.28	1.05	0.3564	0.1046
96232	0.99	0.61	3.20	1.03	0.2986	0.0616
96244	1.42	0.70	3.67	1.09	0.2912	0.0981
96251	1.58	0.74	3.07	0.92	0.4044	0.0528
MEAN	1.49	0.63	3.35	1.03	0.3603	0.0747
S.D.	0.329	0.100	0.245	0.068	0.06847	0.02467
N	5	5	5	5	5	5

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96228	1.08	0.48	3.14	0.88	0.2588	0.0846
96233	1.56	0.47	3.53	1.11	0.5767	0.0641
96236	1.60	0.99	3.28	0.99	0.3893	0.1169
96238	1.76	0.64	3.74	1.06	0.5098	0.0616
96254	1.33	0.59	3.32	1.01	0.3236	0.0479
MEAN	1.47	0.63	3.40	1.01	0.4116	0.0750
S.D.	0.265	0.212	0.235	0.086	0.13085	0.02684
N	5	5	5	5	5	5

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 400 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96241	2.06	0.70	3.36	0.99	0.5069	0.0618
96245	1.17	0.56	3.43	1.03	0.3111	0.0663
96248	1.00	0.54	2.87	0.87	0.6404	0.0452
96250	1.20	0.83	3.20	0.95	0.4086	0.0539
96256	1.32	0.54	3.02	0.91	0.4313	0.0694
MEAN	1.35	0.63	3.18	0.95	0.4597	0.0593
S.D.	0.413	0.128	0.233	0.063	0.12286	0.00981
N	5	5	5	5	5	5

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 8

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96225	1.39	0.70	3.01	1.02	0.4778	0.0490
96237	1.40	0.68	2.94	1.01	0.2918	0.0690
96242	1.55	0.79	3.24	0.96	0.4447	0.0620
96246	1.81	0.57	2.81	0.97	0.3234	0.0753
96252	1.68	0.63	2.87	0.99	0.4979	0.0778
MEAN	1.57	0.67	2.97	0.99	0.4071	0.0666
S.D.	0.181	0.082	0.167	0.025	0.09348	0.01160
N	5	5	5	5	5	5

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 9

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96261	173.	1.82	6.31	1.69	0.90	0.36	0.47	0.1221	0.3068	0.0648
96266	201.	1.76	7.54	1.75	0.86	0.55	0.47	0.1600	0.6682	0.0671
96269	234.	1.91	9.07	2.03	0.95	0.54	0.46	0.1536	0.4405	0.0751
96270	196.	1.85	6.98	2.00	0.85	0.45	0.47	0.1243	0.4169	0.0581
96284	208.	1.93	7.72	2.14	0.92	0.45	0.57	0.1340	0.4433	0.0623
MEAN	202.	1.85	7.52	1.92	0.90	0.47	0.49	0.1388	0.4551	0.0655
S.D.	22.0	0.069	1.025	0.193	0.042	0.078	0.046	0.01718	0.13154	0.00633
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 10

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96280	191.	1.83	6.68	1.70	0.71	0.44	0.29	0.0969	0.2981	0.0562
96285	192.	1.73	7.10	1.59	0.88	0.42	0.42	0.1477	0.4632	0.0706
96289	214.	1.94	8.95	1.98	0.93	0.46	0.43	0.1389	0.4549	0.0784
96290	227.	1.76	8.44	2.20	0.94	0.52	0.40	0.1347	0.3670	0.0737
96291	207.	1.92	7.57	1.87	0.86	0.44	0.31	0.1205	0.3096	0.0707
MEAN	206.	1.84	7.75	1.87	0.86	0.46	0.37	0.1277	0.3786	0.0699
S.D.	15.2	0.093	0.938	0.239	0.092	0.038	0.065	0.01984	0.07803	0.00830
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 11

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96263	180.	1.69	7.35	1.83	0.88	0.38	0.35	0.1275	0.2949	0.0625
96265	202.	1.83	7.98	1.95	0.80	0.51	0.74	0.1060	0.3678	0.0831
96268	191.	1.80	6.91	1.75	0.81	0.43	0.81	0.1150	0.5116	0.0670
96272	230.	1.82	8.79	2.29	1.03	0.48	1.11	0.1504	0.2830	0.0950
96276	209.	1.82	8.13	2.00	0.88	0.57	0.57	0.1623	0.4811	0.0559
MEAN	202.	1.79	7.83	1.96	0.88	0.47	0.72	0.1322	0.3877	0.0727
S.D.	19.0	0.058	0.726	0.207	0.092	0.073	0.283	0.02367	0.10493	0.01600
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 47 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 12

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96259	193.	1.84	7.57	1.96	0.85	0.47	0.57	0.1086	0.3147	0.0753
96260	203.	1.84	7.79	1.85	1.09	0.48	0.57	0.1266	0.2793	0.0794
96273	241.	1.75	9.17	2.10	0.96	0.70	0.46	0.1252	0.3587	0.0946
96279	202.	1.82	7.52	1.71	0.83	0.50	0.34	0.1032	0.3869	0.0705
96281	185.	1.78	7.88	1.76	0.76	0.45	0.76	0.1261	0.3824	0.0723
MEAN	205.	1.81	7.99	1.88	0.90	0.52	0.54	0.1179	0.3444	0.0784
S.D.	21.5	0.040	0.679	0.157	0.129	0.102	0.155	0.01117	0.04630	0.00965
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

POFBWv4.14
02/13/2006

TABLE 48 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96223	396.	1.99	11.94	3.37	1.27	0.73
96230	427.	2.00	14.38	3.80	1.46	0.94
96235	442.	1.98	14.93	3.48	1.51	0.79
96247	392.	2.15	11.90	3.19	1.36	0.68
96249	424.	2.02	12.14	3.43	1.41	0.77
MEAN	416.	2.03	13.06	3.45	1.40	0.78
S.D.	21.4	0.070	1.474	0.222	0.093	0.098
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 48 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96224	351.	2.07	11.17	2.91	1.30	0.69
96231	379.	1.95	11.07	3.50	1.44	0.64
96234	416.	2.16	12.84	3.74	1.44	0.76
96253	367.	1.82	10.10	3.15	1.42	0.64
96255	361.	1.95	11.63	2.90	1.40	0.57
MEAN	375.	1.99	11.36	3.24	1.40	0.66
S.D.	25.2	0.130	0.996	0.371	0.058	0.070
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 48 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96223	1.69	0.65	3.06	1.08	0.5457	0.0491
96230	1.95	1.11	3.36	1.24	0.6519	0.0778
96235	1.87	0.75	3.83	1.41	0.4451	0.0737
96247	2.19	0.78	3.38	1.28	0.3249	0.0644
96249	1.79	0.85	3.43	1.25	0.5709	0.0686
MEAN	1.90	0.83	3.41	1.25	0.5077	0.0667
S.D.	0.190	0.173	0.275	0.118	0.12606	0.01108
N	5	5	5	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 48 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96224	1.41	0.64	3.22	1.21	0.3097	0.0825
96231	2.29	0.64	3.25	1.08	0.2830	0.0669
96234	1.85	0.98	3.41	1.31	0.3686	0.0747
96253	1.35	0.66	3.23	1.08	0.4089	0.0745
96255	1.41	0.69	3.34	1.11	0.4766	0.0635
MEAN	1.66	0.72	3.29	1.16	0.3694	0.0724
S.D.	0.404	0.146	0.082	0.100	0.07759	0.00744
N	5	5	5	5	5	5

PROJECT NO.:WIL-187051
SPONSOR:[redacted]
SPONSOR NO.:05-087

TABLE 48 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96262	223.	1.89	7.68	2.08	0.93	0.47	0.41	0.1133	0.3110	0.0681
96267	201.	1.87	7.42	1.88	0.83	0.46	0.43	0.1231	0.3788	0.0704
96275	215.	1.85	7.17	2.21	0.96	0.56	0.61	0.1131	0.3012	0.0524
96278	227.	2.00	6.86	1.91	0.82	0.44	0.46	0.1551	0.4075	0.0486
96283	233.	1.98	7.66	1.98	0.87	0.46	0.67	0.1265	0.4688	0.0603
MEAN	220.	1.92	7.36	2.01	0.88	0.48	0.52	0.1262	0.3735	0.0600
S.D.	12.4	0.068	0.347	0.135	0.061	0.047	0.117	0.01720	0.06964	0.00951
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 48 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96264	238.	1.94	7.56	1.94	1.09	0.44	0.39	0.1367	0.3441	0.0752
96271	220.	1.88	7.34	1.89	0.95	0.36	0.45	0.1769	0.4164	0.0746
96277	234.	1.88	8.31	2.28	1.14	0.53	0.46	0.1352	0.5373	0.0737
96282	226.	1.90	7.27	2.12	0.95	0.39	0.45	0.1806	0.3994	0.0801
96287	207.	1.87	6.90	2.10	0.93	0.49	0.44	0.1524	0.3237	0.0966
MEAN	225.	1.89	7.48	2.07	1.01	0.44	0.44	0.1564	0.4042	0.0800
S.D.	12.2	0.028	0.523	0.155	0.096	0.070	0.028	0.02156	0.08364	0.00958
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

POFBWv4.14
02/13/2006

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 49 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96226	348.	0.563	3.276	0.859	0.397	0.210
96229	379.	0.575	3.140	0.865	0.354	0.201
96232	321.	0.611	3.109	0.860	0.361	0.184
96244	303.	0.670	2.990	0.908	0.376	0.191
96251	292.	0.712	3.476	1.010	0.373	0.267
MEAN	329.	0.626	3.198	0.900	0.372	0.211
S.D.	35.2	0.0635	0.1857	0.0646	0.0165	0.0330
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96228	306.	0.605	3.258	0.859	0.389	0.219
96233	336.	0.586	2.762	0.857	0.384	0.188
96236	377.	0.544	3.581	0.854	0.377	0.194
96238	386.	0.513	3.262	0.751	0.363	0.231
96254	287.	0.652	3.031	0.948	0.383	0.181
MEAN	338.	0.580	3.179	0.854	0.379	0.203
S.D.	43.2	0.0539	0.3044	0.0698	0.0100	0.0214
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96241	346.	0.535	3.740	0.965	0.393	0.171
96245	313.	0.597	3.661	0.927	0.374	0.188
96248	320.	0.572	3.409	0.878	0.375	0.169
96250	350.	0.534	3.780	0.849	0.357	0.169
96256	345.	0.530	2.986	0.887	0.354	0.197
MEAN	335.	0.554	3.515	0.901	0.371	0.179
S.D.	17.0	0.0296	0.3291	0.0453	0.0158	0.0129
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96225	292.	0.692	3.271	0.925	0.329	0.185
96237	314.	0.611	3.599	1.041	0.389	0.197
96242	331.	0.583	3.565	0.861	0.423	0.208
96246	354.	0.537	3.949	0.850	0.333	0.223
96252	357.	0.524	3.336	0.885	0.375	0.182
MEAN	330.	0.589	3.544	0.912	0.370	0.199
S.D.	27.4	0.0672	0.2671	0.0774	0.0395	0.0169
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96226	0.443	0.138	1.014	0.310	0.130	0.016
96229	0.501	0.164	0.865	0.277	0.094	0.028
96232	0.308	0.190	0.997	0.321	0.093	0.019
96244	0.469	0.231	1.211	0.360	0.096	0.032
96251	0.541	0.253	1.051	0.315	0.138	0.018
MEAN	0.452	0.195	1.028	0.317	0.110	0.023
S.D.	0.0886	0.0472	0.1242	0.0297	0.0219	0.0070
N	5	5	5	5	5	5

TABLE 49 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96228	0.353	0.157	1.026	0.288	0.085	0.028
96233	0.464	0.140	1.051	0.330	0.172	0.019
96236	0.424	0.263	0.870	0.263	0.103	0.031
96238	0.456	0.166	0.969	0.275	0.132	0.016
96254	0.463	0.206	1.157	0.352	0.113	0.017
MEAN	0.432	0.186	1.015	0.302	0.121	0.022
S.D.	0.0471	0.0492	0.1057	0.0378	0.0332	0.0068
N	5	5	5	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 49 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 400 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96241	0.595	0.202	0.971	0.286	0.147	0.018
96245	0.374	0.179	1.096	0.329	0.099	0.021
96248	0.313	0.169	0.897	0.272	0.200	0.014
96250	0.343	0.237	0.914	0.271	0.117	0.015
96256	0.383	0.157	0.875	0.264	0.125	0.020
MEAN	0.402	0.189	0.951	0.284	0.138	0.018
S.D.	0.1116	0.0316	0.0887	0.0262	0.0389	0.0030
N	5	5	5	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 49 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96225	0.476	0.240	1.031	0.349	0.164	0.017
96237	0.446	0.217	0.936	0.322	0.093	0.022
96242	0.468	0.239	0.979	0.290	0.134	0.019
96246	0.511	0.161	0.794	0.274	0.091	0.021
96252	0.471	0.176	0.804	0.277	0.139	0.022
MEAN	0.474	0.207	0.909	0.302	0.124	0.020
S.D.	0.0235	0.0364	0.1058	0.0323	0.0315	0.0022
N	5	5	5	5	5	5

TABLE 49 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96261	173.	1.052	3.647	0.977	0.520	0.208	0.272	0.071	0.177	0.037
96266	201.	0.876	3.751	0.871	0.428	0.274	0.234	0.080	0.332	0.033
96269	234.	0.816	3.876	0.868	0.406	0.231	0.197	0.066	0.188	0.032
96270	196.	0.944	3.561	1.020	0.434	0.230	0.240	0.063	0.213	0.030
96284	208.	0.928	3.712	1.029	0.442	0.216	0.274	0.064	0.213	0.030
MEAN	202.	0.923	3.709	0.953	0.446	0.232	0.243	0.069	0.225	0.032
S.D.	22.0	0.0877	0.1177	0.0787	0.0435	0.0255	0.0317	0.0070	0.0621	0.0029
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 10

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96280	191.	0.958	3.497	0.890	0.372	0.230	0.152	0.051	0.156	0.029
96285	192.	0.901	3.698	0.828	0.458	0.219	0.219	0.077	0.241	0.037
96289	214.	0.907	4.182	0.925	0.435	0.215	0.201	0.065	0.213	0.037
96290	227.	0.775	3.718	0.969	0.414	0.229	0.176	0.059	0.162	0.032
96291	207.	0.928	3.657	0.903	0.415	0.213	0.150	0.058	0.150	0.034
MEAN	206.	0.894	3.750	0.903	0.419	0.221	0.180	0.062	0.184	0.034
S.D.	15.2	0.0701	0.2564	0.0516	0.0317	0.0079	0.0303	0.0097	0.0404	0.0034
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 11

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96263	180.	0.939	4.083	1.017	0.489	0.211	0.194	0.071	0.164	0.035
96265	202.	0.906	3.950	0.965	0.396	0.252	0.366	0.052	0.182	0.041
96268	191.	0.942	3.618	0.916	0.424	0.225	0.424	0.060	0.268	0.035
96272	230.	0.791	3.822	0.996	0.448	0.209	0.483	0.065	0.123	0.041
96276	209.	0.871	3.890	0.957	0.421	0.273	0.273	0.078	0.230	0.027
MEAN	202.	0.890	3.873	0.970	0.436	0.234	0.348	0.065	0.193	0.036
S.D.	19.0	0.0623	0.1717	0.0387	0.0351	0.0277	0.1158	0.0100	0.0567	0.0058
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 49 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 12

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 4

SPONSOR NO.:05-087

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96259	193.	0.953	3.922	1.016	0.440	0.244	0.295	0.056	0.163	0.039
96260	203.	0.906	3.837	0.911	0.537	0.236	0.281	0.062	0.138	0.039
96273	241.	0.726	3.805	0.871	0.398	0.290	0.191	0.052	0.149	0.039
96279	202.	0.901	3.723	0.847	0.411	0.248	0.168	0.051	0.192	0.035
96281	185.	0.962	4.259	0.951	0.411	0.243	0.411	0.068	0.207	0.039
MEAN	205.	0.890	3.909	0.919	0.439	0.252	0.269	0.058	0.170	0.038
S.D.	21.5	0.0954	0.2081	0.0671	0.0567	0.0216	0.0965	0.0072	0.0290	0.0018
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

POFBWv4.14
02/13/2006

TABLE 50 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96223	396.	0.503	3.015	0.851	0.321	0.184
96230	427.	0.468	3.368	0.890	0.342	0.220
96235	442.	0.448	3.378	0.787	0.342	0.179
96247	392.	0.548	3.036	0.814	0.347	0.173
96249	424.	0.476	2.863	0.809	0.333	0.182
MEAN	416.	0.489	3.132	0.830	0.337	0.188
S.D.	21.4	0.0386	0.2299	0.0406	0.0103	0.0186
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 50 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN
96224	351.	0.590	3.182	0.829	0.370	0.197
96231	379.	0.515	2.921	0.923	0.380	0.169
96234	416.	0.519	3.087	0.899	0.346	0.183
96253	367.	0.496	2.752	0.858	0.387	0.174
96255	361.	0.540	3.222	0.803	0.388	0.158
MEAN	375.	0.532	3.033	0.862	0.374	0.176
S.D.	25.2	0.0360	0.1952	0.0492	0.0173	0.0147
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 50 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96223	0.427	0.164	0.773	0.273	0.138	0.012
96230	0.457	0.260	0.787	0.290	0.153	0.018
96235	0.423	0.170	0.867	0.319	0.101	0.017
96247	0.559	0.199	0.862	0.327	0.083	0.016
96249	0.422	0.200	0.809	0.295	0.135	0.016
MEAN	0.458	0.199	0.820	0.301	0.122	0.016
S.D.	0.0585	0.0380	0.0430	0.0220	0.0289	0.0023
N	5	5	5	5	5	5

TABLE 50 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96224	0.402	0.182	0.917	0.345	0.088	0.024
96231	0.604	0.169	0.858	0.285	0.075	0.018
96234	0.445	0.236	0.820	0.315	0.089	0.018
96253	0.368	0.180	0.880	0.294	0.111	0.020
96255	0.391	0.191	0.925	0.307	0.132	0.018
MEAN	0.442	0.192	0.880	0.309	0.099	0.020
S.D.	0.0948	0.0260	0.0432	0.0231	0.0225	0.0026
N	5	5	5	5	5	5

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 50 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96262	223.	0.848	3.444	0.933	0.417	0.211	0.184	0.051	0.139	0.031
96267	201.	0.930	3.692	0.935	0.413	0.229	0.214	0.061	0.188	0.035
96275	215.	0.860	3.335	1.028	0.447	0.260	0.284	0.053	0.140	0.024
96278	227.	0.881	3.022	0.841	0.361	0.194	0.203	0.068	0.180	0.021
96283	233.	0.850	3.288	0.850	0.373	0.197	0.288	0.054	0.201	0.026
MEAN	220.	0.874	3.356	0.917	0.402	0.218	0.235	0.057	0.170	0.027
S.D.	12.4	0.0340	0.2435	0.0761	0.0350	0.0272	0.0482	0.0070	0.0285	0.0056
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 50 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 6

SPONSOR NO.:05-087

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96264	238.	0.815	3.176	0.815	0.458	0.185	0.164	0.057	0.145	0.032
96271	220.	0.855	3.336	0.859	0.432	0.164	0.205	0.080	0.189	0.034
96277	234.	0.803	3.551	0.974	0.487	0.226	0.197	0.058	0.230	0.031
96282	226.	0.841	3.217	0.938	0.420	0.173	0.199	0.080	0.177	0.035
96287	207.	0.903	3.333	1.014	0.449	0.237	0.213	0.074	0.156	0.047
MEAN	225.	0.843	3.323	0.920	0.449	0.197	0.196	0.070	0.179	0.036
S.D.	12.2	0.0392	0.1459	0.0819	0.0258	0.0326	0.0187	0.0115	0.0331	0.0065
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

POFBWv4.14
02/13/2006

TABLE 51 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN
96226	348.	1.96	581.633	152.551	70.408	37.245
96229	379.	2.18	545.872	150.459	61.468	34.862
96232	321.	1.96	509.184	140.816	59.184	30.102
96244	303.	2.03	446.305	135.468	56.158	28.571
96251	292.	2.08	487.981	141.827	52.404	37.500
MEAN	329.	2.04	514.195	144.224	59.924	33.656
S.D.	35.2	0.092	52.1360	7.1106	6.7746	4.1110
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 51 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN
96228	306.	1.85	538.919	142.162	64.324	36.216
96233	336.	1.97	471.066	146.193	65.482	31.980
96236	377.	2.05	658.537	157.073	69.268	35.610
96238	386.	1.98	635.859	146.465	70.707	44.949
96254	287.	1.87	465.241	145.455	58.824	27.807
MEAN	338.	1.94	553.924	147.470	65.721	35.312
S.D.	43.2	0.083	90.2947	5.6368	4.6642	6.3483
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 51 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

MALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN
96241	346.	1.85	699.459	180.541	73.514	31.892
96245	313.	1.87	612.834	155.080	62.567	31.551
96248	320.	1.83	596.175	153.552	65.574	29.508
96250	350.	1.87	707.487	158.824	66.845	31.551
96256	345.	1.83	562.842	167.213	66.667	37.158
MEAN	335.	1.85	635.759	163.042	67.033	32.332
S.D.	17.0	0.020	64.4437	11.1227	4.0077	2.8583
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 51 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN
96225	292.	2.02	472.772	133.663	47.525	26.733
96237	314.	1.92	588.542	170.313	63.542	32.292
96242	331.	1.93	611.399	147.668	72.539	35.751
96246	354.	1.90	735.790	158.421	62.105	41.579
96252	357.	1.87	636.898	168.984	71.658	34.759
MEAN	330.	1.93	609.080	155.810	63.474	34.223
S.D.	27.4	0.056	94.6524	15.3907	10.0673	5.3982
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 51 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 5

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96226	78.571	24.490	180.102	55.102	23.005	2.867
96229	87.156	28.440	150.459	48.165	16.349	4.798
96232	50.510	31.122	163.265	52.551	15.235	3.143
96244	69.951	34.483	180.788	53.695	14.345	4.833
96251	75.962	35.577	147.596	44.231	19.442	2.538
MEAN	72.430	30.822	164.442	50.749	17.675	3.636
S.D.	13.7266	4.5241	15.7570	4.4731	3.5472	1.0981
N	5	5	5	5	5	5

TABLE 51 (DAY 28 PRIMARY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 4

SPONSOR NO.:05-087

MALE GROUP: 160 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96228	58.378	25.946	169.730	47.568	13.989	4.573
96233	79.188	23.858	179.188	56.345	29.274	3.254
96236	78.049	48.293	160.000	48.293	18.990	5.702
96238	88.889	32.323	188.889	53.535	25.747	3.111
96254	71.123	31.551	177.540	54.011	17.305	2.561
MEAN	75.125	32.394	175.069	51.950	21.061	3.840
S.D.	11.3025	9.5908	10.8356	3.8292	6.2814	1.2762
N	5	5	5	5	5	5

TABLE 51 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

MALE GROUP: 400 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96241	111.351	37.838	181.622	53.514	27.400	3.341
96245	62.567	29.947	183.422	55.080	16.636	3.545
96248	54.645	29.508	156.831	47.541	34.995	2.470
96250	64.171	44.385	171.123	50.802	21.850	2.882
96256	72.131	29.508	165.027	49.727	23.568	3.792
MEAN	72.973	34.237	171.605	51.333	24.890	3.206
S.D.	22.3341	6.6910	11.1999	3.0016	6.8471	0.5299
N	5	5	5	5	5	5

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96225	68.812	34.653	149.010	50.495	23.653	2.426
96237	72.917	35.417	153.125	52.604	15.198	3.594
96242	80.311	40.933	167.876	49.741	23.041	3.212
96246	95.263	30.000	147.895	51.053	17.021	3.963
96252	89.840	33.690	153.476	52.941	26.626	4.160
MEAN	81.429	34.939	154.276	51.367	21.108	3.471
S.D.	11.1245	3.9431	7.9902	1.3703	4.8035	0.6876
N	5	5	5	5	5	5

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96261	173.	1.82	346.703	92.857	49.451	19.780	25.824	6.709	16.857	3.560
96266	201.	1.76	428.409	99.432	48.864	31.250	26.705	9.091	37.966	3.813
96269	234.	1.91	474.869	106.283	49.738	28.272	24.084	8.042	23.063	3.932
96270	196.	1.85	377.297	108.108	45.946	24.324	25.405	6.719	22.535	3.141
96284	208.	1.93	400.000	110.881	47.668	23.316	29.534	6.943	22.969	3.228
MEAN	202.	1.85	405.456	103.512	48.333	25.388	26.310	7.501	24.678	3.535
S.D.	22.0	0.069	49.0398	7.3020	1.5529	4.4597	2.0347	1.0453	7.8718	0.3482
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 51 (DAY 28 PRIMARY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96280	191.	1.83	365.027	92.896	38.798	24.044	15.847	5.295	16.290	3.071
96285	192.	1.73	410.405	91.908	50.867	24.277	24.277	8.538	26.775	4.081
96289	214.	1.94	461.340	102.062	47.938	23.711	22.165	7.160	23.448	4.041
96290	227.	1.76	479.545	125.000	53.409	29.545	22.727	7.653	20.852	4.188
96291	207.	1.92	394.271	97.396	44.792	22.917	16.146	6.276	16.125	3.682
MEAN	206.	1.84	422.118	101.852	47.161	24.899	20.232	6.984	20.698	3.813
S.D.	15.2	0.093	47.4560	13.5538	5.6773	2.6478	3.9448	1.2497	4.6059	0.4561
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96263	180.	1.69	434.911	108.284	52.071	22.485	20.710	7.544	17.450	3.698
96265	202.	1.83	436.066	106.557	43.716	27.869	40.437	5.792	20.098	4.541
96268	191.	1.80	383.889	97.222	45.000	23.889	45.000	6.389	28.422	3.722
96272	230.	1.82	482.967	125.824	56.593	26.374	60.989	8.264	15.549	5.220
96276	209.	1.82	446.703	109.890	48.352	31.319	31.319	8.918	26.434	3.071
MEAN	202.	1.79	436.907	109.555	49.146	26.387	39.691	7.381	21.591	4.050
S.D.	19.0	0.058	35.4722	10.3380	5.2754	3.4636	15.1056	1.2921	5.6125	0.8366
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96259	193.	1.84	411.413	106.522	46.196	25.543	30.978	5.902	17.103	4.092
96260	203.	1.84	423.370	100.543	59.239	26.087	30.978	6.880	15.179	4.315
96273	241.	1.75	524.000	120.000	54.857	40.000	26.286	7.154	20.497	5.406
96279	202.	1.82	413.187	93.956	45.604	27.473	18.681	5.670	21.258	3.874
96281	185.	1.78	442.697	98.876	42.697	25.281	42.697	7.084	21.483	4.062
MEAN	205.	1.81	442.933	103.979	49.719	28.877	29.924	6.538	19.104	4.350
S.D.	21.5	0.040	46.9919	10.0181	6.9943	6.2754	8.7323	0.6987	2.8129	0.6108
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

POFBWv4.14
02/13/2006

TABLE 52 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 1

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN
96223	396.	1.99	600.000	169.347	63.819	36.683
96230	427.	2.00	719.000	190.000	73.000	47.000
96235	442.	1.98	754.040	175.758	76.263	39.899
96247	392.	2.15	553.488	148.372	63.256	31.628
96249	424.	2.02	600.990	169.802	69.802	38.119
MEAN	416.	2.03	645.504	170.656	69.228	38.666
S.D.	21.4	0.070	86.1696	14.9937	5.6783	5.5844
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

TABLE 52 (DAY 42 RECOVERY NECROPSY)

PROJECT NO.:WIL-187051 — A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 6

SPONSOR NO.:05-087

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN
96224	351.	2.07	539.614	140.580	62.802	33.333
96231	379.	1.95	567.692	179.487	73.846	32.821
96234	416.	2.16	594.444	173.148	66.667	35.185
96253	367.	1.82	554.945	173.077	78.022	35.165
96255	361.	1.95	596.410	148.718	71.795	29.231
MEAN	375.	1.99	570.621	163.002	70.626	33.147
S.D.	25.2	0.130	24.7403	17.1972	5.9859	2.4342
N	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

PROJECT NO.:WIL-187051
SPONSOR: [redacted]
SPONSOR NO.:05-087

TABLE 52 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

MALE GROUP: 0 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96223	84.925	32.663	153.769	54.271	27.422	2.467
96230	97.500	55.500	168.000	62.000	32.595	3.890
96235	94.444	37.879	193.434	71.212	22.480	3.722
96247	101.860	36.279	157.209	59.535	15.112	2.995
96249	88.614	42.079	169.802	61.881	28.262	3.396
MEAN	93.469	40.880	168.443	61.780	25.174	3.294
S.D.	6.7856	8.8442	15.5573	6.1328	6.6739	0.5749
N	5	5	5	5	5	5

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	SEMINAL VES/COAG	PROS TATE	TESTES	EPIDID YMIDES	THYMUS	ADRENAL GLANDS
96224	68.116	30.918	155.556	58.454	14.961	3.986
96231	117.436	32.821	166.667	55.385	14.513	3.431
96234	85.648	45.370	157.870	60.648	17.065	3.458
96253	74.176	36.264	177.473	59.341	22.467	4.093
96255	72.308	35.385	171.282	56.923	24.441	3.256
MEAN	83.537	36.152	165.770	58.150	18.689	3.645
S.D.	20.0320	5.5692	9.1499	2.0556	4.5092	0.3705
N	5	5	5	5	5	5

TABLE 52 (DAY 42 RECOVERY NECROPSY)
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96262	223.	1.89	406.349	110.053	49.206	24.868	21.693	5.995	16.455	3.603
96267	201.	1.87	396.791	100.535	44.385	24.599	22.995	6.583	20.257	3.765
96275	215.	1.85	387.568	119.459	51.892	30.270	32.973	6.114	16.281	2.832
96278	227.	2.00	343.000	95.500	41.000	22.000	23.000	7.755	20.375	2.430
96283	233.	1.98	386.869	100.000	43.939	23.232	33.838	6.389	23.677	3.045
MEAN	220.	1.92	384.115	105.109	46.084	24.994	26.900	6.567	19.409	3.135
S.D.	12.4	0.068	24.3155	9.6141	4.3822	3.1653	5.9705	0.7028	3.0975	0.5506
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	HEART	SPLEEN	UTERUS	OVARIES/ OVIDUCTS	THYMUS	ADRENAL GLANDS
96264	238.	1.94	389.691	100.000	56.186	22.680	20.103	7.046	17.737	3.876
96271	220.	1.88	390.426	100.532	50.532	19.149	23.936	9.410	22.149	3.968
96277	234.	1.88	442.021	121.277	60.638	28.191	24.468	7.191	28.580	3.920
96282	226.	1.90	382.632	111.579	50.000	20.526	23.684	9.505	21.021	4.216
96287	207.	1.87	368.984	112.299	49.733	26.203	23.529	8.150	17.310	5.166
MEAN	225.	1.89	394.751	109.137	53.418	23.350	23.144	8.260	21.359	4.229
S.D.	12.2	0.028	27.7919	8.9565	4.8317	3.7963	1.7369	1.1727	4.5386	0.5400
N	5	5	5	5	5	5	5	5	5	5

FBW = FINAL BODY WEIGHT

POFBWv4.14
02/13/2006

APPENDIX A

Certificate Of Analysis (Sponsor-Provided Data)

[redacted]

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown viscous liquid

Storage Conditions
Ambient

Expiration Date
1 August 2006

Additional Comments
None

[redacted]

25 July 2005
Date

APPENDIX B

Analyses Of Formulations And Vehicle (Sponsor-Provided Data)

[redacted]

TITLE
The Analytical Report in Support of a 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats (with Functional Observational Battery and Motor Activity Determinations)

SUBMITTED TO SUPPORT THE TESTING OF:
[redacted]
WIL Research Study #WIL-187051
[redacted] Reference #05-087

AUTHOR
[redacted] Principal Investigator

STUDY INITIATION DATE
21 September 2005

ANALYTICAL START DATE
14 October 2005

ANALYTICAL END DATE
2 December 2005

ANALYTICAL STUDY COMPLETION DATE
20 June 2006

PERFORMING LABORATORY
[redacted]

TOTAL PAGES
11

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ANALYTICAL STUDY GLP COMPLIANCE STATEMENT

All analytical tests performed by [redacted] for WIL Research Study #WIL-187051 ([redacted] Reference #05-087) were conducted in compliance with current EPA Good Laboratory Practice (GLP) standards as described by the Toxic Substances Control Act (TSCA) 40 CFR Part 792.

Principal Investigator: [redacted] Date: 30 June 2006

ANALYTICAL STUDY QUALITY ASSURANCE UNIT STATEMENT

The analytical raw data and final report for the [redacted] study have been reviewed by the [redacted] Quality Assurance Team.

The report appears to accurately describe the methods and Standard Operating Procedures (SOPs) used in the study The reported results accurately reflect the raw data of the study

Study #
WIL Research Study #WIL-187051
[redacted] Reference #05-087

Study Title
The Analytical Report in Support of a 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats (with Observational Battery and Motor Activity Determinations)

	Study Director	*Dates Reported to* WIL Research Mgmt	[redacted] Mgmt
Study In-progress Inspection 28 October 2005	20 June 2006	20 June 2006	20 June 2006
Analytical Draft Report Review 12-14, 16, 19-20 June 2006	20 June 2006	20 June 2006	20 June 2006
Analytical Final Report Review 20 June 2006	20 June 2006	20 June 2006	20 June 2006

[redacted]

Date: June 20, 2006

ABSTRACT

Samples of [redacted] in corn oil used in a 28-day repeated dose oral (gavage) toxicity study in rats, WIL Research Study #WIL-187051 ([redacted] Reference #05-087), were analyzed at [redacted] to verify their homogeneity, 10-day resuspension homogeneity, and nominal concentrations. A direct dilution procedure was employed to prepare the samples for elemental analysis by Inductively Coupled Plasma-Atomic Emission Spectroscopy (ICP-AES). Homogeneity and 10-day resuspension homogeneity of [redacted] in corn oil were established. The nominal concentrations of all dosing suspensions were verified by the analytical data.

TEST SUBSTANCE

The test substance used in the preparation of the dosing suspensions was identified as [redacted] Lot # [redacted] The CAS number is confidential, contact [redacted] for further information. The test substance was characterized according to the TSCA GLPs and its stability was established prior to the initiation of the study.

INTRODUCTION

The purpose of this analytical study was the determination and verification of test substance homogeneity, 10-day resuspension homogeneity, and concentration in corn oil. The concentration study samples were aliquots taken from mixtures prepared as dosing suspensions for a 28-day repeated dose oral (gavage) toxicity study in rats as outlined in the protocol for WIL Research Study #WIL-187051.

The analytical portion of the study was performed by the High Volume Services team located in the [redacted] group at [redacted] The analytical start and end dates were 14 October and 2 December 2005 respectively.

EXPERIMENTAL

SAMPLES
Samples were shipped from WIL Research to [redacted] Principal Investigator. Samples were stored at room temperature and in the dark prior to analysis. Sample RX-187051L-0112 leaked during transit from WIL Research to [redacted] and an insufficient amount of sample remained for analysis.

The first batch of samples was transferred to the laboratory and analyzed on 14 October 2005. The analysis of the last set of samples was completed on 2 December 2005.

STANDARDS
Calibration standards for the ICP-AES were made from certified commercially prepared elemental concentrates (Conostan Division of Conoco, Inc). Standard preparation data is archived by [redacted]

ANALYTICAL METHOD
Samples were prepared as stated in [redacted] Test Code 30176, SOP ME-125 "Elemental Analysis of Additives or Additive Mixtures by Direct Dilution and ICP Analysis." The procedures outlined in SOP EQ-130, "IRIS Intrepid XDL II Radial Inductively Coupled Plasma Spectrometer," were followed during the instrumental analysis of the samples

The approach employed in this method was to verify concentration based on the known elemental composition of [redacted] Aliquots of the dosing suspensions were diluted in an o-xylene diluent and the elemental composition was determined by ICP-AES. The calcium concentration of the samples was then used to ascertain the concentration of the test substance in the dosing suspensions.

DISCUSSION

METHOD VALIDATION
Method validation was performed following the recommendations outlined in the International Conference on Harmonisation's Q2B document: Guideline on the Validation of Analytical Procedures Methodology. The limit of detection (LOD) and limit of quantitation (LOQ) were calculated to be 0.063 and 0.192 wt ppm calcium respectively. A reporting limit of 2 wt ppm calcium was determined to be appropriate for vehicle results.

SAMPLE ANALYSIS
The analytical results for the suspensions of [redacted] in corn oil are summarized in the tables located on pages 8 through 11. Seven calibration standards were analyzed to generate a linear calibration curve with inverse concentration weighting. All instrument control checks and quality control samples were within acceptable limits Known amounts of calcium were spiked into 11 samples throughout the duration of the study and gave acceptable percent recoveries of 95 to 98%.

The dosing suspensions were analyzed for calcium, an element present in known concentrations in the test substance. Dosing suspension estimates of weight percent calcium were derived by the following formula:

$$Wt\%\ Ca = \left[\frac{x}{x + \left(D_2 - \frac{xD_2}{D_1} \right)} \right] \%\ Ca\ in\ [redacted]$$

where x is the solute test substance concentration in mg/µL; D_1 is the test substance density (0.9905 g/mL) and D_2 is the vehicle or solvent density (corn oil, 0.9193 g/mL). The concentration of calcium in [redacted] is 5.789 wt%. The measured results of calcium were obtained by ICP-AES and compared against the estimated values Results were converted to wt% from ppm by multiplying by 10^{-4}.

Homogeneity and 10-day resuspension homogeneity were confirmed if the percent differences between the overall dose level mean and individual strata means were 10% or less. Concentration data were evaluated using percent difference The acceptable tolerance was 15% Duplicate analyses were compared using the Contract Laboratories Program (CLP) Guidelines for Inorganic Analyses relative percent difference limit of 20%.

RESULTS AND CONCLUSIONS

The confirmation of dosing suspension homogeneity is supported by the data presented on page 8 The percent difference of all strata means with their respective overall mean is well below the 10% tolerance.

The data shown on page 9 confirms the 10-day resuspension homogeneity of [redacted] in corn oil. The percent difference of all strata means with their respective overall mean is well below the 10% tolerance

The analytical result summary for the concentration study is found on page 10 The nominal concentrations of all dosing suspensions were verified by the analytical data. The percent difference between the estimated and measured concentrations is less than 15% for all dosing levels.

The table on page 11 presents the duplicate precision data The agreement between the duplicates is excellent and well under the CLP relative percent difference guideline of 20%

ARCHIVES

SAMPLES
The unused portion of all samples shall be stored in room [redacted] for a minimum of one year after the final analytical report is issued.

RAW DATA
Instrument, chemical, and standard logbook documentation shall be archived by [redacted] as facility records [redacted] All other raw data shall be archived in the Analytical Study File in [redacted] Analytical Study Archives.

FINAL REPORT
The original copy of the final report shall be archived with the Analytical Study File in [redacted]

PROTOCOL AND SOP DEVIATIONS

Analyses to confirm the stability of [redacted] in corn oil over a 10-day period were not performed as stated in the protocol. The test substance is formulated for use in the high temperature and oxidative environment found in internal combustion engines. Based on information provided by the Sponsor, it is not expected to degrade under conditions used in this toxicology study.

SOP ME-125 states a laboratory control sample (LCS) and matrix spike (MS) shall be prepared for every batch of 20 samples Only one LCS was prepared instead of the expected two during analyses on 14 and 28 October 2006. This did not affect the outcome of the analytical results.

STUDY PERSONNEL

PRINCIPAL INVESTIGATOR	[redacted]
ANALYST	[redacted]
ANALYST	[redacted]
SUPERVISORY PERSONNEL	[redacted]

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187051
[redacted] Reference #05-087

Homogeneity Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	[redacted] mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
0542004001	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0001	1	1	Middle	0	0 000	<2 wt ppm			
0542004002	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0011	1	1	Middle	0	0.000	<2 wt ppm	<2 wt ppm	<2 wt ppm	0 0
0542004003	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0002	1	2	Top	32	0 201	0 198			
0542004004	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0012	1	2	Top	32	0.201	0 199	0 199		1 0
0542004005	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0003	1	2	Middle	32	0 201	0 202		0 201	
0542004006	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0013	1	2	Middle	32	0.201	0.202	0 202		0 5
0542004007	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0004	1	2	Bottom	32	0 201	0 202			
0542004008	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0014	1	2	Bottom	32	0 201	0 201	0 202		0 5
0542004009	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0005	1	3	Top	80	0.501	0 496			
0542004010	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0015	1	3	Top	80	0.501	0 496	0.496		0 4
0542004011	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0006	1	3	Middle	80	0.501	0.499		0 498	
0542004012	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0016	1	3	Middle	80	0.501	0.498	0 499		0 2
0542004013	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0007	1	3	Bottom	80	0.501	0.499			
0542004014	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0017	1	3	Bottom	80	0 501	0.499	0 499		0.2
0542004015	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0008	1	4	Top	200	1 24	1 22			
0542004016	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0018	1	4	Top	200	1 24	1.22	1.22		0 8
0542004017	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0009	1	4	Middle	200	1.24	1.22		1 23	
0542004018	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0019	1	4	Middle	200	1 24	1 24	1 23		0.0
0542004019	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0010	1	4	Bottom	200	1 24	1.23			
0542004020	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0020	1	4	Bottom	200	1 24	1.23	1 23		0 0

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187051
[redacted] Reference #05-087

Resuspension Homogeneity Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	Estimated Concentration [redacted] mg/mL	Estimated Concentration wt% Ca	Measured Concentration, wt% Ca	Strata Mean, wt% Ca	Overall Mean, wt% Ca	Percent Difference, %
0542449001	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0031	2	1	Top	0	0.000	<2 wt ppm			
0542449009	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0039	2	1	Top	0	0.000	<2 wt ppm	<2 wt ppm	<2 wt ppm	0 0
0542449002	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0032	2	1	Bottom	0	0 000	<2 wt ppm			
0542449010	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0040	2	1	Bottom	0	0.000	<2 wt ppm	<2 wt ppm		0.0
0542449003	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0033	2	2	Top	32	0 201	0 194			
0542449011	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0041	2	2	Top	32	0 201	0 195	0.195		0 5
0542449004	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0034	2	2	Bottom	32	0.201	0 198		0 196	
0542449012	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0042	2	2	Bottom	32	0.201	0 196	0 197		0 5
0542449005	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0035	2	3	Top	80	0.501	0.488			
0542449013	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0043	2	3	Top	80	0.501	0 494	0.490		0 6
0542449006	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0036	2	3	Bottom	80	0.501	0 497		0 493	
0542449014	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0044	2	3	Bottom	80	0.501	0 493	0 495		0.4
0542449007	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0037	2	4	Top	200	1 24	1 22			
0542449015	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0045	2	4	Top	200	1.24	1 20	1.21		0.0
0542449008	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0038	2	4	Bottom	200	1 24	1 22		1 21	
0542449016	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0046	2	4	Bottom	200	1.24	1 21	1 22		0 8

PERCENT DIFFERENCE CALCULATION
Absolute value (((Overall Mean-Strata Mean)/Overall Mean)*100)

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187051
[redacted] Reference #05-087

Concentration Study

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	[redacted] Estimated Concentration mg/mL	wt% Ca	Measured Concentration, wt% Ca	Percent Difference, %
0543800001	25-Oct-05	25-Oct-05	28-Oct-05	RX-187051L-0055	3	1	Middle	0	0 000	<2 wt ppm	*
0543800002	25-Oct-05	25-Oct-05	28-Oct-05	RX-187051L-0056	3	2	Middle	32	0.201	0 194	3 5
0543800003	25-Oct-05	25-Oct-05	28-Oct-05	RX-187051L-0057	3	3	Middle	80	0.501	0.490	2.2
0543800004	25-Oct-05	25-Oct-05	28-Oct-05	RX-187051L-0062	3	4	Middle	200	1 24	1 23	0 8
0544764001	25-Oct-05	01-Nov-05	04-Nov-05	RX-187051L-0063	4	1	Middle	0	0.000	<2 wt ppm	*
0544764002	25-Oct-05	01-Nov-05	04-Nov-05	RX-187051L-0064	4	2	Middle	32	0.201	0 191	5 0
0544764003	25-Oct-05	01-Nov-05	04-Nov-05	RX-187051L-0065	4	3	Middle	80	0.501	0.488	2 6
0544764004	25-Oct-05	01-Nov-05	04-Nov-05	RX-187051L-0066	4	4	Middle	200	1 24	1 23	0.8
0544764005	01-Nov-05	01-Nov-05	04-Nov-05	RX-187051L-0071	5	1	Middle	0	0.000	<2 wt ppm	*
0544764006	01-Nov-05	01-Nov-05	04-Nov-05	RX-187051L-0072	5	2	Middle	32	0.201	0.195	3.0
0544764007	01-Nov-05	01-Nov-05	04-Nov-05	RX-187051L-0073	5	3	Middle	80	0.501	0 493	1 6
0544764008	01-Nov-05	01-Nov-05	04-Nov-05	RX-187051L-0074	5	4	Middle	200	1.24	1 21	2 4
0545671001	01-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0079	6	1	Middle	0	0.000	<2 wt ppm	*
0545671002	01-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0080	6	2	Middle	32	0 201	0.196	2 5
0545671003	01-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0081	6	3	Middle	80	0.501	0.495	1.2
0545671004	01-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0082	6	4	Middle	200	1.24	1 23	0.8
0545671005	08-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0087	7	1	Middle	0	0 000	<2 wt ppm	*
0545671006	08-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0088	7	2	Middle	32	0 201	0 200	0.5
0545671007	08-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0089	7	3	Middle	80	0.501	0 499	0 4
0545671008	08-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0090	7	4	Middle	200	1 24	1.23	0 8
0547147001	08-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0095	8	1	Middle	0	0.000	<2 wt ppm	*
0547147002	08-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0096	8	2	Middle	32	0 201	0.192	4.5
0547147003	08-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0097	8	3	Middle	80	0 501	0.488	2 6
0547147004	08-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0098	8	4	Middle	200	1 24	1.19	4 0
0547147005	15-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0103	9	1	Middle	0	0.000	<2 wt ppm	*
0547147006	15-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0104	9	2	Middle	32	0 201	0 196	2.5
0547147007	15-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0105	9	3	Middle	80	0 501	0.494	1.4
0547147008	15-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0106	9	4	Middle	200	1 24	1 20	3 2
0549212001	15-Nov-05	22-Nov-05	02-Dec-05	RX-187051L-0111	10	1	Middle	0	0.000	<2 wt ppm	*
**	15-Nov-05	22-Nov-05	not analyzed	RX-187051L-0112**	10	2	Middle	32	0 201	-	-
0549212002	15-Nov-05	22-Nov-05	02-Dec-05	RX-187051L-0113	10	3	Middle	80	0.501	0 492	1.8
0549212003	15-Nov-05	22-Nov-05	02-Dec-05	RX-187051L-0114	10	4	Middle	200	1 24	1 18	4 8

10

PERCENT DIFFERENCE CALCULATION
Absolute value (((Estimated Concentration-Measured Concentration)/Estimated Concentration)*100)

* Not a significant difference
** Sample leaked in transit

SUMMARY OF ANALYTICAL RESULTS

CONCENTRATION OF CALCIUM IN [redacted] SUSPENSIONS
WIL Research #WIL-187051
[redacted] Reference #05-087

Duplicate Analysis

ILT StarLims #	Date Prepared	Date Sampled	Date Analyzed	WIL Research Sample #	WIL Research Accession #	WIL Research Group #	Aliquot Phase	[redacted] Estimated Concentration [redacted] mg/mL	wt% Ca	Measured Concentration, wt% Ca	Relative Percent Difference, %
0542004017	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0009	1	4	Middle	200	1 24	1 22	
0542004017-Dup	03-Oct-05	03-Oct-05	14-Oct-05	RX-187051L-0009	1	4	Middle	200	1 24	1 22	0.0
0542449005	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0035	1	3	Top	80	0 501	0 488	
0542449005-Dup	03-Oct-05	13-Oct-05	19-Oct-05	RX-187051L-0035	1	3	Top	80	0.501	0 491	0 6
0544764003	25-Oct-05	01-Nov-05	04-Nov-05	RX-187051L-0065	4	3	Middle	80	0 501	0 488	
0544764003-Dup	25-Oct-05	01-Nov-05	04-Nov-05	RX-187051L-0065	4	3	Middle	80	0 501	0.491	0 6
0545671006	08-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0088	7	2	Middle	32	0 201	0 200	
0545671006-Dup	08-Nov-05	08-Nov-05	10-Nov-05	RX-187051L-0088	7	2	Middle	32	0 201	0.200	0 0
0547147003	08-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0097	8	3	Middle	80	0 501	0 488	
0547147003-Dup	08-Nov-05	15-Nov-05	18-Nov-05	RX-187051L-0097	8	3	Middle	80	0 501	0.487	0 2
0549212003	15-Nov-05	22-Nov-05	02-Dec-05	RX-187051L-0114	10	4	Middle	200	1 24	1 18	
0549212003-Dup	15-Nov-05	22-Nov-05	02-Dec-05	RX-187051L-0114	10	4	Middle	200	1.24	1.19	0 8

RELATIVE PERCENT DIFFERENCE CALCULATION
Absolute value (((First Measured Concentration-Duplicate Measured Concentration)/((First Measured Concentration+Duplicate Measured Concentration)/2))*100

APPENDIX C

Pretest Clinical Observations

PROJECT NO.:WIL-187051P
SPONSOR: [redacted]
SPONSOR NO.:05-087

PRETEST CLINICAL OBSERVATIONS
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	10-19-05 TO 10-25-05
GROUP:	1
NORMAL	
-NO SIGNIFICANT CLINICAL OBSERVATIONS	70/35
1- PRETEST	

----- F E M A L E -----

TABLE RANGE: 10-19-05 TO 10-25-05
GROUP: 1

NORMAL
-NO SIGNIFICANT CLINICAL OBSERVATIONS 70/35

1- PRETEST

APPENDIX D

Animal Room Environmental Conditions

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMARY BY STUDY

PROJECT NO [redacted] 187051
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187051

DATE IN: 10/11/05 TIME IN: 11:00
DATE OUT: 12/07/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
11-Oct-05	70.5	21.4	50.6
12-Oct-05	70.3	21.3	53.2
13-Oct-05	70.5	21.4	53.9
14-Oct-05	70.5	21.4	56.1
15-Oct-05	70.5	21.4	48.5
16-Oct-05	70.5	21.4	45.4
17-Oct-05	70.5	21.4	45.2
18-Oct-05	70.5	21.4	50.9
19-Oct-05	70.5	21.4	49.6
20-Oct-05	70.5	21.4	44.1
21-Oct-05	70.5	21.4	48.2
22-Oct-05	70.5	21.4	52.3
23-Oct-05	70.6	21.4	41.1
24-Oct-05	70.5	21.4	44.2
25-Oct-05	70.5	21.4	45.7
26-Oct-05	70.6	21.4	39.5
27-Oct-05	70.5	21.4	36.1
28-Oct-05	70.5	21.4	43.0
29-Oct-05	70.6	21.4	51.4
30-Oct-05	70.5	21.4	51.5
31-Oct-05	70.6	21.5	50.4
01-Nov-05	70.5	21.4	50.7
02-Nov-05	70.6	21.4	49.9

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
2/1/2006 11:34

A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMARY BY STUDY

PROJECT NO. 187051
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187051

DATE IN: 10/11/05 TIME IN: 11:00
DATE OUT: 12/07/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
03-Nov-05	71.0	21.7	45.1
04-Nov-05	70.5	21.4	49.7
05-Nov-05	70.5	21.4	52.6
06-Nov-05	70.5	21.4	50.6
07-Nov-05	70.5	21.4	48.3
08-Nov-05	70.6	21.4	49.7
09-Nov-05	70.6	21.4	51.7
10-Nov-05	70.5	21.4	52.9
11-Nov-05	70.5	21.4	51.5
12-Nov-05	70.5	21.4	50.5
13-Nov-05	70.5	21.4	51.1
14-Nov-05	70.6	21.4	50.5
15-Nov-05	70.6	21.4	53.0
16-Nov-05	70.5	21.4	51.2
17-Nov-05	70.6	21.5	57.0
18-Nov-05	70.6	21.4	54.4
19-Nov-05	70.2	21.2	51.4
20-Nov-05	70.6	21.5	50.5
21-Nov-05	70.6	21.4	46.9
22-Nov-05	70.5	21.4	44.9
23-Nov-05	70.5	21.4	46.7
24-Nov-05	70.5	21.4	43.8
25-Nov-05	70.6	21.4	48.1

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

STUDY SPECIFICATIONS: 187051

DATE IN: 10/11/05 TIME IN: 11:00
DATE OUT: 12/07/05 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
26-Nov-05	70.6	21.4	47.6
27-Nov-05	70.5	21.4	46.6
28-Nov-05	70.6	21.4	51.9
29-Nov-05	70.6	21.5	47.7
30-Nov-05	70.5	21.4	47.5
01-Dec-05	70.6	21.4	47.1
02-Dec-05	70.4	21.4	45.1
03-Dec-05	70.5	21.4	46.5
04-Dec-05	70.6	21.4	44.9
05-Dec-05	70.5	21.4	47.1
06-Dec-05	70.5	21.4	45.7
07-Dec-05	70.5	21.4	45.4

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.2	71.0
TEMPERATURE °C	21.4	21.2	21.7
HUMIDITY (%RH)	48.6	36.1	57.0
N DAYS	58		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

ROOM SPECIFICATIONS:	B ROOM 73				
SPECIES:	RAT				
LOW TEMPERATURE:	66.0	DATE IN:	10/11/05		
HIGH TEMPERATURE:	76.0	TIME IN:	11:00		
LOW HUMIDITY:	30.0	DATE OUT:	12/07/05		
HIGH HUMIDITY:	70.0	TIME OUT:	8:00	TEMPERATURE	HUMIDITY

ROOM B ROOM 73 SUMMARY

MEAN	70.5	48.6
MIN	65.7	11.2
MAX	73.7	92.8
SD	0.34	5.31
N SAMPLES	1361	1361
FIRST DAY	10/11/05	
LAST DAY	12/07/05	
N DAYS	58	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

STUDY 187051 SUMMARY

MEAN	70.5	48.6
MIN	65.7	11.2
MAX	73.7	92.8
SD	0.34	5.31
N SAMPLES	1361	1361
FIRST DAY	10/11/05	
LAST DAY	12/07/05	
N DAYS	58	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

APPENDIX E

Unscheduled Clinical Observations

PROJECT NO.:WIL-187051U
SPONSOR: [redacted]
SPONSOR NO.:05-087

UNSCHEDULED CLINICAL OBSERVATIONS
A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96241	M	400 MG/KG/DAY	EYES/EARS/NOSE	11-17-05	9:22	1	DRIED RED MATERIAL AROUND RIGHT EYE
				11-17-05	9:23	1	DRIED RED MATERIAL AROUND LEFT EYE
96241	M	400 MG/KG/DAY	ORAL/DENTAL	11-17-05	9:22	P	UPPER INCISORS MALALIGNED

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
01/31/2006

APPENDIX F

Summaries Of Validation Studies
(WIL-99140, WIL-99149, WIL-99263,And WIL-99310)

Date Range: April 12-13, 1999

Determination of Test Session Duration and Test Interval for the
San Diego Photobeam Activation System Using Untreated Rats

Study Objective:

Regulatory guidelines require that the length of the locomotor activity monitoring session be long enough to allow untreated rats to approach normal activity levels by the last 20% of the session following their placement into a novel environment habituation). The primary objective of this study was to determine the appropriate test session duration for the locomotor activity measuring apparatus (San Diego Instruments - Photobeam Activity System [SDI-PAS]). A secondary objective was to collect data that could be used to determine an appropriate interval length (epoch) within the test session for the capturing and reporting of locomotor activity data.

Test System:

Juvenile (approximately six-week old) Sprague-Dawley Crl:CD®(SD)IGS BR rats weighing approximately 225 ± 75 grams (males) and 135 ± 25 grams (females) were used on the study. The rats were arbitrarily selected from available stock.

Environmental Conditions:

The rats were acclimated to laboratory conditions for five days prior to monitoring locomotor activity. Animals were housed and maintained under conditions consistent with maintaining good health and as per WIL Standard Operating Procedures. Temperature and humidity were maintained at 72 ± 4° F and 50 ± 20%, respectively, in a room with a 12 hours light/12 hours dark (0600-1800 hrs) photoperiod. The facilities at WIL Research Laboratories, Inc. are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International.

Locomotor Activity Monitoring Methods:

Locomotor activity of 24 untreated rats (12 per sex) was monitored to determine the acceptable test session duration and test interval to be used on subsequent studies. (The test interval is the frequency at which activity counts are captured.) For this testing, the duration of the test session was 120 minutes. The test interval was one minute. That is, total activity (photobeam interruptions) was recorded at one-minute intervals for 120 minutes. Monitoring commenced one minute after placement of the rats into the monitoring units.

Locomotor activity monitoring was performed using the SDI Photobeam Activity System (San Diego Instruments, Inc., San Diego, CA), which includes Photobeam Activity System (PAS) software, analyzer and 24 activity monitors. A local personal computer linked to the laboratory's mainframe computer controls the SDI PAS.

Each locomotor activity monitoring unit consists of seven photobeam emitting/detecting units attached to a mounting frame. A clear acrylic shoe box -style cage (18.5"L x 9.5"W x 8"H) fits into the mounting frame to contain a single animal during the test session. Activity is measured as interruptions of the photobeams.

Photobeam diagnostic checks were performed prior to and following completion of the test session. Confirmation that the software-driven procedure was operating correctly was obtained by manually blocking the photobeams with pre-cut pieces of cardboard.

Monitoring was performed in a sound-attenuated room equipped with a white-noise generator set to operate at approximately 70 db.

Results:

Mean total locomotor activity data are presented graphically as both one-minute and five-minute test intervals (epochs) for the entire 120-minute test session in Figures 1 and 2, respectively. Corresponding numerical data are presented in Tables 1 and 2.

Mean total activity counts per minute were calculated using all 24 animals at each time point. Five-minute epochal data represent grand mean activity counts for each five-minute interval.

Discussion:

Following their placement into the monitoring units, untreated rats returned to normal locomotor activity levels after 36 minutes. Therefore, although a 45-minute test session would be adequate to allow rats to fully habituate to a novel environment, a 60-minute test session was selected for future studies. A test session of 60 minutes duration would comfortably meet the criterion for approaching normal locomotor activity levels by the last 20% of the test session, while providing a slightly extended session that may allow for detection of delayed effects.

No differences in locomotor activity levels were apparent when the data were examined in one-minute versus five-minute test intervals (epochs). Therefore, collection and reporting of locomotor activity with the SDI-PAS using a five-minute test interval was judged to be adequate to detect alterations in locomotor activity.

Alternative locomotor activity monitoring paradigms can be employed as appropriate, necessary or requested, but the above conditions (60-minute test session with five-minute epochs) are considered to be acceptable standards for this laboratory and equipment.

Figure 1

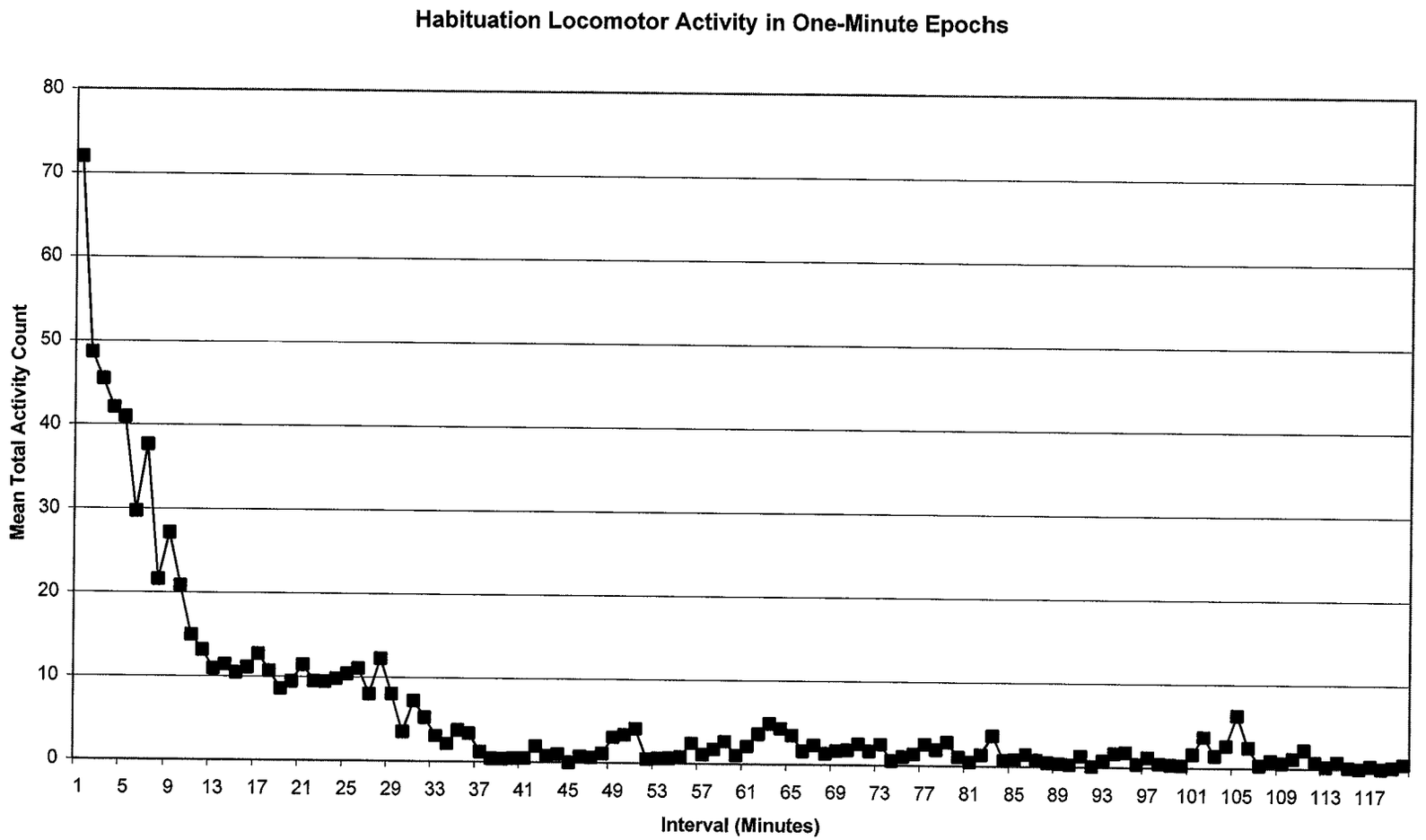
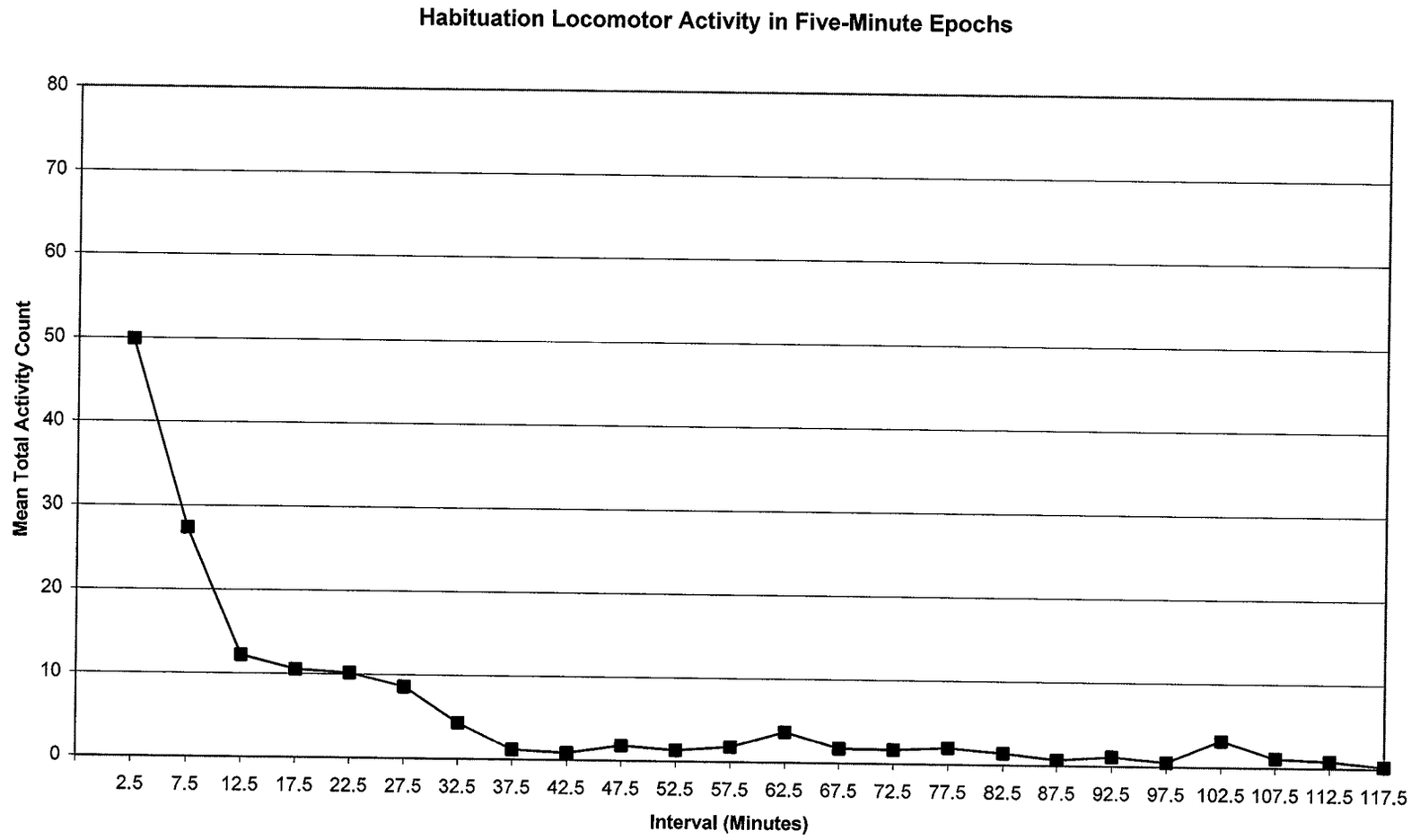

Habituation Locomotor Activity in One-Minute Epochs
Mean Total Activity Count
0
10
20
30
40
50
60
70
80
1 5 9 13 17 21 25 29 33 37 41 45 49 53 57 61 65 69 73 77 81 85 89 93 97 101 105 109 113 117
Interval (Minutes)

Figure 2


Habituation Locomotor Activity in Five-Minute Epochs
Mean Total Activity Count
80
70
60
50
40
30
20
10
0
2.5
7.5
12.5
17.5
22.5
27.5
32.5
37.5
42.5
47.5
52.5
57.5
62.5
67.5
72.5
77.5
82.5
87.5
92.5
97.5
102.5
107.5
112.5
117.5
Interval (Minutes)

WIL-99140

Table 1
Locomotor Activity Data in 1-Minute Epochs

Interval	MAC	Interval	MAC	Interval	MAC	Interval	MAC	Interval	MAC
1	71.95833	25	10.41667	49	3.083333	73	2.5	97	1.208333
2	48.625	26	11.04167	50	3.375	74	0.541667	98	0.458333
3	45.45833	27	8.041667	51	4.125	75	1	99	0.333333
4	42.0833	28	12.25	52	0.5	76	1.375	100	0.25
5	40.95833	29	8.083333	53	0.583333	77	2.541667	101	1.583333
6	29.70833	30	3.541667	54	0.625	78	1.875	102	3.708333
7	37.70833	31	7.25	55	0.75	79	2.833333	103	1.416667
8	21.58333	32	5.291667	56	2.416667	80	1.041667	104	2.625
9	27.16667	33	3.083333	57	1.083333	81	0.5	105	6.333333
10	20.83333	34	2.125	58	1.708333	82	1.333333	106	2.416667
11	14.95833	35	3.791667	59	2.666667	83	3.625	107	0.333333
12	13.16667	36	3.416667	60	1	84	0.708333	108	0.875
13	10.91667	37	1.208333	61	2.125	85	0.791667	109	0.625
14	11.45833	38	0.416667	62	3.625	86	1.416667	110	1.125
15	10.45833	39	0.375	63	4.875	87	0.791667	111	2.208333
16	11.125	40	0.458333	64	4.291667	88	0.5	112	0.708333
17	12.70833	41	0.5	65	3.458333	89	0.375	113	0.208333
18	10.70833	42	1.916667	66	1.583333	90	0.25	114	0.791667
19	8.625	43	0.791667	67	2.333333	91	1.291667	115	0.125
20	9.458333	44	0.958333	68	1.333333	92	0.083333	116	0
21	11.45833	45	0	69	1.666667	93	0.75	117	0.333333
22	9.541667	46	0.708333	70	1.75	94	1.625	118	0
23	9.458333	47	0.625	71	2.5	95	1.75	119	0.166667
24	9.833333	48	1.083333	72	1.666667	96	0.375	120	0.541667

MAC = Mean Activity Count

Table 2
Mean Total Activity Counts in 5-Minute Epochs

Interval	MAC	Interval	MAC	Interval	MAC
5	49.81667	45	0.833334	85	1.391667
10	27.4	50	1.775	90	0.666667
15	12.19167	55	1.316667	95	1.1
20	10.525	60	1.775	100	0.525
25	10.14167	65	3.675	105	3.133333
30	8.591667	70	1.733333	110	1.075
35	4.308333	75	1.641667	115	0.808333
40	1.175	80	1.933333	120	0.208333

MAC = Mean Activity Counts

Date Range: May 17-21, 1999

Demonstration of the Sensitivity of the SDI-PAS
to Detect Alterations in Locomotor Activity in Rats

Study Objective:

Regulatory guidelines require that the testing laboratory demonstrate that the devices and systems used for measuring locomotor activity be able to detect chemically-induced increases and decreases in locomotor activity. The objective of this study was to demonstrate that the locomotor activity measuring apparatus (San Diego Instruments - Photobeam Activity System [SDI-PAS]) and the testing paradigm used by WIL Research Laboratories, Inc., met this criterion.

Test And Control Articles:

Two test articles were employed, one to elicit increases in motor activity (d-amphetamine sulfate, Research Biochemicals International, Natick, MA, Lot. No. BS-111-100) and one to elicit decreases in motor activity (chlorpromazine hydrochloride, Sigma Chemical Company, St. Louis, MO, Lot No. 48 H 1403). Physiological saline was used as the vehicle and for treatment of the concurrent negative control group.

Test System:

Juvenile (approximately six-week old) Sprague-Dawley Crl:CD®(SD)IGS BR rats weighing 175 ± 27 grams (males) and 146 ± 20 grams (females) at the time of randomization were used on the study. The rats were randomly assigned to treatment groups by body weight stratification in a block design, and subsequently allocated to group- and sex-uniform replicates for the locomotor activity evaluations. Dosing and locomotor activity evaluations occurred on the day after randomization (Day 0).

Environmental Conditions:

The rats were acclimated to laboratory conditions for 13 days prior to dosing. Animals were housed and maintained under conditions consistent with maintaining good health and as per WIL Standard Operating Procedures. Temperature and humidity were maintained at 72 ± 4° F and 50 ± 20%, respectively, in a room with a 12 hours light/12 hours dark (0600-1800 hrs) photoperiod. The facilities at WIL Research Laboratories, Inc. are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International.

Treatment Regimen:

Animals were assigned to treatment groups as follows:

Group Number	Test Article	Dosage Level (mg/kg)	Dosage Concentration (mg/ml)	Dosage Volume (mg/kg)	Number of Animals	
					Male	Female
1	PS	0	0	1.0	12	12
2	AMP	2	2	1.0	12	12
3	AMP	4	4	1.0	12	12
4	CPZ	5	5	1.0	12	12
5	CPZ	10	10	1.0	12	12

PS = Physiological Saline AMP = d-Amphetamine Sulfate CPZ = Chlorpromazine Hydrochloride

The test and control articles were administered as a single intraperitoneal injection (Day 0). Individual doses were calculated based on the animals' body weights recorded on the day of dose administration.

Locomotor Activity Monitoring Methods:

Locomotor activity was monitored once 4-5 days prior to dose administration (pretest) and on the day of dose administration. The duration of each test session was 60 minutes. The test interval was five minutes. Monitoring following dosing commenced 15 minutes after test or control article administration. The duration of the test session and length of the test interval were selected based on results of a previous study (WIL-99140).

Locomotor activity monitoring was performed using the SDI Photobeam Activity System (San Diego Instruments, Inc., San Diego, CA), which includes Photobeam Activity System (PAS) software, analyzer and 24 activity monitors. A local personal computer linked to the laboratory's mainframe computer controls the SDI-PAS.

Each locomotor activity monitoring unit consists of seven photobeam emitting/detecting units attached to a mounting frame. A clear acrylic shoe box -style cage (18.5"L x 9.5"W x 8"H) fits into the mounting frame to contain a single animal during the test session. Activity is measured as interruptions of the photobeams.

Photobeam diagnostic checks were performed prior to and following completion of the test session. Confirmation that the software-driven procedure was operating correctly was obtained by manually blocking the photobeams with pre-cut pieces of cardboard or other appropriate devices. After completion of the test session, motor

activity and photobeam files are transferred electronically to the mainframe computer for subsequent manipulation and presentation of the collected information, i.e., generation of tables, including statistical analysis.

Activity counts are presented as Total Activity Counts (ambulatory plus stereotypic counts) and Ambulatory Activity Counts. Sequential interruption of 2 or more photobeams, i.e., gross motor movement, is recorded as one ambulatory activity count. Repeated beam breaks of the same photobeam, i.e., fine motor movement, is recorded as one stereotypic count.

Monitoring was performed in a sound-attenuated room equipped with a white-noise generator set to operate at approximately 70 db.

Statisical Analysis:

Locomotor activity data were analyzed by analysis of variance. A one-way ANOVA followed by Dunnett's test was conducted to determine significant treatment differences from the control group at significance levels of $p < 0.05$ and $p < 0.01$.

Quality Assurance:

The raw data and draft report were audited by the WIL Quality Assurance Unit to assure that the final report accurately describes the conduct and findings of the study.

Results:

Group mean locomotor activity counts are presented in Table 1. The data are presented graphically by sex, interval and activity type in Figures 1-8.

Discussion:

There were no differences in either total or ambulatory activity counts for either sex during the pretest evaluations.

Dose-dependent increases in both total and ambulatory activity counts were observed for both males and females following administration of d-amphetamine sulfate (AMP). For males, over the entire 60-minute test session, total (ambulatory) counts were increased 103 (135)% at 2 mg/kg AMP and 166 (193)% at 4 mg/kg AMP. For females, over the entire 60-minute test session, total (ambulatory) activity counts were increased 37 (46)% at 2 mg/kg AMP and 146 (184)% at 4 mg/kg AMP. With the exception of the 2 mg/kg AMP females, all differences from the vehicle control group were statistically significant ($p < 0.01$).

Dose-dependent decreases in both total and ambulatory activity counts were observed for both males and females following administration of chlorpromazine hydrochloride (CPZ). For males, over the entire 60-minute test session, total (ambulatory) counts were decreased 77 (85)% at 5 mg/kg CPZ and 96 (98)% at 10 mg/kg CPZ. For females, over the entire 60-minute test session, total (ambulatory) activity counts were decreased 88 (92)% at 5 mg/kg CPZ and 97 (99)% at 10 mg/kg CPZ. All differences from the vehicle control group were statistically significant ($p < 0.01$).

Based on the results obtained, the SDI-PAS is sufficiently sensitive to detect dose-related increases and decreases in locomotor activity under the testing paradigm that was used.

TABLE 1

PROJECT NO.:WIL-99149 SENSITIVITY OF THE SDI-PAS TO DETECT LOCOMOTOR ACTIVITY IN RATS PAGE 1

SPONSOR:WIL RESEARCH LABS GROUP MEAN MOTOR ACTIVITY COUNTS

	----- M A L E -----				
GROUP:	0 MG/KG	2 MG/KG AMP	4 MG/KG AMP	5 MG/KG CPZ	10 MG/KG CPZ
PRETEST					
TOTAL					
MEAN	1019.	934.	1246.	1163.	1221.
S.D.	398.2	447.5	735.0	377.1	444.6
N	12	12	12	12	12
AMBULATORY					
MEAN	309.	281.	391.	376.	366.
S.D.	139.5	177.0	280.9	154.3	194.8
N	12	12	12	12	12
DAY 0					
TOTAL					
MEAN	794.	1609.**	2110.**	184.**	33.**
S.D.	293.6	655.8	638.9	195.6	25.6
N	12	12	12	12	12
AMBULATORY					
MEAN	234.	549.**	686.**	34.**	5.**
S.D.	114.9	254.8	330.0	71.3	6.0
N	12	12	12	12	12

For statistical analyses, control group 1 was compared to groups 2 and 3; control group 1 was compared to groups 4 and 5.
** = Significantly different from control group 1 at 0.01 using Dunnett's test

TABLE 1

PROJECT NO.:WIL-99149 SENSITIVITY OF THE SDI-PAS TO DETECT LOCOMOTOR ACTIVITY IN RATS

SPONSOR:WIL RESEARCH LABS GROUP MEAN MOTOR ACTIVITY COUNTS

	----- F E M A L E -----				
GROUP:	0 MG/KG	2 MG/KG AMP	4 MG/KG AMP	5 MG/KG CPZ	10 MG/KG CPZ
PRETEST					
TOTAL					
MEAN	1033.	1190.	974.	853.	1347.
S.D.	463.6	543.2	343.2	231.6	695.0
N	12	12	12	12	12
AMBULATORY					
MEAN	357.	399.	312.	277.	480.
S.D.	193.8	204.5	128.3	105.3	309.4
N	12	12	12	12	12
DAY 0					
TOTAL					
MEAN	1223.	1672.	3005.**	142.**	31.**
S.D.	676.1	759.8	773.4	116.9	45.4
N	12	12	12	12	12
AMBULATORY					
MEAN	442.	646.	1255.**	36.**	4.**
S.D.	251.0	348.5	451.5	39.5	5.2
N	12	12	12	12	12

For statistical analyses, control group 1 was compared to groups 2 and 3; control group 1 was compared to groups 4 and 5.
** = Significantly different from control group 1 at 0.01 using Dunnett's test

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03/30/2000

Figure 1

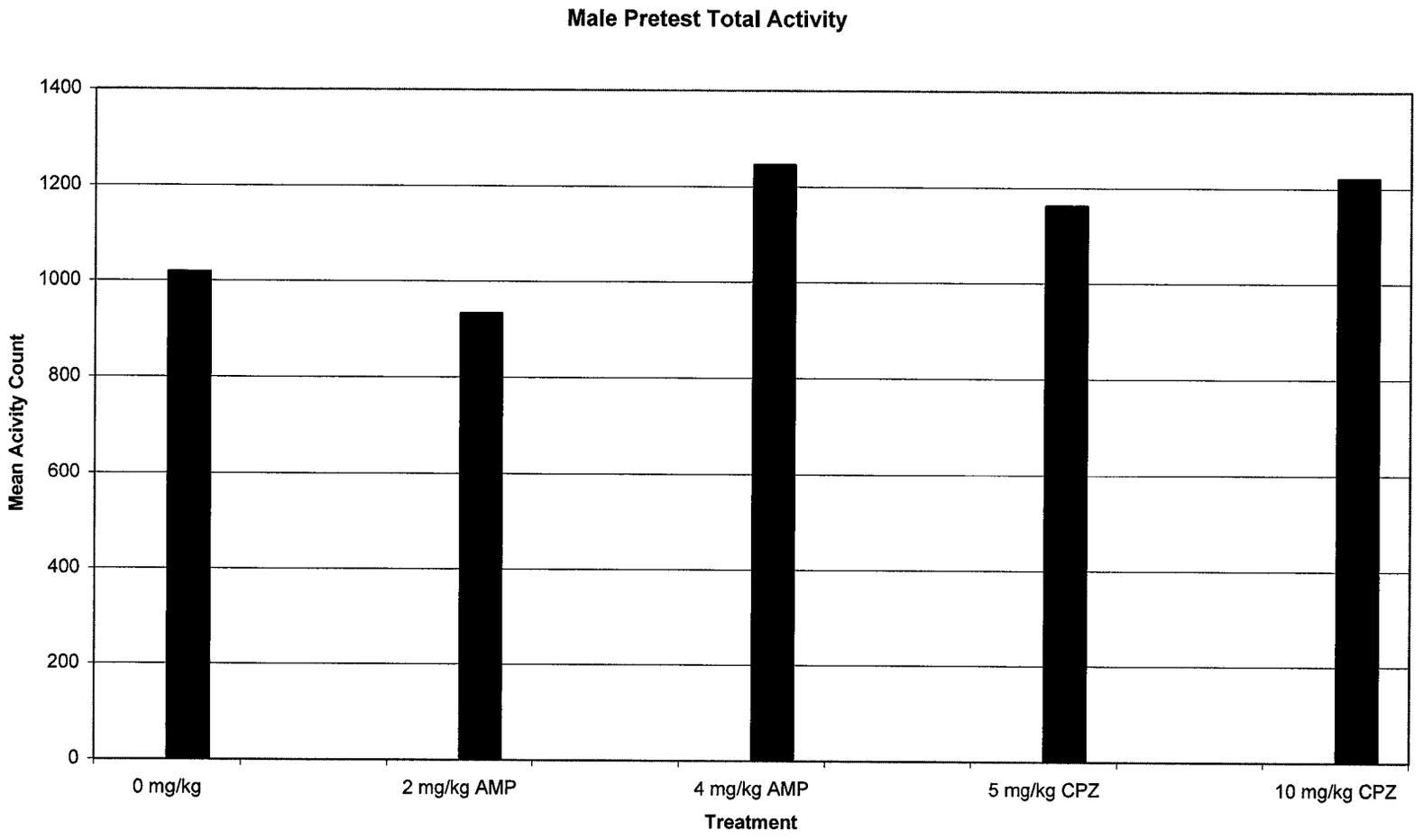

Male Pretest Total Activity
Mean Acivity Count
1400
1200
1000
800
600
400
200
0
0 mg/kg
2 mg/kg AMP
4 mg/kg AMP
5 mg/kg CPZ
10 mg/kg CPZ
Treatment

Figure 2

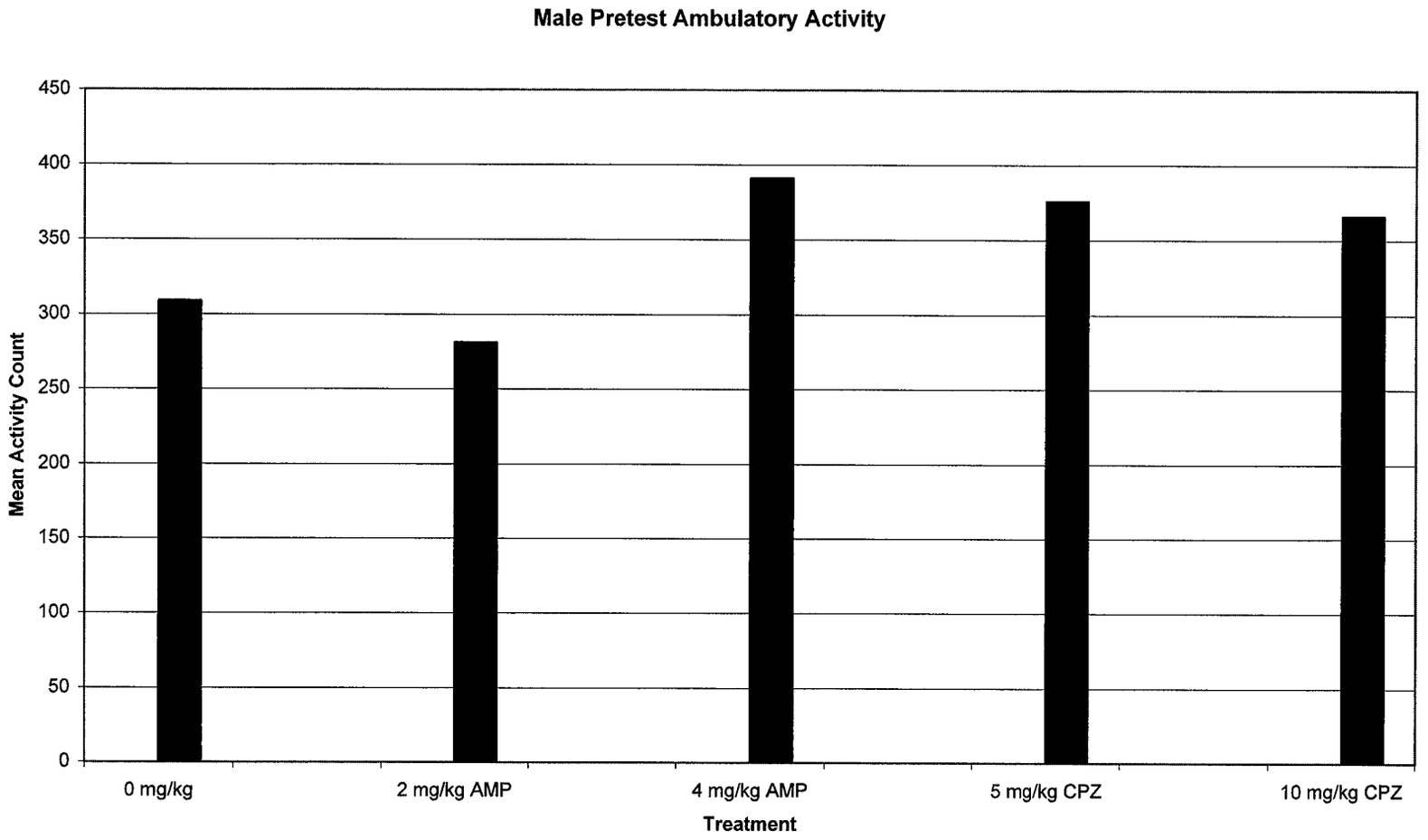

Male Pretest Ambulatory Activity
Mean Activity Count
450
400
350
300
250
200
150
100
50
0
0 mg/kg
2 mg/kg AMP
4 mg/kg AMP
5 mg/kg CPZ
10 mg/kg CPZ
Treatment

Figure 3

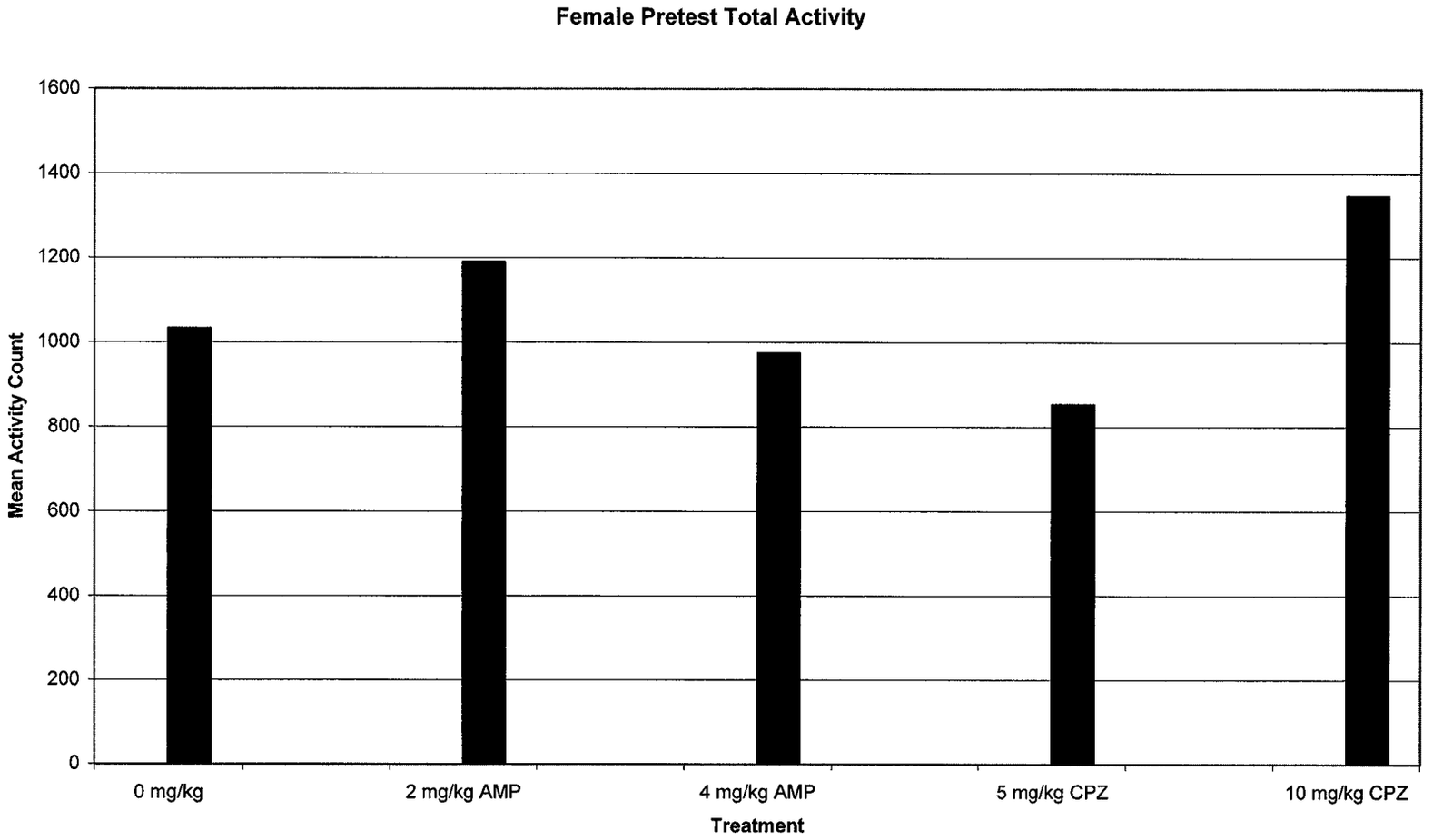

Female Pretest Total Activity
Mean Activity Count
1600
1400
1200
1000
800
600
400
200
0
0 mg/kg
2 mg/kg AMP
4 mg/kg AMP
5 mg/kg CPZ
10 mg/kg CPZ
Treatment

Figure 4

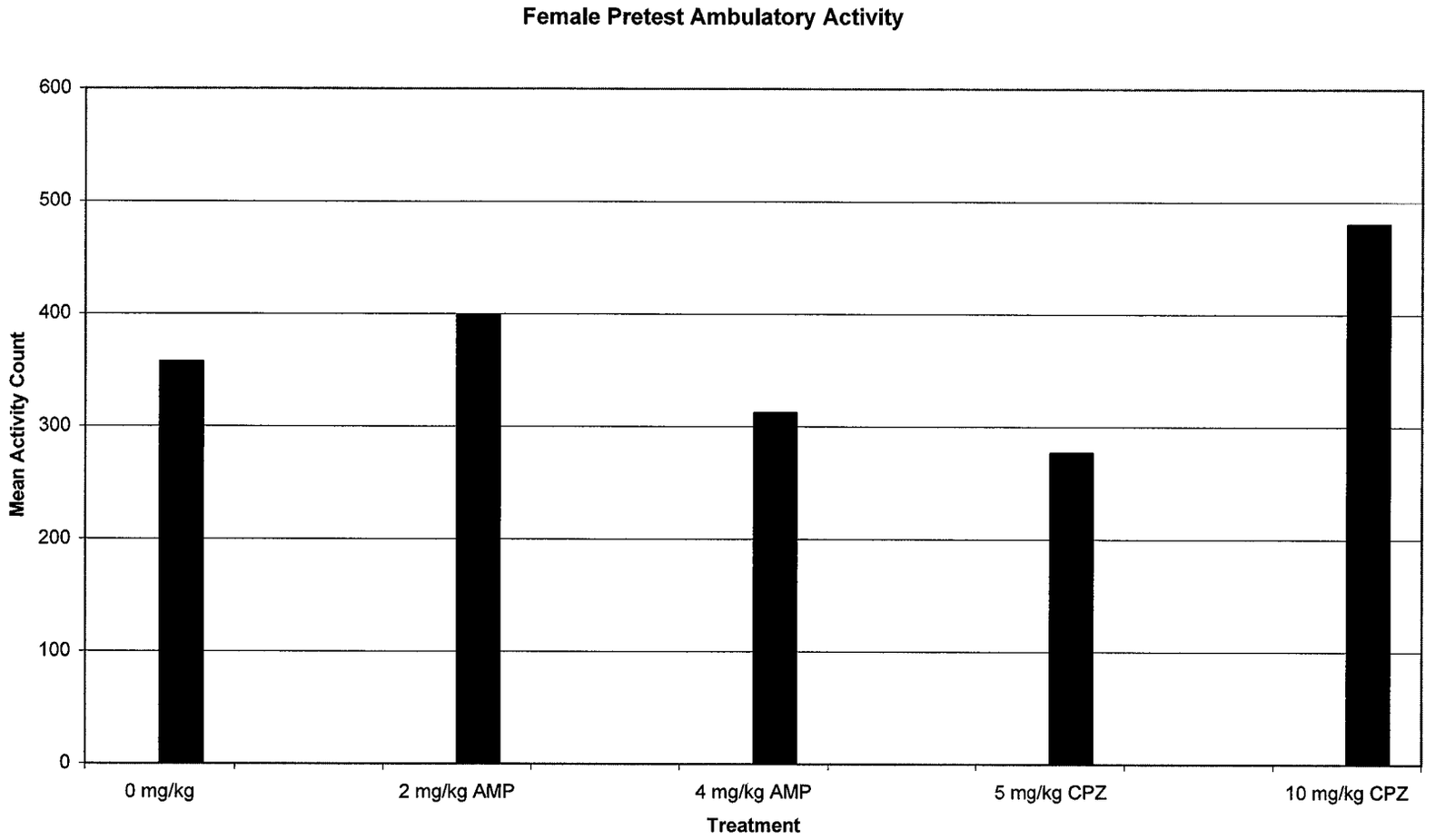
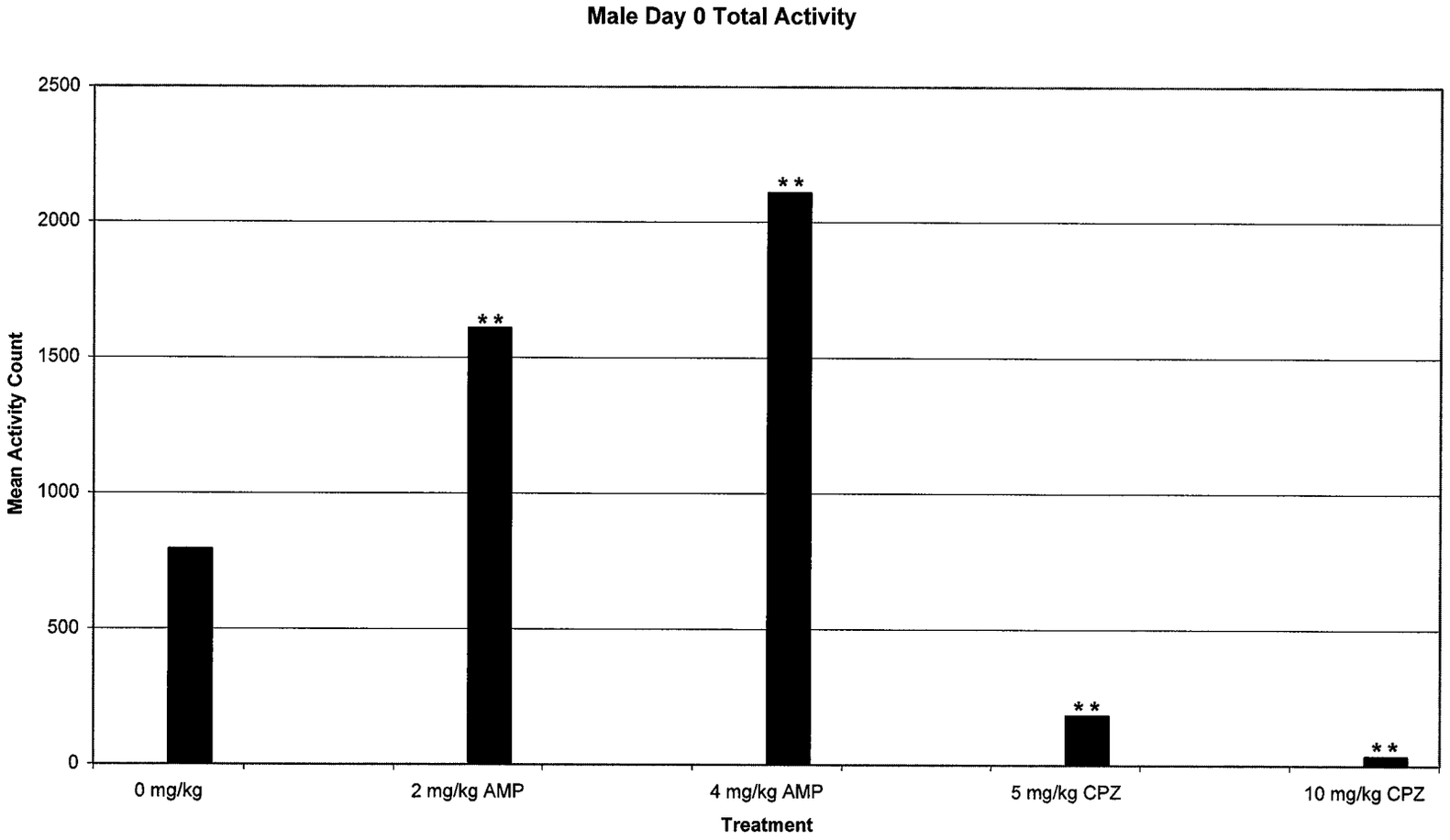
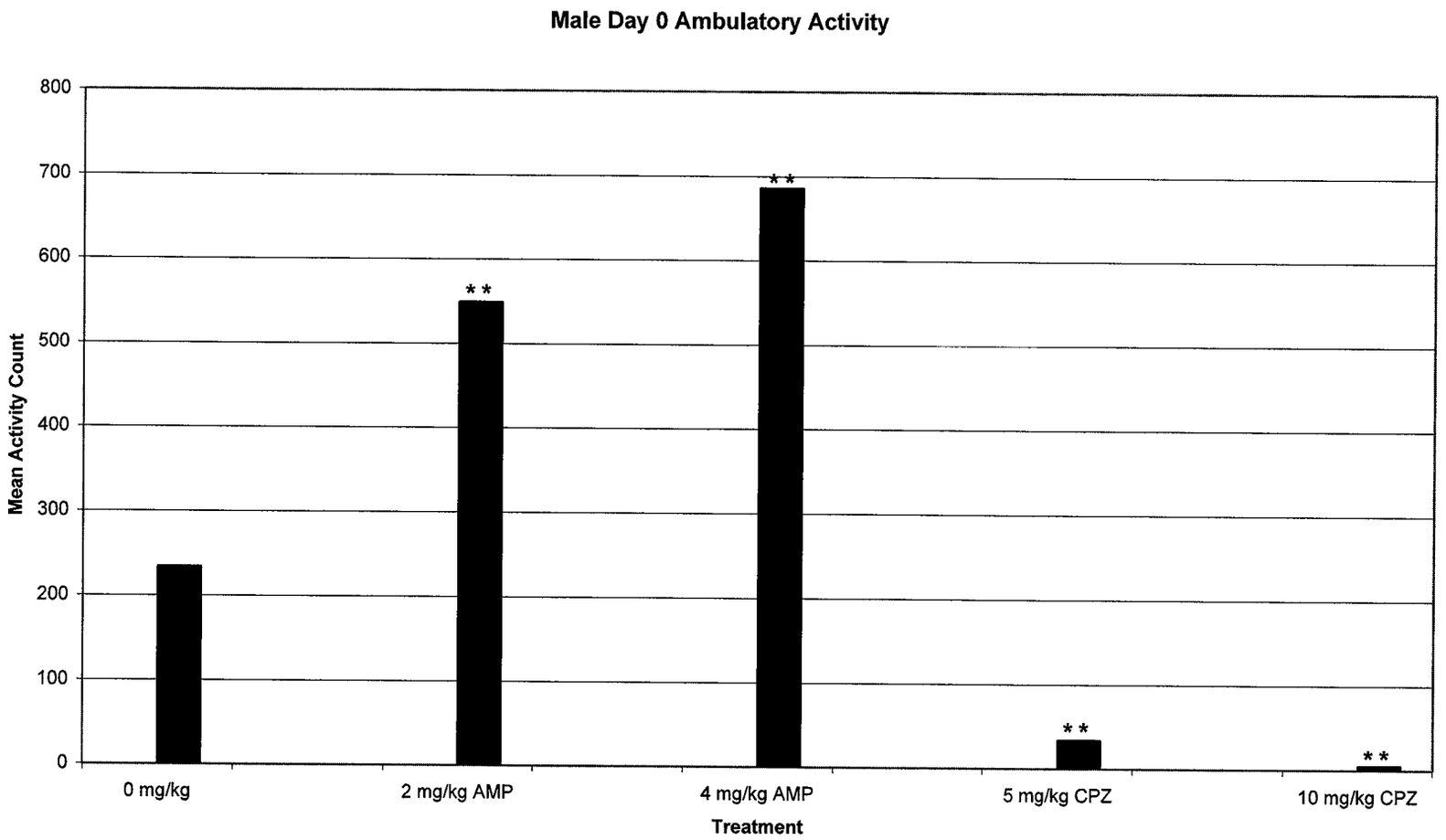

Female Pretest Ambulatory Activity
600
500
400
300
200
100
0
Mean Activity Count
0 mg/kg
2 mg/kg AMP
4 mg/kg AMP
5 mg/kg CPZ
10 mg/kg CPZ
Treatment

Figure 5



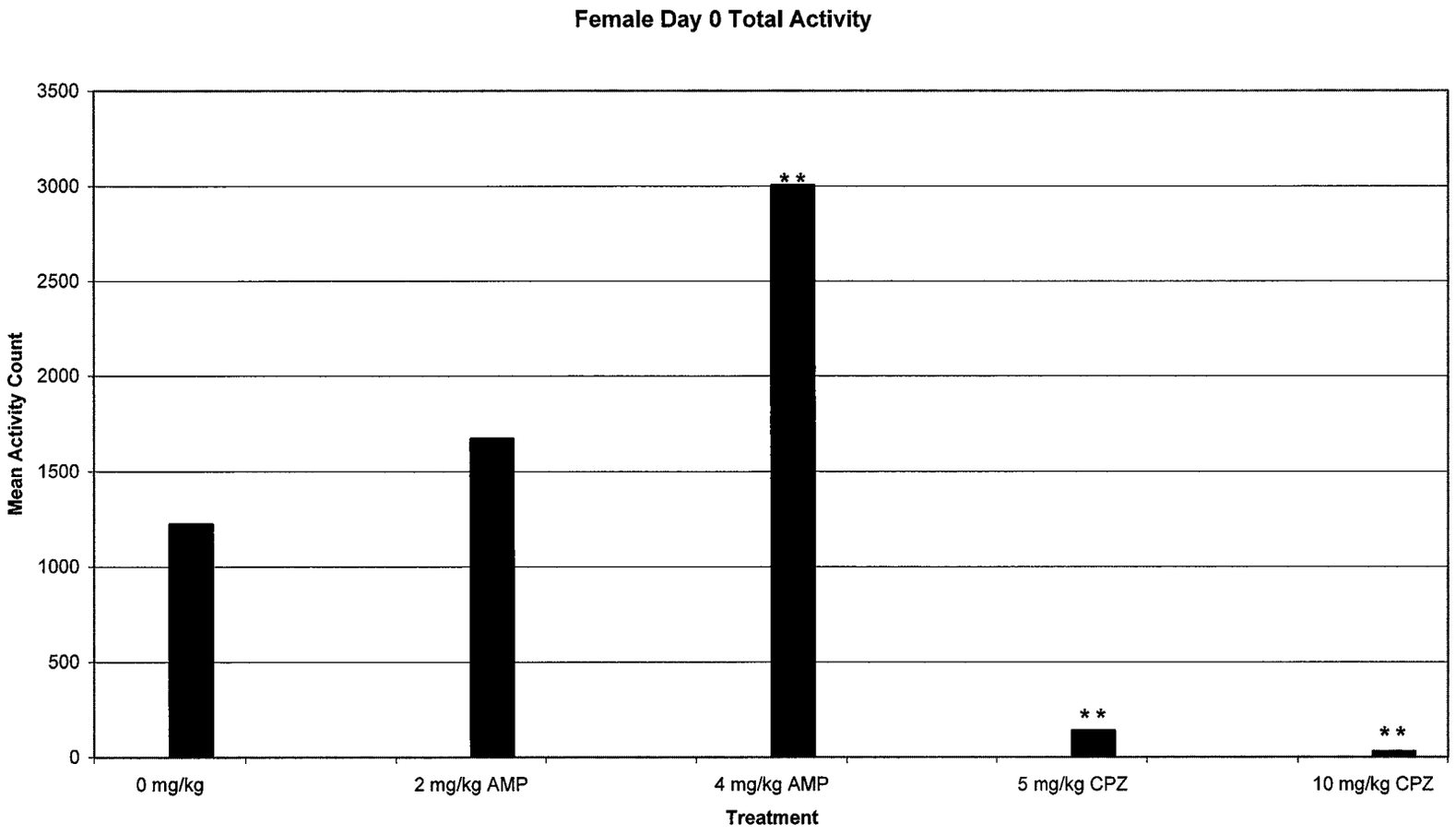
** = Significantly different from control group 1 at 0.01 using Dunnett's test

Figure 6



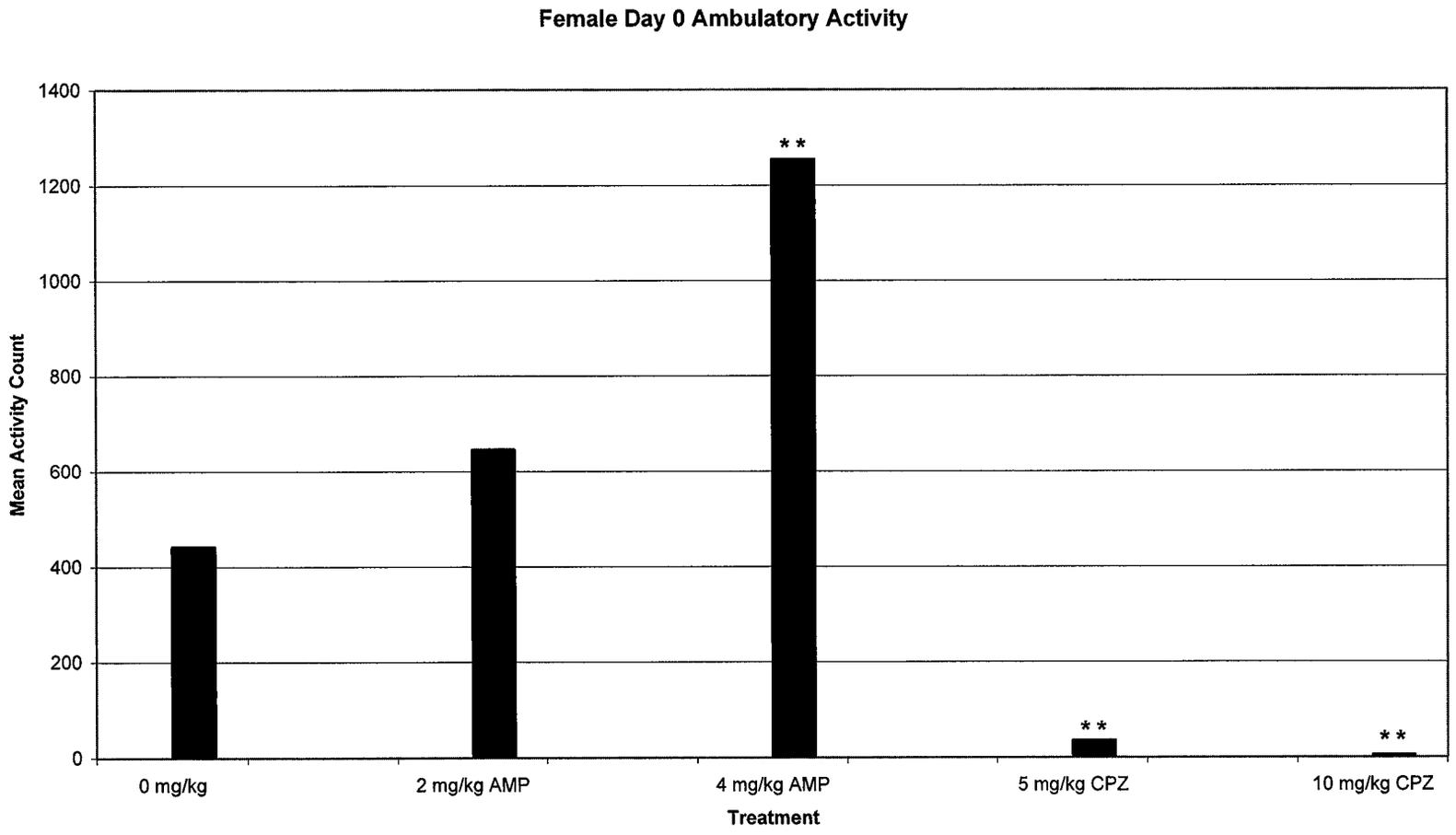
** = Significantly different from control group 1 at 0.01 using Dunnett's test

Figure 7



** = Significantly different from control group 1 at 0.01 using Dunnett's test

Figure 8



** = Significantly different from control group 1 at 0.01 using Dunnett's test

WIL-99263

AN INTER-OBSERVER RELIABILITY STUDY OF TECHNICIANS ASSIGNED TO PERFORM FUNCTIONAL OBSERVATIONAL BATTERY ASSESSMENTS IN RATS

Study Date Range: December 14, 2001 - October 9, 2002

STUDY OBJECTIVE:

The objective of this study was to train personnel to conduct the Functional Observational Battery (FOB) and to assess inter-observer reliability of the same technicians. FOB. inter-observer reliability studies serve as training for new employees, as well as on-going training for current employees.

CONTROL ARTICLES:

Deionized water was used as the negative control article. Two positive control articles, 3,3′-Iminodipropionitrile (IDPN) and Parathion, were used to elicit behavioral changes in the animals. IDPN was administered orally at 2000 mg/kg, and Parathion was administered orally at 4 mg/kg. All control articles were administered as a single dose.

TEST SYSTEM:

All animals used on the study were female Sprague-Dawley Crl:CD® (SD)IGS BR rats obtained from the WIL Research Laboratories, Inc. stock colony. Animals were randomly assigned to treatment groups using a computer program. The study was conducted according the protocol and WIL standard operating procedures.

ENVIRONMENTAL CONDITIONS:

The animals were housed and maintained under conditions consistent with maintaining good health. Temperature and relative humidity were set to maintain at 71 ± 5° C and 30-70%, respectively, in a room with a 12 hour light (6 a.m. to 6 p.m.)/dark photoperiod. Temperature and relative humidity were recorded once daily. The facilities at WIL Research Laboratories, Inc. are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

VIABILITY OBSERVATIONS:

The rats were observed for mortality/moribundity and general condition twice daily, in the morning and in the afternoon.

BODY WEIGHTS:

Body weights were recorded on days of dosing for calculation of doses only.

FUNCTIONAL OBSERVATIONAL BATTERY ASSESSMENTS:

The Functional Observational Battery used at WIL Research Laboratories, Inc. is based on previously developed protocols (Moser et al., 1999; Irwin, 1968; Gad, 1982; Moser et al., 1988; Haggerty, 1989; O'Donoghue, 1989). Testing for Phase III (described below) was performed by trained technicians who did not know the animal's group assignment. The time of testing was determined by the Study Director based on the appearance of the expected behavioral signs following dosing. Animals were observed for the following parameters as described below (see WIL standard operating procedure No. T1-112, as revised, for a description of scoring criteria):

HOME CAGE OBSERVATIONS:

Posture
Convulsions/Tremors
Feces consistency
Biting
Palpebral (eyelid) closure

HANDLING OBSERVATIONS:

Ease of removal from cage
Lacrimation/chromodacryorrhea
Piloerection
Palpebral closure
Red/crusty deposits
Eye prominence
Ease of handling animal in hand
Salivation
Fur appearance
Respiratory rate/character
Mucous membranes/eye/skin color
Muscle tone

OPEN FIELD OBSERVATIONS: (evaluated over a 2-minute observation period)

Mobility
Rearing
Convulsions/tremors
Grooming
Bizarre/stereotypic behavior
Time to first step (seconds)
Gait
Arousal
Urination/defecation
Gait score
Backing

SENSORY OBSERVATIONS:

Approach response
Startle response
Pupil response
Forelimb extension
Air righting reflex
Touch response
Tail pinch
Eyeblink response
Hindlimb extension
Olfactory orientation

The study design consisted of three distinct phases to ensure the most adequate training and reliability among the technicians. Phases were designed as a progression to allow for

training and discussion prior to the final phase, which evaluated the inter-observer reliability. The phases of testing are described as follows:

PHASE I:

Phase I testing consisted of FOB assessments on naive stock animals. Each technician observed up to 60 rats through the entire FOB assessment. The purpose of Phase I testing was to ensure consistent and accurate use of all equipment and to gain a strong knowledge of the stereotypic behavior of naive animals. All rats used in Phase I testing were returned to stock following FOB assessments.

PHASE II:

Phase II testing consisted of an open discussion of each animal's observations conducted in a group setting. Two animals per group were dosed with Parathion, IDPN or deionized water and evaluated by the observers once the effects were apparent. Phase II allowed for open discussion of observations and interpretation of the findings. All animals used in Phase II testing were euthanized by carbon dioxide inhalation and carcasses discarded following testing.

PHASE III:

Phase III testing consisted of three animals per group dosed with a single dose of Parathion, IDPN or deionized water and observed at a time determined by the Study Director. Each technician individually recorded observations for each animal to evaluate the inter-observer reliability. All animals used in Phase III testing were euthanized by carbon dioxide inhalation and carcasses discarded following testing.

CRITERIA FOR EVALUATION OF TECHNICIANS:

The following criteria were used to evaluate the ability of technicians to reliably distinguish signs of neurotoxicity.

1. No omission of findings within the categories of Home Cage Observations, Handling Observations, Open Field Observations and Sensory Observations.

2. A difference of no more than two grades (severity) for a given finding in each category.

RESULTS:

VIABILITY:

All animals survived until scheduled euthanasia.

FUNCTIONAL OBSERVATIONAL BATTERY ASSESSMENTS:

Technicians were consistent in the findings reported when deionized water, IDPN or Parathion was administered (Table 1). There were no obvious or gross inconsistencies among the calls.

It was determined that the previously established criteria for evaluation were fulfilled to a degree deemed acceptable by the Study Director. It should be noted that there were a few apparent omissions of findings (Table 2) which upon further review were found to be of no practical significance.

CONCLUSIONS:

It was determined that the technicians fulfilled the criteria for reliably observing FOB parameters to assess behavioral changes in rats in a manner consistent with good science and WIL Research Laboratories, Inc. standard operating procedures.

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TABLE 1
FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
POSTURE												
1 - SITTING OR STANDING NORMALLY	1	2	1	2					3	2	3	2
2 - ASLEEP, LYING ON SIDE OR CURLED UP	2	1	2	1	3	3	3	3				
3 - ALERT, ORIENTED TOWARD OBSERVER										1		1
4 - SITTING, HEAD HELD LOW												
5 - FLATTENED, LIMBS MAY BE EXTENDED												
6 - LYING ON SIDE, LIMBS IN AIR												
7 - IMMOBILE												
8 - REARING												
9 - SPLAYED HINDLEGS												
10 - PROSTRATION												
CONVULSIONS - CLONIC												
1 - ABSENT	3	3	3	3	3	3	3	3	2	3	3	3
2 - TWITCHES (BACK MUSCLES)												
3 - IRREGULAR JERKING MOVEMENTS OF THE LIMBS												
4 - CLONIC WHOLE-BODY CONVULSIONS												
5 - HEAD AND/OR BODY TWITCHES (MYOCLONUS)												
6 - MUSCLE FASICULATIONS												
7 - REPETITIVE MOVEMENT OF MOUTH AND JAWS (CHEWING)												
CONVULSIONS - TONIC												
1 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
2 - TONIC: CONTRACTION OF EXTENSORS SUCH THAT LIMBS ARE RIGID AND EXTENDED												
3 - OPISTHOTONUS: HEAD, BODY AND LIMBS RIGIDLY ARCHED BACKWARDS												
4 - EMPROSTHOTONUS: HEAD, BODY AND LIMBS EXTENDED FORWARD												
5 - 'POPCORN SEIZURE': ANIMAL REPEATEDLY JUMPS OR BOUNCES IN AIR												
6 - ASPHYXIAL: BOUTS OF SEVERE CLONIC-TONIC CONVULSIONS												
TREMORS												
1 - NONE	3	3	3	3	3	3	3	3	3	3	3	3
2 - SLIGHT (1.5mm)												
3 - MODERATELY COARSE (3 mm)												
4 - MARKEDLY COARSE (4.5mm)												
5 - EXTREMELY COARSE (6 mm)												

Counts indicate the number of animals observed with a particular finding.

TABLE 1

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
BITING												
1 - NONE	3	3	3	3	3	3	3	3	3	2	3	3
2 - BITING OF CAGE												
3 - BITING OF SELF												
PALPEBRAL CLOSURE												
1 - EYELIDS WIDE OPEN	1	2	1	2					2	3	3	3
2 - EYELIDS SLIGHTLY DROOPING									1			
3 - DROOPING EYELIDS (HALF-CLOSED)												
4 - EYELIDS COMPLETELY SHUT	2	1	2	1	3	3	3	3				
FECES CONSISTENCY												
1 - PELLETS									2	2	2	2
2 - PELLETS, PARTIALLY FORMED									1	1	1	1
3 - UNFORMED, DIARRHEA												
4 - PELLETS ABSENT	3	3	3	3	3	3	3	3				
EASE OF REMOVAL												
1 - VERY EASY: ANIMAL SITS QUIETLY, ALLOWS INVESTIGATOR TO PICK IT UP									2	2	2	1
2 - EASY: WITH/WITHOUT VOCALIZATION, WITHOUT RESISTANCE OR SLIGHT RESISTANCE	3	3	3	3	2	2	2	1				1
3 - MODERATELY DIFFICULT: ANIMAL REARS, OFTEN FOLLOWING THE INVESTIGATOR'S HAND					1	1	1	1	1	1	1	1
4 - FREEZES: WITH/WITHOUT VOCALIZATION												
5 - DIFFICULT: RUNS AROUND CAGE, IS HARD TO GRAB, WITH/WITHOUT VOCALIZATION												
6 - VERY DIFFICULT: TAIL AND THROAT RATTLES WITH/WITHOUT VOCALIZATION; MAY ATTACK												
EASE OF HANDLING IN HAND												
1 - LOW: NO RESISTANCE, ANIMAL IS EASY TO HANDLE	2	1	2	1					1	1		1
2 - MODERATELY LOW: SLIGHT RESISTANCE TO BEING HANDLED, WITH/WITHOUT VOCALIZATION	1	2	1	2	2	2	2	2	2	2	3	2
3 - MODERATELY HIGH: MAY FREEZE, BE TENSE OR RIGID, WITH/WITHOUT VOCALIZATION					1	1	1	1				
4 - HIGH: SQUIRMS, TWISTS, ATTEMPTS TO BITE, WITH/WITHOUT VOCALIZATION												
LACRIMATION												
1 - NONE	3	3	3	3	2	2	2	2	3	3	3	3
2 - SLIGHT					1	1	1	1				
3 - SEVERE												
CHROMODACRYORRHEA												
1 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
2 - PRESENT												

Counts indicate the number of animals observed with a particular finding.

TABLE 1
FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
SALIVATION												
1 - NONE	3	3	3	3	3	3	3	3	3	3	3	3
2 - SLIGHT												
3 - SEVERE												
PILOERECTION												
1 - NONE	3	3	3	3	3	3	3	3	3	3	3	3
2 - SLIGHT												
3 - SEVERE												
FUR APPEARANCE												
1 - NORMAL: CLEAN AND GROOMED	3	3	3	3	3	3	3	3	2	2	2	2
2 - SLIGHTLY SOILED									1	1	1	1
3 - VERY SOILED, CRUSTY												
PALPEBRAL CLOSURE												
1 - EYELIDS WIDE OPEN	3	3	3	3	2	2	2	2	3	3	3	3
2 - EYELIDS SLIGHTLY DROOPING					1	1	1	1				
3 - DROOPING EYELIDS (HALF-CLOSED)												
4 - EYELIDS COMPLETELY SHUT												
RESPIRATORY RATE												
1 - NORMAL: BY OBSERVATION (80-110/MIN.)	3	3	3	3	3	3	3	3	3	3	3	3
2 - DECREASED: BELOW 80/MIN.												
3 - INCREASED: ABOVE 110/MIN.												
RESPIRATORY CHARACTER												
1 - NORMAL	3	3	3	3	3	3	2	3	3	3	3	3
2 - RALES: ABNORMAL SOUND ACCOMPANYING BREATHING												
3 - RETCHING												
4 - DYSPNEIC: SHORT OF BREATH												
5 - GASPING												
RED DEPOSITS - eyes												
1 - PRESENT												
2 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
RED DEPOSITS - nose												
1 - PRESENT									1	1	1	1
2 - ABSENT	3	3	3	3	3	3	3	3	2	2	2	2

Counts indicate the number of animals observed with a particular finding.

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
RED DEPOSITS - mouth												
1 - PRESENT												
2 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
CRUSTY DEPOSITS - eyes												
1 - PRESENT												
2 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
CRUSTY DEPOSITS - nose												
1 - PRESENT												
2 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
CRUSTY DEPOSITS - mouth												
1 - PRESENT												
2 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
MUCOUS MEMBRANES - color												
1 - PINK	3	3	3	3	3	3	3	3	3	3	3	3
2 - PALE												
3 - DARKENED												
4 - DARKENED, BROWN												
5 - BRIGHT, DEEP RED FLUSH												
EYES - color												
1 - PINK	3	3	3	3	3	3	3	3	3	3	3	3
2 - PALE												
3 - DARKENED												
4 - DARKENED, BROWN												
5 - BRIGHT, DEEP RED FLUSH												
SKIN - color												
1 - PINK	3	3	3	3	3	3	3	3	3	3	3	3
2 - PALE												
3 - DARKENED												
4 - DARKENED, BROWN												
5 - BRIGHT, DEEP RED FLUSH												

Counts indicate the number of animals observed with a particular finding.

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
EYE PROMINENCE												
1 - NORMAL	3	3	3	3	3	3	3	3	3	3	3	3
2 - EXOPHTHALMUS												
3 - ENOPHTHALMUS												
MUSCLE TONE												
1 - MUSCLE IS FIRM BUT NOT HARD (NORMAL)	2	2	2	2	3	3	3	3	1	1	1	1
2 - MUSCLE IS SOFT AND FLABBY									1	1	1	1
3 - MUSCLE IS TENSE AND HARD	1	1	1	1					1	1	1	1
TIME TO FIRST STEP (seconds)												
REQUIRES NUMERICAL INPUT												
MOBILITY												
1 - NORMAL	3	3	3	3					3	3	3	3
2 - SLIGHTLY IMPAIRED					3	3	3	3				
3 - MODERATELY IMPAIRED												
4 - TOTALLY IMPAIRED, LOCOMOTION IMPOSSIBLE												
GAIT												
1 - NORMAL	3	3	3	3					2	2	1	1
2 - WALKS ON TIPTOES									1	1	2	1
3 - BODY DRAGS, ABDOMEN CONTACTS SURFACE, BODY SWAYS												
4 - HINDLIMBS SPLAYED OR DRAGGING, UNABLE TO SUPPORT WEIGHT					2	3	3	3				1
5 - HUNCHED BODY					2	3	3	3	1	1	1	1
6 - ATAXIA, EXCESSIVE SWAY, ROCKS OR LURCHES AS PROCEEDS FORWARD					3	2	2	3				
7 - WALKS ON METATARSUS												
CONVULSIONS - CLONIC												
1 - ABSENT	3	3	3	3	2	2	1	2	3	3	3	3
2- TWITCHES (BACK MUSCLES)												
3 - REPETITIVE MOVEMENT OF MOUTH AND JAWS					1	1	2	1				
4 - CLONIC TREMORS OF THE LIMBS												
5 - WHOLE BODY TREMORS												
6 - CLONIC CONVULSIONS												
7 - WET DOG SHAKES												

Counts indicate the number of animals observed with a particular finding.

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
CONVULSIONS - TONIC												
1 - ABSENT	3	3	3	3	3	3	3	3	3	3	3	3
2 - TONIC: CONTRACTION OF EXTENSORS SUCH THAT LIMBS ARE RIGID AND EXTENDED												
3 - OPISTHOTONUS: HEAD, BODY AND LIMBS RIGIDLY ARCHED BACKWARDS												
4 - EMPROSTHOTONUS: HEAD, BODY AND LIMBS EXTENDED FORWARD												
5 - 'POPCORN SEIZURE': ANIMAL REPEATEDLY JUMPS OR BOUNCES IN AIR												
6 - ASPHYXIAL: BOUTS OF SEVERE CLONIC-TONIC CONVULSIONS												
TREMORS												
1 - NONE	3	3	3	3	3	3	3	3	3	3	3	3
2 - SLIGHT (1.5mm)												
3 - MODERATELY COARSE (3 mm), SLIGHT IMPAIRMENT OF LOCOMOTION												
4 - MARKEDLY COARSE (4.5mm), MODERATE/MARKED IMPAIRMENT OF LOCOMOTION												
5 - EXTREMELY COARSE (6 mm), LOCOMOTION IMPOSSIBLE												
GAIT SCORE												
1 - NORMAL	3	3	3	3					2	2	2	2
2 - SLIGHT IMPAIRMENT, BUT DEFINITE					3	3	3	3	1	1	1	1
3 - CONSIDERABLE IMPAIRMENT, WITHOUT FALLING												
4 - MARKED IMPAIRMENT, FALLS EVERY 4 TO 6 STEPS												
5 - SEVERE IMPAIRMENT, CANNOT WALK WITHOUT FALLING												
AROUSAL												
1 - VERY LOW: STUPOR, COMA, LITTLE OR NO RESPONSIVENESS												
2 - LOW: SOMEWHAT STUPOROUS						1						
3 - NORMAL: ALERT, EXPLORATORY MOVEMENTS	3	3	3	3	3	2	2	3	3	3	3	3
4 - SOMEWHAT HIGH: SLIGHT EXCITEMENT, TENSE, SUDDEN DARTING OR FREEZING							1					
5 - VERY HIGH: HYPERALERT, EXCITED, SUDDEN BOUTS OF RUNNING OR BODY MOVEMENTS												

Counts indicate the number of animals observed with a particular finding.

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
BIZARRE/STEREOTYPIC BEHAVIOR												
1 - NONE	3	3	3	3					2	2	2	2
2 - HEAD FLICK: HEAD SHAKING OR BACKWARD FLIP OF HEAD					3	3	2	3				
3 - HEAD SEARCH: STEREOTYPED, REPETITIVE TURNING OF HEAD FROM SIDE TO SIDE					3	3	3	3				
4 - HALLUCINATORY: APPEARS TO BE RESPONDING TO OBJECTS NOT PRESENT												
5 - COMPULSIVE LICKING OR BITING												
6 - PRANCING: RESTLESS SHIFTING FROM ONE FORELIMB TO THE OTHER												
7 - UPRIGHT WALKING: ON HINDLIMBS ONLY												
8 - AIMLESS WANDERING: PROGRESSIVE, SLOW, PLODDING MOVEMENTS, NO APPARENT PURPOSE												
9 - CIRCLING: TENDENCY TO MOVE IN CIRCLES AROUND OBJECTS, OR IN AN OPEN ENVIRONMENT					2	2	2	2				
10 - WALTZING: RAPID TURNING IN CIRCLES												
11 - RETROPULSION: ANIMAL WALKS BACKWARDS					1	2	2	2	1	1	1	1
12 - SPATIAL DISORIENTATION: WALKING OR STUMBLING INTO OBJECTS												
13 - SIDE TO SIDE ROCKING												
14 - STRAUB TAIL: INCREASED TAIL ELEVATION												
15 - VERTICAL JUMPING												
16 - PACING WITHOUT PURPOSE												
17 - HEAD BOBBING												
18 - WRITHING: LYING DOWN, WAVELIKE MOVEMENTS OF ABDOMEN, ALTERNATING LIMB MOVEMENTS												
REARING												
REQUIRES NUMERICAL INPUT	17	17	17	17	1	1	1	1	13	13	13	13
BACKING												
REQUIRES NUMERICAL INPUT	0	0	0	0	4	4	4	4	2	2	2	2
GROOMING												
REQUIRES NUMERICAL INPUT	3	3	3	3	1	1	1	1	2	2	2	2
URINATION												
REQUIRES NUMERICAL INPUT	0	0	0	0	1	1	1	1	1	1	1	1
DEFECATION												
REQUIRES NUMERICAL INPUT	1	1	1	1	0	0	0	0	0	0	0	0

Counts indicate the number of animals observed with a particular finding.

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
APPROACH RESPONSE												
1 - NO REACTION	1	1	1	1								
2 - SLOW APPROACH, SNIFFING OR TURNING AWAY	2	2	2	2	3	3	3	3	3	3	2	3
3 - MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION											1	
4 - FREEZES, ACTUAL MUSCLE CONTRACTION												
5 - BIZARRE REACTION: JUMPS, BITES OR ATTACKS												
TOUCH RESPONSE												
1 - NO REACTION												
2 - ANIMAL MAY SLOWLY TURN, WALK AWAY	2	2	2	2	3	3	3	3	3	3	3	3
3 - MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION	1	1	1	1								
4 - FREEZES, ACTUAL MUSCLE CONTRACTION												
5 - BIZARRE REACTION: JUMPS, BITES OR ATTACKS												
STARTLE RESPONSE												
1 - NO REACTION					3	3	3	3				
2 - SLIGHT REACTION, EAR FLICK OR SOME EVIDENCE THAT SNAP WAS HEARD	3	3	2	3					1	2	1	2
3 - MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION			1						2	1	2	1
4 - FREEZES, ACTUAL MUSCLE CONTRACTION												
5 - BIZARRE REACTION: JUMPS, BITES OR ATTACKS												
TAIL PINCH RESPONSE												
1 - NO REACTION												
2 - ANIMAL MAY SLOWLY TURN, WALK AWAY	2	2	2	2	3	3	3	3	2	2	2	2
3 - MORE ENERGETIC RESPONSE THAN (2), WITH/WITHOUT VOCALIZATION	1	1	1	1					1	1	1	1
4 - FREEZES, ACTUAL MUSCLE CONTRACTION												
5 - BIZARRE REACTION: JUMPS, BITES OR ATTACKS												
OLFACTORY ORIENTATION												
1 - NO REACTION PRESENT												
2 - REACTION PRESENT: ANIMAL APPROACHES SWAB MAKING SNIFFING MOVEMENTS WITH NOSE	3	3	3	3	3	3	3	3	3	3	3	3
PUPIL RESPONSE												
1 - NO PUPIL RESPONSE					3	3	3	3				
2 - PUPIL RESPONSE PRESENT	3	3	3	3					3	3	3	3
EYEBLINK RESPONSE												
1 - NO EYEBLINK RESPONSE												
2 - EYEBLINK RESPONSE PRESENT	3	3	3	3	3	3	3	3	3	3	3	3

Counts indicate the number of animals observed with a particular finding.

TABLE 1

FOB OBSERVATIONS - NO. OF OCCURRENCES OF FINDINGS

TREATMENT:	CONTROL				IDPN				Parathion			
TECHNICIAN	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ	GRG	MJM	TAP	AZ
FORELIMB EXTENSION												
1 - NO FORELIMB EXTENSION					2	2	2	2				
2 - FORELIMB EXTENSION PRESENT	3	3	3	3	1	1	1	1	3	3	3	3
HINDLIMB EXTENSION												
1 - NO HINDLIMB EXTENSION					3	3	3	3	2	2	1	1
2 - HINDLIMB EXTENSION PRESENT	3	3	3	3					1	1	2	2
AIR RIGHTING REFLEX												
1 - NORMAL	3	3	3	3					3	3	3	3
2 - SLIGHTLY UNCOORDINATED					1	1	1	1				
3 - LANDS ON SIDE					1	1	1	1				
4 - LANDS ON BACK					1	1	1	1				

Counts indicate the number of animals observed with a particular finding.

TABLE 2
FOB OBSERVATIONS – FINDINGS OMITTED

TECHNICIAN	TREATMENT	CATEGORY OMITTED
TAP	IDPN	RESPIRATORY CHARACTER
AZ	IDPN	EASE OF REMOVAL
GRG	PARATHION	CONVULSIONS – CLONIC
MJM	PARATHION	BITING

WIL-99310

AN INTER-OBSERVER RELIABILITY STUDY OF INDIVIDUALS ASSIGNED TO PERFORM FUNCTIONAL OBSERVATIONAL BATTERY OBSERVATIONS FOR NEUROTOXICITY STUDIES

Study Date Range:

STUDY OBJECTIVE:

The objective of this study was to train personnel to conduct the Functional Observational Battery (FOB) and to assess inter-observer reliability of the same individuals. The inter-observer reliability also included one individual that had been previously trained to further demonstrate inter-observer reliability of the newly trained individuals with those currently approved to conduct neurotoxicity studies. FOB inter-observer reliability studies serve as training for new employees, as well as on-going training for current employees.

CONTROL ARTICLES:

Mazola® corn oil was used as the negative control article. Three positive control articles, 3,3′-Iminodipropionitrile (IDPN), Parathion and d-Amphetamine, were used to elicit behavioral changes in the animals. IDPN was administered orally (gavage) at 2000 mg/kg, Parathion was administered orally (gavage) at 4 mg/kg, and d-Amphetamine was administered by intraperitoneal injection at 2 mg/kg. All positive and negative control articles were administered as a single dose.

TEST SYSTEM:

All animals used on the study were female Sprague-Dawley Crl:CD® (SD)IGS BR rats obtained from the WIL Research Laboratories, Inc. stock colony. Animals were randomly assigned to treatment groups using a computer program. The study was conducted according the protocol and WIL standard operating procedures.

ENVIRONMENTAL CONDITIONS:

The animals were housed and maintained under conditions consistent with maintaining good health. Temperature and relative humidity were set to maintain at 71 ± 5° C and 30-70%, respectively, in a room with a 12 hour light (6 a.m. to 6 p.m.)/dark photoperiod. Temperature and relative humidity were recorded once daily. The ventilation rate was set at a minimum of 10 room air changes per hour using 100% fresh air. The facilities at WIL Research Laboratories, Inc. are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

VIABILITY OBSERVATIONS:

The rats were observed for mortality/moribundity and general condition twice daily, in the morning and in the afternoon.

BODY WEIGHTS:

Body weights were recorded on days of dose administration for calculation of doses only.

FUNCTIONAL OBSERVATIONAL BATTERY ASSESSMENTS:

The Functional Observational Battery used at WIL Research Laboratories, Inc. is based on previously developed protocols (Moser et al., 1999; Irwin, 1968; Gad, 1982; Moser et al., 1988; Haggerty, 1989; O'Donoghue, 1989). Testing for the Inter-observer Reliability testing (described below) was performed by trained technicians who did not know the animal's group assignment. The time of testing was determined by the Study Director based on the appearance of the expected behavioral signs following dosing. Animals were observed for the following parameters as described below (see WIL standard operating procedure No. T1-112, as revised, for a description of scoring criteria):

HOME CAGE OBSERVATIONS:

Posture
Convulsions/Tremors
Feces consistency
Biting
Palpebral (eyelid) closure

HANDLING OBSERVATIONS:

Ease of removal from cage
Lacrimation/chromodacryorrhea
Piloerection
Palpebral closure
Red/crusty deposits
Eye prominence
Ease of handling animal in hand
Salivation
Fur appearance
Respiratory rate/character
Mucous membranes/eye/skin color
Muscle tone

OPEN FIELD OBSERVATIONS: (evaluated over a 2-minute observation period)

Mobility
Rearing
Convulsions/tremors
Grooming
Bizarre/stereotypic behavior
Time to first step (seconds)
Gait
Arousal
Urination/defecation
Gait score
Backing

SENSORY OBSERVATIONS:

Approach response	Touch response
Startle response	Tail pinch
Pupil response	Eyeblink response
Forelimb extension	Hindlimb extension
Air righting reflex	Olfactory orientation

The study design consisted of three distinct phases to ensure the most adequate training and reliability among the technicians. Phases were designed as a progression to allow for training and discussion prior to the final phase, which evaluated the inter-observer reliability. The phases of testing are described as follows:

PHASE I:

Phase I testing consisted of FOB assessments on naive stock animals. Each technician observed up to 60 rats through the entire FOB assessment. The purpose of Phase I testing was to ensure consistent and accurate use of all equipment and to gain a strong knowledge of the stereotypic behavior of naive animals. All rats used in Phase I testing were returned to stock following FOB assessments.

PHASE II:

Phase II testing consisted of an open discussion of each animal's observations conducted in a group setting. Two animals per group were dosed with IDPN, Parathion, d-Amphetamine or corn oil and evaluated by the observers once the effects were apparent. Phase II allowed for open discussion of observations and interpretation of the findings. All animals used in Phase II testing were euthanized by carbon dioxide inhalation and carcasses discarded following testing.

PHASE III:

Inter-observer Reliability testing consisted of three animals per group dosed with a single dose of Parathion, IDPN, d-Amphetamine or corn oil and observed at a time determined by the Study Director or designee. Each observer individually recorded observations for each animal to evaluate the inter-observer reliability. All animals used in Inter-observer Reliability testing were euthanized by carbon dioxide inhalation and carcasses discarded following testing.

CRITERIA FOR EVALUATION OF TECHNICIANS:

The following criteria were used to evaluate the ability of technicians to reliably distinguish signs of neurotoxicity.

1. No omission of findings within the categories of Home Cage Observations, Handling Observations, Open Field Observations and Sensory Observations.

2. A difference of no more than two grades (severity) for a given finding in each category.

RESULTS:

VIABILITY:

All animals survived until scheduled euthanasia.

FUNCTIONAL OBSERVATIONAL BATTERY ASSESSMENTS:

Observers B, C, D and E were consistent in the findings reported when corn oil, IDPN, Parathion or d-Amphetamine was administered (Table 1). There were no obvious or gross inconsistencies among the calls with the exception of observer E who differed consistently when evaluating pupillary response. Therefore, these four observers were considered to have met acceptable for performing the functional observational battery on neurotoxicity studies. However, prior to working independently on studies, observer E will undergo additional training and demonstrate proficiency in the evaluation of pupillary response.

Observer A differed significantly from the common response of the other observers in several categories. Therefore, observer A was not considered to have met acceptable criteria for performing functional observational battery testing on neurotoxicity studies.

It should be noted there were six apparent omissions of observations (Table 2) which upon further review were found to be of no consequence.

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Moser, V.C.; McCormick, J.P.; Creason, J.P.; MacPhail, R.C. Comparison of chlordimeform and carbaryl using a functional observational battery. *Fundamentals of Applied Toxicology* **1988,** *11(2),* 189-206.

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TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

	Animal #52298					Animal #52277					Animal #52222					Animal #52210					Animal #52321					Animal #52315				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
1 - SITTING OR STANDING NORMALLY		X		X	X	X	X		X	X			X								X									
2 - ASLEEP, LYING ON SIDE OR CURLED UP								X																						
3 - ALERT, ORIENTED TOWARD OBSERVER			X								X	X			X	X	X	X	X	X		X	X	X	X	X	X	X	X	X
4 - SITTING, HEAD HELD LOW	X		X																											
5 - FLATTENED, LIMBS MAY BE EXTENDED																														
6 - LYING ON SIDE, LIMBS IN AIR																														
7 - IMMOBILE																														
8 - REARING														X															X	
9 - SPLAYED HINDLEGS																														
10 - PROSTRATION																														
CONVULSIONS - CLONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X
2 - TWITCHES (BACK MUSCLES)																														
3 - IRREGULAR JERKING MOVEMENTS OF THE LIMBS																														
4 - CLONIC WHOLE-BODY CONVULSIONS																														
5 - HEAD AND/OR BODY TWITCHES (MYOCLONUS)																				X										
6 - MUSCLE FASICULATIONS (CHEWING)																														
CONVULSIONS - TONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - TONIC: CONTRACTION OF EXTENSORS SUCH THAT LIMBS ARE RIGID AND EXTENDED																														
ARCHED BACKWARDS																														
EXTENDED FORWARD																														
5 - 'POPCORN SEIZURE'. ANIMAL REPEATEDLY JUMPS OR BOUNCES IN AIR																														
6 - ASPHYXIAL: BOUTS OF SEVERE CLONIC-TONIC CONVULSIONS																														

TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
TREMORS																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X		X	X	X	X
2 - SLIGHT (1.5mm)																X										X				
3 - MODERATELY COARSE (3 mm)																														
4 - MARKEDLY COARSE (4.5mm)																														
5 - EXTREMELY COARSE (6 mm)																														
BITING																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - BITING OF CAGE																														
3 - BITING OF SELF																														
PALPEBRAL CLOSURE																														
1 - EYELIDS WIDE OPEN		X	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - EYELIDS SLIGHTLY DROOPING	X			X	X																									
3 - DROOPING EYELIDS (HALF-CLOSED)																														
4 - EYELIDS COMPLETELY SHUT																														
FECES CONSISTENCY																														
1 - PELLETS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X
2 - PELLETS, PARTIALLY FORMED																														
3 - UNFORMED, DIARRHEA																														
4 - PELLETS ABSENT																														
EASE OF HANDLING IN HAND																														
1 - LOW: NO RESISTANCE, ANIMAL IS EASY TO HANDLE	X	X	X	X	X	X	X		X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - MODERATELY LOW. SLIGHT RESISTANCE TO BEING HANDLED, WITH/WITHOUT VOCALIZATION								X							X															
3 - MODERATELY HIGH: MAY FREEZE, BE TENSE OR RIGID, WITH/WITHOUT VOCALIZATION																														
4 - HIGH: SQUIRMS, TWISTS, ATTEMPTS TO BITE, WITH/WITHOUT VOCALIZATION																														
LACRIMATION																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHT																														
3 - SEVERE																														
CHROMODACRYORRHEA																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PRESENT																														

TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
SALIVATION																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHT																X														
3 - SEVERE																														
PILOERECTION																														
1 - NONE	X	X	X	X	X	X	X	X	X	X		X	X	X		X	X	X	X	X	X	X	X	X	X		X	X		
2 - SLIGHT											X				X											X			X	X
3 - SEVERE																														
FUR APPEARANCE																														
1 - NORMAL: CLEAN AND GROOMED	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHTLY SOILED																														
3 - VERY SOILED, CRUSTY																														
PALPEBRAL CLOSURE																														
1 - EYELIDS WIDE OPEN	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - EYELIDS SLIGHTLY DROOPING																														
3 - DROOPING EYELIDS (HALF-CLOSED)																														
4 - EYELIDS COMPLETELY SHUT																														
RESPIRATORY RATE																														
1 - NORMAL: BY OBSERVATION (80-110/MIN.)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - DECREASED: BELOW 80/MIN.																														
3 - INCREASED: ABOVE 110/MIN.																														
RESPIRATORY CHARACTER																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - RALES: ABNORMAL SOUND ACCOMPANYING BREATHING																														
3 - RETCHING																														
4 - DYSPNEIC. SHORT OF BREATH																														
5 - GASPING																														
RED DEPOSITS - eyes																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
RED DEPOSITS - nose																														
1 - PRESENT																											X			
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X

TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
RED DEPOSITS - mouth																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CRUSTY DEPOSITS - eyes																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CRUSTY DEPOSITS - nose																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CRUSTY DEPOSITS - mouth																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MUCOUS MEMBRANES - color																														
1 - PINK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PALE																														
3 - DARKENED																														
4 - DARKENED, BROWN																														
5 - BRIGHT, DEEP RED FLUSH																														
EYES - color																														
1 - PINK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PALE																														
3 - DARKENED																														
4 - DARKENED, BROWN																														
5 - BRIGHT, DEEP RED FLUSH																														
SKIN - color																														
1 - PINK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PALE																														
3 - DARKENED																														
4 - DARKENED, BROWN																														
5 - BRIGHT, DEEP RED FLUSH																														
EYE PROMINENCE																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X	X	X
2 - EXOPHTHALMUS																X			X											
3 - ENOPHTHALMUS																														

TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
MUSCLE TONE																														
1 - MUSCLE IS FIRM BUT NOT HARD (NORMAL)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - MUSCLE IS SOFT AND FLABBY																														
3 - MUSCLE IS TENSE AND HARD																														
MOBILITY																														
1 - NORMAL						X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHTLY IMPAIRED	X	X	X	X	X																									
3 - MODERATELY IMPAIRED																														
4 - TOTALLY IMPAIRED, LOCOMOTION IMPOSSIBLE																														
GAIT																														
1 - NORMAL						X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X		
2 - WALKS ON TIPTOES																									X					X
3 - BODY DRAGS, ABDOMEN CONTACTS SURFACE, BODY SWAYS																														
4 - HINDLIMBS SPLAYED OR DRAGGING, UNABLE TO SUPPORT WEIGHT	X	X			X																									
5 - HUNCHED BODY	X	X							X																X	X			X	X
6 - ATAXIA, EXCESSIVE SWAY, ROCKS OR LURCHES AS PROCEEDS FORWARD	X	X	X	X																										
7 - WALKS ON METATARSUS																														
CONVULSIONS - CLONIC																														
1 - ABSENT	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
2- TWITCHES (BACK MUSCLES)					X																									
3 - REPETITIVE MOVEMENT OF MOUTH AND JAWS																														
4 - CLONIC TREMORS OF THE LIMBS																														
5 - WHOLE BODY TREMORS																														
6 - CLONIC CONVULSIONS																														
7 - WET DOG SHAKES																														
CONVULSIONS - TONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - TONIC: CONTRACTION OF EXTENSORS SUCH THAT LIMBS ARE RIGID AND EXTENDED																														
3 - OPISTHOTONUS· HEAD, BODY AND LIMBS RIGIDLY ARCHED BACKWARDS																														
4 - EMPROSTHOTONUS. HEAD, BODY AND LIMBS EXTENDED FORWARD																														

TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
5 - 'POPCORN SEIZURE': ANIMAL REPEATEDLY JUMPS OR BOUNCES IN AIR																														
6 - ASPHYXIAL: BOUTS OF SEVERE CLONIC-TONIC CONVULSIONS																														
TREMORS																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X
2 - SLIGHT (1.5mm)																										X				
3 - MODERATELY COARSE (3 mm), SLIGHT IMPAIRMENT OF LOCOMOTION																														
4 - MARKEDLY COARSE (4.5mm), MODERATE/MARKED IMPAIRMENT OF LOCOMOTION																														
5 - EXTREMELY COARSE (6 mm), LOCOMOTION IMPOSSIBLE																														
GAIT SCORE																														
1 - NORMAL						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHT IMPAIRMENT, BUT DEFINITE	X	X	X	X																										
3 - CONSIDERABLE IMPAIRMENT, WITHOUT FALLING					X																									
4 - MARKED IMPAIRMENT, FALLS EVERY 4 TO 6 STEPS																														
5 - SEVERE IMPAIRMENT, CANNOT WALK WITHOUT FALLING																														
AROUSAL																														
1 - VERY LOW: STUPOR, COMA, LITTLE OR NO RESPONSIVENESS																														
2 - LOW. SOMEWHAT STUPOROUS																									X					
3 - NORMAL: ALERT, EXPLORATORY MOVEMENTS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X
4 - SOMEWHAT HIGH: SLIGHT EXCITEMENT, TENSE, SUDDEN DARTING OR FREEZING																														
5 - VERY HIGH. HYPERALERT, EXCITED, SUDDEN BOUTS OF RUNNING OR BODY MOVEMENTS																														

TABLE 1
FOB2 - INTEROBSERVER COMPARISIONS

Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
BIZARRE/STEREOTYPIC BEHAVIOR																														
1 - NONE						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X
2 - HEAD FLICK· HEAD SHAKING OR BACKWARD FLIP OF HEAD	X	X	X	X	X																			X						
3 - HEAD SEARCH· STEREOTYPED, REPETITIVE TURNING OF HEAD FROM SIDE TO SIDE		X		X	X																									
4 - HALLUCINATORY: APPEARS TO BE RESPONDING TO OBJECTS NOT PRESENT																														
5 - COMPULSIVE LICKING OR BITING																														
6 - PRANCING. RESTLESS SHIFTING FROM ONE FORELIMB TO THE OTHER																														
7 - UPRIGHT WALKING· ON HINDLIMBS ONLY																														
8 - AIMLESS WANDERING: PROGRESSIVE, SLOW, PLODDING MOVEMENTS, NO APPARENT PURPOSE																														
BIZARRE/STEREOTYPIC BEHAVIOR (Continued)																														
9 - CIRCLING: TENDENCY TO MOVE IN CIRCLES AROUND OBJECTS, OR IN AN OPEN ENVIRONMENT	X		X		X																									
10 - WALTZING. RAPID TURNING IN CIRCLES																														
11 - RETROPULSION: ANIMAL WALKS BACKWARDS				X																										
12 - SPATIAL DISORIENTATION. WALKING OR STUMBLING INTO OBJECTS	X																													
13 - SIDE TO SIDE ROCKING																														
14 - STRAUB TAIL: INCREASED TAIL ELEVATION																														
15 - VERTICAL JUMPING																														
16 - PACING WITHOUT PURPOSE																														
17 - HEAD BOBBING			X		X																									
18 - WRITHING: LYING DOWN, WAVELIKE MOVEMENTS OF ABDOMEN, ALTERNATING LIMB MOVEMENTS																														
PUPIL RESPONSE																														
1 - NO PUPIL RESPONSE	X	X	X	X	X												X										X			
2 - PUPIL RESPONSE PRESENT						X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X		X	X	X
AIR RIGHTING REFLEX																														
1 - NORMAL						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHTLY UNCOORDINATED																														
3 - LANDS ON SIDE	X			X																										
4 - LANDS ON BACK		X	X		X																									

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52254					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
POSTURE																														
1 - SITTING OR STANDING NORMALLY	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X						X	X	X	X	X
2 - ASLEEP, LYING ON SIDE OR CURLED UP																					X	X	X	X	X					
3 - ALERT, ORIENTED TOWARD OBSERVER			X																											
4 - SITTING, HEAD HELD LOW																														
5 - FLATTENED, LIMBS MAY BE EXTENDED																														
6 - LYING ON SIDE, LIMBS IN AIR																														
7 - IMMOBILE																														
8 - REARING																														
9 - SPLAYED HINDLEGS																														
10 - PROSTRATION																														
CONVULSIONS - CLONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X		X	X	X	X	X	X	X	X	X	X
2 - TWITCHES (BACK MUSCLES)																														
3 - IRREGULAR JERKING MOVEMENTS OF THE LIMBS																														
4 - CLONIC WHOLE-BODY CONVULSIONS																														
5 - HEAD AND/OR BODY TWITCHES (MYOCLONUS)																X				X										
6 - MUSCLE FASICULATIONS																														
7 - REPETITIVE MOVEMENT OF MOUTH AND JAWS (CHEWING)																														
CONVULSIONS - TONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - TONIC: CONTRACTION OF EXTENSORS SUCH THAT LIMBS ARE RIGID AND EXTENDED																														
3 - OPISTHOTONUS: HEAD, BODY AND LIMBS RIGIDLY ARCHED BACKWARDS																														
4 - EMPROSTHOTONUS: HEAD, BODY AND LIMBS EXTENDED FORWARD																														
5 - 'POPCORN SEIZURE': ANIMAL REPEATEDLY JUMPS OR BOUNCES IN AIR																														
6 - ASPHYXIAL: BOUTS OF SEVERE CLONIC-TONIC CONVULSIONS																														
TREMORS																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
2 - SLIGHT (1.5mm)											X																		X	
3 - MODERATELY COARSE (3 mm)																														

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52264					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
4 - MARKEDLY COARSE (4.5mm)																														
5 - EXTREMELY COARSE (6 mm)																														
BITING																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - BITING OF CAGE																														
3 - BITING OF SELF																														
PALPEBRAL CLOSURE																														
1 - EYELIDS WIDE OPEN	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X					X			X	X	X	X	X
2 - EYELIDS SLIGHTLY DROOPING																	X		X	X										
3 - DROOPING EYELIDS (HALF-CLOSED)																														
4 - EYELIDS COMPLETELY SHUT																					X	X		X	X					
FECES CONSISTENCY																														
1 - PELLETS		X		X	X	X	X	X	X	X	X	X	X	X		X	X	X	X		X	X		X			X	X	X	
2 - PELLETS, PARTIALLY FORMED	X		X																	X					X	X				
3 - UNFORMED, DIARRHEA			X												X										X			X		X
4 - PELLETS ABSENT																														
EASE OF HANDLING IN HAND																														
1 - LOW: NO RESISTANCE, ANIMAL IS EASY TO HANDLE	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - MODERATELY LOW: SLIGHT RESISTANCE TO BEING HANDLED, WITH/WITHOUT VOCALIZATION															X															
3 - MODERATELY HIGH: MAY FREEZE, BE TENSE OR RIGID, WITH/WITHOUT VOCALIZATION																														
4 - HIGH: SQUIRMS, TWISTS, ATTEMPTS TO BITE, WITH/WITHOUT VOCALIZATION																														
LACRIMATION																														
1 - NONE	X	X	X	X	X	X	X	X	X	X		X					X	X	X	X		X		X	X	X	X	X	X	
2 - SLIGHT											X		X	X	X	X					X		X							X
3 - SEVERE																														
CHROMODACRYORRHEA																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PRESENT																														
SALIVATION																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHT																														
3 - SEVERE																														

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52254					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
PILOERECTION																														
1 - NONE	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - SLIGHT					X																									
3 - SEVERE																														
FUR APPEARANCE																														
1 - NORMAL: CLEAN AND GROOMED						X	X	X	X	X	X	X	X	X			X	X	X	X		X	X	X		X	X	X	X	X
2 - SLIGHTLY SOILED	X	X	X	X	X										X	X					X				X					
3 - VERY SOILED, CRUSTY																														
PALPEBRAL CLOSURE																														
1 - EYELIDS WIDE OPEN	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				X			X	X	X	X	X
2 - EYELIDS SLIGHTLY DROOPING																				X	X	X		X						
3 - DROOPING EYELIDS (HALF-CLOSED)																									X					
4 - EYELIDS COMPLETELY SHUT																														
RESPIRATORY RATE																														
1 - NORMAL: BY OBSERVATION (80-110/MIN.)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - DECREASED: BELOW 80/MIN.																														
3 - INCREASED: ABOVE 110/MIN.																														
RESPIRATORY CHARACTER																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - RALES: ABNORMAL SOUND ACCOMPANYING BREATHING																														
3 - RETCHING																														
4 - DYSPNEIC: SHORT OF BREATH																														
5 - GASPING																														
RED DEPOSITS - eyes																														
1 - PRESENT											X						X					X								
2 - ABSENT	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X		X	X	X	X		X	X	X	X	X	X	X	X
RED DEPOSITS - nose																														
1 - PRESENT		X														X	X					X								
2 - ABSENT	X		X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X		X	X	X	X	X	X	X	X
RED DEPOSITS - mouth																														
1 - PRESENT																	X													
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
CRUSTY DEPOSITS - eyes																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52254					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
CRUSTY DEPOSITS - nose																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CRUSTY DEPOSITS - mouth																														
1 - PRESENT																														
2 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MUCOUS MEMBRANES - color																														
1 - PINK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PALE																														
3 - DARKENED																														
4 - DARKENED, BROWN																														
5 - BRIGHT, DEEP RED FLUSH																														
EYES - color																														
1 - PINK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PALE																														
3 - DARKENED																														
4 - DARKENED, BROWN																														
5 - BRIGHT, DEEP RED FLUSH																														
SKIN - color																														
1 - PINK	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - PALE																X														
3 - DARKENED																														
4 - DARKENED, BROWN																														
5 - BRIGHT, DEEP RED FLUSH																														
EYE PROMINENCE																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - EXOPHTHALMUS																														
3 - ENOPHTHALMUS																														
MUSCLE TONE																														
1 - MUSCLE IS FIRM BUT NOT HARD (NORMAL)	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X			X		X	X		X	X	X	X	X	X	X
2 - MUSCLE IS SOFT AND FLABBY																	X	X		X			X							
3 - MUSCLE IS TENSE AND HARD					X																									

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52254					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
MOBILITY																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X											X	X	X	X	X
2 - SLIGHTLY IMPAIRED																		X	X	X										
3 - MODERATELY IMPAIRED																X	X				X	X	X	X	X					
4 - TOTALLY IMPAIRED, LOCOMOTION IMPOSSIBLE																														
GAIT																														
1 - NORMAL		X	X	X		X	X	X	X	X	X	X	X	X												X	X	X		
2 - WALKS ON TIPTOES																														
3 - BODY DRAGS, ABDOMEN CONTACTS SURFACE, BODY SWAYS	X																								X					
4 - HINDLIMBS SPLAYED OR DRAGGING, UNABLE TO SUPPORT WEIGHT																X	X		X	X		X		X	X					
5 - HUNCHED BODY	X				X										X	X	X		X		X	X	X	X	X				X	X
6 - ATAXIA, EXCESSIVE SWAY, ROCKS OR LURCHES AS PROCEEDS FORWARD																	X	X	X		X	X	X	X						
7 - WALKS ON METATARSUS																														
CONVULSIONS - CLONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X		X	X	X		X	X	X	X	X
2- TWITCHES (BACK MUSCLES)																									X					
3 - REPETITIVE MOVEMENT OF MOUTH AND JAWS																														
4 - CLONIC TREMORS OF THE LIMBS																														
5 - WHOLE BODY TREMORS																X														
6 - CLONIC CONVULSIONS																					X									
7 - WET DOG SHAKES																														
CONVULSIONS - TONIC																														
1 - ABSENT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2 - TONIC. CONTRACTION OF EXTENSORS SUCH THAT LIMBS ARE RIGID AND EXTENDED																														
3 - OPISTHOTONUS: HEAD, BODY AND LIMBS RIGIDLY ARCHED BACKWARDS																														
4 - EMPROSTHOTONUS: HEAD, BODY AND LIMBS EXTENDED FORWARD																														
5 - 'POPCORN SEIZURE': ANIMAL REPEATEDLY JUMPS OR BOUNCES IN AIR																														
6 - ASPHYXIAL: BOUTS OF SEVERE CLONIC-TONIC CONVULSIONS																														

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52254					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
TREMORS																														
1 - NONE	X	X	X	X	X	X	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
2 - SLIGHT (1.5mm)											X			X															X	
3 - MODERATELY COARSE (3 mm), SLIGHT IMPAIRMENT OF LOCOMOTION																														
4 - MARKEDLY COARSE (4.5mm), MODERATE/MARKED IMPAIRMENT OF LOCOMOTION																														
5 - EXTREMELY COARSE (6 mm), LOCOMOTION IMPOSSIBLE																														
GAIT SCORE																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X											X	X	X	X	X
2 - SLIGHT IMPAIRMENT, BUT DEFINITE																X		X		X			X		X					
3 - CONSIDERABLE IMPAIRMENT, WITHOUT FALLING																	X		X		X	X		X						
4 - MARKED IMPAIRMENT, FALLS EVERY 4 TO 6 STEPS																														
5 - SEVERE IMPAIRMENT, CANNOT WALK WITHOUT FALLING																														
AROUSAL																														
1 - VERY LOW: STUPOR, COMA, LITTLE OR NO RESPONSIVENESS																														
2 - LOW: SOMEWHAT STUPOROUS																					X		X	X			X		X	
3 - NORMAL: ALERT, EXPLORATORY MOVEMENTS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X			X	X		X		X
4 - SOMEWHAT HIGH: SLIGHT EXCITEMENT, TENSE, SUDDEN DARTING OR FREEZING																														
5 - VERY HIGH: HYPERALERT, EXCITED, SUDDEN BOUTS OF RUNNING OR BODY MOVEMENTS																														
BIZARRE/STEREOTYPIC BEHAVIOR																														
1 - NONE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X											X		X	X	X
2 - HEAD FLICK: HEAD SHAKING OR BACKWARD FLIP OF HEAD																	X		X	X	X	X	X	X	X					
3 - HEAD SEARCH: STEREOTYPED, REPETITIVE TURNING OF HEAD FROM SIDE TO SIDE																	X	X	X	X		X	X	X	X					
4 - HALLUCINATORY: APPEARS TO BE RESPONDING TO OBJECTS NOT PRESENT																					X									
5 - COMPULSIVE LICKING OR BITING																														
6 - PRANCING: RESTLESS SHIFTING FROM ONE FORELIMB TO THE OTHER																														
7 - UPRIGHT WALKING: ON HINDLIMBS ONLY																														
8 - AIMLESS WANDERING: PROGRESSIVE, SLOW, PLODDING MOVEMENTS, NO APPARENT PURPOSE																														

TABLE 1
FOB2 - INTER-OBSERVER COMPARISONS

	Animal #52247					Animal #52225					Animal #52216					Animal #51868					Animal #52254					Animal #52338				
Observer:	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B	A	E	D	C	B
BIZARRE/STEREOTYPIC BEHAVIOR (Continued)																														
9 - CIRCLING: TENDENCY TO MOVE IN CIRCLES AROUND OBJECTS, OR IN AN OPEN ENVIRONMENT																X	X			X	X		X							
10 - WALTZING: RAPID TURNING IN CIRCLES																														
11 - RETROPULSION: ANIMAL WALKS BACKWARDS																X	X	X	X	X	X	X		X	X					
12 - SPATIAL DISORIENTATION. WALKING OR STUMBLING INTO OBJECTS																														
13 - SIDE TO SIDE ROCKING																														
14 - STRAUB TAIL: INCREASED TAIL ELEVATION																														
15 - VERTICAL JUMPING																														
16 - PACING WITHOUT PURPOSE																														
17 - HEAD BOBBING																		X		X			X		X					
18 - WRITHING: LYING DOWN, WAVELIKE MOVEMENTS OF ABDOMEN, ALTERNATING LIMB MOVEMENTS																														
PUPIL RESPONSE																														
1 - NO PUPIL RESPONSE		X					X					X		X			X	X	X	X	X	X	X	X	X		X			
2 - PUPIL RESPONSE PRESENT	X		X	X	X	X		X	X	X	X		X		X	X										X		X	X	X
AIR RIGHTING REFLEX																														
1 - NORMAL	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X											X	X	X	X	
2 - SLIGHTLY UNCOORDINATED																														X
3 - LANDS ON SIDE																	X	X	X				X							
4 - LANDS ON BACK																X				X	X	X		X	X					

TABLE 2
FOB OBSERVATIONS – FINDINGS OMITTED

OBSERVER	OBSERVATION	NUMBER OMITTED
E	MOBILITY	1
D	MOBILITY	1
E	CONVULSIONS- CLONIC	1
D	FECES CONSISTENCY	1
A	FECES CONSISTENCY	1
E	BIZARRE/STEREOTYPIC BEHAVIOR	1

APPENDIX G

Scoring Criteria For The Functional Observational Battery

Scoring Criteria for the Functional Observational Battery

Definition:

The Functional Observational Battery (FOB) is a procedure used to detect gross functional deficits in test animals.

Description:

The FOB consists of a series of tests. The tests are categorized into home-cage, handling, open-field, sensory, neuromuscular and physiological observations and are as follows:

1. Home-Cage Observations

    a. Posture
    b. Convulsions
    c. Tremors
    d. Biting
    e. Palpebral (eyelid) closure
    f. Feces Consistency

2. Handling Observations

    a. Ease of removal from cage
    b. Ease of handling animal in hand
    c. Lacrimation
    d. Chromodacryorrhea
    e. Salivation
    f. Piloerection
    g. Fur appearance
    h. Palpebral closure
    i. Respiratory rate
    j. Respiratory character
    k. Red deposits
    l. Crusty deposits
    m. Mucous membranes/eye/skin color
    n. Eye prominence
    o. Muscle tone

3. Open-Field Observations

   a. Time to first step (seconds)
   b. Rearing
   c. Mobility
   d. Backing
   e. Grooming
   f. Gait
   g. Convulsions
   h. Tremors
   i. Gait Score
   j. Arousal
   k. Bizarre/Stereotypic behavior
   l. Urination
   m. Defecation

4. Sensory Observations

   a. Approach response
   b. Touch response
   c. Startle response
   d. Tail pinch
   e. Olfactory orientation
   f. Pupil response
   g. Eyeblink response
   h. Forelimb extension
   i. Hindlimb extension
   j. Air righting reflex

5. Neuromuscular Observations

   a. Hindlimb extensor strength
   b. Grip strength-hind and forelimb
   c. Rotarod performance
   d. Hindlimb foot splay

6. Physiological Observations

   a. Catalepsy
   b. Body Temperature
   c. Body Weight

Procedure

The FOB was performed on those study days specified in the study protocol. Test animals were removed from their cages one at a time on the designated day of testing, and, unless specified in the study protocol, were taken through the FOB in the following order: FOB1 (inclusive of categories 1a-1f and 2a), FOB2 (inclusive of categories 2b-2o, 3a-3m and 4a-4j) and FOB3 (inclusive of categories 5a-5d and 6a-6c).

Testing was performed by trained technicians, who did not know the group assignment of the animals. A description of the scoring criteria for each test is provided below:

1. HOME-CAGE OBSERVATIONS

Observations of the animal in its home cage and while opening the cage were performed and scored as follows:

a. Posture

Sitting or standing normally	1
Asleep, lying on side or curled up	2
Alert, oriented toward observer	3
Sitting, head held low	4
Flattened, limbs may be extended	5
Lying on side, limbs in air	6
Immobile	7
Rearing	8

b. Convulsions

I. Clonic

Absent	1
Repetitive movement of mouth and jaws	2
Clonic tremors of the limbs (contraction followed by relaxation)	3
Whole body tremors	4
Clonic convulsions	5
Wet Dog Shakes	6

II. Tonic

Absent	1
Tonic: contraction of extensors such that limbs are rigid and extended	2
Opisthotonus: head, body and limbs rigidly arched backwards	3
Emprosthotonus: head, body and limbs extended forward	4
'Popcorn seizure': animal repeatedly jumps or bounces in air	5
Asphyxial: bouts of severe clonic-tonic convulsions	6

c. Tremors

None	1
Slight (1.5 mm)	2
Moderately coarse (3 mm), slight impairment of locomotion	3
Markedly coarse (4.5 mm), moderate/marked impairment of locomotion	4
Extremely coarse (6 mm), locomotion impossible	5

d. Biting

None	1
Biting of cage	2
Biting of self	3

e. Palpebral (eyelid) closure

Eyelids wide open	1
Eyelids slightly drooping	2
Drooping eyelids (half closed)	3
Eyelids completely shut	4

f. Feces Consistency

Pellets	1
Pellets, partially formed	2
Unformed, diarrhea	3
Pellets absent	4

2. HANDLING OBSERVATIONS

Animals were removed singly from their cages and observed and scored as follows:

a. Ease of removal from cage

Very easy: animal sits quietly, allows investigator to pick it up	1
Easy: with or without vocalization, without resistance or slight resistance to being picked up	2
Moderately difficult: animal rears, often following Investigator's hand	3
Freezes: with or without vocalization	4
Difficult: runs around cage, is hard to grab, with or without vocalization	5
Very difficult: tail and throat rattles with or without vocalization, may attack hand	6

b. Ease of handling animal in hand

Low: no resistance, animal is easy to handle	1
Moderately low: slight resistance to being handled, with or without vocalization	2
Moderately high: rat may freeze, or be tense or rigid in hand, with or without vocalization	3
High: squirming, twisting, attempting to bite with or without vocalization	4

c. Lacrimation

None	1
Slight	2
Severe	3

d. Chromodacryorrhea

Absent	1
Present	2

e. Salivation

None	1
Slight	2
Severe	3

f. Piloerection

None	1
Slight	2
Severe	3

g. Fur Appearance

Normal: clean and groomed	1
Slightly soiled	2
Very soiled, crusty	3

h. Palpebral closure

Eyelids wide open	1
Eyelids slightly drooping	2
Drooping eyelids (half closed)	3
Eyelids completely shut	4

i. Respiratory Rate

Normal: by observation (80-110/min.)	1
Decreased: below 80/min.	2
Increased: above 110/min.	3

j. Respiratory Character

Normal	1
Rales: abnormal sound accompanying breathing	2
Retching	3
Dyspneic: short of breath	4
Gasping	5

k. Red Deposits - eyes, nose, mouth

Present	1
Absent	2

l. Crusty Deposits - eyes, nose, mouth

Present	1
Absent	2

m. Mucous membranes/eye/skin color

Pink	1
Pale	2
Darkened	3
Darkened, brown	4
Bright, deep red flush	5

n. Eye Prominence

Normal	1
Exophthalmus	2
Enophthalmus	3

o. Muscle Tone

The musculature of the limbs was palpated between the thumb and forefinger.

Muscle is firm but not hard (normal)	1
Muscle is soft and flabby	2
Muscle is tense and hard	3

3. OPEN-FIELD OBSERVATIONS

Animals were placed singly in the open-field arena (24" x 24" x 6"; constructed from Plexiglas® and painted black) and evaluated over a 2-minute observation period as follows:

a. Time to first step (seconds)

The time taken for the animal to take its first step in the open-field arena was recorded in seconds.

b. Rearing

The number of times the animal reared back onto its hind legs and stood up with both front paws raised off the surface was recorded over a 2-minute observation period in the open-field arena.

c. Mobility (scored within 30 seconds of placing animal in the open-field arena)

Normal	1
Slightly Impaired	2
Moderately Impaired	3
Totally Impaired, Locomotion impossible	4

d. Backing

The number of times the animal took three or more backward steps over a 2-minute observation period in the open-field arena was recorded.

e. Grooming

The number of times the animal groomed itself over a 2-minute observation period in the open-field arena was recorded. Grooming includes washing the face and head with the forepaws, scratching the head or body with a hind paw, and biting the fur.

f. Gait

Normal, head horizontal, abdomen just above surface, slight up and down movement with each step	1
Walks on tiptoes	2
Body drags, abdomen makes contact with surface, body sway	3

f. Gait (Continued)

Hindlimbs splayed or dragging, unable to support weight	4
Hunched body, bottom up, nose held down, arched back	5
Ataxia, excessive sway, rocks or lurches as animal proceeds forward	6

g. Convulsions

I. Clonic

Absent	1
Repetitive movement of mouth and jaws	2
Clonic tremors of the limbs (contraction followed by relaxation)	3
Whole body tremors	4
Clonic convulsions	5
Wet Dog Shakes	6

II. Tonic

Absent	1
Tonic: contraction of extensors such that limbs are rigid and extended	2
Opisthotonus: head, body and limbs rigidly arched backwards	3
Emprosthotonus: head, body and limbs arched forward	4
'Popcorn seizure': animal repeatedly jumps or bounces in air	5
Asphyxial: bouts of severe clonic-tonic convulsions	6

h. Tremors

None	1
Slight (1.5mm)	2
Moderately coarse (3 mm), slight impairment of locomotion	3
Markedly coarse (4.5 mm), moderate/marked impairment of locomotion	4
Extremely coarse (6 mm), locomotion impossible	5

i. Gait Score: Ability to locomote despite abnormalities in gait

Normal	1
Slight impairment, but definite	2
Considerable impairment, without falling	3
Marked impairment, falls every 4 to 6 steps	4
Severe impairment, cannot walk without falling	5

j. Arousal

Very low: Stupor, coma, little or no responsiveness	1
Low: Somewhat stuporous	2
Normal: Alert, exploratory movements	3
Somewhat high: Slight excitement, tense, excited sudden darting or freezing	4
Very high: Hyperalert, excited, sudden bouts of running or body movements	5

k. Bizarre/Stereotypic Behavior

None	1
Head Flick: head shaking or backward flip of head	2
Head Search: stereotyped, repetitive turning of head from side to side as though searching the environment	3
Hallucinatory: animal appears to be responding to objects not present	4
Compulsive licking or biting	5
Prancing: restless shifting from one forelimb to other, with slight turning of the body from side to side	6
Upright walking: on hindlimbs only	7
Aimless wandering: progressive, slow, plodding movements about environment, with no apparent purpose	8
Circling: tendency to move in circles around and along objects, or in an open environment	9
Waltzing: rapid turning in circles	10
Retropulsion: where animal walks backwards	11
Spatial disorientation: walking or stumbling into objects	12
Side to side rocking	13
Straub tail: increased tail elevation	14
Vertical Jumping	15
Pacing without purpose	16
Head bobbing	17

k. Bizarre/Stereotypic Behavior (continued)

Writhing: lying down, wavelike movement of abdomen, alternating limb movements	18

l. Urination

The number of pools of urine in the open-field arena was counted.

m. Defecation

The number of fecal boli in the open-field arena was counted.

4. SENSORY OBSERVATIONS

Sensory tests were performed in the open-field arena as follows:

a. Approach Response

The animal was approached head-on with a blunt object held approximately 3 cm from its face for a 4-second period.

No reaction	1
Slow approach, sniffing or turning away	2
More energetic than (2) may include vocalization	3
Freezes, actual muscle contraction	4
Bizarre reaction: jumps, bites or attacks	5

b. Touch Response

The rump of the animal was approached from the side and touched with a blunt object.

No reaction	1
Animal may slowly turn, walk away	2
More energetic response than (2), may include vocalization	3
Freezes, actual muscle contraction	4
Bizarre reaction: jumps, bites or attacks	5

c. Startle Response

A clicker held approximately 5 cm above the head of the animal was used to make a sudden sound.

No reaction	1
Slight reaction, ear flick or some evidence that snap was heard	2
More energetic response than (2), may include vocalization	3
Freezes, actual muscle contraction	4
Bizarre reactions: jumps, attacks, bites	5

d. Tail Pinch

Metal tweezers were used to squeeze tail approximately 2-3 cm from tip.

No reaction	1
Animal may turn or walk away	2
More energetic than (2), may include vocalization	3
Freezes, actual muscle contraction	4
Bizarre reaction: jumps, attacks or bites	5

e. Olfactory Orientation

Approaching the animal from behind, a cotton swab that had been dipped into a jar of commercially available homogenized baby food was brought to within approximately 4-5 cm of the side of the animal's head.

No reaction present	1
Reaction present, animal approaches swab making sniffing movements with nose, may lick swab	2

f. Pupil Response

The beam from a pen light was brought to within approximately 5 mm of the surface of the eye. Changes in pupil size were recorded.

No pupil response	1
Pupil response present	2

g. Eyeblink Response

The corner of the eye was touched gently with a blunt object.

No eyeblink response	1
Eyeblink response present	2

h. Forelimb Extension

The animal was held by the tail and lowered towards a table top. The presence or absence of normal forelimb extension was recorded.

No forelimb extension	1
Forelimb extension present	2

i. Hindlimb Extension

The animal was placed on a table top and lifted by the tail. The presence of normal hindlimb extension was recorded.

No hindlimb extension	1
Hindlimb extension present	2

j. Air Righting Reflex

The animal was held in a supine position and dropped from a height of approximately 30 cm. The ease of landing was scored as follows:

Normal	1
Slightly uncoordinated	2
Lands on side	3
Lands on back	4

5. NEUROMUSCULAR OBSERVATIONS

a. Hindlimb Extensor Strength

The animal was picked up and slight pressure was applied to its hindlimbs. The normal response is for the animal to extend its hindlimbs against the pressure.

a. Hindlimb Extensor Strength (continued)

Hindlimb resistance absent	1
Reduced hindlimb resistance, animal shows some weakness	2
Hindlimb resistance present	3

b. Grip Strength - hind and forelimb

Forelimb and hindlimb grip strength were measured using a device similar to the one described by Meyer *et al* (Neurobehav. Toxicol. 1:233-239, 1979). The animal was allowed to grip a T-shaped grip bar with its forepaws and was pulled back gently along a platform until its grip was broken. As the backward locomotion continued, the animal's hindpaws reached a T-shaped rearlimb grip bar, which it was allowed to grasp and then forced to release by continued pulling. Chatillon push-pull strain gauges (J.A. King, Greensboro, North Carolina) were used to record the maximum strain required to break forelimb and hindlimb grip. The average of three valid measurements was taken as the animal's score for each grip strength measure.

c. Rotarod Performance

During the pretest period, the animals were trained to walk on a rotarod (a 7.0-cm-diameter rod rotating at 12 rpm; AccuScan Instruments, Inc., Columbus, Ohio) for a period of two minutes. The duration of time each animal remained on the rotarod (up to a maximum time of 120 seconds) during testing was recorded.

d. Hindlimb Foot Splay

The heel pads of the hindfeet of the animal were painted with a non-toxic water-based paint. Animals are dropped from a horizontal position approximately 30 cm above a table onto the Hindlimb Foot Splay Test sheet. The distance (to the nearest millimeter) between the inner edge of the ink blots made by each foot was measured. The test was repeated two more times; and the average score (to the nearest millimeter) of the latter two trials was calculated.

6. PHYSIOLOGICAL OBSERVATIONS

a. Catalepsy

The animal was placed on four Plexiglas® platforms (35 mm high and 40 mm in diameter) that were a distance of 100 mm from each other between the fore and hind feet and 60 mm between right and left feet (when measured from the center of the platforms). The time each animal remained on the four platforms was recorded. The duration of immobility was measured (up to a maximum time of 60 seconds).

b. Body Temperature

A thermometer was inserted into the rectum of the animal, and the body temperature was recorded after an equilibration period of approximately 30 seconds.

c. Body Weight

The weight of the animal was recorded.

The Functional Observational Battery is normally recorded on-line via the "IFOB" program in NT-module. In the event that the Data Management System is unavailable for on-line data collection, data are hand-recorded on the Functional Observational Battery Individual Data Sheets (T1-228, as revised). When appropriate, the hand-recorded data are late entered into the Data Management System.

APPENDIX H

Clinical Pathology Methods, Procedures And References

CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Serum Chemistry - Hitachi 912

Albumin - Bromcresol Green (BCG) Method, Modification of the Doumas reaction. Default unit: g/dL. Hitachi 912 Application Code 413. Roche Reagent, catalog number 11970569.

A/G Ratio - Calculated from Albumin and Globulin Results. Default unit: %.

Alkaline Phosphatase - based on the International Federation of Clinical Chemistry (IFCC) Method (Tietz *et al.* J Clin Chem Clin Biochem 1983; 21:731-748). Default unit: U/L. Hitachi 912 Application Code 158. Roche Reagent, catalog number 2172933.

Alanine Aminotransferase - Modification of the International Federation of Clinical Chemistry (IFCC) recommended method. Default unit: U/L. Hitachi 912 Application Code 706. Roche Reagent, catalog number 450065.

Aspartate Aminotransferase - Kinetic method based on the International Federation of Clinical Chemistry (IFCC) recommendations. Default unit: U/L. Hitachi 912 Application Code 715. Roche Reagent, catalog number 450064.

Bilirubin (Total) - Diazo method developed by Wahlefeld *et al.* Scand J Clin Lab Invest 1972; 29: Supplement 126. Default unit: mg/dL. Hitachi 912 Application Code 716. Roche Reagent, catalog number 1039034.

Blood Urea Nitrogen (BUN) - A urease-triggered methodology based upon the method of Talke and Schubert Klin Wschr, 1965; 43:174. Default unit: mg/dL. Hitachi 912 Application Code 427. Roche Reagent, catalog number 1489321.

Calcium - Modified method using a gamma-amino-butyric acid (GABA) buffer. Default unit: mg/dL. Hitachi 912 Application Code 180. Roche Reagent, catalog number 1125621.

Chloride - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog numbers 820638, 836246 and 820639.

Cholesterol - Enzymatic reaction as described by Trinder. Ann Clin Biochem 1974; 12:266. Default unit: mg/dL. Hitachi 912 Application Code 722. Roche Reagent, catalog number 450061.

Serum Chemistry - Hitachi 912 (continued)

Creatinine - Modified Jaffe reaction based on the work of Poper *et al.* Biochem Z 1937; 291:354, and Seelig and Wuest. Aerztl Labor 1969; 15:34. Default unit: mg/dL. Hitachi 912 Application Code 727. Roche Reagent, catalog number 450019.

Globulin - Calculation obtained by subtracting Albumin from Total Protein. Default unit: g/dL.

Glucose - Glucose hexokinase method based on the work of Schmidt, Peterson and Young. Klin Wschr 1961; 39:1244. Methods of Enzymatic Analysis, 2nd Eng ed. New York, Academic Press, 1974; 1196. Anal Biochemistry 1958; 23:301. Default unit: mg/dL. Hitachi 912 Application Code 767. Roche Reagent, catalog number 450058.

Phosphorus - Method involves the formation of ammonium phosphomolybdate. Default unit: mg/dL. Hitachi 912 Application Code 714. Roche Reagent, catalog number 1040898.

Potassium - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog numbers 820638, 836246 and 820639.

Sodium - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog number 820638, 836246 and 820639.

Total Protein - Endpoint biuret method that utilizes a sample blank. Default unit: g/dL. Hitachi 912 Application Code 756. Roche Reagent, catalog number 1040901.

Triglycerides - Method that utilizes lipase from a microorganism to promote rapid and complete hydrolysis of triglycerides to glycerol. Default unit: mg/dL. Hitachi 912 Application Code 781. Roche Reagent, catalog number 1488899.

Hematology - Manual Methods

White Cell Differential - Manual method of counting 100 white cells stained with Wright Giemsa and entered on-line into the data files.

Reticulocyte Count - Manual method of counting the reticulocytes present in 1000 red blood cells stained with New Methylene Blue and entered on-line into the data files.

Red Blood Cell Morphology - Manual method of evaluating red blood cells on a Wright Giemsa-stained slide and entered on-line into the data files.

Hematology - Manual Methods (continued)

Platelet Estimate- Manual method of evaluating platelets on a Wright Giemsa-stained slide. Platelet estimation is evaluated and entered on-line into the data files as decreased, adequate or increased. Platelet clumps present on the slide will be reported as part of the RBC morphology.

AMAX Destiny Amelung Coagulation

Mechanical (Ball Method) Measurement – Mechanical measurement methods depend on the physical formation of fibrin strands that attach to a moving mechanical device that either completes or opens and electrical circuit. The elapsed time from the addition of the starting reagent, up to the beginning of fibrin formation is measured.

Prothrombin Time (Protime-PT)- mechanical clot detection is used to measure and record the time required for plasma specimens to clot by adding an excess of thromboplastin reagent and an optional amount of calcium to citrated plasma. The PT measures from factor VII through fibrin formation (extrinsic and common pathways of coagulation). Default unit: sec.

Activated Partial Thromboplastin Time (APTT)- mechanical clot detection is used to measure and record clotting time in a one-stage procedure which consists of recalcifying plasma in the presence of an excess of platelet-like reagent (cephalin) containing a plasma activator. The APTT measures the clotting time from factor XII through fibrin formation (intrinsic and common pathways of coagulation) Default unit: sec.

Hematology-Bayer Advia® 120

WBC Count - The whole blood sample is mixed with ADVIA® 120 BASO reagent that contains acid and surfactant. The red cells are hemolyzed, and the white blood cells are then analyzed using two angle laser light scatter signals. Default unit: x 10^3 cells/μL

RBC / Platelet Count - Both red blood cells and platelets are analyzed by a single optical cytometer after appropriate dilution of the blood sample with ADVIA® 120 RBC/PLT reagent. The red blood cells are isovolumetrically sphered and lightly fixed with glutaraldehyde to preserve the spherical shape. Red cells and platelets are counted from the signals from a common detector with 2 different gain settings. Default unit RBC: x 10^6cells/μL. Default unit PLT: x 10^3 cells/μL

Hematology-Bayer Advia® 120 (continued)

Hgb - Hemoglobin: The hemoglobin method is a modification of the manual cyanmethemoglobin method developed by the International Committee for standardization in Hematology (ICSH). Default unit: g/dL.

Hematocrit - The percentage of blood volume that is occupied by red blood cells. Also referred to as the packed red cell volume. On the ADVIA® 120 Hematology System this parameter is derived from the measured red cell volume (MCV) and the red cell count (RBC). Default unit: %.

MCH - Mean Corpuscular Hemoglobin: the average weight of hemoglobin in the red blood cells, calculated from the RBC and Hgb measurements. Default unit: pg.

MCHC - Mean Corpuscular Hemoglobin Concentration: the average concentration of hemoglobin in the red blood cells. This parameter is computed from the measured hemoglobin and the computed hematocrit. Default unit: g/dL.

MCV - Mean Corpuscular Volume: the average volume of the red blood cells. Default unit: fL

White blood cell differential - The ADVIA® 120 Hematology System White Blood Cell Differential (WBC DIFF) methods, consists of both the Peroxidase method and the Basophil/Lobularity method. The ADVIA® 120 Hematology System performs a six-part differential that consists of basophils, eosinophils, large unstained cells, lymphocytes, monocytes, and neutrophils. The white blood cell differential count is reported in percent and the actual number of each type of cell per microliter of blood.

Reticulocyte - This method uses a nucleic acid dye (oxazine 750) to stain cellular RNA. The ADVIA® 120 autoRETIC reagent isovolumetrically spheres the erythroid cells and stains cellular RNA. Low-angle laser light scatter, high-angle laser light scatter, and absorption characteristics of all cells are counted and measured. The absorption data are used to classify each cell as a reticulocyte or mature red blood cell based on its RNA content. The reticulocyte is reported in percent and actual number x 10 cells/Liter.

References:

ADVIA® 120 Hematology System Operator's Guide: Copyright© 1997, 1998 Bayer Corporation.

AMAX Destiny Operation Manual SW V 1.1.4, 31/08/05. Trinity Biotech Plc.

APPENDIX I

Individual Clinical Observations

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:05-087

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96223	M	0 MG/KG/DAY	NORMAL	10-26-05	10:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	7:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96223	M	0 MG/KG/DAY	DISPOSITION	12-07-05	6:46	P	SCHEDULED EUTHANASIA
96226	M	0 MG/KG/DAY	NORMAL	10-26-05	10:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96226	M	0 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96229	M	0 MG/KG/DAY	NORMAL	10-26-05	10:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	7:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96229	M	0 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96230	M	0 MG/KG/DAY	NORMAL	10-26-05	10:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	7:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96230	M	0 MG/KG/DAY	DISPOSITION	12-07-05	6:47	P	SCHEDULED EUTHANASIA
96232	M	0 MG/KG/DAY	NORMAL	10-26-05	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	7:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96232	M	0 MG/KG/DAY	NORMAL	11-09-05	8:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96232	M	0 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96235	M	0 MG/KG/DAY	NORMAL	10-26-05	10:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	7:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96235	M	0 MG/KG/DAY	DISPOSITION	12-07-05	6:47	P	SCHEDULED EUTHANASIA
96235	M	0 MG/KG/DAY	ORAL/DENTAL	12-07-05	6:20	P	UPPER INCISORS MALALIGNED
96244	M	0 MG/KG/DAY	NORMAL	10-26-05	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96244	M	0 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96247	M	0 MG/KG/DAY	NORMAL	10-26-05	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96247	M	0 MG/KG/DAY	DISPOSITION	12-07-05	6:47	P	SCHEDULED EUTHANASIA
96249	M	0 MG/KG/DAY	NORMAL	10-26-05	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96249	M	0 MG/KG/DAY	NORMAL	11-23-05	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96249	M	0 MG/KG/DAY	DISPOSITION	12-07-05	6:47	P	SCHEDULED EUTHANASIA
96251	M	0 MG/KG/DAY	NORMAL	10-26-05	10:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96251	M	0 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96228	M	160 MG/KG/DAY	NORMAL	10-26-05	10:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96228	M	160 MG/KG/DAY	DISPOSITION	11-23-05	9:12	P	SCHEDULED EUTHANASIA
96233	M	160 MG/KG/DAY	NORMAL	10-26-05	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96233	M	160 MG/KG/DAY	DISPOSITION	11-23-05	9:12	P	SCHEDULED EUTHANASIA
96236	M	160 MG/KG/DAY	NORMAL	10-26-05	10:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96236	M	160 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96236	M	160 MG/KG/DAY	BODY/INTEGUMENT	11-09-05	8:18	1	HAIR LOSS LEFT FORELIMB
				11-09-05	8:18	1	HAIR LOSS RIGHT FORELIMB
				11-23-05	6:19	1	HAIR LOSS LEFT FORELIMB
				11-23-05	6:19	1	HAIR LOSS RIGHT FORELIMB
96238	M	160 MG/KG/DAY	NORMAL	10-26-05	10:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96238	M	160 MG/KG/DAY	NORMAL	11-02-05	8:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96238	M	160 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96254	M	160 MG/KG/DAY	NORMAL	10-26-05	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96254	M	160 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96241	M	400 MG/KG/DAY	NORMAL	10-26-05	10:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96241	M	400 MG/KG/DAY	DISPOSITION	11-23-05	9:12	P	SCHEDULED EUTHANASIA
96241	M	400 MG/KG/DAY	EYES/EARS/NOSE	11-23-05	6:22	2	DRIED RED MATERIAL AROUND NOSE
96241	M	400 MG/KG/DAY	ORAL/DENTAL	11-23-05	6:22	P	UPPER INCISORS MALALIGNED
96245	M	400 MG/KG/DAY	NORMAL	10-26-05	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96245	M	400 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96248	M	400 MG/KG/DAY	NORMAL	10-26-05	10:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96248	M	400 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96250	M	400 MG/KG/DAY	NORMAL	10-26-05	10:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:05-087

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96250	M	400 MG/KG/DAY	NORMAL	11-02-05	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96250	M	400 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96256	M	400 MG/KG/DAY	NORMAL	10-26-05	10:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96256	M	400 MG/KG/DAY	DISPOSITION	11-23-05	9:13	P	SCHEDULED EUTHANASIA
96224	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96224	M	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96225	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96225	M	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96231	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:05-087

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96231	M	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96234	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96234	M	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96237	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96237	M	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96242	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96242	M	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96246	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96246	M	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96252	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 7

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:05-087

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96252	M	1000 MG/KG/DAY	NORMAL	11-09-05	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96252	M	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:14	P	SCHEDULED EUTHANASIA
96253	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96253	M	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96255	M	1000 MG/KG/DAY	NORMAL	10-26-05	10:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	9:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96255	M	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96261	F	0 MG/KG/DAY	NORMAL	10-26-05	11:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96261	F	0 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96262	F	0 MG/KG/DAY	NORMAL	10-26-05	11:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96262	F	0 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96262	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-30-05	7:18	2	HAIR LOSS LEFT FORELIMB
				11-30-05	7:18	2	HAIR LOSS RIGHT FORELIMB
				12-07-05	6:25	2	HAIR LOSS LEFT FORELIMB
				12-07-05	6:25	2	HAIR LOSS RIGHT FORELIMB
96266	F	0 MG/KG/DAY	NORMAL	10-26-05	11:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96266	F	0 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96267	F	0 MG/KG/DAY	NORMAL	10-26-05	11:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96267	F	0 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96269	F	0 MG/KG/DAY	NORMAL	10-26-05	11:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96269	F	0 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96269	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-02-05	8:34	1	HAIR LOSS LEFT FORELIMB
				11-02-05	8:34	1	HAIR LOSS RIGHT FORELIMB
				11-09-05	8:51	2	HAIR LOSS LEFT FORELIMB
				11-09-05	8:51	2	HAIR LOSS RIGHT FORELIMB
				11-16-05	10:05	2	HAIR LOSS LEFT FORELIMB
				11-16-05	10:06	2	HAIR LOSS RIGHT FORELIMB
				11-23-05	6:30	2	HAIR LOSS LEFT FORELIMB
				11-23-05	6:30	2	HAIR LOSS RIGHT FORELIMB
96270	F	0 MG/KG/DAY	NORMAL	10-26-05	11:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96270	F	0 MG/KG/DAY	NORMAL	11-02-05	8:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96270	F	0 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96275	F	0 MG/KG/DAY	NORMAL	10-26-05	11:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96275	F	0 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96278	F	0 MG/KG/DAY	NORMAL	10-26-05	11:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96278	F	0 MG/KG/DAY	DISPOSITION	12-07-05	6:48	P	SCHEDULED EUTHANASIA
96283	F	0 MG/KG/DAY	NORMAL	10-26-05	11:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96283	F	0 MG/KG/DAY	DISPOSITION	12-07-05	6:49	P	SCHEDULED EUTHANASIA
96283	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-23-05	7:54	1	HAIR LOSS LEFT FORELIMB
				11-23-05	7:54	P	SCABBING LEFT FORELIMB
				11-30-05	7:24	1	HAIR LOSS LEFT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96283	F	0 MG/KG/DAY	BODY/INTEGUMENT	12-07-05	6:26	1	HAIR LOSS LEFT FORELIMB
96284	F	0 MG/KG/DAY	NORMAL	10-26-05	11:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96284	F	0 MG/KG/DAY	DISPOSITION	11-23-05	9:17	P	SCHEDULED EUTHANASIA
96280	F	160 MG/KG/DAY	NORMAL	10-26-05	11:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96280	F	160 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96285	F	160 MG/KG/DAY	NORMAL	10-26-05	11:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96285	F	160 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96289	F	160 MG/KG/DAY	NORMAL	10-26-05	11:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96289	F	160 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96290	F	160 MG/KG/DAY	NORMAL	10-26-05	11:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96290	F	160 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96291	F	160 MG/KG/DAY	NORMAL	10-26-05	11:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96291	F	160 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96291	F	160 MG/KG/DAY	BODY/INTEGUMENT	11-02-05	8:42	1	HAIR LOSS LEFT FORELIMB
				11-02-05	8:42	1	HAIR LOSS RIGHT FORELIMB
				11-09-05	9:03	1	HAIR LOSS LEFT FORELIMB
				11-09-05	9:03	1	HAIR LOSS RIGHT FORELIMB
				11-23-05	6:34	1	HAIR LOSS LEFT FORELIMB
				11-23-05	6:34	1	HAIR LOSS RIGHT FORELIMB
96263	F	400 MG/KG/DAY	NORMAL	10-26-05	11:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96263	F	400 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96265	F	400 MG/KG/DAY	NORMAL	10-26-05	11:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96265	F	400 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96268	F	400 MG/KG/DAY	NORMAL	10-26-05	11:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96268	F	400 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96272	F	400 MG/KG/DAY	NORMAL	10-26-05	11:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS PAGE 12

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:05-087

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96272	F	400 MG/KG/DAY	NORMAL	11-23-05	6:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96272	F	400 MG/KG/DAY	DISPOSITION	11-23-05	9:15	P	SCHEDULED EUTHANASIA
96276	F	400 MG/KG/DAY	NORMAL	10-26-05	11:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96276	F	400 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96276	F	400 MG/KG/DAY	BODY/INTEGUMENT	11-16-05	10:22	1	HAIR LOSS LEFT FORELIMB
				11-16-05	10:22	1	HAIR LOSS RIGHT FORELIMB
				11-16-05	10:23	P	SCABBING LEFT FORELIMB
				11-23-05	6:38	3	HAIR LOSS LEFT FORELIMB
				11-23-05	6:38	3	HAIR LOSS RIGHT FORELIMB
				11-23-05	6:39	P	SCABBING LEFT FORELIMB
				11-23-05	6:39	P	SCABBING RIGHT FORELIMB
96259	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96259	F	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96260	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96260	F	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:16	P	SCHEDULED EUTHANASIA
96264	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96264	F	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:49	P	SCHEDULED EUTHANASIA
96264	F	1000 MG/KG/DAY	BODY/INTEGUMENT	11-16-05	10:26	1	HAIR LOSS RIGHT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96264	F	1000 MG/KG/DAY	BODY/INTEGUMENT	11-23-05	7:55	1	HAIR LOSS RIGHT FORELIMB
				11-30-05	7:25	P	SCABBING LEFT FORELIMB
				11-30-05	7:25	P	SCABBING RIGHT FORELIMB
				11-30-05	7:26	2	HAIR LOSS LEFT FORELIMB
				11-30-05	7:26	2	HAIR LOSS RIGHT FORELIMB
				12-07-05	6:27	2	HAIR LOSS LEFT FORELIMB
				12-07-05	6:27	2	HAIR LOSS RIGHT FORELIMB
96271	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96271	F	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:49	P	SCHEDULED EUTHANASIA
96273	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96273	F	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:17	P	SCHEDULED EUTHANASIA
96277	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96277	F	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:49	P	SCHEDULED EUTHANASIA
96279	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 12-07-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96279	F	1000 MG/KG/DAY	NORMAL	11-02-05	8:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96279	F	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:17	P	SCHEDULED EUTHANASIA
96281	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	6:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96281	F	1000 MG/KG/DAY	DISPOSITION	11-23-05	9:17	P	SCHEDULED EUTHANASIA
96282	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96282	F	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:49	P	SCHEDULED EUTHANASIA
96287	F	1000 MG/KG/DAY	NORMAL	10-26-05	11:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-02-05	8:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-09-05	9:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-16-05	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-23-05	7:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				11-30-05	7:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				12-07-05	6:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
96287	F	1000 MG/KG/DAY	DISPOSITION	12-07-05	6:49	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96248	M	400 MG/KG/DAY	ORAL/DENTAL	11-19-05	12:50	1	SALIVATION
				11-20-05	11:50	2	SALIVATION
96256	M	400 MG/KG/DAY	ORAL/DENTAL	11-04-05	12:49	1	WET CLEAR MATERIAL AROUND MOUTH
96225	M	1000 MG/KG/DAY	ORAL/DENTAL	11-04-05	12:49	P	SALIVATION
				11-10-05	12:48	2	SALIVATION
				11-19-05	12:54	1	SALIVATION
				11-20-05	11:55	1	SALIVATION
96231	M	1000 MG/KG/DAY	ORAL/DENTAL	11-19-05	12:56	2	SALIVATION
				11-20-05	11:55	2	SALIVATION
96234	M	1000 MG/KG/DAY	ORAL/DENTAL	11-19-05	12:55	2	WET CLEAR MATERIAL AROUND MOUTH
96242	M	1000 MG/KG/DAY	ORAL/DENTAL	11-03-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				11-04-05	12:49	1	WET CLEAR MATERIAL AROUND MOUTH
				11-12-05	13:27	1	SALIVATION PRIOR TO DOSING
				11-13-05	13:11	P	SALIVATION PRIOR TO DOSING
				11-19-05	12:56	1	SALIVATION
				11-20-05	11:55	1	SALIVATION
96246	M	1000 MG/KG/DAY	ORAL/DENTAL	11-03-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
				11-13-05	13:10	1	DRIED RED MATERIAL AROUND MOUTH
				11-19-05	12:55	1	WET CLEAR MATERIAL AROUND MOUTH
96253	M	1000 MG/KG/DAY	ORAL/DENTAL	11-03-05	13:14	1	DRIED RED MATERIAL AROUND MOUTH
96255	M	1000 MG/KG/DAY	ORAL/DENTAL	11-03-05	13:14	1	DRIED RED MATERIAL AROUND MOUTH
				11-19-05	12:56	2	SALIVATION
				11-20-05	11:56	1	SALIVATION
96262	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-26-05	12:34	1	HAIR LOSS LEFT FORELIMB
				11-26-05	12:34	1	HAIR LOSS LEFT INGUINAL AREA
				11-25-05	7:02	1	HAIR LOSS LEFT FORELIMB
				11-25-05	7:02	1	HAIR LOSS RIGHT FORELIMB
96278	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-25-05	7:03	1	HAIR LOSS LEFT FORELIMB
96283	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-26-05	12:35	1	HAIR LOSS LEFT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96283	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-26-05	12:35	1	HAIR LOSS RIGHT FORELIMB
96283	F	0 MG/KG/DAY	ORAL/DENTAL	11-13-05	13:23	1	WET CLEAR MATERIAL AROUND MOUTH
96265	F	400 MG/KG/DAY	ORAL/DENTAL	11-19-05	13:09	1	SALIVATION
96268	F	400 MG/KG/DAY	ORAL/DENTAL	11-19-05	13:10	2	SALIVATION
				11-20-05	12:07	1	WET CLEAR MATERIAL AROUND MOUTH
96272	F	400 MG/KG/DAY	ORAL/DENTAL	11-19-05	13:10	1	SALIVATION
				11-20-05	12:07	2	WET CLEAR MATERIAL AROUND MOUTH
96276	F	400 MG/KG/DAY	ORAL/DENTAL	11-03-05	13:09	1	WET CLEAR MATERIAL AROUND MOUTH
				11-19-05	13:09	1	SALIVATION PRIOR TO DOSING
				11-20-05	12:08	1	WET CLEAR MATERIAL AROUND MOUTH
96264	F	1000 MG/KG/DAY	BODY/INTEGUMENT	11-26-05	12:36	P	SCABBING RIGHT FORELIMB
				11-26-05	12:36	1	HAIR LOSS RIGHT FORELIMB
				11-26-05	12:36	1	HAIR LOSS LEFT FORELIMB
				11-25-05	7:04	1	HAIR LOSS LEFT FORELIMB
				11-25-05	7:04	1	HAIR LOSS RIGHT FORELIMB
96271	F	1000 MG/KG/DAY	ORAL/DENTAL	11-19-05	13:15	1	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	12:13	1	WET CLEAR MATERIAL AROUND MOUTH
96273	F	1000 MG/KG/DAY	ORAL/DENTAL	11-19-05	13:16	1	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	12:13	2	WET CLEAR MATERIAL AROUND MOUTH
96277	F	1000 MG/KG/DAY	ORAL/DENTAL	11-20-05	12:13	2	WET CLEAR MATERIAL AROUND MOUTH
96281	F	1000 MG/KG/DAY	ORAL/DENTAL	11-01-05	13:27	1	SALIVATION
				11-03-05	13:11	1	WET CLEAR MATERIAL AROUND MOUTH
				11-05-05	13:18	1	SALIVATION PRIOR TO DOSING
				11-06-05	12:59	1	SALIVATION PRIOR TO DOSING
				11-10-05	13:23	2	SALIVATION
				11-19-05	13:14	1	SALIVATION PRIOR TO DOSING
				11-20-05	12:13	3	SALIVATION
96282	F	1000 MG/KG/DAY	ORAL/DENTAL	11-03-05	13:11	1	WET CLEAR MATERIAL AROUND MOUTH
				11-19-05	13:14	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

AT TIME OF DOSING

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:05-087

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96282	F	1000 MG/KG/DAY	ORAL/DENTAL	11-20-05	12:14	3	SALIVATION
96287	F	1000 MG/KG/DAY	ORAL/DENTAL	11-19-05	13:17	3	SALIVATION
				11-20-05	12:14	2	SALIVATION

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96229	M	0 MG/KG/DAY	EYES/EARS/NOSE	11-20-05	13:13	2	DRIED RED MATERIAL AROUND NOSE
96254	M	160 MG/KG/DAY	EYES/EARS/NOSE	11-20-05	13:15	1	DRIED RED MATERIAL AROUND NOSE
96254	M	160 MG/KG/DAY	ORAL/DENTAL	11-20-05	13:15	1	DRIED RED MATERIAL AROUND MOUTH
96248	M	400 MG/KG/DAY	EYES/EARS/NOSE	11-19-05	14:16	1	DRIED RED MATERIAL AROUND NOSE
				11-20-05	13:15	1	DRIED RED MATERIAL AROUND NOSE
96248	M	400 MG/KG/DAY	ORAL/DENTAL	11-19-05	14:17	1	DRIED RED MATERIAL AROUND MOUTH
96250	M	400 MG/KG/DAY	ORAL/DENTAL	11-07-05	13:55	1	DRIED RED MATERIAL AROUND MOUTH
				11-13-05	14:36	1	DRIED RED MATERIAL AROUND MOUTH
				11-14-05	14:00	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:18	1	DRIED RED MATERIAL AROUND MOUTH
				11-18-05	15:05	2	DRIED RED MATERIAL AROUND MOUTH
				11-20-05	13:16	1	DRIED RED MATERIAL AROUND MOUTH
96256	M	400 MG/KG/DAY	ORAL/DENTAL	11-08-05	13:59	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:18	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-19-05	14:17	2	DRIED CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:13	1	DRIED CLEAR MATERIAL AROUND MOUTH
96224	M	1000 MG/KG/DAY	ORAL/DENTAL	11-07-05	13:56	1	WET CLEAR MATERIAL AROUND MOUTH
				11-08-05	14:00	2	DRIED RED MATERIAL AROUND MOUTH
				11-10-05	14:01	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-14-05	14:01	2	DRIED RED MATERIAL AROUND MOUTH
				11-15-05	12:49	2	SALIVATION
				11-17-05	16:19	1	DRIED RED MATERIAL AROUND MOUTH
				11-18-05	15:05	1	WET CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:13	1	WET CLEAR MATERIAL AROUND MOUTH
96225	M	1000 MG/KG/DAY	BODY/INTEGUMENT	11-06-05	14:08	3	WET CLEAR MATERIAL RIGHT FORELIMB
				11-06-05	14:08	3	WET CLEAR MATERIAL LEFT FORELIMB
96225	M	1000 MG/KG/DAY	ORAL/DENTAL	11-04-05	14:13	2	WET CLEAR MATERIAL AROUND MOUTH
				11-05-05	14:22	2	SALIVATION
				11-05-05	14:22	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96225	M	1000 MG/KG/DAY	ORAL/DENTAL	11-06-05	14:07	3	SALIVATION
				11-07-05	13:57	3	SALIVATION
				11-08-05	14:00	1	DRIED RED MATERIAL AROUND MOUTH
				11-10-05	14:01	3	SALIVATION
				11-12-05	14:55	2	SALIVATION
				11-13-05	14:37	2	SALIVATION
				11-14-05	14:01	2	SALIVATION
				11-15-05	12:50	2	SALIVATION
				11-16-05	16:41	2	SALIVATION
				11-17-05	16:19	2	SALIVATION
				11-18-05	15:06	2	SALIVATION
				11-19-05	14:17	3	SALIVATION
				11-20-05	13:16	3	SALIVATION
				11-21-05	13:14	2	SALIVATION
				11-22-05	14:06	2	SALIVATION
96231	M	1000 MG/KG/DAY	EYES/EARS/NOSE	11-05-05	14:22	1	DRIED RED MATERIAL AROUND NOSE
96231	M	1000 MG/KG/DAY	ORAL/DENTAL	11-05-05	14:22	1	DRIED RED MATERIAL AROUND MOUTH
				11-06-05	14:08	1	WET CLEAR MATERIAL AROUND MOUTH
				11-07-05	13:58	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-08-05	14:01	1	WET CLEAR MATERIAL AROUND MOUTH
				11-09-05	14:35	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-10-05	14:02	1	WET CLEAR MATERIAL AROUND MOUTH
				11-12-05	14:55	1	WET CLEAR MATERIAL AROUND MOUTH
				11-13-05	14:38	2	SALIVATION
				11-15-05	12:50	2	WET CLEAR MATERIAL AROUND MOUTH
				11-16-05	16:42	2	WET CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:20	2	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:08	2	SALIVATION
				11-19-05	14:19	3	SALIVATION

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96231	M	1000 MG/KG/DAY	ORAL/DENTAL	11-20-05	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:15	2	SALIVATION
				11-22-05	14:07	2	SALIVATION
96234	M	1000 MG/KG/DAY	ORAL/DENTAL	11-06-05	14:09	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-09-05	14:35	1	WET CLEAR MATERIAL AROUND MOUTH
				11-10-05	14:02	1	WET CLEAR MATERIAL AROUND MOUTH
				11-13-05	14:38	1	WET CLEAR MATERIAL AROUND MOUTH
				11-15-05	12:50	1	WET CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:20	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:07	1	WET CLEAR MATERIAL AROUND MOUTH
				11-19-05	14:18	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				11-22-05	14:06	1	WET CLEAR MATERIAL AROUND MOUTH
96242	M	1000 MG/KG/DAY	ORAL/DENTAL	11-03-05	14:19	1	WET CLEAR MATERIAL AROUND MOUTH
				11-05-05	14:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-06-05	14:11	1	SALIVATION
				11-07-05	13:59	2	SALIVATION
				11-08-05	14:01	2	SALIVATION
				11-09-05	14:36	2	SALIVATION
				11-10-05	14:03	2	SALIVATION
				11-11-05	13:56	2	SALIVATION
				11-13-05	14:39	3	SALIVATION
				11-14-05	14:02	1	SALIVATION
				11-15-05	12:51	1	WET CLEAR MATERIAL AROUND MOUTH
				11-16-05	16:43	2	SALIVATION
				11-17-05	16:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:07	2	SALIVATION
				11-19-05	14:18	3	SALIVATION
				11-20-05	13:17	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96242	M	1000 MG/KG/DAY	ORAL/DENTAL	11-21-05	13:15	2	SALIVATION
				11-22-05	14:07	2	SALIVATION
96246	M	1000 MG/KG/DAY	BODY/INTEGUMENT	11-06-05	14:10	1	WET CLEAR MATERIAL RIGHT FORELIMB
				11-06-05	14:10	1	WET CLEAR MATERIAL LEFT FORELIMB
96246	M	1000 MG/KG/DAY	ORAL/DENTAL	11-04-05	14:14	1	DRIED RED MATERIAL AROUND MOUTH
				11-05-05	14:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-06-05	14:10	3	SALIVATION
				11-07-05	14:00	3	WET CLEAR MATERIAL AROUND MOUTH
				11-08-05	14:02	2	SALIVATION
				11-09-05	14:37	2	WET CLEAR MATERIAL AROUND MOUTH
				11-10-05	14:04	2	SALIVATION
				11-11-05	13:57	2	SALIVATION
				11-12-05	14:56	2	SALIVATION
				11-13-05	14:39	2	SALIVATION
				11-14-05	14:03	2	WET CLEAR MATERIAL AROUND MOUTH
				11-15-05	12:51	2	WET CLEAR MATERIAL AROUND MOUTH
				11-16-05	16:43	3	WET CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:06	2	WET CLEAR MATERIAL AROUND MOUTH
				11-19-05	14:18	2	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:16	3	WET CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:14	2	WET CLEAR MATERIAL AROUND MOUTH
				11-22-05	14:06	1	WET CLEAR MATERIAL AROUND MOUTH
96253	M	1000 MG/KG/DAY	ORAL/DENTAL	11-05-05	14:23	1	WET CLEAR MATERIAL AROUND MOUTH
				11-06-05	14:10	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-07-05	14:01	2	DRIED CLEAR MATERIAL AROUND MOUTH
				11-08-05	14:03	1	WET CLEAR MATERIAL AROUND MOUTH
				11-10-05	14:04	1	WET CLEAR MATERIAL AROUND MOUTH
				11-11-05	13:57	1	DRIED CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96253	M	1000 MG/KG/DAY	ORAL/DENTAL	11-13-05	14:40	2	WET CLEAR MATERIAL AROUND MOUTH
				11-16-05	16:44	2	WET CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:08	1	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:17	2	WET CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:16	1	WET CLEAR MATERIAL AROUND MOUTH
96255	M	1000 MG/KG/DAY	ORAL/DENTAL	11-07-05	14:02	2	DRIED CLEAR MATERIAL AROUND MOUTH
				11-08-05	14:04	1	DRIED RED MATERIAL AROUND MOUTH
				11-09-05	14:37	1	DRIED RED MATERIAL AROUND MOUTH
				11-10-05	14:05	1	DRIED RED MATERIAL AROUND MOUTH
				11-13-05	14:40	1	WET CLEAR MATERIAL AROUND MOUTH
				11-14-05	14:03	1	DRIED RED MATERIAL AROUND MOUTH
				11-15-05	12:52	2	SALIVATION
				11-16-05	16:44	1	SALIVATION
				11-17-05	16:22	1	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:08	2	SALIVATION
				11-19-05	14:19	1	SALIVATION
96280	F	160 MG/KG/DAY	EYES/EARS/NOSE	11-20-05	13:19	1	DRIED RED MATERIAL AROUND NOSE
96263	F	400 MG/KG/DAY	ORAL/DENTAL	11-11-05	14:00	1	DRIED RED MATERIAL AROUND MOUTH
96265	F	400 MG/KG/DAY	ORAL/DENTAL	11-18-05	15:12	2	WET RED MATERIAL AROUND MOUTH
				11-20-05	13:20	1	SALIVATION
				11-21-05	13:19	1	DRIED RED MATERIAL AROUND MOUTH
96268	F	400 MG/KG/DAY	ORAL/DENTAL	11-07-05	14:07	1	DRIED CLEAR MATERIAL AROUND MOUTH
96272	F	400 MG/KG/DAY	ORAL/DENTAL	11-18-05	15:14	1	WET CLEAR MATERIAL AROUND MOUTH
96276	F	400 MG/KG/DAY	ORAL/DENTAL	11-18-05	15:15	1	DRIED RED MATERIAL AROUND MOUTH
				11-20-05	13:20	1	DRIED RED MATERIAL AROUND MOUTH
96259	F	1000 MG/KG/DAY	ORAL/DENTAL	11-08-05	14:21	1	DRIED RED MATERIAL AROUND MOUTH
				11-11-05	14:01	1	SALIVATION
				11-13-05	15:03	1	DRIED RED MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE RANGE: 10-26-05 TO 11-27-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96259	F	1000 MG/KG/DAY	ORAL/DENTAL	11-15-05	12:55	1	SALIVATION
				11-17-05	16:24	1	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:15	1	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:20	1	WET CLEAR MATERIAL AROUND MOUTH
96264	F	1000 MG/KG/DAY	ORAL/DENTAL	10-27-05	14:26	1	SALIVATION
				11-22-05	14:10	3	WET CLEAR MATERIAL AROUND MOUTH
96271	F	1000 MG/KG/DAY	ORAL/DENTAL	11-11-05	14:01	1	DRIED RED MATERIAL AROUND MOUTH
				11-13-05	15:03	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-16-05	16:47	1	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:16	1	WET CLEAR MATERIAL AROUND MOUTH
				11-19-05	14:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:21	1	DRIED RED MATERIAL AROUND MOUTH
96277	F	1000 MG/KG/DAY	ORAL/DENTAL	11-10-05	14:25	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-14-05	14:11	1	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:16	1	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:22	1	DRIED RED MATERIAL AROUND MOUTH
96279	F	1000 MG/KG/DAY	ORAL/DENTAL	11-18-05	15:16	1	WET CLEAR MATERIAL AROUND MOUTH
				11-19-05	14:21	1	DRIED CLEAR MATERIAL AROUND MOUTH
				11-22-05	14:11	1	WET CLEAR MATERIAL AROUND MOUTH
96281	F	1000 MG/KG/DAY	ORAL/DENTAL	11-07-05	14:09	1	WET CLEAR MATERIAL AROUND MOUTH
				11-08-05	14:22	2	SALIVATION
				11-09-05	14:41	2	WET CLEAR MATERIAL AROUND MOUTH
				11-10-05	14:26	1	SALIVATION
				11-11-05	14:02	1	SALIVATION
				11-16-05	16:48	2	SALIVATION
				11-17-05	16:25	3	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:17	2	WET CLEAR MATERIAL AROUND MOUTH
				11-20-05	13:21	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96281	F	1000 MG/KG/DAY	ORAL/DENTAL	11-21-05	13:21	1	DRIED CLEAR MATERIAL AROUND MOUTH
96282	F	1000 MG/KG/DAY	ORAL/DENTAL	11-05-05	14:27	1	SALIVATION
				11-07-05	14:09	2	WET CLEAR MATERIAL AROUND MOUTH
				11-09-05	14:41	2	SALIVATION
				11-10-05	14:26	1	SALIVATION
				11-11-05	14:03	2	SALIVATION
				11-12-05	14:52	2	SALIVATION
				11-13-05	15:04	1	SALIVATION
				11-14-05	14:10	2	SALIVATION
				11-16-05	16:48	2	WET CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:26	2	WET CLEAR MATERIAL AROUND MOUTH
				11-18-05	15:17	3	SALIVATION
				11-19-05	14:22	1	SALIVATION
				11-20-05	13:21	2	WET CLEAR MATERIAL AROUND MOUTH
				11-21-05	13:22	1	SALIVATION
96287	F	1000 MG/KG/DAY	ORAL/DENTAL	11-07-05	14:09	2	WET CLEAR MATERIAL AROUND MOUTH
				11-09-05	14:42	1	DRIED RED MATERIAL AROUND MOUTH
				11-13-05	15:05	2	WET CLEAR MATERIAL AROUND MOUTH
				11-16-05	16:49	1	WET CLEAR MATERIAL AROUND MOUTH
				11-17-05	16:26	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

DAILY OBSERVATIONS - RECOVERY PERIOD

PROJECT NO.:WIL-187051 A 28-DAY REPEATED DOSE TOXICITY STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:05-087

TABLE RANGE: 11-28-05 TO 12-06-05

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
96235	M	0 MG/KG/DAY	ORAL/DENTAL	12-01-05	9:17	P	UPPER INCISORS MALALIGNED
96262	F	0 MG/KG/DAY	BODY/INTEGUMENT	11-29-05	7:06	2	HAIR LOSS LEFT INGUINAL AREA
				11-29-05	7:06	2	HAIR LOSS LEFT FORELIMB
				12-01-05	9:19	2	HAIR LOSS LEFT FORELIMB
				12-01-05	9:19	2	HAIR LOSS RIGHT FORELIMB
96283	F	0 MG/KG/DAY	BODY/INTEGUMENT	12-01-05	9:20	1	HAIR LOSS LEFT FORELIMB
96264	F	1000 MG/KG/DAY	BODY/INTEGUMENT	11-29-05	7:07	P	SCABBING LEFT FORELIMB
				11-29-05	7:07	1	HAIR LOSS LEFT FORELIMB
				11-29-05	7:07	1	HAIR LOSS RIGHT FORELIMB
				12-01-05	9:21	2	HAIR LOSS LEFT FORELIMB
				12-01-05	9:21	2	HAIR LOSS RIGHT FORELIMB
				12-01-05	9:21	P	SCABBING LEFT FORELIMB
				12-01-05	9:21	P	SCABBING RIGHT FORELIMB

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

APPENDIX J

Statistical Summary Report (BioSTAT Consultants, Inc.)

Statistical Analysis Summary
WIL Research Laboratories, LLC
Study Protocol – 187051
Version 1.0

1 Statistical Methodology
1.1 Analysis Endpoints
1.2 Motor Activity Analysis Methodology
2 Results
3 Statistical Analysis Summaries
Table 3.1: Analysis Summary Table for Motor Activity

Report Approval:

[redacted]

June 19, 2006
Date

BioSTAT Consultants, Inc.
Statement of Quality Control

This report was quality checked in accordance with BioSTAT Procedural Guideline 2.1 (Quality Control Process for Tables and Reports). The statistical methodology and results of inferential statistics were verified by an independent quality control statistician. Based on these documented quality control activities, it is concluded that the statistical results incorporated in this report accurately reflect the statistical analysis of data received by BioSTAT.

1 Statistical Methodology

1.1 Analysis Endpoints

- Motor Activity
  - Total Counts
  - Ambulatory Counts

1.2 Motor Activity Analysis Methodology

Each analysis endpoint (total and ambulatory counts) was analyzed, by sex and session, with a repeated measure analysis of variance (RANOVA). Factors in the model included treatment group (TRT), time interval (TIME), and the interaction of time interval and treatment group (TRT*TIME). The SAS® procedure PROC MIXED was used for analysis with the random effect of animal included as the repeated measurement. The covariance structure across time was selected by comparing Akiake's Information Criterion (AIC) for first-order autoregressive homogeneous [AR(1)] and compound symmetric (CS) structures.

The monotonic dose response relationship was evaluated using sequential linear trend tests based on ordinal spacing of dose levels. The linear dose by time interaction (LinTrt*Time) was evaluated and, if significant at the 0.05 level, trend tests on treatment means were performed at the 0.05 level for each time interval. If the linear dose by time interaction was not significant, the trend test was conducted across the pooled time intervals of the entire session only.

Nonmonotonic dose responses were evaluated whenever no significant linear trends were detected but TRT and/or TRT*TIME interaction was significant at the 0.01 level. Within the framework of the RANOVA, pairwise comparisons were made for each individual treated group with the control group through linear contrasts. If TRT* TIME was significant, the comparisons were conducted for each time interval. If only the TRT effect was significant, the comparisons were conducted across the pooled time intervals of the entire session. These nonmonotonic dose response comparisons were conducted at the 0.01 significance level.

All statistical analyses were conducted using SAS version 8.2 (SAS Institute, Inc., 1999-2001) software.

2 Results

Results of statistical analyses are summarized in Section 3.

Tables Legend

Treatments:

Treatment #	Dosage Level (mg/kg/day)
1	0
2	160
3	400
4	1000

S.D. = standard deviation
N = number of animals
LSMean = least squares mean
Linear Trend p-value = p-value for the treatment linear trend test
Trt F-test p-value = p-value for treatment group effect
INTN = treatment dose by time (MA) or trial (SR) interactions tested
Trt*Time p-value = p-value for the treatment by time interaction
LinTrt*Time p-value = p-value for the linear trend by time interaction
Covariance Structure: AR1=Autoregressive order 1, CS=Compound symmetric

References

SAS® Proprietary Software, Version 8.2; SAS Institute Inc.: Cary, NC, 1999-2001.

3 Statistical Analysis Summaries

Table 3.1: Analysis Summary Table for Motor Activity

					Minutes					
Period	Sex	Variable		Statistic	0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	M	TOTAL	1	Mean	777.20	265.60	64.800	29.800	284.35	1137.40
				S.D.	205.823	129.094	99.6980	63.3340	NA	466.163
				N	5	5	5	5	5	5
				LSMean	777.20	265.60	64.800	29.800	284.35	NA
				Linear Trend p-value#						NA
			2	Mean	616.60	200.60	58.800	52.000	232.00	928.00
				S.D.	323.986	204.659	110.5111	85.9447	NA	222.588
				N	5	5	5	5	5	5
				LSMean	616.60	200.60	58.800	52.000	232.00	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	627.00	213.40	50.400	31.200	230.50	922.00
				S.D.	143.854	151.299	90.1127	65.9219	NA	166.741
				N	5	5	5	5	5	5
				LSMean	627.00	213.40	50.400	31.200	230.50	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	804.00	232.00	13.000	45.000	273.50	1094.00
				S.D.	233.256	144.907	27.4044	92.3363	NA	277.965
				N	5	5	5	5	5	5
				LSMean	804.00	232.00	13.000	45.000	273.50	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.860	NA
			ALL	Trt F-test p-value++					0.732	
			INTN	Trt*Time p-value++					0.815	
				LinTrt*Time p-value#					0.920	
				Covariance Structure					AR1	

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

Table 3.1: Analysis Summary Table for Motor Activity

Period	Sex	Variable		Statistic	Minutes 0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	M	AMBULATORY	1	Mean	260.80	71.600	15.400	10.200	89.500	358.00
				S.D.	87.004	40.9060	30.1048	21.7071	NA	171.213
				N	5	5	5	5	5	5
				LSMean	260.80	71.600	15.400	10.200	89.500	NA
				Linear Trend p-value#						NA
			2	Mean	186.20	41.800	15.000	11.400	63.600	254.40
				S.D.	131.570	59.9725	30.2985	22.7991	NA	118.018
				N	5	5	5	5	5	5
				LSMean	186.20	41.800	15.000	11.400	63.600	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	191.00	63.800	11.200	6.4000	68.100	272.40
				S.D.	81.511	44.4826	16.7541	14.31084	NA	85.019
				N	5	5	5	5	5	5
				LSMean	191.00	63.800	11.200	6.4000	68.100	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	288.80	49.000	0.0000	12.800	87.650	350.60
				S.D.	84.942	34.7347	0.00000	28.6217	NA	99.896
				N	5	5	5	5	5	5
				LSMean	288.80	49.000	-0.0000	12.800	87.650	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.989	NA
			ALL	Trt F-test p-value++					0.613	
			INTN	Trt*Time p-value++					0.266	
				LinTrt*Time p-value#					0.745	
				Covariance Structure					AR1	

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

Table 3.1: Analysis Summary Table for Motor Activity

Period	Sex	Variable		Statistic	Minutes 0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	F	TOTAL	1	Mean	831.40	318.40	127.80	90.200	341.95	1367.80
				S.D.	156.439	311.781	176.503	65.8232	NA	327.447
				N	5	5	5	5	5	5
				LSMean	831.40	318.40	127.80	90.200	341.95	NA
				Linear Trend p-value#						NA
			2	Mean	673.00	270.00	152.80	0.0000	273.95	1095.80
				S.D.	160.075	207.030	142.670	0.00000	NA	299.951
				N	5	5	5	5	5	5
				LSMean	673.00	270.00	152.80	0.0000	273.95	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	795.00	278.20	105.60	123.00	325.45	1301.80
				S.D.	124.619	205.504	130.722	181.693	NA	369.891
				N	5	5	5	5	5	5
				LSMean	795.00	278.20	105.60	123.00	325.45	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	716.00	154.40	61.600	153.20	271.30	1085.20
				S.D.	182.872	139.715	124.5685	195.661	NA	216.368
				N	5	5	5	5	5	5
				LSMean	716.00	154.40	61.600	153.20	271.30	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.386	NA
			ALL	Trt F-test p-value++					0.513	
			INTN	Trt*Time p-value++					0.752	
				LinTrt*Time p-value#					0.407	
				Covariance Structure					AR1	

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

Table 3.1: Analysis Summary Table for Motor Activity

					Minutes					
Period	Sex	Variable		Statistic	0-15	16-30	31-45	46-60	Overall	Cumulative
WEEK003	F	AMBULATORY	1	Mean	332.60	105.40	47.000	21.800	126.70	506.80
				S.D.	63.865	115.578	69.3506	22.7200	NA	116.446
				N	5	5	5	5	5	5
				LSMean	332.60	105.40	47.000	21.800	126.70	NA
				Linear Trend p-value#						NA
			2	Mean	284.40	81.200	35.800	0.0000	100.35	401.40
				S.D.	69.291	60.3796	39.3472	0.00000	NA	92.533
				N	5	5	5	5	5	5
				LSMean	284.40	81.200	35.800	0.0000	100.35	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			3	Mean	316.00	73.800	17.800	52.200	114.95	459.80
				S.D.	51.015	73.1997	27.2066	83.6672	NA	114.205
				N	5	5	5	5	5	5
				LSMean	316.00	73.800	17.800	52.200	114.95	NA
				Linear Trend p-value#	NT	NT	NT	NT	NT	NA
			4	Mean	294.00	40.400	21.400	47.000	100.70	402.80
				S.D.	97.645	35.6553	47.2948	65.7723	NA	24.773
				N	5	5	5	5	5	5
				LSMean	294.00	40.400	21.400	47.000	100.70	NA
				Linear Trend p-value#	NT	NT	NT	NT	0.199	NA
			ALL	Trt F-test p-value++					0.270	
			INTN	Trt*Time p-value++					0.892	
				LinTrt*Time p-value#					0.398	
				Covariance Structure					CS	

: Level of Significance tested = .05.
* : Statistically Significant.
++ : Level of Significance tested = .01.
NT : Not tested. NA : Not applicable.

APPENDIX K

WIL Functional Observational Battery Historical Control Data

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA - MALES

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HOME CAGE OBSERVATIONS					
POSTURE					
1- SITTING OR STANDING NORMALLY	52	5	33	9	1
2- ASLEEP, LYING ON SIDE OR CURLED UP	21	4	9	4	3
3- ALERT, ORIENTED TOWARD OBSERVER	7	1	13	2	6
CONVULSIONS - CLONIC					
1- ABSENT	80	10	55	15	10
CONVULSIONS -TONIC					
1- ABSENT	80	10	55	15	10
TREMORS					
1- NONE	80	10	55	15	10
BITING					
1- NONE	80	10	54	15	10
3- BITING OF SELF	NA	NA	1	NA	NA
PALPEBRAL CLOSURE					
1- EYELIDS WIDE OPEN	63	8	47	12	7
2- EYELIDS SLIGHTLY DROOPING	1	1	1	NA	1
3- DROOPING EYELIDS (HALF-CLOSED)	7	1	1	2	2
4- EYELIDS COMPLETELY SHUT	9	NA	6	1	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HOME CAGE OBSERVATIONS				
POSTURE				
1- SITTING OR STANDING NORMALLY	6	11	27	5
2- ASLEEP, LYING ON SIDE OR CURLED UP	1	3	20	3
3- ALERT, ORIENTED TOWARD OBSERVER	3	11	16	2
CONVULSIONS - CLONIC				
1- ABSENT	10	25	63	10
CONVULSIONS -TONIC				
1- ABSENT	10	25	63	10
TREMORS				
1- NONE	10	25	63	10
BITING				
1- NONE	10	25	63	10
3- BITING OF SELF	NA	NA	NA	NA
PALPEBRAL CLOSURE				
1- EYELIDS WIDE OPEN	9	25	41	6
2- EYELIDS SLIGHTLY DROOPING	NA	NA	2	1
3- DROOPING EYELIDS (HALF-CLOSED)	NA	NA	6	2
4- EYELIDS COMPLETELY SHUT	1	NA	14	1

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HOME CAGE OBSERVATIONS (CONTINUED)					
FECES CONSISTENCY					
1- PELLETS	70	8	41	10	6
4- PELLETS ABSENT	10	2	14	5	4
HANDLING OBSERVATIONS					
EASE OF REMOVAL					
1- VERY EASY	63	4	45	10	6
2- EASY	17	6	10	5	4
3- MODERATELY DIFFICULT	NA	NA	NA	NA	NA
6- VERY DIFFICULT	NA	NA	NA	NA	NA
EASE OF HANDLING IN HAND					
1- LOW	80	10	48	14	10
2- MODERATELY LOW	NA	NA	7	1	NA
4- HIGH	NA	NA	NA	NA	NA
LACRIMATION					
1- NONE	80	10	55	15	10
CHROMODACRYORRHEA					
1-ABSENT	80	10	55	15	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HOME CAGE OBSERVATIONS (CONTINUED)				
FECES CONSISTENCY				
1- PELLETS	8	15	35	4
4- PELLETS ABSENT	2	10	28	6
HANDLING OBSERVATIONS				
EASE OF REMOVAL				
1- VERY EASY	4	10	52	10
2- EASY	6	15	9	
3- MODERATELY DIFFICULT	NA	NA	1	NA
6- VERY DIFFICULT	NA	NA	1	NA
EASE OF HANDLING IN HAND				
1- LOW	8	22	59	10
2- MODERATELY LOW	2	3	3	NA
4- HIGH	NA	NA	1	NA
LACRIMATION				
1- NONE	10	25	63	10
CHROMODACRYORRHEA				
1-ABSENT	10	25	63	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HANDLING OBSERVATIONS (CONTINUED)					
SALIVATION					
1- NONE	80	10	55	15	10
2- SLIGHT	NA	NA	NA	NA	NA
PILOERECTION					
1- NONE	80	9	54	15	9
2- SLIGHT	NA	1	1	NA	1
FUR APPEARANCE					
1- NORMAL; CLEAN AND GROOMED	80	9	55	15	10
2- SLIGHTLY SOILED	NA	1	NA	NA	NA
PALPEBRAL CLOSURE					
1- EYELIDS WIDE OPEN	80	10	55	15	10
RESPIRATORY RATE					
1- NORMAL: BY OBSERVATION (80-110/MIN.)	80	10	55	15	10
RESPIRATORY CHARACTER					
1- NORMAL	80	10	55	15	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HANDLING OBSERVATIONS (CONTINUED)				
SALIVATION				
1- NONE	10	25	62	10
2- SLIGHT	NA	NA	1	NA
PILOERECTION				
1- NONE	10	25	59	10
2- SLIGHT	NA	NA	4	NA
FUR APPEARANCE				
1- NORMAL; CLEAN AND GROOMED	10	24	60	8
2- SLIGHTLY SOILED	NA	1	3	2
PALPEBRAL CLOSURE				
1- EYELIDS WIDE OPEN	10	25	63	10
RESPIRATORY RATE				
1- NORMAL: BY OBSERVATION (80-110/MIN.)	10	25	63	10
RESPIRATORY CHARACTER				
1- NORMAL	10	25	63	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HANDLING OBSERVATIONS (CONTINUED)					
RED DEPOSITS- EYES					
1- PRESENT	1	NA	4	NA	NA
2- ABSENT	79	10	51	15	10
RED DEPOSITS- NOSE					
1- PRESENT	7	1	5	1	NA
2- ABSENT	73	9	50	14	10
RED DEPOSITS- MOUTH					
2- ABSENT	80	10	55	15	10
CRUSTY DEPOSITS- EYES					
1- PRESENT	NA	NA	2	NA	NA
2- ABSENT	80	10	53	15	10
CRUSTY DEPOSITS- NOSE					
1- PRESENT	NA	NA	2	NA	NA
2- ABSENT	80	10	53	15	10
CRUSTY DEPOSITS- MOUTH					
2- ABSENT	80	10	55	15	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HANDLING OBSERVATIONS (CONTINUED)				
RED DEPOSITS- EYES				
1- PRESENT	NA	1	1	1
2- ABSENT	10	24	62	9
RED DEPOSITS- NOSE				
1- PRESENT	NA	1	1	NA
2- ABSENT	10	24	62	10
RED DEPOSITS- MOUTH				
2- ABSENT	10	25	63	10
CRUSTY DEPOSITS- EYES				
1- PRESENT	NA	NA	NA	1
2- ABSENT	10	25	63	9
CRUSTY DEPOSITS- NOSE				
1- PRESENT	NA	NA	1	NA
2- ABSENT	10	25	62	10
CRUSTY DEPOSITS- MOUTH				
2- ABSENT	10	25	63	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HANDLING OBSERVATIONS (CONTINUED)					
MUCOUS MEMBRANES- COLOR					
1- PINK	80	10	55	15	10
EYES- COLOR					
1- PINK	80	10	55	15	10
SKIN- COLOR					
1- PINK	80	10	55	15	10
EYE PROMINENCE					
1- NORMAL	80	10	55	15	10
2- EXOPHTHALMUS	NA	NA	NA	NA	NA
MUSCLE TONE					
1- FIRM BUT NOT HARD (NORMAL)	80	10	55	15	10
OPEN-FIELD OBSERVATIONS					
TIME TO FIRST STEP (SECONDS)					
MEAN:	0.4	0.7	0.6	0.6	0.7
SD:	0.24	0.40	1.31	0.17	0.21
MINIMUM:	0.2	0.3	0.2	0.4	0.3
MAXIMUM:	1.7	1.3	10.0	0.9	1.0

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HANDLING OBSERVATIONS (CONTINUED)				
MUCOUS MEMBRANES- COLOR				
1- PINK	10	25	63	10
EYES- COLOR				
1- PINK	10	25	63	10
SKIN- COLOR				
1- PINK	10	25	63	10
EYE PROMINENCE				
1- NORMAL	10	25	62	10
2- EXOPHTHALMUS	NA	NA	1	NA
MUSCLE TONE				
1- FIRM BUT NOT HARD (NORMAL)	10	25	63	10
OPEN-FIELD OBSERVATIONS				
TIME TO FIRST STEP (SECONDS)				
MEAN:	0.7	0.5	0.4	0.4
SD:	0.17	0.28	0.17	0.15
MINIMUM:	0.5	0.3	0.2	0.2
MAXIMUM:	1.0	1.6	1.0	0.7

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
OPEN-FIELD OBSERVATIONS (CONTINUED)					
MOBILITY					
1- NORMAL	80	10	55	15	10
2- SLIGHTLY IMPAIRED	NA	NA	NA	NA	NA
GAIT					
1- NORMAL	80	10	53	15	10
4- HINDLIMBS SPLAYED, UNABLE TO SUPPORT WEIGHT	NA	NA	1	NA	NA
5- HUNCHED BODY, ARCHED BACK	NA	NA	1	NA	NA
CONVULSIONS - CLONIC					
1- ABSENT	80	10	55	15	10
CONVULSIONS - TONIC					
1- ABSENT	80	10	55	15	10
TREMORS					
1- NONE	80	10	55	14	10
2- SLIGHT (1.5 mm)	NA	NA	NA	1	NA
GAIT SCORE					
1- NORMAL	80	10	54	15	10
2- SLIGHT IMPAIRMENT	NA	NA	1	NA	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
OPEN-FIELD OBSERVATIONS (CONTINUED)				
MOBILITY				
1- NORMAL	10	25	63	9
2- SLIGHTLY IMPAIRED	NA	NA	NA	1
GAIT				
1- NORMAL	10	25	63	9
4- HINDLIMBS SPLAYED, UNABLE TO SUPPORT WEIGHT	NA	NA	NA	NA
5- HUNCHED BODY, ARCHED BACK	NA	NA	NA	1
CONVULSIONS - CLONIC				
1- ABSENT	10	25	63	10
CONVULSIONS - TONIC				
1- ABSENT	10	25	63	10
TREMORS				
1- NONE	10	25	62	10
2- SLIGHT (1.5 mm)	NA	NA	1	NA
GAIT SCORE				
1- NORMAL	10	25	63	9
2- SLIGHT IMPAIRMENT	NA	NA	NA	1

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
OPEN-FIELD OBSERVATIONS (CONTINUED)					
AROUSAL					
1- VERY LOW: STUPOR	NA	NA	NA	1	NA
2- LOW: SOMEWHAT STUPOROUS	1	5	4	3	NA
3- NORMAL: ALERT, EXPLORATORY	79	5	51	11	10
BIZARRE/STEREOTYPIC BEHAVIOR					
1- NONE	80	10	55	14	10
11- RETROPULSION	NA	NA	NA	1	NA
REARING					
MEAN:	5.6	2.8	3.9	6.1	5.4
SD:	3.51	3.79	3.70	5.67	4.40
MINIMUM:	0	0	0	0	0
MAXIMUM:	14	10	14	18	12
BACKING					
MEAN:	0.0	0.0	0.0	0.1	0.0
SD:	0.11	0.00	0.13	0.26	0.00
MINIMUM:	0	0	0	0	0
MAXIMUM:	1	0	1	1	0

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
OPEN-FIELD OBSERVATIONS (CONTINUED)				
AROUSAL				
1- VERY LOW: STUPOR	NA	NA	NA	NA
2- LOW: SOMEWHAT STUPOROUS	NA	1	3	1
3- NORMAL: ALERT, EXPLORATORY	10	24	60	9
BIZARRE/STEREOTYPIC BEHAVIOR				
1- NONE	10	25	63	10
11- RETROPULSION	NA	NA	NA	NA
REARING				
MEAN:	9.2	5.9	5.4	3.7
SD:	3.88	5.25	4.20	3.33
MINIMUM:	2	0	0	0
MAXIMUM:	15	21	20	8
BACKING				
MEAN:	0.0	0.0	0.1	0.0
SD:	0.00	0.00	0.63	0.00
MINIMUM:	0	0	0	0
MAXIMUM:	0	0	5	0

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
OPEN-FIELD OBSERVATIONS (CONTINUED)					
GROOMING					
MEAN:	0.3	0.0	0.1	0.3	0.1
SD:	0.71	0.00	0.30	0.70	0.32
MINIMUM:	0	0	0	0	0
MAXIMUM:	3	0	2	2	1
URINATION					
MEAN:	0.6	1.5	1.5	1.1	0.7
SD:	0.76	1.96	2.43	1.46	0.67
MINIMUM:	0	0	0	0	0
MAXIMUM:	4	5	15	5	2
DEFECATION					
MEAN:	0.9	1.2	1.0	0.9	0.8
SD:	1.36	1.87	1.47	1.06	1.75
MINIMUM:	0	0	0	0	0
MAXIMUM:	6	5	6	3	5

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
OPEN-FIELD OBSERVATIONS (CONTINUED)				
GROOMING				
MEAN:	0.0	0.2	0.2	0.0
SD:	0.00	0.52	0.63	0.00
MINIMUM:	0	0	0	0
MAXIMUM:	0	2	3	0
URINATION				
MEAN:	1.8	1.4	0.7	0.8
SD:	1.55	1.19	0.86	0.79
MINIMUM:	0	0	0	0
MAXIMUM:	5	4	4	2
DEFECATION				
MEAN:	0.3	0.7	0.5	1.0
SD:	0.67	1.03	0.93	0.94
MINIMUM:	0	0	0	0
MAXIMUM:	2	3	4	2

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
SENSORY OBSERVATIONS					
APPROACH RESPONSE					
1- NO REACTION	13	8	10	7	2
2- SLOW APPROACH, SNIFFING	67	2	43	8	8
4- FREEZES, ACTUAL MUSCLE CONTRACTION	NA	NA	1	NA	NA
5- BIZARRE REACTION; JUMPS, BITES	NA	NA	1	NA	NA
TOUCH RESPONSE					
1- NO REACTION	9	2	11	6	NA
2- MAY SLOWLY TURN, WALK AWAY	71	8	43	9	10
4- FREEZES, ACTUAL MUSCLE CONTRACTION	NA	NA	1	NA	NA
STARLE RESPONSE					
1- NO REACTION	NA	NA	2	NA	NA
2- SLIGHT REACTION, EAR FLICK	79	9	52	13	10
3- MORE ENERGETIC RESPONSE THAN (2)	1	1	1	2	NA
TAIL PINCH RESPONSE					
1- NO REACTION	3	1	3	2	NA
2- MAY SLOWLY TURN, WALK AWAY	59	7	42	6	9
3- MORE ENERGETIC RESPONSE THAN (2)	18	2	10	7	1

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
SENSORY OBSERVATIONS				
APPROACH RESPONSE				
1- NO REACTION	NA	2	4	NA
2- SLOW APPROACH, SNIFFING	10	23	59	10
4- FREEZES, ACTUAL MUSCLE CONTRACTION	NA	NA	NA	NA
5- BIZARRE REACTION; JUMPS, BITES	NA	NA	NA	NA
TOUCH RESPONSE				
1- NO REACTION	1	2	NA	NA
2- MAY SLOWLY TURN, WALK AWAY	9	23	63	10
4- FREEZES, ACTUAL MUSCLE CONTRACTION	NA	NA	NA	NA
STARLE RESPONSE				
1- NO REACTION	1	NA	NA	NA
2- SLIGHT REACTION, EAR FLICK	9	22	62	10
3- MORE ENERGETIC RESPONSE THAN (2)	NA	3	1	NA
TAIL PINCH RESPONSE				
1- NO REACTION	1	NA	1	NA
2- MAY SLOWLY TURN, WALK AWAY	6	18	49	9
3- MORE ENERGETIC RESPONSE THAN (2)	3	7	13	1

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
SENSORY OBSERVATIONS (CONTINUED)					
OLFACTORY ORIENTATION					
1- NO REACTION	NA	1	7	2	NA
2- REACTION PRESENT	80	9	48	13	10
PUPIL RESPONSE					
1- NO PUPIL RESPONSE	NA	NA	2	NA	NA
2- PUPIL RESPONSE PRESENT	80	10	53	15	10
EYEBLINK RESPONSE					
2- EYEBLINK RESPONSE PRESENT	80	10	55	15	10
FORELIMB EXTENSION					
1- NO FORELIMB EXTENSION	NA	NA	NA	NA	NA
2- FORELIMB EXTENSION PRESENT	80	10	55	15	10
HINDLIMB EXTENSION	1	NA	NA	NA	NA
1- NO HINDLIMB EXTENSION	79	10	55	15	10
2- HINDLIMB EXTENSION PRESENT					
AIR RIGHTING REFLEX					
1- NORMAL	80	10	54	15	10
2- SLIGHTLY UNCOORDINATED	NA	NA	1	NA	NA
3- LANDS ON SIDE	NA	NA	NA	NA	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
SENSORY OBSERVATIONS (CONTINUED)				
OLFACTORY ORIENTATION				
1- NO REACTION	NA	5	NA	NA
2- REACTION PRESENT	10	20	63	10
PUPIL RESPONSE				
1- NO PUPIL RESPONSE	NA	NA	NA	NA
2- PUPIL RESPONSE PRESENT	10	25	63	10
EYEBLINK RESPONSE				
2- EYEBLINK RESPONSE PRESENT	10	25	63	10
FORELIMB EXTENSION				
1- NO FORELIMB EXTENSION	NA	NA	1	NA
2- FORELIMB EXTENSION PRESENT	10	25	62	10
HINDLIMB EXTENSION	NA	NA	NA	NA
1- NO HINDLIMB EXTENSION	10	25	63	10
2- HINDLIMB EXTENSION PRESENT				
AIR RIGHTING REFLEX				
1- NORMAL	9	24	58	10
2- SLIGHTLY UNCOORDINATED	1	1	4	NA
3- LANDS ON SIDE	NA	NA	1	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
NEUROMUSCULAR OBSERVATIONS					
HINDLIMB EXTENSOR STRENGTH					
2- REDUCED HINDLIMB RESISTANCE	NA	1	NA	NA	NA
3- HINDLIMB RESISTANCE PRESENT	80	9	55	15	10
GRIP STRENGTH- FORELIMB (g)					
MEAN:	479.7	807.5	704.4	810.0	614.1
SD:	129.61	142.10	238.02	314.13	160.82
MINIMUM:	257	608	400	292	375
MAXIMUM:	883	992	1558	1383	908
GRIP STRENGTH- HINDLIMB (g)					
MEAN:	255.3	565.9	425.8	591.7	460.1
SD:	80.46	109.10	148.45	229.79	151.87
MINIMUM:	97	342	233	283	275
MAXIMUM:	490	675	925	975	725
ROTAROD PERFORMANCE (SECONDS)					
MEAN:	88.3	87.3	82.6	88.0	85.3
SD:	43.78	36.30	38.60	38.30	39.24
MINIMUM:	9.5	32.9	4.0	24.1	29.5
MAXIMUM:	120.0	120.0	120.0	120.0	120.0

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
NEUROMUSCULAR OBSERVATIONS				
HINDLIMB EXTENSOR STRENGTH				
2- REDUCED HINDLIMB RESISTANCE	NA	NA	NA	NA
3- HINDLIMB RESISTANCE PRESENT	10	25	63	10
GRIP STRENGTH- FORELIMB (g)				
MEAN:	675.8	882.6	936.6	836.7
SD:	130.76	368.48	349.06	274.58
MINIMUM:	517	317	308	500
MAXIMUM:	858	1733	1692	1233
GRIP STRENGTH- HINDLIMB (g)				
MEAN:	389.2	652.3	528.4	470.1
SD:	73.49	257.07	270.03	104.03
MINIMUM:	275	283	175	292
MAXIMUM:	508	1233	1500	667
ROTAROD PERFORMANCE (SECONDS)				
MEAN:	86.5	84.7	53.9	51.8
SD:	49.07	46.16	49.38	55.11
MINIMUM:	5.5	1.2	0.4	2.3
MAXIMUM:	120.0	120.0	120.0	120.0

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
NEUROMUSCULAR OBSERVATIONS (CONTINUED)					
HINDLIMB FOOTSPLAY (mm)					
MEAN:	74.3	87.2	76.9	72.0	77.6
SD:	15.17	14.56	17.06	14.13	17.03
MINIMUM:	41	62	32	49	55
MAXIMUM:	108	113	111	90	100
PHYSIOLOGICAL OBSERVATIONS					
CATALEPSY (SECONDS)					
MEAN:	0.4	0.5	0.5	0.3	0.3
S.D.	0.18	0.20	0.24	0.15	0.16
MINIMUM:	0.2	0.2	0.2	0.2	0.2
MAXIMUM:	1.0	0.7	1.1	0.8	0.7
BODY TEMPERATURE (degrees C)					
MEAN:	38.3	38.3	38.7	38.3	38.3
SD:	0.71	0.16	0.90	0.88	0.72
MINIMUM:	35.6	38.0	36.6	36.3	37.3
MAXIMUM:	39.5	38.6	42.1	39.4	39.2

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
NEUROMUSCULAR OBSERVATIONS (CONTINUED)				
HINDLIMB FOOTSPLAY (mm)				
MEAN:	66.5	80.6	75.5	80.1
SD:	10.29	23.50	21.75	18.73
MINIMUM:	42	24	36	51
MAXIMUM:	82	131	137	109
PHYSIOLOGICAL OBSERVATIONS				
CATALEPSY (SECONDS)				
MEAN:	0.2	0.5	0.6	0.8
S.D.	0.05	0.66	0.44	1.10
MINIMUM:	0.2	0.2	0.2	0.2
MAXIMUM:	0.3	3.5	3.0	3.8
BODY TEMPERATURE (degrees C)				
MEAN:	38.4	38.6	38.4	38.5
SD:	0.49	0.76	0.83	0.55
MINIMUM:	37.2	36.7	36.3	37.7
MAXIMUM:	39.0	39.5	41.0	39.2

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
PHYSIOLOGICAL OBSERVATIONS (CONTINUED)					
BODY WEIGHT (g)					
MEAN:	189.3	318.2	360.2	385.6	412.2
SD:	29.90	31.08	37.46	40.62	49.63
MINIMUM:	129.7	261.4	283.6	315.3	351.0
MAXIMUM:	249.9	361.1	436.0	448.7	500.3

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	63	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23

PHYSIOLOGICAL OBSERVATIONS (CONTINUED)

BODY WEIGHT (g)				
MEAN:	439.9	437.5	522.8	570.2
SD:	40.00	45.36	56.43	41.57
MINIMUM:	389.2	342.0	376.8	476.0
MAXIMUM:	510.9	533.5	692.7	609.9

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HOME CAGE OBSERVATIONS					
POSTURE					
1- SITTING OR STANDING NORMALLY	57	5	40	8	7
2- ASLEEP, LYING ON SIDE OR CURLED UP	17	1	2	1	1
3- ALERT, ORIENTED TOWARD OBSERVER	5	4	12	6	1
5- FLATTENED, LIMBS MAY BE EXTENDED	1	NA	NA	NA	NA
8- REARING	NA	NA	1	NA	1
CONVULSIONS - CLONIC					
1- ABSENT	80	10	55	15	10
CONVULSIONS -TONIC					
1- ABSENT	80	10	55	15	10
TREMORS					
1- NONE	80	10	54	15	10
2- SLIGHT (1.5 mm)	NA	NA	1	NA	NA
BITING					
1- NONE	80	10	54	14	10
2- BITING OF CAGE	NA	NA	1	NA	NA
3- BITING OF SELF	NA	NA	NA	1	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HOME CAGE OBSERVATIONS				
POSTURE				
1- SITTING OR STANDING NORMALLY	4	11	34	3
2- ASLEEP, LYING ON SIDE OR CURLED UP	2	1	10	NA
3- ALERT, ORIENTED TOWARD OBSERVER	4	12	20	6
5- FLATTENED, LIMBS MAY BE EXTENDED	NA	NA	NA	NA
8- REARING	NA	1	1	1
CONVULSIONS - CLONIC				
1- ABSENT	10	25	65	10
CONVULSIONS -TONIC				
1- ABSENT	10	25	65	10
TREMORS				
1- NONE	10	25	64	10
2- SLIGHT (1.5 mm)	NA	NA	1	NA
BITING				
1- NONE	10	25	64	9
2- BITING OF CAGE	NA	NA	1	NA
3- BITING OF SELF	NA	NA	NA	1

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HOME CAGE OBSERVATIONS (CONTINUED)					
PALPEBRAL CLOSURE					
1- EYELIDS WIDE OPEN	65	9	52	14	9
2- EYELIDS SLIGHTLY DROOPING	4	NA	1	NA	NA
3- DROOPING EYELIDS (HALF-CLOSED)	2	NA	1	NA	1
4- EYELIDS COMPLETELY SHUT	9	1	1	1	NA
FECES CONSISTENCY					
1- PELLETS	65	4	38	9	5
2- PELLETS, PARTIALLY FORMED	NA	NA	1	NA	NA
4- PELLETS ABSENT	15	6	16	6	5
HANDLING OBSERVATIONS					
EASE OF REMOVAL					
1- VERY EASY	54	6	45	9	4
2- EASY	23	4	10	6	6
3- MODERATELY DIFFICULT	1	NA	NA	NA	NA
5- DIFFICULT	2	NA	NA	NA	NA
EASE OF HANDLING IN HAND					
1- LOW	75	9	51	13	10
2- MODERATELY LOW	5	1	4	2	NA

NA = NOT APPLICABLE

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA - FEMALES

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HOME CAGE OBSERVATIONS (CONTINUED)				
PALPEBRAL CLOSURE				
1- EYELIDS WIDE OPEN	8	24	52	10
2- EYELIDS SLIGHTLY DROOPING	NA	NA	4	NA
3- DROOPING EYELIDS (HALF-CLOSED)	NA	NA	4	NA
4- EYELIDS COMPLETELY SHUT	2	1	5	NA
FECES CONSISTENCY				
1- PELLETS	9	10	45	5
2- PELLETS, PARTIALLY FORMED	NA	NA	1	NA
4- PELLETS ABSENT	1	15	19	5
HANDLING OBSERVATIONS				
EASE OF REMOVAL				
1- VERY EASY	6	8	55	9
2- EASY	4	16	8	NA
3- MODERATELY DIFFICULT	NA	1	2	NA
5- DIFFICULT	NA	NA	NA	1
EASE OF HANDLING IN HAND				
1- LOW	9	25	61	10
2- MODERATELY LOW	1	NA	4	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HANDLING OBSERVATIONS (CONTINUED)					
LACRIMATION					
1- NONE	80	10	54	15	10
2- SLIGHT	NA	NA	1	NA	NA
CHROMODACRYORRHEA					
1-ABSENT	80	10	55	15	10
SALIVATION					
1- NONE	80	10	55	15	10
PILOERECTION					
1- NONE	80	10	55	15	10
2- SLIGHT	NA	NA	NA	NA	NA
FUR APPEARANCE					
1- NORMAL; CLEAN AND GROOMED	80	10	55	15	10
PALPEBRAL CLOSURE					
1- EYELIDS WIDE OPEN	80	10	55	15	10
RESPIRATORY RATE					
1- NORMAL: BY OBSERVATION (80-110/MIN.)	80	10	55	15	10

NA = NOT APPLICABLE

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA - FEMALES

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HANDLING OBSERVATIONS (CONTINUED)				
LACRIMATION				
1- NONE	10	25	65	10
2- SLIGHT	NA	NA	NA	NA
CHROMODACRYORRHEA				
1-ABSENT	10	25	65	10
SALIVATION				
1- NONE	10	25	65	10
PILOERECTION				
1- NONE	10	25	63	10
2- SLIGHT	NA	NA	2	NA
FUR APPEARANCE				
1- NORMAL; CLEAN AND GROOMED	10	25	65	10
PALPEBRAL CLOSURE				
1- EYELIDS WIDE OPEN	10	25	65	10
RESPIRATORY RATE				
1- NORMAL: BY OBSERVATION (80-110/MIN.)	10	25	65	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HANDLING OBSERVATIONS (CONTINUED)					
RESPIRATORY CHARACTER					
1- NORMAL	80	10	55	15	10
RED DEPOSITS- EYES					
1- PRESENT	NA	NA	1	NA	NA
2- ABSENT	80	10	54	15	10
RED DEPOSITS- NOSE					
1- PRESENT	2	NA	NA	NA	NA
2- ABSENT	78	10	55	15	10
RED DEPOSITS- MOUTH					
2- ABSENT	80	10	55	15	10
CRUSTY DEPOSITS- EYES					
2- ABSENT	80	10	55	15	10
CRUSTY DEPOSITS- NOSE					
2- ABSENT	80	10	55	15	10
CRUSTY DEPOSITS- MOUTH					
2- ABSENT	80	10	55	15	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HANDLING OBSERVATIONS (CONTINUED)				
RESPIRATORY CHARACTER				
1- NORMAL	10	25	65	10
RED DEPOSITS- EYES				
1- PRESENT	NA	NA	1	1
2- ABSENT	10	25	64	9
RED DEPOSITS- NOSE				
1- PRESENT	NA	NA	1	NA
2- ABSENT	10	25	64	10
RED DEPOSITS- MOUTH				
2- ABSENT	10	25	65	10
CRUSTY DEPOSITS- EYES				
2- ABSENT	10	25	65	10
CRUSTY DEPOSITS- NOSE				
2- ABSENT	10	25	65	10
CRUSTY DEPOSITS- MOUTH				
2- ABSENT	10	25	65	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
HANDLING OBSERVATIONS (CONTINUED)					
MUCOUS MEMBRANES- COLOR					
1- PINK	80	10	55	15	10
2- PALE	NA	NA	NA	NA	NA
EYES- COLOR					
1- PINK	80	10	55	15	10
SKIN- COLOR					
1- PINK	80	10	55	15	10
EYE PROMINENCE					
1- NORMAL	80	10	54	15	10
2- EXOPHTHALMUS	NA	NA	1	NA	NA
MUSCLE TONE					
1- FIRM BUT NOT HARD (NORMAL)	79	10	55	15	10
2- SOFT AND FLABBY	1	NA	NA	NA	NA
3- TENSE AND HARD	NA	NA	NA	NA	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
HANDLING OBSERVATIONS (CONTINUED)				
MUCOUS MEMBRANES- COLOR				
1- PINK	10	24	65	10
2- PALE	NA	1	NA	NA
EYES- COLOR				
1- PINK	10	25	65	10
SKIN- COLOR				
1- PINK	10	25	65	10
EYE PROMINENCE				
1- NORMAL	10	25	62	9
2- EXOPHTHALMUS	NA	NA	3	1
MUSCLE TONE				
1- FIRM BUT NOT HARD (NORMAL)	10	25	63	10
2- SOFT AND FLABBY	NA	NA	NA	NA
3- TENSE AND HARD	NA	NA	2	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
OPEN-FIELD OBSERVATIONS					
TIME TO FIRST STEP (SECONDS)					
MEAN:	0.4	0.5	0.4	0.4	0.3
SD:	0.13	0.25	0.17	0.16	0.14
MINIMUM:	0.1	0.3	0.2	0.3	0.0
MAXIMUM:	0.8	1.1	0.9	0.8	0.5
MOBILITY					
1- NORMAL	80	10	55	15	10
GAIT					
1- NORMAL	80	10	55	15	10
CONVULSIONS - CLONIC					
1- ABSENT	80	10	55	15	10
CONVULSIONS - TONIC					
1- ABSENT	80	10	55	15	10
TREMORS					
1- NONE	80	10	54	15	10
2- SLIGHT (1.5 mm)	NA	NA	1	NA	NA

NA = NOT APPLICABLE

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA - FEMALES

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
OPEN-FIELD OBSERVATIONS				
TIME TO FIRST STEP (SECONDS)				
MEAN:	0.5	0.4	0.4	0.3
SD:	0.17	0.16	0.18	0.08
MINIMUM:	0.3	0.2	0.2	0.2
MAXIMUM:	0.7	0.8	1.5	0.4
MOBILITY				
1- NORMAL	10	25	65	10
GAIT				
1- NORMAL	10	25	65	10
CONVULSIONS - CLONIC				
1- ABSENT	10	25	65	10
CONVULSIONS - TONIC				
1- ABSENT	10	25	65	10
TREMORS				
1- NONE	10	25	65	10
2- SLIGHT (1.5 mm)	NA	NA	NA	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
OPEN-FIELD OBSERVATIONS (CONTINUED)					
GAIT SCORE					
1- NORMAL	80	10	55	15	10
3- CONSIDERABLE IMPAIRMENT, WITHOUT FALLING	NA	NA	NA	NA	NA
AROUSAL					
2- LOW: SOMEWHAT STUPOROUS	NA	1	1	NA	NA
3- NORMAL: ALERT, EXPLORATORY	80	9	52	15	9
4- SOMEWHAT HIGH: SLIGHT EXCITEMENT	NA	NA	2	NA	1
BIZARRE/STEREOTYPIC BEHAVIOR					
1- NONE	80	10	54	15	10
9- CIRCLING	NA	NA	1	NA	NA
REARING					
MEAN:	7.0	10.9	6.8	12.3	9.2
SD:	3.55	7.59	4.59	5.32	5.14
MINIMUM:	1	2	0	4	2
MAXIMUM:	18	25	18	23	16

NA = NOT APPLICABLE

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA - FEMALES

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
OPEN-FIELD OBSERVATIONS (CONTINUED)				
GAIT SCORE				
1- NORMAL	9	25	65	10
3- CONSIDERABLE IMPAIRMENT, WITHOUT FALLING	1	NA	NA	NA
AROUSAL				
2- LOW: SOMEWHAT STUPOROUS	NA	NA	NA	NA
3- NORMAL: ALERT, EXPLORATORY	10	25	65	9
4- SOMEWHAT HIGH: SLIGHT EXCITEMENT	NA	NA	NA	1
BIZARRE/STEREOTYPIC BEHAVIOR				
1- NONE	10	25	65	10
9- CIRCLING	NA	NA	NA	NA
REARING				
MEAN:	11.6	8.7	9.9	10.1
SD:	3.31	5.45	4.23	7.45
MINIMUM:	7	0	1	2
MAXIMUM:	18	22	19	21

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
OPEN-FIELD OBSERVATIONS (CONTINUED)					
BACKING					
MEAN:	0.0	0.0	0.0	0.0	0.0
SD:	0.22	0.00	0.00	0.00	0.00
MINIMUM:	0	0	0	0	0
MAXIMUM:	2	0	0	0	0
GROOMING					
MEAN:	0.4	0.1	0.1	0.1	1.0
SD:	0.69	0.32	0.42	0.35	1.89
MINIMUM:	0	0	0	0	0
MAXIMUM:	2	1	2	1	5
URINATION					
MEAN:	0.6	0.2	0.6	0.1	0.0
SD:	1.13	0.42	1.34	0.35	0.00
MINIMUM:	0	0	0	0	0
MAXIMUM:	5	1	8	1	0
DEFECATION					
MEAN:	0.2	0.0	0.0	0.0	0.2
SD:	0.55	0.00	0.19	0.00	0.63
MINIMUM:	0	0	0	0	0
MAXIMUM:	3	0	1	0	2

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
OPEN-FIELD OBSERVATIONS (CONTINUED)				
BACKING				
MEAN:	0.0	0.0	0.0	0.0
SD:	0.00	0.00	0.00	0.00
MINIMUM:	0	0	0	0
MAXIMUM:	0	0	0	0
GROOMING				
MEAN:	0.1	0.1	0.4	0.4
SD:	0.32	0.40	0.80	0.52
MINIMUM:	0	0	0	0
MAXIMUM:	1	2	4	1
URINATION				
MEAN:	1.2	0.2	0.2	0.1
SD:	1.48	0.52	0.52	0.32
MINIMUM:	0	0	0	0
MAXIMUM:	4	2	2	1
DEFECATION				
MEAN:	0.0	0.2	0.1	0.0
SD:	0.00	0.47	0.30	0.00
MINIMUM:	0	0	0	0
MAXIMUM:	0	2	2	0

NA = NOT APPLICABLE

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA - FEMALES

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
SENSORY OBSERVATIONS					
APPROACH RESPONSE					
1- NO REACTION	10	2	9	4	2
2- SLOW APPROACH, SNIFFING	69	8	45	11	7
3- MORE ENERGETIC RESPONSE THAN (2)	1	NA	1	NA	1
TOUCH RESPONSE					
1- NO REACTION	4	5	6	2	1
2- MAY SLOWLY TURN, WALK AWAY	75	5	46	13	9
3- MORE ENERGETIC RESPONSE THAN (2)	1	NA	3	NA	NA
STARLE RESPONSE					
1- NO REACTION	NA	1	NA	1	NA
2- SLIGHT REACTION, EAR FLICK	76	8	50	11	10
3- MORE ENERGETIC RESPONSE THAN (2)	4	1	5	3	NA
TAIL PINCH RESPONSE					
1- NO REACTION	1	1	4	NA	NA
2- MAY SLOWLY TURN, WALK AWAY	58	5	34	11	6
3- MORE ENERGETIC RESPONSE THAN (2)	21	4	17	4	4
OLFACTORY ORIENTATION					
1- NO REACTION	1	2	2	1	NA
2- REACTION PRESENT	79	8	53	14	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
SENSORY OBSERVATIONS				
APPROACH RESPONSE				
1- NO REACTION	NA	NA	3	NA
2- SLOW APPROACH, SNIFFING	10	23	62	10
3- MORE ENERGETIC RESPONSE THAN (2)	NA	2	NA	NA
TOUCH RESPONSE				
1- NO REACTION	NA	NA	2	NA
2- MAY SLOWLY TURN, WALK AWAY	10	24	63	10
3- MORE ENERGETIC RESPONSE THAN (2)	NA	1	NA	NA
STARLE RESPONSE				
1- NO REACTION	4	NA	NA	NA
2- SLIGHT REACTION, EAR FLICK	6	22	64	10
3- MORE ENERGETIC RESPONSE THAN (2)	NA	3	1	NA
TAIL PINCH RESPONSE				
1- NO REACTION	NA	NA	4	NA
2- MAY SLOWLY TURN, WALK AWAY	5	22	47	8
3- MORE ENERGETIC RESPONSE THAN (2)	5	3	14	2
OLFACTORY ORIENTATION				
1- NO REACTION	NA	3	1	NA
2- REACTION PRESENT	10	22	64	10

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
SENSORY OBSERVATIONS (CONTINUED)					
PUPIL RESPONSE					
1- NO PUPIL RESPONSE	NA	NA	3	NA	NA
2- PUPIL RESPONSE PRESENT	80	10	52	15	10
EYEBLINK RESPONSE					
2- EYEBLINK RESPONSE PRESENT	80	10	55	15	10
FORELIMB EXTENSION					
1- NO FORELIMB EXTENSION	1	NA	NA	NA	1
2- FORELIMB EXTENSION PRESENT	79	10	55	15	9
HINDLIMB EXTENSION					
1- NO HINDLIMB EXTENSION	NA	NA	NA	NA	1
2- HINDLIMB EXTENSION PRESENT	80	10	55	15	9
AIR RIGHTING REFLEX					
1- NORMAL	79	10	55	15	10
2- SLIGHTLY UNCOORDINATED	1	NA	NA	NA	NA
3- LANDS ON SIDE	NA	NA	NA	NA	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
SENSORY OBSERVATIONS (CONTINUED)				
PUPIL RESPONSE				
1- NO PUPIL RESPONSE	NA	NA	NA	NA
2- PUPIL RESPONSE PRESENT	10	25	65	10
EYEBLINK RESPONSE				
2- EYEBLINK RESPONSE PRESENT	10	25	65	10
FORELIMB EXTENSION				
1- NO FORELIMB EXTENSION	NA	NA	NA	NA
2- FORELIMB EXTENSION PRESENT	10	25	65	10
HINDLIMB EXTENSION				
1- NO HINDLIMB EXTENSION	1	NA	NA	NA
2- HINDLIMB EXTENSION PRESENT	9	25	65	10
AIR RIGHTING REFLEX				
1- NORMAL	10	24	63	10
2- SLIGHTLY UNCOORDINATED	NA	1	1	NA
3- LANDS ON SIDE	NA	NA	1	NA

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
NEUROMUSCULAR OBSERVATIONS					
HINDLIMB EXTENSOR STRENGTH					
3- HINDLIMB RESISTANCE PRESENT	80	10	55	15	10
GRIP STRENGTH- FORELIMB (g)					
MEAN:	445.0	660.9	576.8	621.7	543.2
SD:	119.39	95.44	169.86	247.84	174.28
MINIMUM:	213	567	192	333	300
MAXIMUM:	783	842	1025	1292	833
GRIP STRENGTH- HINDLIMB (g)					
MEAN:	255.3	480.1	384.0	534.3	427.4
SD:	78.60	125.72	145.87	168.59	156.17
MINIMUM:	107	275	200	300	225
MAXIMUM:	513	642	892	842	683
ROTAROD PERFORMANCE (SECONDS)					
MEAN:	70.9	75.4	87.5	83.8	87.8
SD:	47.92	48.63	41.09	46.72	52.00
MINIMUM:	0.0	19.1	4.5	10.8	7.0
MAXIMUM:	120	120	120	120	120

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
NEUROMUSCULAR OBSERVATIONS				
HINDLIMB EXTENSOR STRENGTH				
3- HINDLIMB RESISTANCE PRESENT	10	25	65	10
GRIP STRENGTH- FORELIMB (g)				
MEAN:	651.6	780.5	741.2	627.5
SD:	191.40	293.60	267.62	271.76
MINIMUM:	342	342	233	333
MAXIMUM:	983	1600	1375	1308
GRIP STRENGTH- HINDLIMB (g)				
MEAN:	288.3	541.3	442.7	406.7
SD:	99.00	153.36	247.19	102.74
MINIMUM:	158	325	150	233
MAXIMUM:	467	1067	1142	592
ROTAROD PERFORMANCE (SECONDS)				
MEAN:	76.1	108.0	76.5	104.3
SD:	42.37	33.54	49.14	29.64
MINIMUM:	1.1	3.8	1.4	43.2
MAXIMUM:	120	120	120	120

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13
NEUROMUSCULAR OBSERVATIONS (CONTINUED)					
HINDLIMB FOOTSPLAY (mm)					
MEAN:	62.5	55.1	61.4	55.2	69.9
SD:	15.80	20.84	17.71	25.10	17.41
MINIMUM:	21	24	18	16	40
MAXIMUM:	90	81	91	87	94
PHYSIOLOGICAL OBSERVATIONS					
CATALEPSY (SECONDS)					
MEAN:	0.3	0.4	0.4	0.2	0.4
S.D.	0.16	0.24	0.20	0.06	0.16
MINIMUM:	0.1	0.2	0.2	0.2	0.2
MAXIMUM:	0.8	0.9	0.9	0.4	0.7
BODY TEMPERATURE (degrees C)					
MEAN:	38.5	38.8	39.0	39.0	39.0
SD:	0.66	0.72	0.91	0.41	0.40
MINIMUM:	36.4	37.5	37.3	38.3	38.5
MAXIMUM:	40.1	39.6	42.3	39.5	39.6

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23
NEUROMUSCULAR OBSERVATIONS (CONTINUED)				
HINDLIMB FOOTSPLAY (mm)				
MEAN:	58.6	67.0	61.2	59.1
SD:	9.67	15.76	15.72	18.62
MINIMUM:	44	35	34	29
MAXIMUM:	78	94	104	88
PHYSIOLOGICAL OBSERVATIONS				
CATALEPSY (SECONDS)				
MEAN:	0.3	0.3	0.5	0.4
S.D.	0.05	0.13	0.41	0.18
MINIMUM:	0.2	0.2	0.2	0.2
MAXIMUM:	0.3	0.6	3.0	0.8
BODY TEMPERATURE (degrees C)				
MEAN:	38.8	39.1	38.9	39.0
SD:	0.31	0.69	0.83	0.71
MINIMUM:	38.1	37.6	37.6	37.5
MAXIMUM:	39.1	40.3	41.5	39.9

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	PRETEST	2	3	4	5
NUMBER OF STUDIES	13	2	8	3	2
NUMBER OF ANIMALS TESTED	80	10	55	15	10
AGE RANGE OF ANIMALS (WEEKS)	5-7	8	9-11	10-11	11-13

PHYSIOLOGICAL OBSERVATIONS (CONTINUED)

BODY WEIGHT (g)					
MEAN:	149.5	206.2	226.3	239.1	250.1
SD:	18.39	18.45	17.96	19.37	20.57
MINIMUM:	98.3	179.6	165.1	213.9	214.4
MAXIMUM:	187.2	243.9	262.3	289.6	276.5

NA = NOT APPLICABLE

TIMEPOINT (STUDY WEEK)	6	7	12	16
NUMBER OF STUDIES	1	2	6	2
NUMBER OF ANIMALS TESTED	10	25	65	10
AGE RANGE OF ANIMALS (WEEKS)	12	13-14	18-19	23

PHYSIOLOGICAL OBSERVATIONS (CONTINUED)

BODY WEIGHT (g)				
MEAN:	258.6	255.9	287.6	287.8
SD:	21.70	20.18	23.28	29.33
MINIMUM:	228.3	202.2	229.3	257.7
MAXIMUM:	303.4	291.0	354.3	347.3

NA = NOT APPLICABLE

WIL HISTORICAL CONTROL DATA
Crl:CD®(SD)IGS BR RATS

FUNCTIONAL OBSERVATIONAL BATTERY
HISTORICAL CONTROL DATA
STUDY INFORMATION

STUDY	ROUTE	VEHICLE	AGE (WEEKS) AT STUDY INITIATION	INTERVALS EVALUATED (WEEKS)	STUDY START	STUDY END
1	ORAL	DIET	7	PRETEST, 12	11/2000	02/2001
2	ORAL	SESAME OIL	7	12	10/2000	01/2001
3	ORAL	PEG 400	6	PRETEST, 3, 5	07/1999	09/1999
4	ORAL	DISTILLED WATER	6	PRETEST, 3	06/1999	06/1999
5	ORAL	DISTILLED WATER	8	PRETEST, 3, 5	11/1999	12/1999
6	ORAL	0.5% MC / 0.2% TWEEN 80	7	PRETEST, 3	08/2000	09/2000
7	ORAL	DEIONIZED WATER	7	PRETEST, 3	01/2001	02/2001
8	ORAL	DEIONIZED WATER	7	PRETEST, 4	11/2001	12/2001
9	ORAL	OLIVE OIL	7	PRETEST, 3	11/2001	12/2001
10	ORAL	CORN OIL	7	PRETEST, 12, 16	04/2000	08/2000
11	ORAL	CORN OIL	6	PRETEST, 2, 4	06/1999	07/1999
12	ORAL	CORN OIL	6	PRETEST, 2, 4	06/1999	08/1999
13	ORAL	DIET	7	PRETEST, 3, 7, 12, 16	06/1999	10/1999
14	ORAL	DIET	6	PRETEST, 3, 7, 12	01/2001	04/2001
15	ORAL	DEIONIZED WATER	6	6, 12	02/2001	05/2001

PEG = POLYETHYLENE GLYCOL, MC = METHYLCELLULOSE

APPENDIX L

WIL Motor Activity Historical Control Data

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			PRETEST 6-7 Weeks in Age TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	602	164	97	87	949	240
2	Diet	Dietary	389	84	54	14	541	160
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	396	206	83	38	724	204
5	Diet	Dietary	374	48	252	11	684	154
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	613	226	49	56	944	326
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	331	111	18	48	508	117
9	Deionized water	Gavage	335	160	52	70	617	135
10	Olive Oil	Gavage	536	216	147	88	988	319
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	447	152	94	52	744	207
		SD	117.5	65.5	74.9	29.9	192.2	81.2
		SEM	41.6	23.2	26.5	10.6	67.9	28.7
		Count	8	8	8	8	8	8
		Median	393	162	68	52	704	182
		Minimum	331	48	18	11	508	117
		Maximum	613	226	252	88	988	326
		25th Quartile	364	104	51	32	598	149
		75th Quartile	552	209	109	74	945	260

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 3					
			9-10 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	758	337	208	165	1468	444
2	Diet	Dietary	663	209	101	65	1037	291
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	419	169	54	23	664	174
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	489	150	71	57	766	178
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	649	356	176	131	1313	347
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	595	244	122	88	1050	287
		SD	138.1	96.2	67.2	58.4	344.0	115.1
		SEM	61.7	43.0	30.0	26.1	153.8	51.5
		Count	5	5	5	5	5	5
		Median	649	209	101	65	1037	291
		Minimum	419	150	54	23	664	174
		Maximum	758	356	208	165	1468	444
		25th Quartile	489	169	71	57	766	178
		75th Quartile	663	337	176	131	1313	347

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 4					
			10-11 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	NA	NA	NA	NA	NA	NA
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	568	240	95	67	969	230
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	568	240	95	67	969	230
		SD	0.0	0.0	0.0	0.0	0.0	0.0
		SEM	0.0	0.0	0.0	0.0	0.0	0.0
		Count	1	1	1	1	1	1
		Median	568	240	95	67	969	230
		Minimum	568	240	95	67	969	230
		Maximum	568	240	95	67	969	230
		25th Quartile	568	240	95	67	969	230
		75th Quartile	568	240	95	67	969	230

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 6					
			12-13 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	830	332	248	135	1545	459
4	Diet	Dietary	NA	NA	NA	NA	NA	NA
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	830	332	248	135	1545	459
		SD	0.0	0.0	0.0	0.0	0.0	0.0
		SEM	0.0	0.0	0.0	0.0	0.0	0.0
		Count	1	1	1	1	1	1
		Median	830	332	248	135	1545	459
		Minimum	830	332	248	135	1545	459
		Maximum	830	332	248	135	1545	459
		25th Quartile	830	332	248	135	1545	459
		75th Quartile	830	332	248	135	1545	459

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 7					
			13-14 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	507	169	151	47	873	214
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	513	221	122	109	965	237
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	510	195	136	78	919	225
		SD	4.0	36.3	20.2	44.4	64.6	16.9
		SEM	2.8	25.7	14.3	31.4	45.6	11.9
		Count	2	2	2	2	2	2
		Median	510	195	136	78	919	225
		Minimum	507	169	122	47	873	214
		Maximum	513	221	151	109	965	237
		25th Quartile	508	182	129	62	896	219
		75th Quartile	511	208	143	94	942	231

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 12					
			18-19 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	575	155	111	39	879	203
3	Deionized water	Gavage	719	338	218	160	1434	420
4	Diet	Dietary	512	208	69	59	847	199
5	Diet	Dietary	752	267	174	65	1258	278
6	Sesame Oil	Gavage	557	307	181	112	1157	251
7	Corn Oil	Gavage	463	194	100	78	834	168
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	596	245	142	85	1068	253
		SD	115.2	70.7	57.4	43.8	251.9	90.6
		SEM	47.0	28.9	23.4	17.9	102.8	37.0
		Count	6	6	6	6	6	6
		Median	566	237	142	71	1018	227
		Minimum	463	155	69	39	834	168
		Maximum	752	338	218	160	1434	420
		25th Quartile	523	198	103	61	855	200
		75th Quartile	683	297	179	103	1233	271

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 16 (Recovery)					
			22-23 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	547	238	81	17	883	187
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	419	205	76	50	750	154
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	483	222	79	34	817	170
		SD	90.5	23.2	3.4	23.6	93.5	22.9
		SEM	64.0	16.4	2.4	16.7	66.1	16.2
		Count	2	2	2	2	2	2
		Median	483	222	79	34	817	170
		Minimum	419	205	76	17	750	154
		Maximum	547	238	81	50	883	187
		25th Quartile	451	213	78	25	783	162
		75th Quartile	515	230	80	42	850	179

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
MALES

			WEEK 26					
			35 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	NA	NA	NA	NA	NA	NA
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	438	145	81	57	721	106
		Mean	438	145	81	57	721	106
		SD	0.0	0.0	0.0	0.0	0.0	0.0
		SEM	0.0	0.0	0.0	0.0	0.0	0.0
		Count	1	1	1	1	1	1
		Median	438	145	81	57	721	106
		Minimum	438	145	81	57	721	106
		Maximum	438	145	81	57	721	106
		25th Quartile	438	145	81	57	721	106
		75th Quartile	438	145	81	57	721	106

NA = NOT APPLICABLE

Study Number	Vehicle	Route	Study Start	Study End
1	Deionized water	Gavage	01/2001	02/2001
2	Diet	Dietary	01/2001	04/2001
3	Deionized water	Gavage	02/2001	05/2001
4	Diet	Dietary	06/1999	10/1999
5	Diet	Dietary	11/2000	02/2001
6	Sesame Oil	Gavage	10/2000	01/2001
7	Corn Oil	Gavage	04/2000	08/2000
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	08/2000	09/2000
9	Deionized water	Gavage	11/2001	12/2001
10	Olive Oil	Gavage	11/2001	12/2001
11	Sponsor-Provided Vehicle	Intramuscular Injection	02/2001	09/2001

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			PRETEST					
			6-7 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	839	129	62	52	1082	408
2	Diet	Dietary	422	141	66	21	649	203
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	472	144	128	66	809	267
5	Diet	Dietary	508	17	17	11	552	187
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	565	260	98	38	961	349
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	610	169	144	147	1070	387
9	Deionized water	Gavage	499	314	134	104	1051	352
10	Olive Oil	Gavage	467	166	80	107	820	290
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	548	167	91	68	874	305
		SD	131.6	89.1	43.2	47.6	200.5	82.4
		SEM	46.5	31.5	15.3	16.8	70.9	29.1
		Count	8	8	8	8	8	8
		Median	503	155	89	59	891	319
		Minimum	422	17	17	11	552	187
		Maximum	839	314	144	147	1082	408
		25th Quartile	470	138	65	33	769	251
		75th Quartile	576	192	130	105	1056	361

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 3					
			9-10 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	728	317	338	211	1594	617
2	Diet	Dietary	575	260	98	144	1078	343
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	531	217	155	120	1022	337
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	590	245	119	9	964	324
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	628	259	234	206	1327	481
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	611	260	189	138	1197	420
		SD	74.3	36.4	98.4	81.9	261.6	127.3
		SEM	33.2	16.3	44.0	36.6	117.0	56.9
		Count	5	5	5	5	5	5
		Median	590	259	155	144	1078	343
		Minimum	531	217	98	9	964	324
		Maximum	728	317	338	211	1594	617
		25th Quartile	575	245	119	120	1022	337
		75th Quartile	628	260	234	206	1327	481

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 4					
			10-11 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	NA	NA	NA	NA	NA	NA
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	619	265	207	171	1261	431
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	619	265	207	171	1261	431
		SD	0.0	0.0	0.0	0.0	0.0	0.0
		SEM	0.0	0.0	0.0	0.0	0.0	0.0
		Count	1	1	1	1	1	1
		Median	619	265	207	171	1261	431
		Minimum	619	265	207	171	1261	431
		Maximum	619	265	207	171	1261	431
		25th Quartile	619	265	207	171	1261	431
		75th Quartile	619	265	207	171	1261	431

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 6					
			12-13 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	636	242	156	223	1257	423
4	Diet	Dietary	NA	NA	NA	NA	NA	NA
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	636	242	156	223	1257	423
		SD	0.0	0.0	0.0	0.0	0.0	0.0
		SEM	0.0	0.0	0.0	0.0	0.0	0.0
		Count	1	1	1	1	1	1
		Median	636	242	156	223	1257	423
		Minimum	636	242	156	223	1257	423
		Maximum	636	242	156	223	1257	423
		25th Quartile	636	242	156	223	1257	423
		75th Quartile	636	242	156	223	1257	423

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 7					
			13-14 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	525	164	171	110	969	278
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	458	186	202	145	991	330
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
Mean			491	175	186	127	980	304
SD			47.5	15.6	22.4	24.7	15.2	36.7
SEM			33.6	11.0	15.9	17.5	10.7	26.0
Count			2	2	2	2	2	2
Median			491	175	186	127	980	304
Minimum			458	164	171	110	969	278
Maximum			525	186	202	145	991	330
25th Quartile			474	170	179	119	975	291
75th Quartile			508	181	194	136	986	317

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 12					
			18-19 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	636	249	113	163	1161	395
3	Deionized water	Gavage	574	217	151	138	1079	387
4	Diet	Dietary	559	187	121	99	966	341
5	Diet	Dietary	671	136	112	7	926	320
6	Sesame Oil	Gavage	648	205	163	118	1135	369
7	Corn Oil	Gavage	318	155	180	139	792	255
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	568	192	140	111	1010	345
		SD	129.8	41.5	28.7	55.1	141.1	52.3
		SEM	53.0	17.0	11.7	22.5	57.6	21.3
		Count	6	6	6	6	6	6
		Median	605	196	136	128	1023	355
		Minimum	318	136	112	7	792	255
		Maximum	671	249	180	163	1161	395
		25th Quartile	563	163	115	104	936	325
		75th Quartile	645	214	160	139	1121	383

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 16 (Recovery) 22-23 Weeks in Age TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	417	105	195	73	790	231
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	423	264	145	173	1006	353
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	NA	NA	NA	NA	NA	NA
		Mean	420	185	170	123	898	292
		SD	4.4	112.9	35.4	70.6	152.5	86.1
		SEM	3.1	79.8	25.0	49.9	107.8	60.9
		Count	2	2	2	2	2	2
		Median	420	185	170	123	898	292
		Minimum	417	105	145	73	790	231
		Maximum	423	264	195	173	1006	353
		25th Quartile	418	145	158	98	844	262
		75th Quartile	421	225	183	148	952	323

NA = NOT APPLICABLE

LOCOMOTOR ACTIVITY
SDI PHOTOBEAM ACTIVITY SYSTEM (SAN DIEGO INSTRUMENTS, INC.)
FEMALES

			WEEK 26					
			35 Weeks in Age					
			TOTAL					
Study Number	Vehicle	Route	0-15 MIN	16-30 MIN	31-45 MIN	46-60 MIN	SESSION TOTALS	AMBULATORY COUNTS
1	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
2	Diet	Dietary	NA	NA	NA	NA	NA	NA
3	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
4	Diet	Dietary	NA	NA	NA	NA	NA	NA
5	Diet	Dietary	NA	NA	NA	NA	NA	NA
6	Sesame Oil	Gavage	NA	NA	NA	NA	NA	NA
7	Corn Oil	Gavage	NA	NA	NA	NA	NA	NA
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	NA	NA	NA	NA	NA	NA
9	Deionized water	Gavage	NA	NA	NA	NA	NA	NA
10	Olive Oil	Gavage	NA	NA	NA	NA	NA	NA
11	Sponsor-Provided Vehicle	Intramuscular Injection	674	215	111	120	1120	336
		Mean	674	215	111	120	1120	336
		SD	0.0	0.0	0.0	0.0	0.0	0.0
		SEM	0.0	0.0	0.0	0.0	0.0	0.0
		Count	1	1	1	1	1	1
		Median	674	215	111	120	1120	336
		Minimum	674	215	111	120	1120	336
		Maximum	674	215	111	120	1120	336
		25th Quartile	674	215	111	120	1120	336
		75th Quartile	674	215	111	120	1120	336

NA = NOT APPLICABLE

Study Number	Vehicle	Route	Study Start	Study End
1	Deionized water	Gavage	01/2001	02/2001
2	Diet	Dietary	01/2001	04/2001
3	Deionized water	Gavage	02/2001	05/2001
4	Diet	Dietary	06/1999	10/1999
5	Diet	Dietary	11/2000	02/2001
6	Sesame Oil	Gavage	10/2000	01/2001
7	Corn Oil	Gavage	04/2000	08/2000
8	0.5% Methylcellulose/ 0.2% Tween 80	Gavage	08/2000	09/2000
9	Deionized water	Gavage	11/2001	12/2001
10	Olive Oil	Gavage	11/2001	12/2001
11	Sponsor-Provided Vehicle	Intramuscular Injection	02/2001	09/2001

APPENDIX M

WIL Clinical Pathology Historical Control Data

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 67 / 68
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

A/G RATIO

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
NA	1.96	0.290	575	2.54 / 1.38	2.83 / 1.09	1.03 / 3.00

ALANINE TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	38	9.7	574	57 / 19	67 / 9	17 / 84

ALBUMIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	4.2	0.28	576	4.8 / 3.6	5.1 / 3.4	3.3 / 5.2

ALKALINE PHOS'TS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	198	52.3	576	302 / 93	354 / 41	62 / 435

ASPARTAT TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	93	20.0	573	133 / 53	153 / 33	44 / 176

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 67 / 68
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

CALCIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	10.8	0.90	576	12.6 / 9.0	13.5 / 8.1	9.1 / 13.9

CHLORIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	102	2.4	575	107 / 97	109 / 94	93 / 109

CHOLESTEROL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	52	12.5	576	77 / 27	90 / 15	22 / 102

CREATINE KINASE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	388	208.7	146	806 / 0.0	1014 / 0.0	89 / 1193

CREATININE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.2	0.07	574	0.4 / 0.1	0.4 / 0.0	0.0 / 0.4

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 67 / 68
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

GLOBULIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	2.2	0.28	576	2.8 / 1.6	3.0 / 1.3	1.3 / 3.2

GLUCOSE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	130	28.7	576	188 / 73	216 / 44	41 / 243

GLUTAMYL TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	0.2	0.47	360	1.1 / 0.0	1.6 / 0.0	0.0 / 3.4

PHOSPHORUS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	10.0	1.85	575	13.7 / 6.3	15.5 / 4.4	6.7 / 18.1

POTASSIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	5.96	1.236	576	8.43 / 3.48	9.66 / 2.25	3.48 / 10.52

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 67 / 68
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

SODIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	146	3.1	575	152 / 140	155 / 136	136 / 160

TOTAL BILIRUBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.2	0.06	574	0.3 / 0.0	0.3 / 0.0	0.0 / 0.4

TOTAL PROTEIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	6.4	0.40	576	7.2 / 5.6	7.6 / 5.2	5.2 / 7.8

TRIGLYCERIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	45	21.5	366	87 / 2	109 / 0.0	9 / 160

UREA NITROGEN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	14.7	3.30	575	21.3 / 8.1	24.6 / 4.7	5.4 / 27.0

Sex: M	Study Type: SUBCHRONIC	Number of Studies/Control Groups: 67 / 68
Species: RAT	Age: 9 - 12 Weeks	Range of Study Dates: 08/99 - 07/05
Strain: Crl:CD(SD)		Report Type: **Excluding +/- 5 S.D.**

Version 2.1
07-Jan-06

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 62 / 63
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

A/G RATIO

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
NA	2.12	0.358	537	2.84 / 1.40	3.19 / 1.05	1.18 / 3.69

ALANINE TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	34	11.0	536	56 / 12	67 / 1	16 / 108

ALBUMIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	4.6	0.37	537	5.3 / 3.8	5.7 / 3.4	3.1 / 6.1

ALKALINE PHOS'TS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	118	37.9	538	194 / 43	232 / 5	38 / 258

ASPARTAT TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	93	24.9	537	143 / 43	168 / 18	51 / 306

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 62 / 63
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

CALCIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	10.9	0.94	538	12.8 / 9 0	13.7 / 8.0	9.1 / 14.1

CHLORIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	102	2.3	538	107 / 98	109 / 96	97 / 109

CHOLESTEROL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	67	15.4	538	98 / 36	113 / 20	30 / 124

CREATINE KINASE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	389	288.3	101	966 / 0.0	1254 / 0.0	82 / 1718

CREATININE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.3	0.08	538	0.4 / 0.1	0.5 / 0.0	0.1 / 0.5

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 62 / 63
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

GLOBULIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	2.2	0.31	537	2.8 / 1.6	3.1 / 1.3	1.3 / 3.2

GLUCOSE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	119	21.5	538	162 / 76	184 / 55	66 / 216

GLUTAMYL TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	0.3	0.48	343	1.3 / 0.0	1.7 / 0.0	0.0 / 2.3

PHOSPHORUS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	9.5	2.34	538	14.2 / 4.8	16.6 / 2.5	4.4 / 18.1

POTASSIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	6.01	1.426	538	8.87 / 3.16	10.29 / 1.74	3.95 / 12.23

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 62 / 63
Range of Study Dates: 08/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

SODIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	145	3.1	538	151 / 139	154 / 136	137 / 156

TOTAL BILIRUBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.2	0.08	537	0.3 / 0.0	0.4 / 0.0	0.1 / 0.6

TOTAL PROTEIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	6.7	0.48	538	7.7 / 5.8	8.2 / 5.3	5.2 / 8.4

TRIGLYCERIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	39	14.2	323	68 / 11	82 / 0.0	13 / 107

UREA NITROGEN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	16.3	3.09	537	22.5 / 10.2	25.6 / 7.1	9.4 / 28.3

Sex: F	Study Type: SUBCHRONIC	Number of Studies/Control Groups: 62 / 63
Species: RAT	Age: 9 - 12 Weeks	Range of Study Dates: 08/99 - 07/05
Strain: Crl:CD(SD)		Report Type: **Excluding +/- 5 S.D.**

Version 2.1
07-Jan-06

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 60 / 61
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

APTT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	19.2	3.42	346	26.0 / 12.4	29.5 / 8.9	8.9 / 29.7

BASOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.0	0.14	507	0.3 / 0.0	0.4 / 0.0	0.0 / 1.0

BASOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.00	0.017	507	0.04 / 0.0	0.06 / 0.0	0.00 / 0.20

EOSINOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.8	0.72	504	2.2 / 0.0	2.9 / 0.0	0.0 / 4.0

EOSINOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.09	0.099	504	0.29 / 0.0	0.38 / 0.0	0.00 / 0.70

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 60 / 61
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

HEMATOCRIT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	42.9	3.24	526	49.4 / 36.4	52.6 / 33.2	33.9 / 56.9

HEMOGLOBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	15.2	1.04	518	17.2 / 13.1	18.3 / 12.0	11.6 / 19.3

LG UNSTAIN CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.9	0.30	35	1.5 / 0.3	1.8 / 0.0	0.4 / 1.5

LUC ABSOLUTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.09	0.053	35	0.19 / 0.0	0.25 / 0.0	0.03 / 0.31

LYMPHOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	82.2	6.14	507	94.5 / 69.9	100.6 / 63.8	53.0 / 100.0

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 60 / 61
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LYMPHOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	9.13	3.221	508	15.57 / 2.69	18.80 / 0.0	3.20 / 22.60

MCH

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
uug	20.0	0.79	517	21.5 / 18.4	22.3 / 17.6	17.4 / 22.2

MCHC

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	35.4	1.12	517	37.6 / 33.2	38.8 / 32.0	31.8 / 37.7

MCV

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
fL	56.4	2.43	518	61.3 / 51.6	63.7 / 49.1	49.8 / 67.4

METHEMOGLOBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.9	0.30	30	1.5 / 0.3	1.8 / 0.0	0.5 / 1.6

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 60 / 61
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

MONOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	5.2	3.29	508	11.7 / 0.0	15.0 / 0.0	0.0 / 18.0

MONOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.57	0.402	507	1.37 / 0.0	1.77 / 0.0	0.00 / 2.40

NEUTROPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	11.7	4.68	506	21.0 / 2.3	25.7 / 0.0	0.0 / 33.0

NEUTROPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1.27	0.664	505	2.60 / 0.0	3.27 / 0.0	0.00 / 4.60

PLATELET

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1205	308.4	508	1822 / 589	2131 / 280	271 / 2736

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 60 / 61
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

PROTIME

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	14.1	1.07	345	16.3 / 12.0	17.4 / 10.9	11.9 / 18.8

RED CELLS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	7.60	0.577	518	8.76 / 6.45	9.33 / 5.87	6.00 / 9.93

RETICULOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.8	1.58	203	4.9 / 0.0	6.5 / 0.0	0.0 / 8.3

RETICULOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	0.128	0.1122	201	0.352 / 0.0	0.464 / 0.0	0.000 / 0.552

WHITE CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	11.1	3.80	508	18.7 / 3.5	22.5 / 0.0	4.0 / 28.0

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 60 / 61
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

WHITE CELL (%)

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	11.2	2.75	10	16.7 / 5.7	19.5 / 2.9	7 1 / 16.5

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Sex: F
Species: RAT
Strain: Crl:CD(SD)
Study Type: SUBCHRONIC
Age: 9 - 12 Weeks
Number of Studies/Control Groups: 57 / 58
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

APTT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	15.0	2.83	320	20.6 / 9.3	23.5 / 6.5	9.3 / 23.8

BASOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.0	0.12	487	0.3 / 0.0	0.4 / 0.0	0.0 / 1.0

BASOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.00	0.014	488	0.03 / 0.0	0.05 / 0.0	0.00 / 0.20

EOSINOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.0	0.91	485	2.8 / 0.0	3.7 / 0.0	0.0 / 6.0

EOSINOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.09	0.102	485	0.30 / 0.0	0.40 / 0.0	0.00 / 0.70

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 57 / 58
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

HEMATOCRIT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	41.2	3.35	499	47.9 / 34.5	51.3 / 31.2	30.0 / 54.2

HEMOGLOBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	14.7	1.09	499	16.8 / 12.5	17.9 / 11.4	11.0 / 18.6

LG UNSTAIN CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.8	0.33	35	1.5 / 0.2	1.8 / 0.0	0.3 / 1.7

LUC ABSOLUTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.07	0.039	35	0.14 / 0.0	0.18 / 0.0	0.01 / 0.16

LYMPHOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	83.4	6.77	490	97.0 / 69.9	103.7 / 63.1	55.0 / 97.0

Sex: F
Species: RAT
Strain: Crl:CD(SD)
Study Type: SUBCHRONIC
Age: 9 - 12 Weeks
Number of Studies/Control Groups: 57 / 58
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LYMPHOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	7.48	2.767	490	13.01 / 1.95	15.78 / 0.0	-1.80 / 19.90

MCH

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
uug	20.1	0.71	498	21.5 / 18.7	22.2 / 18.0	17.1 / 22.7

MCHC

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	35.6	1.06	499	37.7 / 33.5	38.8 / 32.4	31.3 / 38.3

MCV

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
fL	56.5	2.21	499	60.9 / 52.1	63.1 / 49.9	46.6 / 66.7

METHEMOGLOBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.0	0.36	30	1.7 / 0.3	2.1 / 0.0	0.5 / 2.0

Sex: F | Study Type: SUBCHRONIC | Number of Studies/Control Groups: 57 / 58
Species: RAT | Age: 9 - 12 Weeks | Range of Study Dates: 08/99 - 05/05
Strain: Crl:CD(SD) | Report Type: **Excluding +/- 5 S.D.**

MONOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	4.5	2.72	490	10.0 / 0.0	12.7 / 0.0	0.0 / 16.0

MONOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.41	0.267	488	0.94 / 0.0	1.21 / 0.0	0.00 / 1.50

NEUTROPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	10.9	5.24	490	21.4 / 0.4	26.6 / 0.0	0.0 / 33.0

NEUTROPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.95	0.563	488	2.07 / 0.0	2.64 / 0.0	-0.20 / 3.70

PLATELET

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1195	284.2	489	1763 / 626	2047 / 342	39 / 2476

Sex: F | Study Type: SUBCHRONIC | Number of Studies/Control Groups: 57 / 58
Species: RAT | Age: 9 - 12 Weeks | Range of Study Dates: 08/99 - 05/05
Strain: Crl:CD(SD) | Report Type: **Excluding +/- 5 S.D.**

PROTIME

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	13.8	0.95	317	15.8 / 11.9	16.7 / 11.0	10.4 / 18.6

RED CELLS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	7.31	0.591	499	8.49 / 6.13	9.08 / 5.54	5.46 / 9.63

RETICULOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.7	1.68	198	5.0 / 0.0	6.7 / 0.0	0.0 / 9.7

RETICULOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	0.126	0.1332	196	0.392 / 0.0	0.525 / 0.0	0.000 / 0.869

WHITE CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	9.0	3.13	489	15.3 / 2.7	18.4 / 0.0	2.4 / 22.2

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 57 / 58
Range of Study Dates: 08/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

WHITE CELL (%)

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	11.5	5.51	10	22.6 / 0.5	28.1 / 0.0	6.0 / 21.7

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07-Sep-05

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

A/G RATIO

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
NA	1.71	0.255	121	2.22 / 1.20	2.48 / 0.94	1.06 / 2.60

ALANINE TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	42	10.5	120	63 / 21	74 / 10	25 / 90

ALBUMIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	4.2	0.32	121	4.8 / 3.6	5.2 / 3.2	3.1 / 5.1

ALKALINE PHOS'TS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	148	41.8	121	232 / 65	274 / 23	72 / 274

ASPARTAT TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	105	30.0	121	165 / 45	195 / 15	62 / 219

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

CALCIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	10.6	0.85	121	12.3 / 8.9	13.1 / 8.0	9.4 / 13.4

CHLORIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	101	2.7	121	107 / 96	109 / 93	93 / 110

CHOLESTEROL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	54	15.2	121	84 / 23	99 / 8	27 / 101

CREATINE KINASE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	742	523.2	31	1789 / 0.0	2312 / 0.0	130 / 1856

CREATININE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.3	0.09	121	0.4 / 0.1	0.5 / 0.0	0.1 / 0.6

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

GLOBULIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	2.5	0.29	121	3.1 / 1.9	3.4 / 1.6	1.7 / 3.5

GLUCOSE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	127	26.4	121	179 / 74	206 / 48	79 / 208

GLUTAMYL TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	0.0	0.04	68	0.1 / 0.0	0.1 / 0.0	0.0 / 0.3

PHOSPHORUS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	8.7	1.76	121	12.2 / 5.2	14.0 / 3.5	5.9 / 14.4

POTASSIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	5.91	1.275	121	8.46 / 3.36	9.74 / 2.09	4.12 / 10.62

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

SODIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	146	2.9	121	151 / 140	154 / 137	139 / 157

TOTAL BILIRUBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.2	0.06	121	0.3 / 0.0	0.3 / 0.0	0.1 / 0.3

TOTAL PROTEIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	6.7	0.41	121	7.5 / 5.9	7.9 / 5.5	5.6 / 8.6

TRIGLYCERIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	54	28.8	75	112 / 0.0	141 / 0.0	15 / 185

UREA NITROGEN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	16.3	2.76	121	21.9 / 10.8	24.6 / 8.1	11.5 / 28.9

Sex: M	Study Type: SUBCHRONIC	Number of Studies/Control Groups: 15 / 16
Species: RAT	Age: 13 - 15 Weeks	Range of Study Dates: 12/99 - 07/05
Strain: Crl:CD(SD)		Report Type: **Excluding +/- 5 S.D.**

Version 2.1
07-Jan-06

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

A/G RATIO

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
NA	1.89	0.296	120	2.48 / 1.30	2.78 / 1.00	1.37 / 3.06

ALANINE TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	38	12.9	119	64 / 12	76 / 0.0	21 / 108

ALBUMIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	4.6	0.38	120	5.4 / 3.8	5.8 / 3.4	3.9 / 5.7

ALKALINE PHOS'TS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	89	29.3	120	148 / 31	177 / 2	46 / 201

ASPARTAT TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	105	31.2	120	167 / 42	198 / 11	59 / 210

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type. SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

CALCIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	10.7	0.93	120	12.6 / 8.9	13.5 / 7.9	9.3 / 13.3

CHLORIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	103	2.4	119	108 / 98	110 / 96	97 / 109

CHOLESTEROL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	66	13.7	120	94 / 39	108 / 25	40 / 119

CREATINE KINASE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	606	408.1	30	1422 / 0.0	1830 / 0.0	141 / 1631

CREATININE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.3	0.08	120	0.5 / 0.2	0.6 / 0.1	0.2 / 0.5

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

GLOBULIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	2.5	0.27	120	3.0 / 1.9	3.3 / 1.6	1.8 / 3.2

GLUCOSE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	121	21.5	120	164 / 78	186 / 57	77 / 195

GLUTAMYL TRANSFER

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
U/L	0.1	0.30	74	0.7 / 0.0	1.0 / 0.0	0.0 / 1.0

PHOSPHORUS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	8.0	2.42	120	12.9 / 3.2	15.3 / 0.8	3.9 / 16.3

POTASSIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	5.63	1.330	119	8.29 / 2.97	9.62 / 1.64	3.93 / 11.22

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 07/05
Report Type: **Excluding +/- 5 S.D.**

SODIUM

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mEq/L	145	3.0	119	151 / 139	154 / 136	140 / 156

TOTAL BILIRUBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	0.2	0.11	118	0.4 / 0.0	0.5 / 0.0	0.1 / 0.9

TOTAL PROTEIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	7.1	0.45	120	8.0 / 6.2	8.4 / 5.7	6.2 / 8.4

TRIGLYCERIDE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	44	17.4	73	79 / 9	97 / 0.0	14 / 107

UREA NITROGEN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mg/dL	17.5	3.08	120	23.6 / 11.3	26.7 / 8.2	11.6 / 32.5

Sex: F	Study Type: SUBCHRONIC	Number of Studies/Control Groups: 14 / 15
Species: RAT	Age: 13 - 15 Weeks	Range of Study Dates: 12/99 - 07/05
Strain: Crl:CD(SD)		Report Type: **Excluding +/- 5 S.D.**

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Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

APTT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	19.3	3.03	60	25.3 / 13.2	28.4 / 10.2	11.9 / 26.1

BASOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.0	0.17	125	0.4 / 0.0	0.6 / 0.0	0.0 / 1.0

BASOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.01	0.018	125	0.04 / 0.0	0.06 / 0.0	0.00 / 0.10

EOSINOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.8	0.77	126	2.4 / 0.0	3.1 / 0.0	0.0 / 3.0

EOSINOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.09	0.089	126	0.27 / 0.0	0.36 / 0.0	0.00 / 0.40

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

HEMATOCRIT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	42.0	2.82	126	47.6 / 36.3	50.4 / 33.5	34.7 / 51.0

HEMOGLOBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	15.0	0.90	126	16.8 / 13.2	17.7 / 12.3	12.4 / 18.0

LG UNSTAIN CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.2	0.47	10	2.1 / 0.2	2.6 / 0.0	0.5 / 2.0

LUC ABSOLUTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.14	0.070	10	0.28 / 0.0	0.35 / 0.0	0.06 / 0.25

LYMPHOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	80.7	7.78	126	96.3 / 65.2	104.0 / 57.4	55.0 / 94.0

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LYMPHOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	9.55	2.619	126	14 79 / 4.31	17.40 / 1.69	2.50 / 18.30

MCH

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
uug	18.9	0.66	125	20.3 / 17.6	20.9 / 16.9	17.4 / 20.5

MCHC

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	35.8	0.98	126	37.8 / 33.8	38.8 / 32.9	33.3 / 37.7

MCV

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
fL	52.9	1.66	125	56.2 / 49.6	57.9 / 47.9	48.8 / 57.3

MONOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	5.0	3.55	126	12.1 / 0.0	15.6 / 0.0	0.0 / 14.0

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

MONOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.58	0.451	126	1.48 / 0.0	1.93 / 0.0	0.00 / 2.00

NEUTROPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	13.3	5.53	126	24.3 / 2.2	29.9 / 0.0	1.0 / 35.0

NEUTROPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1.51	0.684	125	2.88 / 0.14	3.56 / 0.0	0.10 / 4.30

PLATELET

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1249	306.9	126	1863 / 635	2170 / 328	725 / 2451

PROTIME

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	14.5	1.13	60	16.7 / 12.2	17.9 / 11.1	12.5 / 18.0

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 15 / 16
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

RED CELLS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	7.96	0.558	126	9.08 / 6.85	9.64 / 6.29	6.64 / 10.00

RETICULOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.6	0.93	31	3.5 / 0.0	4.4 / 0.0	0.0 / 2.8

RETICULOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	0.128	0.0735	31	0.275 / 0.0	0.348 / 0.0	0.000 / 0.235

WHITE CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	11.8	2.99	126	17.8 / 5.8	20.8 / 2.8	3.8 / 22.0

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Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

APTT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	15.7	3.24	57	22.1 / 9.2	25.4 / 6.0	9.9 / 23.1

BASOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	0.0	0.07	120	0.2 / 0.0	0.2 / 0.0	0.0 / 0.4

BASOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.01	0.019	124	0.04 / 0.0	0.06 / 0.0	0.00 / 0.10

EOSINOPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.1	0.84	123	2.8 / 0.0	3.6 / 0.0	0.0 / 3.0

EOSINOPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.10	0.082	123	0.26 / 0.0	0.34 / 0.0	0.00 / 0.40

Sex: F | Study Type: SUBCHRONIC | Number of Studies/Control Groups: 14 / 15
Species: RAT | Age: 13 - 15 Weeks | Range of Study Dates: 12/99 - 05/05
Strain: Crl:CD(SD) | Report Type: **Excluding +/- 5 S.D.**

HEMATOCRIT

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	40.4	3.02	124	46.4 / 34.3	49.4 / 31.3	30.1 / 49.2

HEMOGLOBIN

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	14.5	0.95	124	16.4 / 12.6	17.4 / 11.7	10.7 / 16.7

LG UNSTAIN CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.1	0.22	10	1.6 / 0.7	1.8 / 0.5	0.8 / 1.4

LUC ABSOLUTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.11	0.027	10	0.17 / 0.06	0.20 / 0.03	0.07 / 0.15

LYMPHOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	81.6	7.05	123	95.7 / 67.5	102.7 / 60.4	56.6 / 94.0

Sex: F
Species: RAT
Strain: Crl:CD(SD)
Study Type: SUBCHRONIC
Age: 13 - 15 Weeks
Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LYMPHOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	7.11	2.125	124	11.36 / 2 86	13.48 / 0.73	2.20 / 15.53

MCH

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
uug	19.5	0.62	124	20.8 / 18.3	21.4 / 17.7	18.0 / 21.0

MCHC

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
g/dL	36.0	1.05	124	38.1 / 33.9	39.1 / 32.8	33.4 / 37.9

MCV

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
fL	54.3	2.00	124	58.3 / 50.3	60.3 / 48.4	51.2 / 61.5

MONOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	4.3	2.73	124	9.7 / 0.0	12.4 / 0.0	0.0 / 14.0

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

MONOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	0.37	0.255	124	0.88 / 0.0	1.14 / 0.0	0.00 / 1.30

NEUTROPHIL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	12.9	5.85	123	24.6 / 1.2	30.4 / 0.0	2.0 / 36.0

NEUTROPHIL - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1.12	0.645	123	2.41 / 0.0	3.05 / 0.0	0.20 / 3.76

PLATELET

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	1275	336.9	124	1949 / 601	2286 / 265	635 / 2272

PROTIME

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
seconds	14.1	0.90	57	15.9 / 12.3	16.8 / 11.4	12.0 / 15.9

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 14 / 15
Range of Study Dates: 12/99 - 05/05
Report Type: **Excluding +/- 5 S.D.**

RED CELLS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	7.44	0.586	124	8.61 / 6 27	9.20 / 5.68	5.28 / 9.02

RETICULOCYTE

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
%	1.7	0.99	28	3.7 / 0.0	4.7 / 0.0	0.2 / 4.0

RETICULOCYTE - ABS

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
mil/uL	0.126	0.0750	28	0.276 / 0.0	0.351 / 0.0	0.017 / 0.315

WHITE CELL

Unit	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
thous/uL	8.8	2.68	124	14.2 / 3.4	16.8 / 0.8	3.3 / 20.4

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FINAL REPORT

Volume 3 of 3
(Appendices N-P)

STUDY TITLE

A 28-DAY REPEATED DOSE ORAL (GAVAGE)
TOXICITY STUDY OF [redacted] IN RATS (WITH FUNCTIONAL
OBSERVATIONAL BATTERY AND MOTOR ACTIVITY DETERMINATIONS)

STUDY NUMBER

WIL-187051

STUDY DIRECTOR

[redacted]

STUDY INITIATION DATE

21 September 2005

STUDY COMPLETION DATE

28 June 2006

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

05-087

SPONSOR

[redacted]

APPENDIX N

WIL Organ Weight Historical Control Data

WIL Research Laboratories - Historical Control Summary of Organ Weights

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 56 / 57
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

ADRENAL GLANDS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0621	0.01001	439	0.0821 / 0.0421	0.0921 / 0.0321	0.0272 / 0.0945
OW relative to FBW:	0.019	0.0033	439	0.026 / 0.013	0.029 / 0.009	0.007 / 0.030
OW relative to brain:	3.220	0.5091	429	4.238 / 2.202	4.747 / 1.693	1.439 / 4.978

BRAIN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.93	0.096	429	2.12 / 1.74	2.22 / 1.64	1.59 / 2.26
OW relative to FBW:	0.596	0.0734	429	0.743 / 0.449	0.816 / 0.376	0.408 / 0.844
OW relative to brain:	NA					

EPIDIDYMIDES

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.94	0.157	251	1.25 / 0.62	1.41 / 0.47	0.48 / 1.36
OW relative to FBW:	0.279	0.0381	251	0.355 / 0.203	0.394 / 0.165	0.168 / 0.369
OW relative to brain:	48.363	7.7824	251	63.928 / 32.798	71.710 / 25.016	26.263 / 65.574

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 56 / 57
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

HEART

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.24	0.164	391	1.57 / 0.91	1.73 / 0.75	0.82 / 1.90
OW relative to FBW:	0.381	0.0409	391	0.463 / 0.299	0.504 / 0.258	0.287 / 0.522
OW relative to brain:	64.467	8.1136	391	80.695 / 48.240	88.808 / 40.126	44.503 / 102.703

KIDNEYS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	2.62	0.380	433	3.38 / 1.86	3.76 / 1.48	1.84 / 4.51
OW relative to FBW:	0.802	0.0835	433	0.969 / 0.635	1.052 / 0.551	0.625 / 1.383
OW relative to brain:	136.196	18.5626	423	173.321 / 99.070	191.883 / 80.508	96.078 / 238.624

LEFT CAUDA EPID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.2004	0.01652	10	0.2334 / 0.1674	0.2500 / 0.1508	0.1662 / 0.2199
OW relative to FBW:	0.069	0.0042	10	0.078 / 0.061	0.082 / 0.057	0.061 / 0.075
OW relative to brain:	10.789	0.7720	10	12.333 / 9.245	13.105 / 8.473	9.182 / 11.630

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 56 / 57
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LEFT EPIDIDYMIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.5240	0.03273	10	0.5895 / 0.4585	0.6222 / 0.4258	0.4600 / 0.5700
OW relative to FBW:	0.182	0.0105	10	0.203 / 0.161	0.213 / 0.150	0.165 / 0.201
OW relative to brain:	28.232	1.7383	10	31.709 / 24.756	33.447 / 23.017	24.599 / 30.978

LEFT TESTIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.62	0.091	10	1.80 / 1.43	1.89 / 1.34	1.46 / 1.73
OW relative to FBW:	0.561	0.0297	10	0.620 / 0.501	0.650 / 0.472	0.505 / 0.604
OW relative to brain:	87.119	4.8142	10	96.747 / 77.490	101.561 / 72.676	80.000 / 94.022

LIVER

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	10.3	1.80	439	13.9 / 6.7	15.7 / 4.9	6.4 / 16.6
OW relative to FBW:	3.149	0.3778	439	3.904 / 2.393	4.282 / 2.015	2.452 / 4.966
OW relative to brain:	535.850	88.1164	429	712.083 / 359.618	800.200 / 271.501	366.316 / 859.043

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 56 / 57
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LUNGS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.46	0.184	65	1.83 / 1.09	2.01 / 0.91	1.07 / 1.99
OW relative to FBW:	0.467	0.0515	65	0.570 / 0.364	0.621 / 0.313	0.358 / 0.601
OW relative to brain:	77.494	8.7304	55	94.955 / 60.033	103.685 / 51.303	60.000 / 99.500

PITUITARY

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0119	0.00221	197	0.0163 / 0.0074	0.0185 / 0.0052	0.0062 / 0.0178
OW relative to FBW:	0.004	0.0006	197	0.005 / 0.002	0.006 / 0.002	0.002 / 0.005
OW relative to brain:	0.616	0.1084	197	0.833 / 0.399	0.941 / 0.291	0.339 / 0.959

PROSTATE

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.77	0.189	94	1.15 / 0.39	1.34 / 0.21	0.36 / 1.41
OW relative to FBW:	0.225	0.0520	94	0.329 / 0.121	0.381 / 0.069	0.099 / 0.433
OW relative to brain:	39.795	9.8050	94	59.404 / 20.185	69.209 / 10.380	18.090 / 75.287

Sex: M | Study Type: SUBCHRONIC | Number of Studies/Control Groups: 56 / 57
Species: RAT | Age: 9 - 12 Weeks | Range of Study Dates: 02/00 - 05/05
Strain: Crl:CD(SD) | Report Type: **Excluding +/- 5 S.D.**

RIGHT CAUDA EPID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.1944	0.01233	10	0.2191 / 0.1698	0.2314 / 0.1575	0.1801 / 0.2216
OW relative to FBW:	0.067	0.0032	10	0.074 / 0.061	0.077 / 0.058	0.064 / 0.075
OW relative to brain:	10.482	0.7507	10	11.983 / 8.980	12.734 / 8.230	9.651 / 11.672

RIGHT EPIDIDYMIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.52	0.038	10	0.60 / 0.45	0.64 / 0.41	0.46 / 0.57
OW relative to FBW:	0.182	0.0150	10	0.212 / 0.152	0.227 / 0.137	0.156 / 0.201
OW relative to brain:	28.245	2.1728	10	32.591 / 23.900	34.763 / 21.727	23.590 / 29.891

RIGHT TESTIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.63	0.092	10	1.81 / 1.44	1.90 / 1.35	1.50 / 1.83
OW relative to FBW:	0.564	0.0340	10	0.632 / 0.496	0.666 / 0.462	0.519 / 0.647
OW relative to brain:	87.501	3.6536	10	94.808 / 80.194	98.462 / 76.541	81.538 / 94.330

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 56 / 57
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

SEM VES/COAG GL.

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.0925	0.21658	8	1.5257 / 0.6593	1.7422 / 0.4428	0.6700 / 1.2900
OW relative to FBW:	0.371	0.0655	8	0.502 / 0.240	0.567 / 0.174	0.250 / 0.420
OW relative to brain:	57.275	9.7714	8	76.818 / 37.732	86.589 / 27.961	37.853 / 64.824

SPLEEN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.67	0.110	401	0.89 / 0.45	1.00 / 0.34	0.38 / 1.04
OW relative to FBW:	0.206	0.0302	401	0.266 / 0.146	0.296 / 0.115	0.129 / 0.374
OW relative to brain:	34.609	5.3982	401	45.405 / 23 812	50.803 / 18.414	20.994 / 51.163

TESTES

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	3.16	0.279	388	3.72 / 2.60	4.00 / 2.33	1.21 / 3.89
OW relative to FBW:	0.975	0.1211	388	1.217 / 0.732	1.338 / 0.611	0.423 / 1.383
OW relative to brain:	164.211	14.5684	378	193.348 / 135.074	207.917 / 120.506	67.222 / 205.618

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 56 / 57
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

TESTES/EPID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	3.96	0.402	40	4.76 / 3.15	5.16 / 2.75	2.94 / 4.81
OW relative to FBW:	1.221	0.1258	40	1.473 / 0.969	1.598 / 0.844	0.900 / 1.437
OW relative to brain:	204.118	19.4113	40	242.940 / 165.295	262.351 / 145.884	144.828 / 247.938

THYMUS GLAND

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.5359	0.13322	365	0.8023 / 0.2695	0.9356 / 0.1363	0.2052 / 1.1446
OW relative to FBW:	0.166	0.0433	365	0.252 / 0.079	0.295 / 0.036	0.071 / 0.336
OW relative to brain:	27.846	7.0117	365	41.870 / 13.823	48.881 / 6.811	10.577 / 59.615

THYROID/PARATHYROID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0221	0.00581	351	0.0337 / 0.0105	0.0396 / 0.0047	0.0084 / 0.0447
OW relative to FBW:	0.007	0.0017	351	0.010 / 0.003	0.012 / 0.002	0.003 / 0.014
OW relative to brain:	1.150	0.2978	351	1.745 / 0.554	2.043 / 0.256	0.442 / 2.271

Sex:	M	Study Type:	SUBCHRONIC	Number of Studies/Control Groups:	56 / 57
Species:	RAT	Age:	9 - 12 Weeks	Range of Study Dates:	02/00 - 05/05
Strain:	Crl:CD(SD)			Report Type:	**Excluding +/- 5 S.D.**

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Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 53 / 54
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

ADRENAL GLANDS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0717	0.01049	409	0.0926 / 0.0507	0.1031 / 0.0402	0.0455 / 0.1292
OW relative to FBW:	0.034	0.0051	409	0.045 / 0.024	0.050 / 0.019	0.021 / 0.059
OW relative to brain:	3.957	0.5631	399	5.083 / 2.831	5.646 / 2.268	2.519 / 6.836

BRAIN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.81	0.089	399	1.99 / 1.63	2.08 / 1.54	1.40 / 2.06
OW relative to FBW:	0.871	0.0900	399	1.051 / 0.691	1.141 / 0.601	0.653 / 1.302
OW relative to brain:	NA					

HEART

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.86	0.098	361	1.05 / 0.66	1.15 / 0.56	0.57 / 1.16
OW relative to FBW:	0.410	0.0406	361	0.491 / 0.329	0.532 / 0.288	0.306 / 0.567
OW relative to brain:	47.338	5.3388	361	58.016 / 36.661	63.355 / 31.322	33.929 / 64.088

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 53 / 54
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

KIDNEYS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.69	0.194	408	2.08 / 1.31	2.28 / 1.11	0.82 / 2.25
OW relative to FBW:	0.812	0.0802	408	0.972 / 0.652	1.053 / 0.572	0.451 / 1.198
OW relative to brain:	93.840	10.0475	398	113.935 / 73.745	123.983 / 63.698	46.857 / 129.412

LIVER

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	6.9	0.97	409	8.8 / 5.0	9.8 / 4.0	4.5 / 11.1
OW relative to FBW:	3.302	0.3549	409	4.012 / 2.592	4.367 / 2.237	2.608 / 5.056
OW relative to brain:	382.583	51.2538	399	485.090 / 280.075	536.344 / 228.821	268.452 / 604.891

LUNGS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.20	0.125	64	1.45 / 0.95	1.58 / 0.83	0.94 / 1.56
OW relative to FBW:	0.588	0.0514	64	0.691 / 0.486	0.743 / 0.434	0.484 / 0.701
OW relative to brain:	66.290	6.6662	54	79.622 / 52.957	86.289 / 46.291	50.811 / 87.857

Sex: F Study Type: SUBCHRONIC Number of Studies/Control Groups: 53 / 54
Species: RAT Age: 9 - 12 Weeks Range of Study Dates: 02/00 - 05/05
Strain: Crl:CD(SD) Report Type: **Excluding +/- 5 S.D.**

OVARIES

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.1492	0.02932	15	0.2078 / 0.0906	0.2372 / 0.0612	0.1119 / 0.1971
OW relative to FBW:	0.066	0.0131	15	0.092 / 0.040	0.106 / 0.027	0.051 / 0.093
OW relative to brain:	8.206	1.5034	15	11.213 / 5.200	12.717 / 3.696	5.952 / 10.668

OVARIES/OVIDUCTS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.1310	0.01856	370	0.1681 / 0.0939	0.1867 / 0.0753	0.0838 / 0.1827
OW relative to FBW:	0.063	0.0088	370	0.081 / 0.046	0.089 / 0.037	0.042 / 0.089
OW relative to brain:	7.257	1.0042	370	9.265 / 5.249	10.269 / 4.244	4.798 / 10.429

PITUITARY

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0144	0.00286	173	0.0201 / 0.0086	0.0229 / 0.0058	0.0088 / 0.0249
OW relative to FBW:	0.007	0.0012	173	0.009 / 0.005	0.010 / 0.003	0.005 / 0.011
OW relative to brain:	0.790	0.1474	173	1.084 / 0.495	1.232 / 0.348	0.489 / 1.311

Sex: F Study Type: SUBCHRONIC Number of Studies/Control Groups: 53 / 54
Species: RAT Age: 9 - 12 Weeks Range of Study Dates: 02/00 - 05/05
Strain: Crl:CD(SD) Report Type: **Excluding +/- 5 S.D.**

SPLEEN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.49	0.083	391	0.66 / 0.33	0.74 / 0.24	0.30 / 0.79
OW relative to FBW:	0.235	0.0340	391	0.303 / 0.167	0.337 / 0.133	0.163 / 0.414
OW relative to brain:	27.150	4.3525	391	35.855 / 18.445	40.207 / 14.092	17.098 / 44.382

THYMUS GLAND

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.4804	0.10726	356	0.6949 / 0.2659	0.8022 / 0.1586	0.2289 / 0.8438
OW relative to FBW:	0.230	0.0525	356	0.335 / 0.125	0.388 / 0.073	0.101 / 0.434
OW relative to brain:	26.618	5.9650	356	38.548 / 14.688	44.513 / 8.723	12.788 / 48.096

THYROID/PARATHYROID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0196	0.00434	326	0.0282 / 0.0109	0.0326 / 0.0066	0.0088 / 0.0357
OW relative to FBW:	0.009	0.0020	326	0.013 / 0.005	0.015 / 0.004	0.005 / 0.016
OW relative to brain:	1.085	0.2421	326	1.569 / 0.600	1.811 / 0.358	0.492 / 1.921

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 9 - 12 Weeks

Number of Studies/Control Groups: 53 / 54
Range of Study Dates: 02/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

UTERUS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.52	0.176	204	0.87 / 0.17	1.05 / 0.00	0.27 / 1.17
OW relative to FBW:	0.256	0.0888	204	0.434 / 0.079	0.523 / -0.010	0.115 / 0.680
OW relative to brain:	28.852	9.6189	204	48.089 / 9.614	57.708 / -0.005	14.136 / 61.494

UTERUS/CERVIX

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.65	0.213	22	1.08 / 0.22	1.29 / 0.01	0.39 / 1.23
OW relative to FBW.	0.315	0.1122	22	0.539 / 0.090	0.651 / -0.022	0.186 / 0.647
OW relative to brain:	36.677	12.6505	22	61.978 / 11.376	74.629 / -1.274	20.968 / 69.101

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Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 12 / 13
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

ADRENAL GLANDS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0638	0.01089	73	0.0856 / 0.0420	0.0965 / 0.0311	0.0419 / 0.0939
OW relative to FBW:	0.017	0.0022	73	0.021 / 0.012	0.024 / 0.010	0.013 / 0.024
OW relative to brain:	3.180	0.4905	73	4.161 / 2.199	4.652 / 1.709	2.064 / 4.367

BRAIN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	2.01	0.096	79	2.20 / 1.82	2.29 / 1.72	1.82 / 2.29
OW relative to FBW:	0.535	0.0489	79	0.633 / 0.437	0.682 / 0.388	0.428 / 0.632
OW relative to brain:	NA					

EPIDIDYMIDES

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.18	0.157	49	1.50 / 0.87	1.65 / 0.71	0.49 / 1.52
OW relative to FBW:	0.311	0.0491	49	0.409 / 0.213	0.459 / 0.164	0.120 / 0.411
OW relative to brain:	58.980	7.5708	49	74.121 / 43.838	81.692 / 36.267	24.623 / 73.077

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 12 / 13
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

HEART

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.35	0.197	74	1.74 / 0.95	1.94 / 0.76	0.95 / 2.33
OW relative to FBW:	0.361	0.0479	74	0.456 / 0.265	0.504 / 0.217	0.287 / 0.645
OW relative to brain:	67.298	9.6065	74	86.511 / 48.085	96.117 / 38.478	52.174 / 119.487

KIDNEYS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	2.82	0.351	66	3.52 / 2.12	3.87 / 1.77	2.04 / 3.48
OW relative to FBW:	0.749	0.0677	66	0.884 / 0.613	0.952 / 0.546	0.615 / 0.917
OW relative to brain:	140.657	15.7139	66	172.084 / 109.229	187.798 / 93.515	110.798 / 178.421

LEFT EPIDIDYMIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.4500	0.05071	8	0.5514 / 0.3486	0.6021 / 0.2979	0.3800 / 0.5200
OW relative to FBW:	0.124	0.0165	8	0.157 / 0.091	0.174 / 0.075	0.102 / 0.146
OW relative to brain:	22.531	2.4183	8	27.367 / 17.694	29.786 / 15.276	18.812 / 25.871

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 12 / 13
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

LEFT TESTIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.53	0.109	8	1.75 / 1.31	1.85 / 1.20	1.40 / 1.68
OW relative to FBW:	0.421	0.0295	8	0.480 / 0.362	0.509 / 0.332	0.388 / 0.470
OW relative to brain:	76.627	5.8775	8	88.382 / 64.872	94.260 / 58.995	70.149 / 88.421

LIVER

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	11.5	2.07	79	15.6 / 7.3	17.7 / 5.2	7.8 / 17.8
OW relative to FBW:	3.035	0.4896	79	4.014 / 2.055	4.503 / 1.566	2.474 / 4.769
OW relative to brain:	571.326	101.1036	79	773.533 / 369.119	874.637 / 268.015	405.729 / 898.421

LUNGS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.48	0.202	6	1.89 / 1.08	2.09 / 0.88	1.21 / 1.78
OW relative to FBW:	0.402	0.0386	6	0.479 / 0.325	0.517 / 0.286	0.355 / 0.452
OW relative to brain:	72.276	9.7311	6	91.738 / 52.814	101.469 / 43.083	59.024 / 86.408

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 12 / 13
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

PROSTATE

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.81	0.154	10	1.12 / 0.51	1.28 / 0.35	0.62 / 1.16
OW relative to FBW:	0.227	0.0468	10	0.321 / 0.134	0.368 / 0.087	0.152 / 0.297
OW relative to brain:	40.623	6.7882	10	54.199 / 27.047	60.987 / 20.258	31.373 / 53.953

RIGHT EPIDIDYMIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.45	0.047	8	0.54 / 0.36	0.59 / 0.31	0.39 / 0.54
OW relative to FBW:	0.124	0.0126	8	0.150 / 0.099	0.162 / 0.086	0.105 / 0.145
OW relative to brain:	22.588	2.2049	8	26.998 / 18.179	29.203 / 15.974	19.307 / 25.714

RIGHT TESTIS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.54	0.105	8	1.75 / 1.33	1.86 / 1.23	1.41 / 1.68
OW relative to FBW:	0.425	0.0261	8	0.477 / 0.373	0.503 / 0.347	0.396 / 0.467
OW relative to brain:	77.377	5.6121	8	88.601 / 66.153	94.213 / 60.541	70.149 / 88.421

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 12 / 13
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

SEM VES/COAG GL.

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.6370	0.36170	10	2.3604 / 0.9136	2.7221 / 0.5519	1.1800 / 2.3300
OW relative to FBW:	0.455	0.0940	10	0.643 / 0.267	0.737 / 0.173	0.322 / 0.596
OW relative to brain:	81.549	15.7511	10	113.051 / 50.046	128.802 / 34.295	60.513 / 108.372

SPLEEN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.69	0.128	79	0.95 / 0.44	1.08 / 0.31	0.40 / 1.21
OW relative to FBW:	0.184	0.0294	79	0.243 / 0.125	0.272 / 0.096	0.121 / 0.342
OW relative to brain:	34.630	6.2609	79	47.152 / 22.109	53.413 / 15.848	19.512 / 62.371

TESTES

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	3.28	0.258	64	3.79 / 2.76	4.05 / 2.50	2.64 / 3.83
OW relative to FBW:	0.870	0.1012	64	1.072 / 0.668	1.173 / 0.566	0.607 / 1.116
OW relative to brain:	163.721	13.3422	64	190.406 / 137.037	203.748 / 123.695	140.426 / 196.257

Sex: M
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 12 / 13
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

THYMUS GLAND

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.4348	0.10824	58	0.6512 / 0.2183	0.7595 / 0.1101	0.2301 / 0.7043
OW relative to FBW:	0.115	0.0254	58	0.166 / 0.064	0.191 / 0.038	0.066 / 0.178
OW relative to brain:	21.558	5.3197	58	32.197 / 10.919	37.517 / 5.599	11.505 / 35.571

THYROID/PARATHYROID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0257	0.00539	38	0.0365 / 0.0150	0.0419 / 0.0096	0.0186 / 0.0427
OW relative to FBW:	0.007	0.0014	38	0.009 / 0.004	0.011 / 0.003	0.004 / 0.011
OW relative to brain:	1.288	0.2574	38	1.803 / 0.774	2.061 / 0.516	0 936 / 2.053

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Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 11 / 12
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

ADRENAL GLANDS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0770	0.01142	71	0.0998 / 0.0541	0.1112 / 0.0427	0.0541 / 0.1217
OW relative to FBW:	0.032	0.0048	71	0.042 / 0.022	0.047 / 0.017	0.021 / 0.047
OW relative to brain:	4.082	0.5527	71	5.187 / 2.976	5.740 / 2.424	2.832 / 5.908

BRAIN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.89	0.084	77	2.06 / 1.72	2.14 / 1.64	1.66 / 2.06
OW relative to FBW:	0.786	0.0743	77	0.935 / 0.638	1.009 / 0.563	0.617 / 0.980
OW relative to brain:	NA					

HEART

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.94	0.096	72	1.13 / 0.75	1.22 / 0.65	0.67 / 1.19
OW relative to FBW:	0.388	0.0356	72	0.460 / 0.317	0.495 / 0.282	0.330 / 0.497
OW relative to brain:	49.520	5.2300	72	59.980 / 39.060	65.210 / 33.830	36.813 / 64.458

WIL Research Laboratories - Historical Control Summary of Organ Weights

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 11 / 12
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

KIDNEYS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.83	0.193	67	2.22 / 1.45	2.41 / 1.25	1.45 / 2.48
OW relative to FBW:	0.752	0.0685	67	0.889 / 0.615	0.957 / 0.547	0.622 / 1.005
OW relative to brain:	97.262	8.9247	67	115.112 / 79.413	124.036 / 70.488	75.369 / 122.772

LIVER

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	7.7	1.29	77	10.3 / 5.1	11.5 / 3.8	5.5 / 11.7
OW relative to FBW:	3.158	0.3270	77	3.812 / 2.504	4.139 / 2.177	2.668 / 4.527
OW relative to brain:	406.336	64.9895	77	536.315 / 276.357	601.304 / 211.367	292.105 / 580.220

LUNGS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	1.33	0.133	6	1.60 / 1.06	1.73 / 0.93	1.12 / 1.49
OW relative to FBW:	0.554	0.0287	6	0.611 / 0.496	0.640 / 0.467	0.519 / 0.582
OW relative to brain:	69.276	8.3793	6	86.034 / 52.517	94.414 / 44.138	55.172 / 77.604

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 11 / 12
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

OVARIES

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.1263	0.01913	15	0.1646 / 0.0881	0.1837 / 0.0689	0.0925 / 0.1710
OW relative to FBW:	0.054	0.0089	15	0.072 / 0.037	0.081 / 0.028	0.042 / 0.077
OW relative to brain:	6.890	1.1251	15	9.140 / 4.639	10.265 / 3.514	4.843 / 9.553

OVARIES/OVIDUCTS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.1371	0.01952	46	0.1762 / 0.0981	0.1957 / 0.0786	0.0803 / 0.1748
OW relative to FBW:	0.057	0.0084	46	0.073 / 0.040	0.082 / 0.031	0.036 / 0.073
OW relative to brain:	7.242	0.9448	46	9.132 / 5.353	10.077 / 4.408	4.837 / 8.989

SPLEEN

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.53	0.093	77	0.72 / 0.35	0.81 / 0.25	0.40 / 0.87
OW relative to FBW:	0.220	0.0297	77	0.280 / 0.161	0.310 / 0.131	0.151 / 0.316
OW relative to brain:	28.267	4.7624	77	37.792 / 18.742	42.554 / 13.979	21.320 / 43.069

Sex: F
Species: RAT
Strain: Crl:CD(SD)

Study Type: SUBCHRONIC
Age: 13 - 15 Weeks

Number of Studies/Control Groups: 11 / 12
Range of Study Dates: 07/00 - 05/05
Report Type: **Excluding +/- 5 S.D.**

THYMUS GLAND

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.3880	0.08222	56	0.5524 / 0.2236	0.6347 / 0.1413	0.1897 / 0.6362
OW relative to FBW:	0.163	0.0349	56	0.232 / 0.093	0.267 / 0.058	0.091 / 0.218
OW relative to brain:	20.548	4.4316	56	29.411 / 11.685	33.843 / 7.253	9.984 / 31.495

THYROID/PARATHYROID

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.0220	0.00506	38	0.0322 / 0.0119	0.0372 / 0.0069	0.0115 / 0.0349
OW relative to FBW:	0.009	0.0020	38	0.013 / 0.005	0.015 / 0.003	0.005 / 0.014
OW relative to brain:	1.174	0.2787	38	1.731 / 0.616	2.010 / 0.337	0.661 / 2.017

UTERUS

	Mean	S.D.	N	Mean +/- 2 S.D.	Mean +/- 3 S.D.	Observed Low/High Value
Absolute OW:	0.58	0.163	30	0.90 / 0.25	1.07 / 0.09	0.37 / 1.06
OW relative to FBW:	0.238	0.0656	30	0.369 / 0.106	0.434 / 0.041	0.163 / 0.453
OW relative to brain:	30.433	8.4807	30	47.395 / 13.472	55.875 / 4.991	19.786 / 54.922

Sex: F	Study Type: SUBCHRONIC	Number of Studies/Control Groups: 11 / 12
Species: RAT	Age: 13 - 15 Weeks	Range of Study Dates: 07/00 - 05/05
Strain: Crl:CD(SD)		Report Type: **Excluding +/- 5 S.D.**

Version 2.0
08-Aug-05

APPENDIX O

Study Protocol

Study Number: WIL-187051

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor No.: 05-087

A. Title of Study:

A 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats (with Functional Observational Battery and Motor Activity Determinations)

B. Protocol Modification:

1) **3** **STUDY SCHEDULE**:

Proposed Experimental Termination (Completion) Date: January 25, 2006

Proposed Audited Draft Report Date: March 1, 2006

2) **5.4** **Number on Study:**

In accordance with the Study Director Notification dated September 28, 2005:

35 animals of each sex were ordered.

3) **8.8.3** **Microscopic Examination:**

The second sentence is corrected as follows:

Gross lesions will be examined from animals in Groups 2 and 3.

4) Please add the following:

Prepared slides will be evaluated by:

[redacted]

C. Reason for Protocol Modification:

1) The study schedule has been determined.

2) To document a change in the number of animals ordered.

3) The groups from which gross lesions will be examined are corrected.

4) To provide information for outsourcing the pathological evaluation.

Approved By:

[redacted]

[redacted]

15 December 2005
Date

Prepared By:

WIL Research Laboratories, LLC

[redacted]

12/13/2005
Date

[redacted]

12/13/2005
Date

PROTOCOL

A 28-DAY REPEATED DOSE ORAL (GAVAGE) TOXICITY STUDY OF [redacted] IN RATS (WITH FUNCTIONAL OBSERVATIONAL BATTERY AND MOTOR ACTIVITY DETERMINATIONS)

(OECD Guideline 407)

Sponsor Study Number: 05-087

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

1 OBJECTIVE:

The objective of this study is to evaluate the possible toxic effects of the test material when administered orally to rats for 28 days, and to assess recovery from such effects. This will include evaluation of potential neurotoxicity by functional observational battery (FOB) and motor activity (MA) assessment.

This protocol has been designed and the study will be conducted in general accordance with the OECD (Organisation for Economic Cooperation and Development) Guidelines for Testing of Chemicals, Health Effects Test Guidelines, Section 407, July 27, 1995.

The study will be conducted in compliance with the OECD Good Laboratory Practice (GLP) Standards, [C(97) 186/Final]. The study will be performed according to the protocol and WIL standard operating procedures.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]

2.2 WIL Study Director:

[redacted]

2.3 WIL Deputy Director:

[redacted]
Staff Toxicologist

2.4 WIL Departmental Responsibilities:

[redacted]
President, Director

[redacted]

2.5 **Repeated Measures Statistical Analysis:**

[redacted]
BioSTAT Consultants, Inc.

3 STUDY SCHEDULE:

Proposed Experimental Starting Date (Animal Receipt):	October 11, 2005
Proposed Experimental Start Date:	October 26, 2005
Proposed Necropsy Dates	
Primary:	November 23, 2005
Recovery:	December 7, 2005
Proposed Experimental Termination (Completion) Date:	To be determined.
Proposed Audited Draft Report Date:	To be determined.

4 TEST MATERIAL:

4.1 Identification:

[redacted]

4.2 Lot Number:

[redacted]

4.3 Purity:

100%

4.4 Stability:

The test article is considered stable under the storage conditions provided by the Sponsor.

4.5 Physical Description:

Dark brown viscous liquid.

4.6 Storage Conditions:

Store at ambient conditions.

4.7 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures.

4.8 Personnel Safety:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A Material Safety Data Sheet (MSDS) will accompany the test article upon arrival at the laboratory.

4.9 Vehicle:

Corn oil.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Crl:CD®(SD)

5.3 Source:

Charles River Laboratories
Raleigh, NC

5.4 Number of Study:

Forty (40) animals of each sex will be ordered. Thirty males and 30 females will be placed on study. Animals not utilized on study will be deemed as part of the stock colony or euthanized by CO_2 inhalation and discarded.

5.5 Approximate Age and Weight:

Animals will be 4 to 6 weeks of age when received, and 6 to 8 weeks of age at initiation of dosing. The males will weigh approximately 160-260 g and the females approximately 110-180 g at initiation of dosing.

5.6 Identification System:

Animals will be uniquely identified by a metal eartag displaying the animal number. Individual cage cards will be affixed to each cage and will display the animal number, group number and study number.

5.7 Justification for Selection:

This species and strain of animal is recognized to be appropriate for subchronic toxicity studies. The Sprague-Dawley rat will be used because it is a widely used strain for which significant control data are available. The number of animals is the minimum required to yield scientifically meaningful and statistically significant data.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

Weanling animals (less than approximately 35 days of age) will be housed three per cage by sex in an environmentally controlled room in clean suspended wire-mesh cages for approximately three days following receipt. If the number of animals received does not allow for all animals to be housed three per cage by sex, than some animals will be pair-housed by sex. Thereafter, the animals will be housed individually. The cages will be elevated above cage-board or other suitable material which will be changed at least three times each week.

The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71° ± 5°F (22 ± 3°C) and an average daily relative humidity of approximately 50 ± 20%.

Fluorescent lighting will provide illumination for 12 hours per day. The light/dark period may be interrupted, however, to allow for protocol-specified activities. Temperature and relative humidity will be monitored continually and scheduled for automatic hourly data capturing. Ventilation rate will be set at 10 to 15 room changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-treated tap water will be available *ad libitum*. Filters servicing the automatic watering system will be changed regularly according to standard operating procedures. The municipal water supplying the laboratory will be analyzed for contaminants according to standard operating procedures to ascertain that none are present at concentrations that would be expected to affect the outcome of the study.

6.4 Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 (meal) will be offered *ad libitum* during the study except during fasting prior to clinical pathology blood collection. Each lot utilized will be identified and recorded. Standard operating procedures provide specifications for acceptable levels of heavy metals and pesticides that are reasonably expected to be present in the diet without interfering with the purpose or conduct of the study. Each lot of feed has been analyzed to assure specifications are met. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Acclimation:

Each animal will be inspected by a qualified technician upon receipt. Animals judged to be in good health will be placed immediately in acclimation for at least 10 days. All animals will be weighed and assigned a permanent animal number. During the acclimation period, each animal will be observed twice daily for changes in general appearance or behavior. The animals will be allowed a pretreatment week (as part of the acclimation period) during which body weights and food consumption will be recorded and general health will be monitored, but they will not receive the test material. All animals will receive a detailed physical examination approximately one week prior to initiation of dosing and at the time of animal selection for randomization.

7.2 Randomization:

Animals judged to be suitable for testing will be assigned to groups at random based on body weight stratification into a block design using a computer program. A printout containing the animal numbers and individual group

assignments will be generated. Animals will then be arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean for each sex. If, after randomization, significant differences between groups exist, new randomizations will be generated until group mean body weights are not statistically different between groups by sex. For Groups 1 and 4, animals will be assigned to recovery (which will be the same animals used for FOB and MA assessment). Following the group randomization procedure, the study animals will be randomly assigned to replicates for FOB and MA assessment as described in WIL SOP T1-126, as revised. Each dose group and sex will be approximately equally represented in each study replicate to avoid introduction of bias into the recorded observations related to these variables.

7.3 Route and Rationale of Test Material Administration:

The route of administration will be oral by gavage since this is an acceptable and standard method for administering test material per OECD Guideline 407. Appropriate-sized flexible, Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels will be determined from the results of a 14-day dose range-finder study (WIL-187047) and will be provided by the Sponsor Representative after consultation with the WIL Study Director. The following diagram presents the study group arrangement.

Group Number	Treatment	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals	
					Males	Females
1	Vehicle	0	0	5	10[a]	10[a]
2	[redacted]	160	32	5	5	5
3	[redacted]	400	80	5	5	5
4	[redacted]	1000	200	5	10[a]	10[a]

a = At the end of the 28 day dosing period, 5 rats/sex will be randomly assigned to the primary necropsy and ≤ 5 rats/sex will be randomly assigned to a 14-day recovery period (which will be the same animals used for FOB and MA assessment).

7.4.2 Vehicle:

Corn oil will be used as the vehicle.

7.4.3 Treatment Regimen:

The test material and vehicle will be administered once daily for a minimum of 28 consecutive days (until the day prior to necropsy). Day 0 is the first day of dosing, and Day 28 is the day of necropsy and the first day of recovery. The first week of dosing is week 0.

7.4.4 Adjustment of Dosages:

Individual doses will be adjusted weekly for the duration of the study, based on the most recent body weights. Adjusted doses will become effective the day of collection of the weekly body weights.

7.5 Preparation and Analysis of Test Material Preparations:

7.5.1 Test Material Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of the Test Material Preparations:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration, if possible. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The methods employed will be one or more of the following:

[redacted] SOP #ME-125

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

8 PARAMETERS TO BE EVALUATED:

8.1 Viability Observations:

All animals will be observed for mortality/moribundity twice daily, once in the morning and once in the afternoon. Moribund animals will be euthanized to ensure that tissues will not be lost due to autolysis.

8.2 Clinical Observations:

8.2.1 Daily Observations:

A clinical examination will be performed daily for all animals at the time of dosing and approximately 1-2 hours after dosing. During the recovery period, animals will be examined once daily. The clinical observations prior to dosing and during the recovery period need not be

recorded on the days of detailed physical examinations. Observations will include, but are not limited to, changes in the skin, fur, eyes and mucous membranes; respiratory, circulatory, autonomic and central nervous systems functions; somatomotor activity and behavior patterns. Findings noted at the clinical examination will be recorded for individual animals; the condition of animals without signs will be documented in a general comment.

8.2.2 Detailed Physical Examinations:

A detailed physical examination will be conducted at least once during the pretreatment period, once weekly during the treatment and recovery periods and on the day(s) of necropsy. The animals will be removed from their home cages and placed in a standard arena for observations. Observations will be detailed and carefully recorded. Where appropriate, explicitly defined scoring systems will be used if, in the opinion of the Study Director, doing so increases the utility of the data. Signs noted shall include, but are not limited to, changes in skin, fur, eyes, mucous membranes; occurrence of secretions and excretions and autonomic activity (e.g.-lacrimation, piloerection, pupil size, unusual respiratory pattern). Changes in gait, posture and response to handling, as well as the presence of clonic or tonic movements, stereotypies (e.g.-excessive grooming, repetitive circling) or bizarre behavior (e.g. -self-mutilation, walking backwards) will be recorded. Animals without signs will be noted individually.

8.2.3 Unscheduled Observations:

A separate computer protocol will be used to collect any findings outside the above-specified observations. Only the presence of findings will be recorded; the absence of findings will thus not be recorded.

8.3 Individual Body Weights:

Individual body weights will be recorded during acclimation, at pretest initiation, at randomization, at least weekly during treatment and recovery and on the days of necropsy (fasted).

8.4 Individual Food Consumption:

Individual food consumption will be recorded approximately weekly, beginning at least one week prior to test material administration.

8.5 Ophthalmic Examinations:

Ophthalmic examinations will not be performed.

8.6 Functional Observational Battery:

The FOB utilized at WIL Research Laboratories, LLC, is based on previously developed protocols (Moser, 1991, Irwin, 1968, Gad, 1982, Moser 1988, Haggerty, 1989, O'Donoghue, 1989). Observations on 5 animals/sex/group will be made during the 4th week of the test material administration (prior to dosing). FOB evaluations may also be performed on the 5 recovery animals/sex from Groups 1 and 4 near the end of the 14-day recovery period (if added by protocol amendment). The same animals will be used for the appropriate time points. Testing will be performed by the same trained technicians, wherever possible, who will not know the animals' group assignment. Animals will be observed for the following as described below (see WIL standard operating procedures No. T1-112, as revised, for a description of scoring criteria):

8.6.1 Home Cage Observations:

Biting
Convulsions/tremors
Feces consistency
Palpebral (eyelid) closure
Posture

8.6.2 Handling Observations:

Ease of handling animal in hand
Ease of removal from cage
Eye prominence
Fur appearance
Lacrimation/chromodacryorrhea
Mucous membranes/eye/skin color
Muscle tone
Palpebral closure
Piloerection
Red/crusty deposits
Respiratory rate/character
Salivation

8.6.3 Open Field Observations (Evaluated Over a 2-Minute Observation Period):

Arousal
Backing
Bizarre/stereotypic behavior
Convulsions/tremors
Gait
Gait score
Grooming
Mobility
Rearing
Time to first step (seconds)
Urination/defecation

8.6.4 Sensory Observations:

Air righting reflex	Olfactory orientation
Approach response	Pupil response
Eyeblink response	Startle response
Forelimb extension	Tail pinch response
Hindlimb extension	Touch response

8.6.5 Neuromuscular Observations:

Grip strength-hind and forelimb	Hindlimb foot splay
Hindlimb extensor strength	Rotarod performance

8.6.6 Physiological Observations:

Body temperature	Catalepsy
Body weight	

8.6.7 Locomotor Activity:

Locomotor activity will be monitored on 5 animals/sex/group during the 4th week of the test material administration (prior to dosing). Locomotor Activity evaluations may also be performed on the 5 recovery animals/sex from Groups 1 and 4 near the end of the 14-day recovery period (if added by protocol amendment). The same animals will be used for the appropriate time points. Testing of treatment groups will be balanced across the day of testing, and executed by appropriately trained technicians. Locomotor Activity will be measured using SDI Photobeam Activity System (San Diego Instruments, San Diego, CA) as described in WIL Research Laboratories, LLC, SOP No. T1-185, as revised. The test session will be of 60 minutes duration and will consist of twelve 5-minute intervals. Locomotor activity measures evaluated are total and ambulatory activity counts obtained for the 60-minute test session.

All FOB and Locomotor Activity sessions will be performed in a sound-attenuated room equipped with a white noise generation system set to operate at 70 $\pm$10 dB (see WIL Research Laboratories, LLC, SOP No. T1-124, as revised) to minimize environmental variations in the test conditions.

8.7 Clinical Pathology:

The following clinical pathology parameters will be evaluated on all surviving rats just prior to their scheduled necropsy. The animals will be fasted overnight

before taking blood samples. Blood for hematology and serum chemistry evaluations will be collected from the retro-orbital sinus of isoflurane-anesthetized animals prior to necropsy. Blood for coagulation parameters will be collected from the vena cava at the time of necropsy.

Anticoagulants used will be potassium EDTA for the hematology and sodium citrate for the coagulation tests. Samples for serum chemistry will be collected without anticoagulants.

8.7.1 Hematology:

Activated partial thromboplastin time	MCHC
Differential leukocyte count[a]	MCV
Erythrocyte count	Platelet count
Hematocrit	Prothrombin time
Hemoglobin	Reticulocyte count
MCH	Total leukocyte count

a = If performed manually, results will include platelet estimates and RBC morphology.

8.7.2 Serum Chemistry:

A/G ratio	Glucose
Alanine aminotransferase	Phosphorus
Albumin	Potassium
Alkaline phosphatase	Sodium
Aspartate aminotransferase	Total bilirubin
Calcium	Total cholesterol
Chloride	Total protein
Creatinine	Triglycerides
Globulin	Urea nitrogen

8.8 Anatomic Pathology:

8.8.1 Macroscopic Examination:

A complete necropsy will be conducted on all animals dying spontaneously, euthanized *in extremis* or at the scheduled primary or recovery necropsies. Animals euthanized *in extremis* or at the scheduled necropsies will be anesthetized via carbon dioxide and exsanguinated. Necropsy will include examination of the external surface, all orifices and the cranial, thoracic, abdominal and pelvic cavities (including viscera). At the time of necropsy, the following tissues and organs will be collected and placed in 10% neutral-buffered formalin (except as noted):

Adrenals (2)
Bone with marrow
  Sternum
  Femur
Bone marrow smear (from femur[a])
Brain
  Cerebrum Level 1
  Cerebrum Level 2
  Cerebellum with medulla/pons
Epididymides (2)[b]
Gastrointestinal tract
  Stomach
  Duodenum
  Jejunum
  Ileum
  Cecum
  Colon
  Rectum
Heart
Kidneys (2)
Liver (sections of two lobes)
Lungs (including bronchi, fixed by inflation with fixative)
Lymph node
  Mesenteric
  Mandibular
Mammary gland (females only)
Ovaries with oviducts (2)
Peripheral nerve (sciatic)
Prostate
Seminal vesicles (2)
Spinal cord
  Cervical
  Midthoracic
  Lumbar
Spleen
Testes (2)[b]
Thymus
Thyroids [with parathyroids, if present (2)][c]
Trachea
Urinary bladder
Uterus
Cervix
Vagina
All gross lesions (when possible)

a = Not taken from animals found dead, not placed in formalin; to be examined only if scientifically warranted.
b = To be placed in Bouin's solution.
c = Parathyroids will be examined microscopically if in the plane of section, or if gross lesions are present.

8.8.2 Organ Weights:

The following organs will be weighed from all animals at the scheduled necropsies:

Adrenals
Brain
Epididymides
Heart
Kidneys
Liver
Ovaries with oviducts
Prostate
Seminal vesicle/coagulating gland
Spleen
Testes
Thymus
Uterus

Paired organs will be weighed together. Organ-to-body-weight and organ-to-brain-weight ratios will be calculated from animals euthanized at the scheduled necropsies.

8.8.3 Microscopic Examination:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the tissues listed in Section 8.8.1 from all animals in the control and high dose groups (primary necropsy), and from all animals that die or are euthanized *in extremis*. Gross lesions will be examined from animals in Groups 2, 3 and 4. Microscopic examination may be extended by amendment (additional cost) to include other animals (including recovery necropsy) if a potential target organ is noted based on histopathological examination of tissues from the high dose group or other parameters (organ weights, clinical pathology, etc.). Special stains may be used at the discretion of the pathologist to further characterize lesions and changes. Any special stains used will be documented in the individual animal data and interpretation of results will be included in the final report.

9 STATISTICAL METHODS:

All analyses will be two-tailed for significance levels of 5% and 1%. All means will be presented with standard deviations. All statistical tests will be performed using appropriate computing devices or programs. Body weights, body weight changes, food consumption, Functional Observational Battery, as well as clinical pathology values and absolute and relative organ weights will be analyzed by a one-way analysis of variance (ANOVA). (Snedecor, 1980) If significant differences are indicated by the ANOVA, Dunnett's test (Dunnett, 1964) will be used to compare the control and treated groups. Functional Observational Battery parameters which yield scalar or descriptive data will be analyzed by Fisher's Exact Test (Steel, 1980)

The locomotor activity data will be analyzed by BioSTAT Consultants, Inc. Each analysis endpoint (total and ambulatory counts) will be analyzed, by sex and session, with a repeated measure analysis of variance (RANOVA). Factors in the model will include treatment group (TRT), time interval (TIME), and the interaction of time interval and treatment group (TRT*TIME). The SAS® procedure PROC MIXED will be used for analysis with the random effect of animal included as the repeated measurement. The covariance structure across time will be selected by comparing Akaike's Information Criterion (AIC) for first-order autoregressive homogeneous [AR(1)] and compound symmetric (CS) structures.

The monotonic dose response relationship will be evaluated using sequential linear trend tests based on ordinal spacing of dose levels. The linear dose by time interaction (LinTrt*Time) will be evaluated and, if significant at the 0.05 level, trend

tests on treatment means will be performed at the 0.05 level for each time interval. If the linear dose by time interaction is not significant, the trend test will be conducted across the pooled time intervals of the entire session only.

Nonmonotonic dose responses will be evaluated whenever no significant linear trends are detected but TRT and/or TRT*TIME interaction is significant at the 0.01 level. Within the framework of the RANOVA, pairwise comparisons will be made for each individual treated group with the control group through linear contrasts. If TRT*TIME is significant, the comparisons will be conducted for each time interval. If only the TRT effect is significant, the comparisons will be conducted across the pooled time intervals of the entire session. These nonmonotonic dose response comparisons will be conducted at the 0.01 significance level.

All statistical analyses will be conducted by BioSTAT Consultants, Inc. using SAS version 8.2 (SAS Institute, Inc., 1999-2001)software.

10 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with OECD Good Laboratory Practice regulations, adherence to the protocol and to WIL Standard Operating Procedures. The raw data and draft report will be audited by the WIL Quality Assurance Unit to assure that the final report accurately describes the conduct and the findings of the study.

This study is a regulated study and will be included on the WIL master list of regulated studies.

11 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 12 in the Archives at WIL Research Laboratories, LLC.

12 WORK PRODUCT:

Sponsor will have title to all documentation records, raw data, slides, specimens, or other work product generated during the performance of the study. All work product including raw paper data, pertinent electronic storage media and specimens will be retained at no charge for a period of 6 months following issuance of the final report in the Archives at WIL Research Laboratories, LLC. All work product, including raw paper data, pertinent electronic storage media and specimens, will be returned to the Sponsor after a period of six months or following issuance of the final report. Any remaining formulation or clinical pathology samples will be discarded following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

13 REPORTS:

The final report will contain a summary, test material data, methods and procedures, appropriate individual animal and summary data tables, a copy of the protocol and amendments (if any) and an interpretation and discussion of the study results. The report will contain all information necessary to conform with current OECD specifications. The report will be comprehensive and shall attempt to define toxicity and the no-observed-effect level(s) under the conditions of this investigation.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional electronic or paper copies of the final report may result in additional charges.

14 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

15 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the verbal or written permission of the Sponsor. In the event that the Sponsor verbally requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of a protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

16 REFERENCES:

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O'Donoghue, J.L. Screening for neurotoxicity using a neurologically based examination and neuropathology. *Journal of American College of Toxicology*. **1989,** *8*, (1) 97-116.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

Steel, R.G.D.; Torrie, J.H. *Principles and Procedures of Statistics, A Biometrical Approach*, 2nd ed.; McGraw-Hill Book Company: New York, NY, **1980**; pp 504-506.

17 PROTOCOL APPROVAL:

Sponsor approval received via phone on September 14, 2005.

[redacted]

Sponsor Representative

22 September 2005
Date

WIL Research Laboratories, LLC

[redacted]

Study Director

9/21/2005
Date

[redacted]

Director, Developmental and
Reproductive Toxicology

9/21/05
Date

APPENDIX P

Report of Results of 28-Day Repeated-Dose Toxicity Test in Mammalia

Form 1. Report of Results of 28-day Repeated Dose Toxicity Test in Mammalia

1. General Items

(Remarks) Because physicochemical properties are reference materials, fill in spaces to extent possible.

1. "Stability" – Fill in the stability for water, other solvents, heat, light, etc.
2. "Vapor pressure" – Fill in the vapor pressure of the test substance at 25°C.
3. "Partition coefficient" – Fill in the value, the temperature used and the name of the solvent used for the measurement. Fill in the value at 37°C, if available.
4. "Solubility" – Fill in such information as water soluble, soluble in oil.
5. "Degree of solubility" – Fill in the solubility at 25°C for each solvent.

2. Acute Toxicity Test

Test No.	Kind and period of the test	Animal species	Number of animals per group	Route of administration	Dose levels (mg/kg)	LD_{50} or NOEL[a] (mg/kg)	Testing institution
1 2 3							

[a]NOEL: no-observed-effect level

28-Day Repeated Dose Toxicity Test

Administration period of the test substance	from 26 October 2005					to 22 November 2005					
Animal species and strain: Rat, Sprague-Dawley	Number of animals per group										
Route of administration: Oral (gavage)	Main study: Male:5 Female:5 Recovery (Groups 1 and 4): Male:5 Female:5										
Sex:	Male						Female					
Phase:	Main				Recovery		Main				Recovery	
Group:	1	2	3	4	1	4	1	2	3	4	1	4
Body weight	N	N	N	Y	N	N	N	N	N	N	N	N
Food consumption	N	N	N	N	N	N	N	N	N	N	N	N
General appearance	N	N	Y	Y	N	N	N	N	Y	Y	N	N
Functional Observational Battery	N	N	N	N	--	--	N	N	N	N	--	--
Locomotor Activity	N	N	N	N	--	--	N	N	N	N	--	--
Hematology	N	N	N	Y	N	N	N	N	N	Y	N	N
Serum chemistry	N	N	Y	Y	N	N	N	N	Y	Y	N	N
Organ weight	N	N	N	N	N	N	N	N	N	N	N	N
Macroscopic examination	N	N	N	N	N	N	N	N	N	N	N	N
Histopathology	N	N	N	N	N	N	N	N	N	N	N	N
NOEL (mg/kg/day)	Male: 160 mg/kg/day						Female: 160 mg/kg/day					
Change(s) by which NOEL is estimated	clinical findings, lower body weights, serum chemistry effects and coagulation parameter effects											

Key: Group: 1 = Control - 0 mg/kg/day
2 = Low dose - 160 mg/kg/day
3 = Mid dose - 400 mg/kg/day
4 = High dose - 1000 mg/kg/day
N = no test substance-related adverse effect noted
Y = test substance-related effect
-- = not tested

3. Others

[redacted]

8EHQ-02-15211

COMPANY SANITIZED

AUDITED DRAFT

Volume 1 of 2
(Text and Tables 1-31)

STUDY TITLE

A 90-DAY REPEATED DOSE
ORAL (GAVAGE) TOXICITY STUDY OF [redacted] IN RATS

STUDY NUMBER

WIL-187054

DATA REQUIREMENT

OECD Guideline 408

STUDY DIRECTOR

[redacted]

STUDY INITIATION DATE

20 February 2006

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

06-012

SPONSOR

[redacted]

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COMPLIANCE STATEMENT

This study, designated WIL-187054, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C (97) 186/Final], 26 November 1997; the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) Good Laboratory Practice for Agricultural Chemicals (11 Nousan No. 6283), 1 October 1999; European Union (EU) Directives 2004/9/EC and 2004/10/EC; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor with the following exception. Stability of the test article in the dosing formulations was not tested. However, in the professional judgment of the sponsor, the formulations were stable under the conditions of this study, because the test article is intended for use at high temperatures and under oxidative conditions.

The protocol was designed to be in general accordance with the OECD (Organisation for Economic Cooperation and Development) Guidelines for Testing of Chemicals, Health Effects Test Guidelines, Section 408, September 1998.

_____ _____

[redacted]
Staff Toxicologist
Study Director

Date

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1. SUMMARY

1.1. OBJECTIVE

The objective of this study was to evaluate the possible toxic effects of [redacted] when administered orally to rats for at least 90 days.

1.2. STUDY DESIGN

[redacted] in the vehicle, corn oil, was administered orally by gavage once daily for 91 or 92 consecutive days to 3 groups (Groups 2-4) of Crl:CD(SD) rats. Dosage levels were 160, 400 and 1000 mg/kg/day. A concurrent control group (Group 1) received the vehicle on a comparable regimen. The dosage volume was 5 mL/kg for all groups. Each group consisted of 10 animals/sex. Following 13 weeks of dose administration, all animals were euthanized.

All animals were observed twice daily for mortality and moribundity. Clinical examinations were performed daily, and detailed physical examinations were performed weekly. Individual body weights and food consumption were recorded weekly. Ophthalmic examinations were performed during study weeks -1 and 12. Clinical pathology evaluations (hematology and serum chemistry) were performed on all surviving rats just prior to the scheduled necropsy. Complete necropsies were conducted on all animals, and selected organs were weighed at the scheduled necropsy. Selected tissues were examined microscopically from all animals in the control and 1000 mg/kg/day groups and all animals found dead or euthanized in extremeis. Gross lesions were examined from animals in the 160 and 400 mg/kg/day groups.

1.3. RESULTS

There were no test article-related effects on survival. There were no test article-related macroscopic or microscopic findings.

Test article-related clinical findings of evidence of increased salivation (clear material around the mouth, nose, facial area, ventral neck or forelimbs) were noted primarily in

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the 1000 mg/kg/day group males and females at 1 hour after dose administration beginning during study week 1 and continuing throughout the study. Clear material around the mouth was also noted in the 400 mg/kg/day group at a lower incidence, most frequently seen at 1 hour post-dosing beginning during study week 2.

Test article-related effects on body weights were observed in the 1000 mg/kg/day group males. Lower body weight gains in the 1000 mg/kg/day group were observed during study week 1 to 2 through study week 8 to 9; the difference from the control group during study week 3 to 4 was statistically significant. As a result, lower mean cumulative body weight gains and lower mean absolute body weights in the 1000 mg/kg/day group were observed beginning during study week 4 and persisting to the end of the study. As a result, at study week 13 mean body weight for the 1000 mg/kg/day group males was 12.2% lower than the control group. Transiently lower mean food consumption compared to the control group was noted for the 1000 mg/kg/day group males for study week 0 to 1.

Potential test article-related hepatic alteration manifested as higher liver enzyme values (alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase) was noted in males and females for all test article-treated groups. Additionally, lower total protein and globulin and increased coagulation times in the 160, 400 and 1000 mg/kg/day group males as well as lower globulin and cholesterol values in the 160, 400 and 1000 mg/kg/day group females were also likely associated with hepatocyte alteration, although the lack of effect on albumin levels is atypical. These differences were considered to be potentially test article-related but not adverse as no related clinical signs were seen, and correlating macroscopic or microscopic changes in the liver were not observed, and there was no effect on liver weights. Higher adrenal gland (at 400 and 1000 mg/kg/day) and ovaries/oviduct weights (at 1000 mg/kg/day) had no microscopic correlates and were considered not adverse.

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Higher adrenal gland weights and ovaries/oviducts weights were noted in the 400 and/or 1000 mg/kg/day group females and this occurred in a dose-related manner.

1.4. CONCLUSIONS

Based on the results of this study, test article-related findings were observed at dosage levels of 160, 400 and 1000 mg/kg/day as evidenced by clinical findings of increased salivation (400 and 1000 mg/kg/day groups), lower body weights and food consumption (1000 mg/kg/day group males), higher prothrombin times and APTT, higher alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, lower globulin values and a correspondingly higher A/G ratio as well as lower total protein values (1000 mg/kg/day group males), lower cholesterol levels (1000 mg/kg/day group females) and higher mean adrenal gland and ovaries/oviducts weights (females). No target organ of toxicity was identified by histologic assessment. As the differences at 400 mg/kg/day were considered to be potentially test article-related but not adverse due to small magnitude, the no-observed-adverse-effect level (NOAEL) for oral (gavage) administration of [redacted] to Crl:CD(SD) rats for 91 consecutive days was 400 mg/kg/day.

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2. INTRODUCTION

2.1. GENERAL STUDY INFORMATION

This report presents the data from "A 90-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats". Due to software spacing constraints, the study title appears as "A 90-Day Repeated Dose Oral Study of [redacted] in Rats" on the report tables.

The following computer protocols were used for data collection during the study:

Computer Protocol	Type of Data Collected
WIL-187054	Main study data
WIL-187054P	Pretest data
WIL-187054U	Unscheduled clinical observations

2.2. KEY STUDY DATES

Date(s)	Event(s)
21 February 2006	Experimental starting date (animal receipt)
2 March 2006	Assignment to study groups
6 March 2006	Experimental start date (initiation of dose administration; study week 0)
5 and 6 June 2006	Scheduled necropsy (study week 13)
9 August 2006	Experimental termination (completion) date (last histopathological examination)

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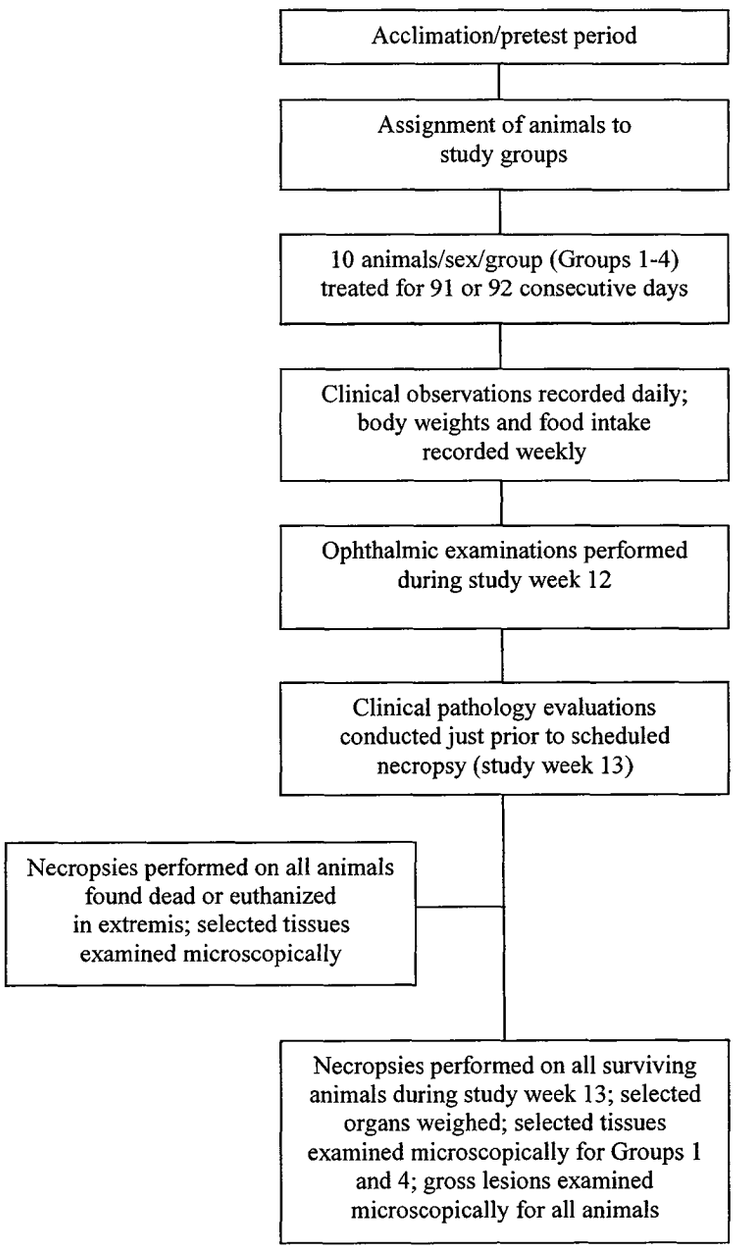
3. STUDY DESIGN



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4. EXPERIMENTAL PROCEDURES - MATERIALS AND METHODS

4.1. TEST ARTICLE AND VEHICLE

4.1.1. TEST ARTICLE IDENTIFICATION

The test article, [redacted] was received from [redacted] as follows:

Identification	Quantity Received	Physical Description	Date of Receipt
[redacted] Lot no. [redacted] Exp. date: 1 August 2006 [WIL log no. 6578A]	1 can Gross weight: 3395.4 g	Dark brown, viscous liquid	27 July 2005
[redacted] Lot no. [redacted] Exp. date: 1 August 2006 [WIL log no. 6950A]	1 can Gross weight: 4277.2 g	Dark brown, viscous liquid	10 May 2006

Data documenting the purity and stability of the test article are on file with the sponsor. A Certificate of Analysis for the test article was provided by the sponsor and is presented in Appendix A. The purity of the test article was 100%. The test article was stored at room temperature and was considered stable under this condition. Reserve samples of the test article (approximately 1 g) were collected on 28 July 2005 and 31 May 2006 from WIL log nos. 6578A and 6950A, respectively, and stored in the Archives of WIL Research Laboratories, LLC.

4.1.2. VEHICLE IDENTIFICATION

The vehicle used in preparation of the test article formulations and for administration to the control group was 100% pure Mazola® corn oil (exp. dates: 2 January 2007, 1 and 23 February 2007 and 7 March 2007) distributed by ACH Food Companies, Inc., Memphis, Tennessee and purchased locally.

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4.1.3. PREPARATION

For the control group (Group 1), a sufficient volume of corn oil was transferred to a glass container approximately weekly. The corn oil was stirred continuously using a magnetic stirrer throughout sampling and dosing. Aliquots of the vehicle were prepared for daily dispensation and stored at room temperature.

Dosing formulations were prepared at the concentrations indicated in the following table:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)[a]
2	[redacted]	160	32
3		400	80
4		1000	200

[a] = The dosing formulations were not adjusted for purity.

The appropriate amount of the test article for each group was weighed into tared, calibrated glass containers. Vehicle was added to each container to bring the formulations nearly to the calibration mark. The formulations were mixed until uniform using a magnetic stirrer and heated in a water bath at approximately 60°C as necessary. Vehicle was then added to each container to bring the formulations to the calibration mark.

The test article formulations for the toxicology (Groups 2-4) groups were prepared approximately weekly as single formulations for each dosage level, divided into aliquots for daily dispensation and stored at room temperature. The test article formulations were stirred continuously throughout the preparation, sampling and dose administration procedures. On 3 March 2006, the formulations were visually inspected by [redacted] Staff Toxicologist, Developmental, Reproductive Toxicology, WIL Deputy Director.

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4.1.4. SAMPLING AND ANALYSES

Prior to the initiation of dose administration, triplicate samples (5 mL each) for homogeneity determination were collected on 3 March 2006 from the top, middle and bottom strata of the 32, 80 and 200 mg/mL dosing formulations and the middle stratum of the vehicle. In addition, triplicate samples (5 mL each) for resuspension homogeneity and stability determinations were collected following 10 days storage at room temperature from the top and bottom strata of these same dosing suspensions. After thorough mixing of formulations, duplicate samples (5 mL each) for concentration analyses were collected on the first day formulations were prepared for study weeks 0, 4 8 and 12 from the middle stratum of each dosing formulation (including the vehicle). Two of the 3 sets of samples for homogeneity and stability and 1 set of samples for concentration analysis were shipped at ambient temperature to [redacted] All remaining samples were retained at WIL Research Laboratories, LLC under normal laboratory conditions for possible future analysis. All analyses were conducted by [redacted] **The methodology and results of these analyses will be presented in Appendix B and the results will be summarized in Section 6.1.**

4.2. TEST SYSTEM

Crl:CD(SD) rats from Charles River Laboratories, Inc., Raleigh, North Carolina were used as the test system on this study. This species and strain of animal is recognized as appropriate for subchronic toxicity studies. The Sprague-Dawley rat was used because it is a widely used strain for which significant historical control data are available.

4.3. ORGANIZATION OF TEST GROUPS, DOSAGE LEVELS AND TREATMENT REGIMEN

The vehicle and test article formulations were administered orally by gastric intubation via appropriately sized flexible Teflon®-shafted, stainless steel ball-tipped dosing cannula (Natume, Japan) once daily for 91 or 92 consecutive days, through the day prior to the scheduled primary necropsy. The dosage volume for all groups was 5 mL/kg. Individual

doses were based on the most recently recorded body weights to provide the correct mg/kg/day dosage. Adjusted doses became effective the day of collection of the weekly body weights.

The following table presents the study group assignment:

Group Number	Test Article[a]	Dosage Level (mg/kg/day)	Dosage Volume (mL/kg)	Number of Animals Males	Females
1	Vehicle	0	5	10	10
2	[redacted]	160	5	10	10
3		400	5	10	10
4		1000	5	10	10

[a] = The dosing formulations were not adjusted for purity

Dosage levels were determined from the results of a 28-day study ([redacted], 2006) and were provided by the sponsor representative after consultation with the WIL study director.

The selected route of administration for this study was oral (gavage) because this is an acceptable and standard method for administering test article per OECD Guideline 408. The number of animals selected for this study was the minimum required to yield statistically and scientifically meaningful data and was consistent with regulatory agency expectations.

4.4. ANIMAL RECEIPT AND ACCLIMATION/PRETEST PERIOD

Forty-six male and 46 female Crl:CD(SD) rats were received in good health on 21 February 2006, from Charles River Laboratories, Inc., Raleigh, North Carolina. The animals were approximately 31 days old at receipt. Each animal was examined by a qualified technician on the day of receipt and weighed 3 days later. Each animal was uniquely identified by a Monel® metal eartag displaying the permanent identification number. All animals were housed for a 13-day acclimation/pretest period. During this

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period, each animal was observed twice daily for mortality and changes in general appearance or behavior.

Pretest data collection began on 24 February 2006. Individual body weights were recorded and detailed physical examinations were performed periodically during the pretest period. Food consumption and ophthalmic examination data were also recorded for pretest animals prior to the initiation of dose administration. Pretest clinical observations are presented in Appendix C.

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4.5. ANIMAL HOUSING

Upon arrival, all animals were housed 3 per cage by sex for approximately 3 days. Thereafter, all animals were housed individually in clean, stainless steel, wire-mesh cages suspended above cage-board. Animals were maintained in accordance with the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 1996). The animal facilities at WIL Research Laboratories, LLC are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

4.6. DIET, DRINKING WATER AND MAINTENANCE

The basal diet used in this study, PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002, is a certified feed with appropriate analyses performed by the manufacturer and provided to WIL Research Laboratories, LLC. Reverse osmosis-treated (on-site) drinking water, delivered by an automatic watering system, and the basal diet were provided ad libitum throughout the study, except during the period of fasting prior to blood collection when food, but not water, was withheld. Municipal water supplying the facility was sampled for contaminants according to the standard operating procedures. The results of the diet and water analyses are maintained at WIL Research Laboratories, LLC. No contaminants were present in animal feed or water at concentrations sufficient to interfere with the objectives of this study.

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4.7. ENVIRONMENTAL CONDITIONS

All animals were housed throughout the acclimation period and during the study in an environmentally controlled room. The room temperature and humidity controls were set to maintain daily averages of 71 ± 5°F (22 ± 3°C) and 50 ± 20% relative humidity. Room temperature and relative humidity were controlled and monitored using the Metasys® DDC Electronic Environmental control system. These data were recorded approximately hourly and are summarized in Appendix D. Actual mean daily temperature ranged from 70.4°F to 71.2°F (21.3°C to 21.8°C) and mean daily relative humidity ranged from 28.1% to 54.6% during the study. Light timers were set to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide a minimum of 10 fresh air changes per hour. The 12-hour light/12-hour dark photoperiod was interrupted as necessary to allow for the performance of protocol-specified activities.

4.8. ASSIGNMENT OF ANIMALS TO TREATMENT GROUPS

On 2 March 2006 (4 days prior to the initiation of dose administration), all available rats were weighed and examined in detail for physical abnormalities. These data were collected using the WIL Toxicology Data Management System (WTDMS™) and reviewed by the study director. The animals judged suitable for assignment to the study were selected for use in a computerized randomization procedure. A printout containing the animal numbers, corresponding body weights and individual group assignments was generated based on body weight stratification in a block design. The animals were then arranged into groups according to the printout. Individual body weights at randomization were within ± 20% of the mean for each sex. Each group (Groups 1-4) consisted of 10 males and 10 females. The selected animals were approximately 6 weeks old at the initiation of dose administration; individual body weights ranged from 204 g to 236 g for males and from 151 g to 184 g for females.

5. PARAMETERS EVALUATED

5.1. CLINICAL OBSERVATIONS AND SURVIVAL

All animals were observed twice daily, once in the morning and once in the afternoon, for mortality and moribundity.

Clinical examinations were performed twice daily, at the time of dose administration and approximately 1 to 2 hours following dose administration (designated as 1 hour post-dosing for report presentation purposes). All significant findings were recorded. Detailed physical examinations were conducted on all animals weekly, beginning approximately 2 weeks prior to test article administration and prior to the scheduled necropsy. Observations at the time of dosing were not performed on days when detailed physical examinations were conducted. A separate computer protocol was used to record any observations noted outside of the above-specified intervals. These unscheduled clinical observations are presented in Appendix E.

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5.2. BODY WEIGHTS

Individual body weights were recorded at least weekly during treatment, beginning approximately 2 weeks prior to test article administration (study week -2) and on the day prior to the first day of scheduled necropsy (non-fasted). Mean body weights and mean body weight changes were calculated for the corresponding intervals. Final body weights (fasted) were recorded prior to the scheduled necropsy.

5.3. FOOD CONSUMPTION

Individual food consumption was recorded weekly, beginning approximately 2 weeks prior to test article administration (study week -2 to -1). Food intake was calculated as g/animal/day for the corresponding body weight intervals. When food consumption could not be measured for a given interval (due to spillage, weighing error, obvious erroneous value, etc.), the appropriate interval was footnoted as "NA" (Not Applicable) on the individual tables.

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5.4. CLINICAL PATHOLOGY

Blood samples for clinical pathology evaluations (hematology and serum chemistry) were collected from all animals on the day of the scheduled necropsy (study week 13). The animals were fasted overnight prior to blood collection. Blood for hematology and serum chemistry parameters was collected via the retro-orbital sinus of animals anesthetized by isoflurane inhalation prior to the scheduled necropsy. Blood for coagulation parameters was collected via the vena cava at the time of necropsy. Blood was collected into tubes containing EDTA (hematology), sodium citrate (clotting determinations) or no anticoagulant (serum chemistry). Clinical pathology methods, procedures and references are presented in Appendix F. The following parameters were evaluated:

5.4.1. HEMATOLOGY

Total leukocyte count (White Cells)
Erythrocyte count (Red Cells)
Hemoglobin
Hematocrit
Mean corpuscular volume (MCV)
Mean corpuscular hemoglobin (MCH)
Mean corpuscular hemoglobin concentration (MCHC)
Platelet count (Platelet)
Prothrombin time (ProTime)
Activated partial thromboplastin time (APTT)
Reticulocyte count
  Percent (Reticulocyte)
  Absolute (Retic Absolute)
Differential leukocyte count -
  Percent and absolute
  -Neutrophil
  -Lymphocyte
  -Monocyte
  -Eosinophil
  -Basophil
  -Large unstained cell
Platelet estimate[a]
Red cell morphology (RBC Morphology)[a]

( ) - Designates tabular abbreviation
[a] - Presented on individual tables if the automated differential data were verified by manual review of slides

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5.4.2. SERUM CHEMISTRY

Albumin
Total protein
Globulin [by calculation]
Albumin/globulin ratio (A/G Ratio) [by calculation]
Total bilirubin (Total Bili)
Urea nitrogen
Creatinine
Alkaline phosphatase (AlkalinePhos'tse)
Alanine aminotransferase (Alanine Transfer)
Aspartate aminotransferase (AspartatTransfer)
Glucose
Total cholesterol (Cholesterol)
Calcium
Chloride
Phosphorus
Potassium
Sodium
Triglycerides (Triglyceride)

( ) - Designates tabular abbreviation

5.5. OPHTHALMIC EXAMINATIONS

Ocular examinations were conducted on all animals prior to randomization and the initiation of dose administration (2 March 2006; study week -1) and near the end of the treatment period (1 June 2006; study week 12). All ocular examinations were conducted using an indirect ophthalmoscope and slit lamp biomicroscope preceded by pupillary dilation with an appropriate mydriatic agent. Examinations were performed by [redacted] (Appendix G).

5.6. ANATOMIC PATHOLOGY

5.6.1. MACROSCOPIC EXAMINATION

A complete necropsy was conducted on all animals. Animals were euthanized by carbon dioxide inhalation followed by exsanguination. The necropsies included, but were not limited to, examination of the external surface, all orifices, and the cranial, thoracic, abdominal and pelvic cavities, including viscera. Clinical findings that were confirmed macroscopically were designated CEO (correlates with externally observed) on the individual macroscopic data tables. The following tissues and organs were collected and placed in 10% neutral-buffered formalin (except as noted):

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Adrenal glands (2)
Aorta
Bone with marrow
  Sternum
Bone marrow smear (from femur)[a]
Brain
  Cerebrum level 1
  Cerebrum level 2
  Cerebellum with medulla/pons
Cervix
Epididymides (2)[b]
Eyes with optic nerve (2)[c]
Gastrointestinal tract
  Esophagus
  Stomach
  Duodenum
  Jejunum with Peyer's patches
  Ileum
  Cecum
  Colon
  Rectum
Harderian glands (2)
Heart
Kidneys (2)
Lacrimal glands [exorbital (2)]
Larynx
Liver (sections of 2 lobes)
Lungs (including bronchi, fixed by inflation with fixative)
Lymph nodes
  Mandibular
  Mesenteric
  Popliteal[d]
Mammary gland (females only)
Nasal tissues[e]
Ovaries (2) with oviducts[f]
Pancreas
Peripheral nerve (sciatic)
Pharynx
Pituitary
Prostate
Salivary glands [mandibular (2)]
Seminal vesicles (2)
Skeletal muscle (rectus femoris)
Skin
Spinal cord (cervical, thoracic, lumbar)
Spleen
Testes (2)[b]
Thymus
Thyroid (with parathyroids[f])
Trachea
Urinary bladder
Uterus
Vagina
Gross lesions (when possible)

[a] - Not taken from animals found dead; bone marrow smears were obtained at necropsy, but not placed in formalin; slides were examined only if scientifically warranted.
[b] - Fixed in Bouin's solution
[c] - Fixed in Davidson's solution
[d] - As many per side as found were retained for microscopic evaluation.
[e] - Levels I and III according to the method of Young (Young 1981) were examined.
[f] - Examined microscopically if in the plane of section, or if gross lesions were present.

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5.6.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsy:

Adrenal glands	Prostate
Brain	Seminal vesicles/coagulating gland
Epididymides	Spleen
Heart	Testes
Kidneys	Thymus
Liver	Thyroid with parathyroids*
Ovaries with oviducts	Uterus
Popliteal lymph nodes	

Paired organs were weighed together with the exception of popliteal lymph nodes. Designated organs (*) were weighed after fixation. Organ to final body weight and organ to brain weight ratios were calculated.

5.6.3. SLIDE PREPARATION AND MICROSCOPIC EXAMINATION

After fixation, protocol-specified tissues were trimmed according to standard operating procedures and the protocol. Trimmed tissues were processed into paraffin blocks, sectioned at 4 to 8 microns, mounted on glass microscope slides and stained with hematoxylin and eosin.

Microscopic examination was performed on all tissues listed in Section 5.6.1. from all animals in the control and 1000 mg/kg/day groups at the scheduled necropsy and from all animals found dead or euthanized in extremis. Gross lesions were examined from all animals. Missing tissues were identified as not found at necropsy, lost at necropsy, lost during processing, not in plane of section or other designations as appropriate. Microscopic examination was performed by [redacted], Staff Pathologist, WIL Research Laboratories, LLC (Appendix H).

5.7. STATISTICAL METHODS

All statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests (except as noted otherwise) for minimum

significance levels of 1% and 5%, comparing each test article-treated group to the control group by sex. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. In addition, percent change from control is presented for body weights, clinical pathology parameters and organ weights. Due to the different rounding conventions inherent in the types of software used, the means and standard deviations on the summary and individual tables may differ by ±1 in the last significant figure.

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Body weight, body weight change, food consumption, clinical pathology and organ weight data were subjected to a parametric 1-way analysis of variance (ANOVA) (Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

5.8. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor.

Reserve samples of the test article, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

6. RESULTS AND DISCUSSION

6.1. ANALYTICAL CHEMISTRY

Analytical Chemistry Report: Appendix B

To be added upon receipt.

6.2. CLINICAL OBSERVATIONS AND SURVIVAL

Summary Data: Tables 1, 2, 3, 4

Individual Data: Table 18; Appendices E, I

A 400 mg/kg/day group female (no. 19673) was found dead on study day 65 and a control group male (no. 19639) was euthanized in extremis on study day 70. Suppurative rhinitis with intralesional bacteria was noted in male no. 19639 and may have been associated with the death of the animal (i.e., blockage of nasal passages by debris), although an exact cause could not be determined; no significant histologic findings were observed in female no. 19673. Both deaths were considered spontaneous and unrelated to test article exposure. All other animals survived to the scheduled necropsy (study day 91 or 92).

Test article-related clinical findings of evidence of excessive salivation (clear material around the mouth, nose, facial area, ventral neck or forelimbs) were noted primarily in the 1000 mg/kg/day group males and females at 1 hour after dose administration beginning during study week 1 and continuing throughout the study. Clear material around the mouth was also noted in the 400 mg/kg/day group at a lower incidence, most frequently seen at 1 hour post-dosing beginning during study week 2. All other clinical findings in the test article-treated groups were noted with similar incidence in the control group, were limited to single animals, were not noted in a dose-related manner and/or were common findings for laboratory rats of this age and strain.

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6.3. BODY WEIGHTS

Summary Data: Tables 5, 6, 7

Individual Data: Tables 19, 20, 21

Test article-related effects on body weights were observed in the 1000 mg/kg/day group males. Lower body weight gains in the 1000 mg/kg/day group were observed during study week 1 to 2 through study week 8 to 9; the difference from the control group during study week 3 to 4 was statistically significant. Body weight gains during the remainder of the study were similar to (within 2 grams) or higher than the control group. As a result, lower mean cumulative body weight gains and lower mean absolute body weights in the 1000 mg/kg/day group were observed beginning during study week 4 and persisting to the end of the study. The differences from the control group during study weeks 11, 12 and 13 were statistically significant. As a result, at study week 13 mean body weight for the 1000 mg/kg/day group males was statistically significantly lower (12.2%) than the control group. Mean body weights for the 1000 mg/kg/day group females were similar to the control group throughout the study. There were no other remarkable differences when the control and test article-treated groups were compared.

6.4. FOOD CONSUMPTION

Summary Data: Table 8

Individual Data: Table 22

A transient test article-related effect on food consumption was noted in the 1000 mg/kg/day group males. Statistically significantly lower mean food consumption was noted for the 1000 mg/kg/day group males for study week 0 to 1. Mean food consumption for the 1000 mg/kg/day group females when compared to the control group was statistically significantly higher for study weeks 2 to 3, 7 to 8, 8 to 9, 10 to 11 and 12 to 13. However, there were no corresponding effects on body weight in these females. There were no other statistically significant differences when the control and test article-treated groups were compared.

6.5. CLINICAL PATHOLOGY

6.5.1. HEMATOLOGY

Summary Data: Table 9; Appendix H

Individual Data: Table 23

The following alterations in coagulation parameters were considered to be related to test article administration:

Text Table 1
Toxicologically relevant hematological changes

Parameter	Direction and magnitude of change	Dosage Level(s) (mg/kg/day)	Sex	Interval
Prothrombin time	↑ 7.1%, 13.0%, 53.3%*	160, 400, 1000	M	SN
APTT	↑ 11.2%*, 17.3%*, 44.7%*	160, 400, 1000	M	SN

* = significantly ($p<0.05$ or $p<0.01$) different from the control group using Dunnett's test.

Mean prothrombin time and APTT values were higher in the test article-treated males as compared to the control group. A dose relationship was observed, and all prothrombin values (including the control group values) and the APTT value for the 1000 mg/kg/day group were above WIL historical control data ranges (version 2.1). Increases in both prothrombin time and APTT suggest a deficiency in the common pathway of the coagulation cascade or multiple defects involving the intrinsic, extrinsic and common pathways.

There were no other test article-related effects on hematology data. However, platelet count was statistically significantly higher (32.8%; $p<0.05$ using Dunnett's test) in the 400 mg/kg/day group females as compared to the control group. This group mean difference was not considered to be test article-related because there was no dose response, the value was within WIL historical control data range and a low outlier in the control group contributed to a low mean control group value.

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6.5.2. SERUM CHEMISTRY

Summary Data: Tables 10; Appendix H

Individual Data: Table 24

The following alterations in serum chemistry parameters were considered to be related to test article administration:

Text Table 2
Test article-related serum chemistry changes

Parameter	Direction and magnitude of change	Dosage Level(s) (mg/kg/day)	Sex	Interval
Alkaline phosphatase	↑ 45.1%*, 82.4%*, 95.6%* ↑ 68.1%*, 72.3%*, 159.6%*	160, 400, 1000	M F	SN
Alanine aminotransferase	↑ 15.8%, 110.5%, 552.6%* ↑ 15.6%, 71.9%, 465.6%*	160, 400, 1000	M F	SN
Aspartate aminotransferase	↑ 1.4%, 12.9%, 74.3%* ↑ 13.2%, 16.2%, 64.7%*	160, 400, 1000	M F	SN
Total Protein	↓ 2.9%, 2.9%, 8.6%*	160, 400, 1000	M	SN
Globulin	↓ 7.7%, 7.7%, 19.2%* ↓ 4.3%, 8.7%, 13.0%*	160, 400, 1000	M F	SN
A/G ratio	↑ 8.9%, 11.2%, 20.1%* ↑ 6.2%, 10.2%, 15.5%	160, 400, 1000	M F	SN
Cholesterol	↓ 1.4%, 17.8%, 21.9%*	160, 400, 1000	F	SN

* = significantly ($p<0.05$ or $p<0.01$) different from the control group using Dunnett's test.

Several mean liver enzyme values (alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase) were higher in the test article-treated animals as compared to the control group, and this was observed in a dose-related manner in both males and females. Although the mean values for alanine aminotransferase and aspartate aminotransferase in the 160 and 400 mg/kg/day groups were not statistically significantly different from the control group, there were generally individual animals with enzyme values outside of the range of the concurrent control animals. In addition, mean alkaline phosphatase and alanine aminotransferase values were above the WIL historical control

data ranges for the 400 and 1000 mg/kg/day group males; these values were also above historical control ranges for the 1000 mg/kg/day group females.

Statistically significantly lower mean total protein and globulin values and higher A/G ratio were noted in the 1000 mg/kg/day group males as compared to the control group values. Lower globulin levels were primarily responsible for the altered A/G ratio, while the difference in total protein was minor. There was no clear dose response. Mean globulin values were also statistically significantly lower in the 1000 mg/kg/day group females as compared to the control group value, and a dose response was observed. The A/G ratios in the test article-treated females were also higher than the control group value, although the differences were not statistically significant for this parameter. In addition, mean cholesterol was statistically significantly lower in the 1000 mg/kg/day group females as compared to the control group value, and this occurred in a dose-related manner. Although there were no statistically significant differences in the low- and mid-dose groups, there were generally individual animals in these groups with values outside of the range of the concurrent control animals.

There were no other test article-related effects on serum chemistry data.

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6.6. OPHTHALMIC EXAMINATIONS

Summary Data: Tables 11, 12; Appendix G

Individual Data: Tables 25, 26

No ophthalmic lesions indicative of toxicity were observed in any of the test article-treated groups. All findings observed were typical in prevalence and appearance for laboratory rats of this age and strain.

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6.7. ANATOMIC PATHOLOGY

6.7.1. MACROSCOPIC EXAMINATION

Summary Data: Tables 13, 14; Appendix H

Individual Data: Tables 27, 28

There were no test article-related macroscopic findings. All macroscopic changes were considered to be spontaneous and/or incidental in nature and unrelated to test article exposure.

6.7.2. ORGAN WEIGHTS

Summary Data: Table 15; Appendix H

Individual Data: Tables 29, 30, 31

Mean final (fasted) body weight was statistically significantly (13.3%) lower in the 1000 mg/kg/day group males as compared to the control group. There were no other statistically significant mean final body weight differences.

The following organ weight changes were considered to be test article-related:

Text Table 3
Toxicologically relevant organ weight changes

Organ	Dosage Level(s) (mg/kg/day)			Sex	Histologic Correlate
	160	400	1000		
Adrenal Glands					
absolute	↑ 8.6%	↑ 21.8%*	↑ 26.3%*	F	None
relative to body weight	↑ 8.3%	↑ 25.0%*	↑ 29.2%*		
relative to brain weight	↑ 6.4%	↑ 17.4%	↑ 25.5%*		
Ovaries/Oviducts					
absolute	↑ 8.3%	↑ 13.5%	↑ 17.6%	F	None
relative to body weight	↑ 6.4%	↑ 17.0%	↑ 21.3%*		
relative to brain weight	↑ 6.6%	↑ 9.5%	↑ 17.0%		

* = significantly ($p<0.05$ or $p<0.01$) different from the control group using Dunnett's test.

Mean adrenal gland weights were statistically significantly higher in the 400 and 1000 mg/kg/day group females as compared to the control group, and these differences occurred in a dose-related manner. A statistically significantly higher mean ovaries/oviducts weight (relative to body weight) was observed in the 1000 mg/kg/day group females. Although remaining group mean differences in ovaries/oviducts weights lacked statistical significance, a dose response was evident.

Brain, testes and kidney weights relative to final body weights were statistically significantly higher (12.4% to 14.2%) in the 1000 mg/kg/day group males when compared to the control group at the scheduled necropsy. However, these changes were considered to be a result of a test article-related effect on final body weight, not a direct effect on the organs.

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There were no other test article-related effects on organ weights. However, statistically significant lower mean absolute heart weight (12.7%; $p<0.05$ using Dunnett's test) in the 1000 mg/kg/day group males, higher mean absolute and relative (to body weight) kidney weights (8.7% and 11.1%, respectively; $p<0.05$ using Dunnett's test) in the 1000 mg/kg/day group females and higher mean liver weight relative to body weight (13.3%; $p<0.01$ using Dunnett's test) in the 1000 mg/kg/day group females were observed as compared to the control group. These group mean differences were not considered to be toxicologically relevant because there was no dose response, the values were generally within WIL historical control data ranges (except for the mean liver weight relative to body weight in the females), and there were no histologic correlates observed.

6.7.3. MICROSCOPIC EXAMINATION

Summary Data: Tables 16, 17; Appendix H

Individual Data: Tables 27, 28

There were no test article-related histologic changes. Histologic changes were considered to be incidental findings, manifestations of spontaneous diseases, or related to

some aspect of experimental manipulation other than exposure to the test article. There was no test article-related alteration in the incidence, severity or histologic character of those incidental and spontaneous tissue alterations.

6.7.4. DISCUSSION OF ANATOMIC PATHOLOGY FINDINGS

Administration of [redacted] to Crl:CD(SD) rats via daily oral gavage for a minimum of 90 consecutive days resulted in hepatic alteration manifested as higher liver enzyme values (alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase) in both males and females. Additionally, lower total protein and globulin and increased coagulation times in the males as well as lower globulin and cholesterol values in the females were also likely associated with hepatocyte alteration, although the lack of effect on albumin levels is atypical. These differences were considered to be potentially test article-related but not adverse as no related clinical signs were seen, correlating macroscopic or microscopic changes in the liver were not observed, and there was no effect on liver weights. Higher adrenal gland and ovaries/oviduct weights had no microscopic correlates and were considered not adverse.

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7. CONCLUSIONS

Based on the results of this study, test article-related findings were observed at dosage levels of 160, 400 and 1000 mg/kg/day as evidenced by clinical findings of increased salivation (400 and 1000 mg/kg/day groups), lower body weights and food consumption (1000 mg/kg/day group males), higher prothrombin times and APTT, higher alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, lower globulin values and a correspondingly higher A/G ratio as well as lower total protein values (1000 mg/kg/day group males), lower cholesterol levels (1000 mg/kg/day group females) and higher mean adrenal gland and ovaries/oviducts weights (females). No target organ of toxicity was identified by histologic assessment. As the differences at 400 mg/kg/day were considered to be potentially test article-related but not adverse, the no-observed-adverse-effect level (NOAEL) for oral (gavage) administration of [redacted] to Crl:CD(SD) rats for 91 consecutive days was 400 mg/kg/day.

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8. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

[redacted] Date

Staff Toxicologist
Study Director

Report Prepared By:

[redacted] Date

Study Analyst

Report Reviewed By:

[redacted] Date

Director, Toxicology

[redacted] Date

Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology

[redacted] Date

Group Supervisor, Study Analysis and Reports

[redacted] Date

Scheduling Coordinator, Regulatory Affairs and Services

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KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Study Personnel:

[redacted]	Manager, Clinical Pathology
	Senior Operations Manager, Vivarium
	Manager, Gross Pathology and Developmental Toxicology Laboratory
	Operations Manager, Toxicology
	Group Manager, Formulations Laboratory
[redacted]	Manager, Histology
	Manager, Reporting and Regulatory Technical Services

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9. QUALITY ASSURANCE UNIT STATEMENT

9.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
03-Mar-2006	Test Article Preparation	06-Mar-2006	24-Apr-2006	[redacted]
04-Apr-2006	Animal Care and Equipment	04-Apr-2006	23-May-2006	
01-Jun-2006	Ophthalmology Examination	01-Jun-2006	25-Jul-2006	
05-Jun-2006	Blood Collection and Analysis	05-Jun-2006	25-Jul-2006	
05-Jun-2006	Necropsy	05-Jun-2006	25-Jul-2006	
16-Jun-2006	Trimming of Tissues	16-Jun-2006	25-Jul-2006	
20-Jul-2006 27-Jul-2006	Study Records (I-2, I-3)	27-Jul-2006	25-Aug-2006	
14-Jul-2006 20-Jul-2006 28-Jul-2006	Study Records (I-1)	28-Jul-2006	25-Aug-2006	
20-Jul-2006 28-Jul-2006 31-Jul-2006	Study Records (N-1)	31-Jul-2006	25-Aug-2006	
14-Aug-2006	Study Records (Rx-1)	14-Aug-2006	Sep-2006	
14-Aug-2006	Study Records (C-1)	14-Aug-2006	Sep-2006	
21-Aug-2006	Draft Pathology Report	21-Aug-2006	Sep-2006	
11-Aug-2006 14-Aug-2006 21-Aug-2006	Draft Report, excluding Pathology appendix	21-Aug-2006	Sep-2006	
21-Aug-2006	Study Records (H-1)	21-Aug-2006	Sep-2006	
21-Aug-2006	Study Records (P-1)	21-Aug-2006	Sep-2006	

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR 792), the OECD Principles of Good Laboratory Practice [C(97)

186/Final], the Japanese MAFF Good Laboratory Practice Standards, European Union (EU) Directives 2004/9/EC and 2004/10/EC, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendments, with the following exceptions. The data located in Appendices A (Certificate of Analysis) and B (Analyses of Dosing Formulations) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s) and the final report will be stored in the Archives at WIL Research Laboratories, LLC for a period of 6 months following issuance of the final report and thereafter will be returned to the sponsor. Any remaining formulation or clinical pathology samples will be discarded following issuance of the final report.

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9.2. APPROVAL

This study was inspected according to the criteria discussed in Section 9.1.

Report Audited By:

[redacted] Date

Group Supervisor, Quality Assurance

Report Released By:

[redacted] Date

Manager, Quality Assurance

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10. REFERENCES

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

[redacted] A 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats (with Functional Observational Battery and Motor Activity Determinations) (Study No. WIL-187051). WIL Research Laboratories, LLC, Ashland, OH, **2006.**

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Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods,* 7th ed.; The Iowa State University Press: Ames, IA, **1980;** pp 215-237.

Young, J.T. Histopathological examination of the rat nasal cavity. *Fundamental and Applied Toxicology* **1981,** *1,* 309-312.

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11. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 6.2** states that controls for the animal room will be set to maintain an average daily relative humidity of approximately 50 ± 20%. On 21 February 06 (study day -13), the average daily humidity was 28.1%, which was outside the allowable range.
- **Protocol Section 8.7.1** states that adrenal glands (2) and thyroids (with parathyroids) will be collected and placed in 10% neutral-buffered formalin, trimmed and weighed. On 6 June 2006 (study day 92), the adrenal glands for male no. 19643 (1000 mg/kg/day group) and the left thyroid/parathyroid for female no. 19695 (1000 mg/kg/day group) were lost at necropsy. Therefore, weights were not obtained for these organs, and the tissues were not examined. Also on 6 June 2006, 1 adrenal gland for female no. 19701 (1000 mg/kg/day group) was lost after weighing at necropsy, and the tissue was not examined.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

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TABLES 1 - 31

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TABLE 1

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF SURVIVAL AND DISPOSITION

MALES

GROUP :	1				2				3				4			
WEEK	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
1	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
2	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
3	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
4	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
5	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
6	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
7	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
8	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
9	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
10	9	0	1	0	10	0	0	0	10	0	0	0	10	0	0	0
11	9	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
12	9	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
13	0	0	0	9	0	0	0	10	0	0	0	10	0	0	0	10

WEEK = WEEK OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 1

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SUMMARY OF SURVIVAL AND DISPOSITION

SPONSOR NO.:06-012

FEMALES

GROUP :	1				2				3				4			
WEEK	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
1	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
2	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
3	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
4	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
5	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
6	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
7	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
8	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0
9	10	0	0	0	10	0	0	0	9	1	0	0	10	0	0	0
10	10	0	0	0	10	0	0	0	9	0	0	0	10	0	0	0
11	10	0	0	0	10	0	0	0	9	0	0	0	10	0	0	0
12	10	0	0	0	10	0	0	0	9	0	0	0	10	0	0	0
13	0	0	0	10	0	0	0	10	0	0	0	9	0	0	0	10

WEEK = WEEK OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-06-06			
GROUP:	1	2	3	4
NORMAL				
-NO SIGNIFICANT CLINICAL OBSERVATIONS	125/10	120/10	121/10	104/10
DISPOSITION				
-SENT TO NECROPSY TO BE EUTHANIZED IN EXTREMIS- PHYSICAL CONDITION	1/ 1	0/ 0	0/ 0	0/ 0
-PRIMARY NECROPSY (WEEK 13)	9/ 9	10/10	10/10	10/10
BEHAVIOR/CNS				
-HYPOACTIVITY	1/ 1	0/ 0	0/ 0	0/ 0
-UNKEMPT APPEARANCE	1/ 1	0/ 0	0/ 0	0/ 0
BODY/INTEGUMENT				
-HAIR LOSS FORELIMB(S)	5/ 2	9/ 1	18/ 3	13/ 3
CARDIO-PULMONARY				
-RESPIRATION SHALLOW	1/ 1	0/ 0	0/ 0	0/ 0
-RALES	1/ 1	0/ 0	0/ 0	0/ 0
EYES/EARS/NOSE				
-RED DISCHARGE RIGHT EYE	0/ 0	1/ 1	1/ 1	0/ 0
-DRIED RED MATERIAL AROUND LEFT EYE	1/ 1	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-06-06			
GROUP:	1	2	3	4
EYES/EARS/NOSE				
-DRIED RED MATERIAL AROUND RIGHT EYE	1/ 1	5/ 1	0/ 0	3/ 2
-DRIED RED MATERIAL AROUND NOSE	1/ 1	1/ 1	0/ 0	0/ 0
EXCRETA				
-DEFECATION DECREASED	1/ 1	0/ 0	0/ 0	0/ 0
-SOFT FECES	0/ 0	1/ 1	0/ 0	0/ 0
BODY/INTEG II				
-SCABBING FORELIMB(S)	0/ 0	0/ 0	0/ 0	4/ 2
ORAL/DENTAL				
-DRIED YELLOW MATERIAL AROUND MOUTH	1/ 1	0/ 0	0/ 0	0/ 0
-UPPER INCISOR(S) BROKEN	2/ 1	6/ 1	0/ 0	8/ 2
-UPPER INCISOR(S) MISSING	0/ 0	2/ 1	0/ 0	1/ 1
-UPPER INCISOR(S) LONG, TRIMMED	0/ 0	0/ 0	0/ 0	3/ 2
-UPPER INCISOR(S) MALALIGNED	2/ 2	7/ 1	0/ 0	21/ 3
-LOWER INCISOR(S) LONG, TRIMMED	2/ 2	8/ 1	0/ 0	23/ 3
SPECIAL				
-SWOLLEN LEFT EAR	3/ 1	0/ 0	0/ 0	0/ 0
-SWOLLEN RIGHT EAR	2/ 1	0/ 0	0/ 0	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-06-06			
GROUP:	1	2	3	4
BODY INTEG III				
-DRIED YELLOW MATERIAL UROGENITAL AREA	1/ 1	0/ 0	0/ 0	2/ 2
-DRIED YELLOW MATERIAL VENTRAL TRUNK	1/ 1	0/ 0	0/ 0	0/ 0
-DRIED YELLOW MATERIAL ANOGENITAL AREA	1/ 1	0/ 0	0/ 0	2/ 2
-DRIED BROWN MATERIAL ANOGENITAL AREA	0/ 0	1/ 1	0/ 0	3/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- F E M A L E -----

TABLE RANGE:	03-06-06 TO 06-06-06			
GROUP:	1	2	3	4
NORMAL				
-NO SIGNIFICANT CLINICAL OBSERVATIONS	127/10	127/10	129/10	125/10
DISPOSITION				
-FOUND DEAD	0/ 0	0/ 0	1/ 1	0/ 0
-PRIMARY NECROPSY (WEEK 13)	10/10	10/10	9/ 9	10/10
BODY/INTEGUMENT				
-HAIR LOSS FORELIMB(S)	8/ 3	9/ 3	6/ 1	12/ 3
-HAIR LOSS VENTRAL NECK	0/ 0	4/ 1	0/ 0	0/ 0
-HAIR LOSS BASE OF TAIL	0/ 0	2/ 1	0/ 0	0/ 0
EYES/EARS/NOSE				
-DRIED RED MATERIAL AROUND RIGHT EYE	0/ 0	0/ 0	0/ 0	3/ 3
-DRIED RED MATERIAL AROUND NOSE	1/ 1	1/ 1	0/ 0	0/ 0
EXCRETA				
-SOFT FECES	0/ 0	0/ 0	1/ 1	0/ 0
BODY/INTEG II				
-SCABBING FORELIMB(S)	0/ 0	0/ 0	0/ 0	1/ 1
ORAL/DENTAL				
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- F E M A L E -----

TABLE RANGE:	03-06-06 TO 06-06-06			
GROUP:	1	2	3	4
ORAL/DENTAL				
-UPPER INCISOR(S) BROKEN	0/ 0	1/ 1	0/ 0	0/ 0
-UPPER INCISOR(S) LONG, TRIMMED	0/ 0	0/ 0	0/ 0	2/ 1
-UPPER INCISOR(S) MALALIGNED	0/ 0	0/ 0	0/ 0	2/ 1
-LOWER INCISOR(S) LONG, TRIMMED	0/ 0	0/ 0	1/ 1	2/ 1
SPECIAL				
-SWOLLEN LEFT EAR	4/ 1	0/ 0	0/ 0	0/ 0
-SWOLLEN RIGHT EAR	2/ 1	0/ 0	0/ 0	0/ 0
-REDDENED LEFT EAR	2/ 1	0/ 0	0/ 0	0/ 0
BODY INTEG III				
-DRIED RED MATERIAL FORELIMB(S)	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
BEHAVIOR/CNS				
-UNKEMPT APPEARANCE	1/ 1	0/ 0	0/ 0	0/ 0
BODY/INTEGUMENT				
-HAIR LOSS FORELIMB(S)	0/ 0	1/ 1	0/ 0	0/ 0
-THIN	1/ 1	0/ 0	0/ 0	0/ 0
CARDIO-PULMONARY				
-RESPIRATION LABORED	1/ 1	0/ 0	0/ 0	0/ 0
-RALES	1/ 1	0/ 0	0/ 0	0/ 0
EYES/EARS/NOSE				
-RED DISCHARGE RIGHT EYE	0/ 0	0/ 0	1/ 1	0/ 0
-DRIED RED MATERIAL AROUND LEFT EYE	1/ 1	0/ 0	0/ 0	0/ 0
-DRIED RED MATERIAL AROUND RIGHT EYE	1/ 1	0/ 0	4/ 1	0/ 0
-DRIED RED MATERIAL AROUND NOSE	4/ 3	1/ 1	1/ 1	1/ 1
EXCRETA				
-DEFECATION DECREASED	2/ 1	0/ 0	0/ 0	0/ 0
-SOFT FECES	1/ 1	0/ 0	0/ 0	0/ 0
-URINE CONTAINING WHITE MATERIAL	3/ 2	2/ 1	2/ 2	2/ 2
ORAL/DENTAL				
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	5/ 1	5/ 2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted]

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
ORAL/DENTAL				
-DRIED RED MATERIAL AROUND MOUTH	2/ 1	0/ 0	0/ 0	1/ 1
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	2/ 1
SPECIAL				
-SWOLLEN LEFT EAR	4/ 1	0/ 0	0/ 0	0/ 0
-SWOLLEN RIGHT EAR	3/ 1	0/ 0	0/ 0	0/ 0
-REDDENED LEFT EAR	3/ 1	0/ 0	0/ 0	0/ 0
-REDDENED RIGHT EAR	3/ 1	0/ 0	0/ 0	0/ 0
BODY INTEG III				
-WET YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	3/ 2
-WET YELLOW MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	0/ 0	1/ 1
-WET YELLOW MATERIAL ANOGENITAL AREA	1/ 1	0/ 0	0/ 0	1/ 1
-DRIED YELLOW MATERIAL UROGENITAL AREA	3/ 1	0/ 0	0/ 0	2/ 2
-DRIED YELLOW MATERIAL VENTRAL TRUNK	1/ 1	0/ 0	0/ 0	0/ 0
-DRIED YELLOW MATERIAL ANOGENITAL AREA	1/ 1	0/ 0	0/ 0	1/ 1
-DRIED RED MATERIAL FORELIMB(S)	1/ 1	0/ 0	0/ 0	0/ 0
-DRIED BROWN MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	5/ 2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- F E M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
EYES/EARS/NOSE				
-DRIED RED MATERIAL AROUND RIGHT EYE	0/ 0	0/ 0	0/ 0	1/ 1
-DRIED RED MATERIAL AROUND NOSE	0/ 0	2/ 1	2/ 1	0/ 0
EXCRETA				
-SOFT FECES	0/ 0	0/ 0	1/ 1	0/ 0
-RED MATERIAL ON CAGE FLOOR	0/ 0	0/ 0	0/ 0	1/ 1
-URINE CONTAINING WHITE MATERIAL	4/ 3	3/ 2	1/ 1	0/ 0
ORAL/DENTAL				
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	1/ 1	13/ 5
-WET RED MATERIAL AROUND MOUTH	0/ 0	1/ 1	0/ 0	1/ 1
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	1/ 1	0/ 0	1/ 1
SPECIAL				
-SWOLLEN LEFT EAR	5/ 1	0/ 0	0/ 0	0/ 0
-SWOLLEN RIGHT EAR	4/ 1	0/ 0	0/ 0	0/ 0
-REDDENED LEFT EAR	3/ 1	0/ 0	0/ 0	0/ 0
-REDDENED RIGHT EAR	3/ 1	0/ 0	0/ 0	0/ 0
BODY INTEG III				
-WET YELLOW MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
CARDIO-PULMONARY				
-RALES	1/ 1	0/ 0	0/ 0	0/ 0
EYES/EARS/NOSE				
-RED DISCHARGE RIGHT EYE	0/ 0	0/ 0	1/ 1	0/ 0
-DRIED RED MATERIAL AROUND RIGHT EYE	0/ 0	0/ 0	4/ 1	0/ 0
-RED NASAL DISCHARGE	0/ 0	1/ 1	0/ 0	0/ 0
-DRIED RED MATERIAL AROUND NOSE	3/ 3	1/ 1	3/ 2	1/ 1
-WET RED MATERIAL AROUND NOSE	0/ 0	0/ 0	1/ 1	1/ 1
-WET CLEAR MATERIAL AROUND NOSE	0/ 0	0/ 0	2/ 2	2/ 1
EXCRETA				
-SOFT FECES	1/ 1	0/ 0	0/ 0	0/ 0
-RED PENILE DISCHARGE	0/ 0	1/ 1	0/ 0	0/ 0
-URINE CONTAINING WHITE MATERIAL	1/ 1	0/ 0	0/ 0	0/ 0
ORAL/DENTAL				
-WET CLEAR MATERIAL AROUND MOUTH	2/ 2	6/ 3	32/ 8	119/10
-WET CLEAR MATERIAL VENTRAL NECK	0/ 0	6/ 5	9/ 6	9/ 5
-WET CLEAR MATERIAL FORELIMB(S)	0/ 0	1/ 1	6/ 5	2/ 2
-WET CLEAR MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	0/ 0	1/ 1
-WET YELLOW MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	4/ 3

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
ORAL/DENTAL				
-DRIED YELLOW MATERIAL AROUND MOUTH	0/ 0	2/ 2	1/ 1	3/ 3
-WET RED MATERIAL AROUND MOUTH	0/ 0	1/ 1	2/ 2	2/ 1
-DRIED RED MATERIAL AROUND MOUTH	1/ 1	3/ 3	10/ 4	6/ 4
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	4/ 2	9/ 5
-WET CLEAR MATERIAL FACIAL AREA	0/ 0	0/ 0	1/ 1	0/ 0
SPECIAL				
-SWOLLEN LEFT EAR	4/ 1	0/ 0	0/ 0	0/ 0
-SWOLLEN RIGHT EAR	4/ 1	0/ 0	0/ 0	0/ 0
-REDDENED LEFT EAR	3/ 1	0/ 0	0/ 0	0/ 0
-REDDENED RIGHT EAR	3/ 1	0/ 0	0/ 0	0/ 0
BODY INTEG III				
-WET YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	3/ 3	10/ 6
-WET YELLOW MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	0/ 0	2/ 1
-WET YELLOW MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	2/ 1
-DRIED YELLOW MATERIAL UROGENITAL AREA	3/ 1	0/ 0	2/ 2	4/ 2
-DRIED YELLOW MATERIAL VENTRAL TRUNK	1/ 1	0/ 0	0/ 0	0/ 0
-DRIED YELLOW MATERIAL ANOGENITAL AREA	2/ 2	0/ 0	0/ 0	3/ 1
-WET RED MATERIAL UROGENITAL AREA	0/ 0	0/ 0	2/ 2	0/ 0
-DRIED RED MATERIAL FORELIMB(S)	1/ 1	0/ 0	0/ 0	0/ 0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR: [redacted]

SPONSOR NO.:06-012

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
BODY INTEG III				
-WET BROWN MATERIAL ANOGENITAL AREA	1/ 1	0/ 0	0/ 0	1/ 1
-DRIED BROWN MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	8/ 2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- F E M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
EYES/EARS/NOSE				
-CLEAR DISCHARGE LEFT EYE	0/ 0	0/ 0	2/ 2	1/ 1
-CLEAR DISCHARGE RIGHT EYE	0/ 0	0/ 0	1/ 1	2/ 2
-RED DISCHARGE RIGHT EYE	0/ 0	0/ 0	1/ 1	0/ 0
-DRIED RED MATERIAL AROUND RIGHT EYE	0/ 0	0/ 0	0/ 0	1/ 1
-RED NASAL DISCHARGE	0/ 0	0/ 0	0/ 0	2/ 2
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	2/ 2	4/ 3
-WET RED MATERIAL AROUND NOSE	0/ 0	0/ 0	1/ 1	0/ 0
-WET CLEAR MATERIAL AROUND NOSE	0/ 0	0/ 0	1/ 1	0/ 0
EXCRETA				
-URINE CONTAINING WHITE MATERIAL	1/ 1	0/ 0	2/ 2	0/ 0
-MUCOID FECES	1/ 1	0/ 0	0/ 0	0/ 0
ORAL/DENTAL				
-WET CLEAR MATERIAL AROUND MOUTH	1/ 1	1/ 1	48/ 4	73/10
-WET CLEAR MATERIAL VENTRAL NECK	0/ 0	2/ 2	8/ 2	9/ 7
-WET CLEAR MATERIAL FORELIMB(S)	0/ 0	2/ 2	3/ 2	2/ 2
-WET CLEAR MATERIAL VENTRAL TRUNK	0/ 0	2/ 2	0/ 0	0/ 0
-WET YELLOW MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	3/ 3
-WET YELLOW MATERIAL VENTRAL NECK	0/ 0	0/ 0	0/ 0	1/ 1
-DRIED YELLOW MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	2/ 2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:06-012

----- F E M A L E -----

TABLE RANGE:	03-06-06 TO 06-05-06			
GROUP:	1	2	3	4
ORAL/DENTAL				
-WET RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	1/ 1
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	4/ 3	10/ 6
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	2/ 1	2/ 1
-WET CLEAR MATERIAL FACIAL AREA	0/ 0	0/ 0	2/ 1	0/ 0
-WET CLEAR MATERIAL HINDLIMB(S)	0/ 0	1/ 1	0/ 0	0/ 0
SPECIAL				
-SWOLLEN LEFT EAR	8/ 1	0/ 0	0/ 0	0/ 0
-SWOLLEN RIGHT EAR	8/ 1	0/ 0	0/ 0	0/ 0
-REDDENED LEFT EAR	6/ 1	0/ 0	0/ 0	0/ 0
-REDDENED RIGHT EAR	6/ 1	0/ 0	0/ 0	0/ 0
BODY INTEG III				
-WET YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	8/ 4
-DRIED YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	1/ 1
-DRIED YELLOW MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	0/ 0	1/ 1
-DRIED RED MATERIAL FORELIMB(S)	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF BODY WEIGHTS [G]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -2				
MEAN	122.	122.	122.	123.
% CHANGE		0.0	0.0	0.8
S.D.	5.1	4.4	5.9	4.9
N	10	10	10	10
-1				
MEAN	181.	182.	181.	182.
% CHANGE		0.6	0.0	0.6
S.D.	7.1	5.9	5.9	5.7
N	10	10	10	10
0				
MEAN	216.	214.	214.	214.
% CHANGE		-0.9	-0.9	-0.9
S.D.	9.0	10.4	7.3	6.7
N	10	10	10	10
1				
MEAN	268.	268.	268.	264.
% CHANGE		0.0	0.0	-1.5
S.D.	15.7	19.1	9.2	9.4
N	10	10	10	10
2				
MEAN	316.	315.	318.	305.
% CHANGE		-0.3	0.6	-3.5
S.D.	21.6	26.3	14.4	19.0
N	10	10	10	10

None significantly different from control group

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TABLE 5
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHTS [G]

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 3				
MEAN	349.	347.	352.	335.
% CHANGE		-0.6	0.9	-4.0
S.D.	28.7	33.9	19.2	22.8
N	10	10	10	10
4				
MEAN	390.	383.	387.	363.
% CHANGE		-1.8	-0.8	-6.9
S.D.	34.6	40.9	25.4	25.9
N	10	10	10	10
5				
MEAN	421.	411.	419.	393.
% CHANGE		-2.4	-0.5	-6.7
S.D.	38.5	44.2	28.1	28.2
N	10	10	10	10
6				
MEAN	448.	435.	447.	413.
% CHANGE		-2.9	-0.2	-7.8
S.D.	42.0	49.0	29.8	28.8
N	10	10	10	10
7				
MEAN	469.	456.	471.	428.
% CHANGE		-2.8	0.4	-8.7
S.D.	47.2	53.3	34.5	28.4
N	10	10	10	10

None significantly different from control group

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted]

SUMMARY OF BODY WEIGHTS [G]

SPONSOR NO.:06-012

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
WEEK 8				
MEAN	491.	471.	487.	445.
% CHANGE		-4.1	-0.8	-9.4
S.D.	51.7	65.7	33.8	31.7
N	10	10	10	10
9				
MEAN	509.	492.	502.	454.
% CHANGE		-3.3	-1.4	-10.8
S.D.	53.8	66.1	39.2	33.3
N	10	10	10	10
10				
MEAN	513.	508.	521.	463.
% CHANGE		-1.0	1.6	-9.7
S.D.	77.9	65.5	40.5	41.3
N	10	10	10	10
11				
MEAN	548.	527.	534.	479.*
% CHANGE		-3.8	-2.6	-12.6
S.D.	50.9	67.9	44.7	38.8
N	9	10	10	10
12				
MEAN	555.	532.	545.	484.*
% CHANGE		-4.1	-1.8	-12.8
S.D.	51.3	69.3	48.8	36.4
N	9	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF BODY WEIGHTS [G]

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 13				
MEAN	565.	544.	554.	496.*
% CHANGE		-3.7	-1.9	-12.2
S.D.	54.7	70.3	51.3	39.3
N	9	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 5

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF BODY WEIGHTS [G]

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -2				
MEAN	107.	107.	110.	110.
% CHANGE		0.0	2.8	2.8
S.D.	6.4	5.8	5.9	5.3
N	10	10	10	10
-1				
MEAN	150.	150.	151.	151.
% CHANGE		0.0	0.7	0.7
S.D.	7.1	8.2	7.6	6.4
N	10	10	10	10
0				
MEAN	168.	166.	166.	166.
% CHANGE		-1.2	-1.2	-1.2
S.D.	8.9	8.8	8.6	7.6
N	10	10	10	10
1				
MEAN	189.	190.	188.	190.
% CHANGE		0.5	-0.5	0.5
S.D.	13.6	10.7	13.5	12.5
N	10	10	10	10
2				
MEAN	210.	210.	209.	207.
% CHANGE		0.0	-0.5	-1.4
S.D.	13.6	14.8	14.7	16.8
N	10	10	10	10

None significantly different from control group

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF BODY WEIGHTS [G]

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 3				
MEAN	225.	223.	222.	221.
% CHANGE		-0.9	-1.3	-1.8
S.D.	16.6	14.7	17.2	16.5
N	10	10	10	10
4				
MEAN	240.	241.	235.	233.
% CHANGE		0.4	-2.1	-2.9
S.D.	18.2	16.6	20.8	21.8
N	10	10	10	10
5				
MEAN	247.	250.	245.	242.
% CHANGE		1.2	-0.8	-2.0
S.D.	18.4	15.5	19.5	19.7
N	10	10	10	10
6				
MEAN	256.	262.	252.	251.
% CHANGE		2.3	-1.6	-2.0
S.D.	14.3	15.4	19.6	17.2
N	10	10	10	10
7				
MEAN	262.	270.	261.	256.
% CHANGE		3.1	-0.4	-2.3
S.D.	16.7	13.9	16.0	17.8
N	10	10	10	10

None significantly different from control group

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 7
SPONSOR:[redacted] SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-012

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 8				
MEAN	269.	275.	267.	264.
% CHANGE		2.2	-0.7	-1.9
S.D.	14.6	14.8	15.9	19.0
N	10	10	10	10
9				
MEAN	271.	280.	269.	267.
% CHANGE		3.3	-0.7	-1.5
S.D.	16.7	19.5	17.4	22.7
N	10	10	10	10
10				
MEAN	277.	288.	274.	276.
% CHANGE		4.0	-1.1	-0.4
S.D.	13.7	19.7	19.7	21.2
N	10	10	9	10
11				
MEAN	281.	291.	283.	282.
% CHANGE		3.6	0.7	0.4
S.D.	16.2	20.1	16.3	21.2
N	10	10	9	10
12				
MEAN	285.	296.	282.	282.
% CHANGE		3.9	-1.1	-1.1
S.D.	17.9	18.4	16.3	21.9
N	10	10	9	10

None significantly different from control group

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TABLE 5

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 13				
MEAN	285.	298.	285.	286.
% CHANGE		4.6	0.0	0.4
S.D.	16.4	21.0	17.1	21.6
N	10	10	9	10

None significantly different from control group

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 6
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -2 TO -1				
MEAN	59.	60.	59.	59.
S.D.	3.6	3.8	3.5	2.5
N	10	10	10	10
-1 TO 0				
MEAN	35.	33.	33.	32.
S.D.	3.9	5.9	3.1	3.4
N	10	10	10	10
0 TO 1				
MEAN	52.	54.	54.	51.
S.D.	9.2	10.4	7.1	5.4
N	10	10	10	10
1 TO 2				
MEAN	48.	48.	49.	41.
S.D.	7.6	9.6	7.4	13.8
N	10	10	10	10
2 TO 3				
MEAN	33.	32.	35.	30.
S.D.	8.8	9.5	6.2	8.7
N	10	10	10	10

None significantly different from control group

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TABLE 6

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 3 TO 4				
MEAN	41.	36.	34.	28.*
S.D.	7.9	9.7	12.3	5.8
N	10	10	10	10
4 TO 5				
MEAN	31.	28.	33.	30.
S.D.	6.6	6.6	8.5	6.9
N	10	10	10	10
5 TO 6				
MEAN	27.	24.	28.	20.
S.D.	6.7	8.3	6.0	7.2
N	10	10	10	10
6 TO 7				
MEAN	22.	21.	24.	15.
S.D.	8.4	6.4	6.1	4.0
N	10	10	10	10
7 TO 8				
MEAN	22.	15.	15.	17.
S.D.	7.8	17.9	14.1	8.4
N	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 6

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-012

	MALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 8 TO 9				
MEAN	18.	21.	16.	9.
S.D.	4.1	10.6	13.0	16.0
N	10	10	10	10
9 TO 10				
MEAN	4.	15.	18.	9.
S.D.	37.5	5.1	7.1	13.0
N	10	10	10	10
10 TO 11				
MEAN	16.	19.	14.	17.
S.D.	5.5	7.0	8.0	9.7
N	9	10	10	10
11 TO 12				
MEAN	7.	5.	10.	5.
S.D.	4.9	5.1	7.4	6.8
N	9	10	10	10
12 TO 13				
MEAN	9.	13.	9.	12.
S.D.	4.3	3.5	5.5	5.9
N	9	10	10	10

None significantly different from control group

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 6
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -2 TO -1				
MEAN	42.	43.	42.	40.
S.D.	4.7	4.5	3.6	4.1
N	10	10	10	10
-1 TO 0				
MEAN	18.	16.	15.	15.
S.D.	3.2	3.9	4.3	2.9
N	10	10	10	10
0 TO 1				
MEAN	21.	24.	22.	24.
S.D.	6.7	5.6	7.3	7.7
N	10	10	10	10
1 TO 2				
MEAN	21.	20.	21.	17.
S.D.	4.0	5.9	3.6	5.9
N	10	10	10	10
2 TO 3				
MEAN	15.	13.	13.	14.
S.D.	7.5	5.3	8.4	6.4
N	10	10	10	10

None significantly different from control group

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TABLE 6

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES			
GROUP:		0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 3 TO 4					
	MEAN	15.	18.	13.	13.
	S.D.	3.7	5.2	7.4	10.1
	N	10	10	10	10
4 TO 5					
	MEAN	7.	9.	10.	8.
	S.D.	4.8	6.5	8.5	8.4
	N	10	10	10	10
5 TO 6					
	MEAN	9.	13.	7.	9.
	S.D.	8.3	8.0	6.1	3.9
	N	10	10	10	10
6 TO 7					
	MEAN	7.	8.	8.	5.
	S.D.	5.8	4.9	6.3	3.4
	N	10	10	10	10
7 TO 8					
	MEAN	7.	5.	6.	8.
	S.D.	3.9	5.1	2.7	5.1
	N	10	10	10	10

None significantly different from control group

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TABLE 6

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 8 TO 9				
MEAN	2.	5.	2.	3.
S.D.	3.9	8.2	5.8	6.3
N	10	10	10	10
9 TO 10				
MEAN	6.	8.	5.	9.
S.D.	5.2	4.6	8.9	4.4
N	10	10	9	10
10 TO 11				
MEAN	4.	3.	9.	6.
S.D.	5.8	5.5	5.9	4.2
N	10	10	9	10
11 TO 12				
MEAN	4.	4.	-2.*	0.
S.D.	4.6	5.7	2.4	4.0
N	10	10	9	10
12 TO 13				
MEAN	0.	2.	3.	4.
S.D.	3.1	4.4	3.2	5.3
N	10	10	9	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 7
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

		MALES			
GROUP:		0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 1	MEAN	52.	54.	54.	51.
	S.D.	9.2	10.4	7.1	5.4
	N	10	10	10	10
0 TO 2	MEAN	100.	101.	103.	91.
	S.D.	15.8	18.6	12.5	17.2
	N	10	10	10	10
0 TO 3	MEAN	133.	133.	138.	121.
	S.D.	23.1	26.6	17.6	20.1
	N	10	10	10	10
0 TO 4	MEAN	173.	169.	173.	149.
	S.D.	29.1	34.5	22.0	23.7
	N	10	10	10	10
0 TO 5	MEAN	204.	197.	205.	179.
	S.D.	32.5	37.8	24.1	25.8
	N	10	10	10	10

None significantly different from control group

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		MALES			
	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK	0 TO 6				
	MEAN	231.	221.	233.	199.
	S.D.	36.7	43.4	25.5	27.6
	N	10	10	10	10
	0 TO 7				
	MEAN	253.	242.	257.	214.
	S.D.	41.7	47.9	30.2	28.0
	N	10	10	10	10
	0 TO 8				
	MEAN	275.	257.	273.	231.
	S.D.	46.6	61.0	29.6	30.9
	N	10	10	10	10
	0 TO 9				
	MEAN	293.	278.	288.	240.
	S.D.	48.7	60.5	34.9	31.9
	N	10	10	10	10
	0 TO 10				
	MEAN	297.	294.	307.	249.
	S.D.	74.1	60.4	35.6	39.9
	N	10	10	10	10

None significantly different from control group

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GROUP:		MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 11					
	MEAN	332.	313.	320.	265.*
	S.D.	45.2	62.5	39.5	36.9
	N	9	10	10	10
0 TO 12					
	MEAN	339.	318.	331.	270.*
	S.D.	45.5	64.0	43.2	34.1
	N	9	10	10	10
0 TO 13					
	MEAN	348.	330.	340.	282.*
	S.D.	49.0	65.0	45.6	37.5
	N	9	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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Modified: 8/30/2006

TABLE 7
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

		FEMALES			
GROUP:		0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 0 TO 1					
	MEAN	21.	24.	22.	24.
	S.D.	6.7	5.6	7.3	7.7
	N	10	10	10	10
0 TO 2					
	MEAN	42.	43.	43.	41.
	S.D.	6.5	9.0	8.2	12.2
	N	10	10	10	10
0 TO 3					
	MEAN	57.	56.	56.	55.
	S.D.	10.6	9.3	13.0	12.1
	N	10	10	10	10
0 TO 4					
	MEAN	72.	75.	69.	68.
	S.D.	11.5	11.0	16.1	17.9
	N	10	10	10	10
0 TO 5					
	MEAN	79.	84.	79.	76.
	S.D.	12.9	11.2	16.1	16.0
	N	10	10	10	10

None significantly different from control group

Audited Draft

Modified: 8/30/2006

TABLE 7

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 5
SPONSOR:[redacted] SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-012

		FEMALES			
	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK	0 TO 6				
	MEAN	88.	96.	86.	85.
	S.D.	7.5	10.0	15.7	14.1
	N	10	10	10	10
	0 TO 7				
	MEAN	95.	104.	95.	90.
	S.D.	11.7	8.8	13.7	15.7
	N	10	10	10	10
	0 TO 8				
	MEAN	101.	109.	101.	98.
	S.D.	10.0	11.3	12.9	16.5
	N	10	10	10	10
	0 TO 9				
	MEAN	103.	114.	103.	101.
	S.D.	11.5	16.3	14.8	20.0
	N	10	10	10	10
	0 TO 10				
	MEAN	109.	122.	107.	110.
	S.D.	8.3	15.6	17.2	18.5
	N	10	10	9	10

None significantly different from control group

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Modified: 8/30/2006

TABLE 7

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:06-012 — SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
WEEK 0 TO 11				
MEAN	113.	125.	116.	117.
S.D.	12.0	16.1	14.4	18.1
N	10	10	9	10
0 TO 12				
MEAN	117.	130.	114.	116.
S.D.	13.4	14.1	13.4	18.5
N	10	10	9	10
0 TO 13				
MEAN	118.	132.	117.	121.
S.D.	12.2	17.1	14.7	18.6
N	10	10	9	10

None significantly different from control group

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07/25/2006

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Modified: 8/30/2006

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 8
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -2 TO -1				
MEAN	22.	22.	22.	22.
% CHANGE		0.0	0.0	0.0
S.D.	0.7	0.7	1.1	0.7
N	10	10	10	10
0 TO 1				
MEAN	25.	25.	24.	23.*
% CHANGE		0.0	-4.0	-8.0
S.D.	2.1	2.3	1.9	1.3
N	10	10	10	10
1 TO 2				
MEAN	25.	26.	26.	25.
% CHANGE		4.0	4.0	0.0
S.D.	2.5	2.5	1.9	2.9
N	10	10	10	10
2 TO 3				
MEAN	25.	25.	26.	24.
% CHANGE		0.0	4.0	-4.0
S.D.	2.3	2.9	1.8	3.3
N	10	10	10	10
3 TO 4				
MEAN	24.	23.	24.	24.
% CHANGE		-4.2	0.0	0.0
S.D.	2.2	3.8	3.1	3.0
N	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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	MALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 4 TO 5				
MEAN	25.	25.	27.	25.
% CHANGE		0.0	8.0	0.0
S.D.	2.6	3.3	2.2	2.2
N	9	10	10	10
5 TO 6				
MEAN	25.	25.	26.	24.
% CHANGE		0.0	4.0	-4.0
S.D.	2.6	3.2	2.2	2.1
N	10	10	10	10
6 TO 7				
MEAN	25.	25.	26.	25.
% CHANGE		0.0	4.0	0.0
S.D.	3.4	3.4	1.8	2.8
N	10	10	10	10
7 TO 8				
MEAN	24.	23.	25.	24.
% CHANGE		-4.2	4.2	0.0
S.D.	2.6	5.3	2.1	2.0
N	10	10	10	10
8 TO 9				
MEAN	24.	24.	25.	24.
% CHANGE		0.0	4.2	0.0
S.D.	2.5	3.3	2.3	4.0
N	10	10	10	10

None significantly different from control group

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Modified: 8/30/2006

TABLE 8

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

SPONSOR NO.:06-012

	MALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 9 TO 10				
MEAN	23.	24.	25.	23.
% CHANGE		4.3	8.7	0.0
S.D.	4.5	3.4	2.1	3.7
N	10	10	10	10
10 TO 11				
MEAN	24.	24.	24.	24.
% CHANGE		0.0	0.0	0.0
S.D.	1.7	3.1	2.7	2.0
N	9	10	10	10
11 TO 12				
MEAN	24.	23.	25.	24.
% CHANGE		-4.2	4.2	0.0
S.D.	2.5	2.9	2.4	2.2
N	9	10	10	10
12 TO 13				
MEAN	24.	23.	25.	24.
% CHANGE		-4.2	4.2	0.0
S.D.	2.2	2.4	2.4	2.1
N	9	10	10	10

None significantly different from control group

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TABLE 8

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:06-012 — SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK -2 TO -1				
MEAN	19.	19.	18.	19.
% CHANGE		0.0	-5.3	0.0
S.D.	1.2	1.4	1.2	1.6
N	10	10	10	10
0 TO 1				
MEAN	19.	18.	17.	18.
% CHANGE		-5.3	-10.5	-5.3
S.D.	2.0	1.6	1.8	1.8
N	10	10	10	10
1 TO 2				
MEAN	18.	17.	17.	18.
% CHANGE		-5.6	-5.6	0.0
S.D.	1.3	1.2	1.5	2.4
N	10	9	10	9
2 TO 3				
MEAN	19.	18.	18.	21.*
% CHANGE		-5.3	-5.3	10.5
S.D.	1.6	1.8	2.3	2.7
N	10	10	10	10
3 TO 4				
MEAN	17.	18.	16.	18.
% CHANGE		5.9	-5.9	5.9
S.D.	1.4	1.6	1.9	2.1
N	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 8

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

SPONSOR NO.:06-012

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 4 TO 5				
MEAN	18.	18.	17.	19.
% CHANGE		0.0	-5.6	5.6
S.D.	1.5	1.6	1.8	1.5
N	10	10	10	10
5 TO 6				
MEAN	17.	18.	16.	19.
% CHANGE		5.9	-5.9	11.8
S.D.	1.7	1.5	1.6	2.3
N	10	10	10	10
6 TO 7				
MEAN	17.	19.	17.	19.
% CHANGE		11.8	0.0	11.8
S.D.	1.8	2.5	1.3	2.2
N	10	10	9	10
7 TO 8				
MEAN	17.	17.	17.	19.**
% CHANGE		0.0	0.0	11.8
S.D.	1.8	1.5	2.1	1.9
N	10	10	10	10
8 TO 9				
MEAN	16.	17.	16.	19.**
% CHANGE		6.3	0.0	18.8
S.D.	1.7	1.8	0.9	2.4
N	10	10	10	9

** = Significantly different from the control group at 0.01 using Dunnett's test

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 8
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF FOOD CONSUMPTION [G/ANIMAL/DAY]

	FEMALES			
GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
WEEK 9 TO 10				
MEAN	17.	17.	16.	19.
% CHANGE		0.0	-5.9	11.8
S.D.	1.5	1.4	1.9	3.2
N	10	10	9	10
10 TO 11				
MEAN	16.	17.	16.	20.**
% CHANGE		6.3	0.0	25.0
S.D.	1.4	1.4	0.9	2.7
N	10	10	9	10
11 TO 12				
MEAN	17.	17.	16.	18.
% CHANGE		0.0	-5.9	5.9
S.D.	1.6	1.4	1.6	2.2
N	10	10	9	10
12 TO 13				
MEAN	16.	16.	17.	18.*
% CHANGE		0.0	6.3	12.5
S.D.	1.5	1.4	1.4	2.4
N	10	10	9	10

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1
SPONSOR: [redacted]
SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
WHITE CELLS (thous/uL)				
WEEK 13 MEAN	8.57	8.82	8.88	9.60
% CHANGE		2.9	3.6	12.0
S.D.	2.710	2.040	2.406	2.630
N	8	10	8	9
RED CELLS (mil/uL)				
WEEK 13 MEAN	9.13	9.25	8.94	8.93
% CHANGE		1.3	-2.1	-2.2
S.D.	0.414	0.283	0.363	0.289
N	8	10	8	9
HEMOGLOBIN (g/dL)				
WEEK 13 MEAN	16.3	16.4	16.2	15.9
% CHANGE		0.6	-0.6	-2.5
S.D.	0.47	0.46	0.64	0.65
N	8	10	8	9
HEMATOCRIT (%)				
WEEK 13 MEAN	49.8	50.0	49.1	47.8
% CHANGE		0.4	-1.4	-4.0
S.D.	1.78	1.85	1.54	2.33
N	8	10	8	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

Audited Draft

Modified: 8/30/2006

TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS	GROUP:	MALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MCV (fL)					
WEEK 13	MEAN	54.7	54.1	55.0	53.5
	% CHANGE		-1.1	0.5	-2.2
	S.D.	2.97	1.64	1.36	1.73
	N	8	10	8	9
MCH (pg)					
WEEK 13	MEAN	17.9	17.7	18.2	17.8
	% CHANGE		-1.1	1.7	-0.6
	S.D.	0.88	0.65	0.45	0.51
	N	8	10	8	9
MCHC (g/dL)					
WEEK 13	MEAN	32.7	32.7	33.0	33.2
	% CHANGE		0.0	0.9	1.5
	S.D.	0.67	0.87	0.38	0.52
	N	8	10	8	9
PLATELET (thous/uL)					
WEEK 13	MEAN	910.	1010.	1041.	1071.
	% CHANGE		11.0	14.4	17.7
	S.D.	224.8	139.8	148.3	122.3
	N	8	10	8	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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Modified: 8/30/2006

TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES			
PROTIME (seconds)					
WEEK 13	MEAN	16.9	18.1	19.1	25.9**
	% CHANGE		7.1	13.0	53.3
	S.D.	2.08	2.36	2.69	3.84
	N	9	10	10	10
APTT (seconds)					
WEEK 13	MEAN	19.7	21.9*	23.1**	28.5**
	% CHANGE		11.2	17.3	44.7
	S.D.	0.90	1.23	1.41	3.25
	N	9	10	10	10
RETICULOCYTE (%)					
WEEK 13	MEAN	1.7	1.6	1.5	1.6
	% CHANGE		-5.9	-11.8	-5.9
	S.D.	0.16	0.28	0.34	0.42
	N	8	10	8	9
RETIC ABSOLUTE (thous/uL)					
WEEK 13	MEAN	150.7	143.4	138.2	141.6
	% CHANGE		-4.8	-8.3	-6.0
	S.D.	14.68	26.04	28.76	38.46
	N	8	10	8	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES			
NEUTROPHIL (%)					
WEEK 13	MEAN	15.1	14.5	15.4	14.3
	% CHANGE		-4.0	2.0	-5.3
	S.D.	5.72	5.41	4.69	4.03
	N	8	10	8	9
LYMPHOCYTE (%)					
WEEK 13	MEAN	80.1	81.7	80.4	81.8
	% CHANGE		2.0	0.4	2.1
	S.D.	6.45	5.50	5.42	4.23
	N	8	10	8	9
MONOCYTE (%)					
WEEK 13	MEAN	1.8	1.3	1.8	1.4
	% CHANGE		-27.8	0.0	-22.2
	S.D.	0.56	0.26	0.67	0.40
	N	8	10	8	9
EOSINOPHIL (%)					
WEEK 13	MEAN	1.9	1.5	1.4	1.5
	% CHANGE		-21.1	-26.3	-21.1
	S.D.	0.84	0.44	0.62	0.37
	N	8	10	8	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

MALES

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BASOPHIL (%)				
WEEK 13 MEAN	0.4	0.4	0.4	0.4
% CHANGE		0.0	0.0	0.0
S.D.	0.07	0.15	0.19	0.10
N	8	10	8	9
LG UNSTAIN CELL (%)				
WEEK 13 MEAN	0.8	0.6	0.6	0.7
% CHANGE		-25.0	-25.0	-12.5
S.D.	0.26	0.15	0.29	0.16
N	8	10	8	9
NEU ABSOLUTE (thous/uL)				
WEEK 13 MEAN	1.37	1.29	1.33	1.35
% CHANGE		-5.8	-2.9	-1.5
S.D.	0.956	0.595	0.396	0.440
N	8	10	8	9
LYMPH ABSOLUTE (thous/uL)				
WEEK 13 MEAN	6.79	7.20	7.19	7.87
% CHANGE		6.0	5.9	15.9
S.D.	1.762	1.696	2.163	2.290
N	8	10	8	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

MALES

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MONO ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.16	0.12	0.15	0.13
% CHANGE		-25.0	-6.3	-18.8
S.D.	0.092	0.029	0.046	0.046
N	8	10	8	9
EOS ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.15	0.13	0.12	0.14
% CHANGE		-13.3	-20.0	-6.7
S.D.	0.063	0.059	0.043	0.050
N	8	10	8	9
BASO ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.03	0.04	0.03	0.04
% CHANGE		33.3	0.0	33.3
S.D.	0.015	0.021	0.019	0.017
N	8	10	8	9
LUC ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.07	0.06	0.05	0.07
% CHANGE		-14.3	-28.6	0.0
S.D.	0.048	0.019	0.031	0.029
N	8	10	8	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
WHITE CELLS (thous/uL)				
WEEK 13 MEAN	5.90	6.43	6.13	6.08
% CHANGE		9.0	3.9	3.1
S.D.	1.497	0.819	1.078	1.767
N	8	9	9	9
RED CELLS (mil/uL)				
WEEK 13 MEAN	8.25	8.37	8.25	8.07
% CHANGE		1.5	0.0	-2.2
S.D.	0.601	0.260	0.251	0.352
N	8	9	9	9
HEMOGLOBIN (g/dL)				
WEEK 13 MEAN	15.5	15.7	15.5	15.4
% CHANGE		1.3	0.0	-0.6
S.D.	0.67	0.49	0.56	0.43
N	8	9	9	9
HEMATOCRIT (%)				
WEEK 13 MEAN	46.5	46.8	46.1	45.9
% CHANGE		0.6	-0.9	-1.3
S.D.	2.28	1.90	2.03	1.10
N	8	9	9	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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Modified: 8/30/2006

TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS	GROUP:	FEMALES 0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
MCV (fL)					
WEEK 13	MEAN	56.5	56.0	55.8	56.9
	% CHANGE		-0.9	-1.2	0.7
	S.D.	3.36	1.80	1.46	2.07
	N	8	9	9	9
MCH (pg)					
WEEK 13	MEAN	18.8	18.8	18.7	19.1
	% CHANGE		0.0	-0.5	1.6
	S.D.	0.85	0.51	0.38	0.52
	N	8	9	9	9
MCHC (g/dL)					
WEEK 13	MEAN	33.3	33.5	33.6	33.5
	% CHANGE		0.6	0.9	0.6
	S.D.	0.78	0.50	0.66	0.59
	N	8	9	9	9
PLATELET (thous/uL)					
WEEK 13	MEAN	850.	1105.	1129.*	1072.
	% CHANGE		30.0	32.8	26.1
	S.D.	372.8	143.2	174.1	85.9
	N	8	9	9	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES

SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
	FEMALES			
PROTIME (seconds)				
WEEK 13 MEAN	12.2	12.2	12.7	12.4
% CHANGE		0.0	4.1	1.6
S.D.	0.48	0.42	1.11	0.40
N	10	10	9	10
APTT (seconds)				
WEEK 13 MEAN	17.5	18.0	18.5	18.2
% CHANGE		2.9	5.7	4.0
S.D.	0.94	2.16	0.87	1.19
N	10	10	9	10
RETICULOCYTE (%)				
WEEK 13 MEAN	1.8	1.6	1.6	1.7
% CHANGE		-11.1	-11.1	-5.6
S.D.	0.29	0.31	0.26	0.44
N	8	9	9	9
RETIC ABSOLUTE (thous/uL)				
WEEK 13 MEAN	145.9	132.2	135.3	137.5
% CHANGE		-9.4	-7.3	-5.8
S.D.	23.93	24.45	22.99	39.73
N	8	9	9	9

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None significantly different from control group

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
NEUTROPHIL (%)				
WEEK 13 MEAN	13.4	13.4	14.4	13.0
% CHANGE		0.0	7.5	-3.0
S.D.	5.50	4.52	3.09	4.67
N	8	9	9	9
LYMPHOCYTE (%)				
WEEK 13 MEAN	82.2	83.3	81.4	82.9
% CHANGE		1.3	-1.0	0.9
S.D.	5.96	4.66	3.59	5.64
N	8	9	9	9
MONOCYTE (%)				
WEEK 13 MEAN	1.5	1.2	1.5	1.3
% CHANGE		-20.0	0.0	-13.3
S.D.	0.45	0.58	0.49	0.27
N	8	9	9	9
EOSINOPHIL (%)				
WEEK 13 MEAN	1.8	1.4	1.6	1.7
% CHANGE		-22.2	-11.1	-5.6
S.D.	0.83	0.44	0.55	0.99
N	8	9	9	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 11
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF HEMATOLOGY VALUES

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
BASOPHIL (%)				
WEEK 13 MEAN	0.3	0.3	0.4	0.3
% CHANGE		0.0	33.3	0.0
S.D.	0.12	0.18	0.07	0.08
N	8	9	9	9
LG UNSTAIN CELL (%)				
WEEK 13 MEAN	0.7	0.5	0.7	0.8
% CHANGE		-28.6	0.0	14.3
S.D.	0.19	0.36	0.21	0.25
N	8	9	9	9
NEU ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.76	0.84	0.87	0.79
% CHANGE		10.5	14.5	3.9
S.D.	0.244	0.263	0.191	0.392
N	8	9	9	9
LYMPH ABSOLUTE (thous/uL)				
WEEK 13 MEAN	4.89	5.37	5.00	5.04
% CHANGE		9.8	2.2	3.1
S.D.	1.467	0.840	0.989	1.481
N	8	9	9	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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TABLE 9

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
MONO ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.09	0.07	0.09	0.08
% CHANGE		-22.2	0.0	-11.1
S.D.	0.030	0.032	0.033	0.036
N	8	9	9	9
EOS ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.10	0.09	0.10	0.10
% CHANGE		-10.0	0.0	0.0
S.D.	0.042	0.035	0.032	0.053
N	8	9	9	9
BASO ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.02	0.02	0.02	0.02
% CHANGE		0.0	0.0	0.0
S.D.	0.011	0.013	0.004	0.009
N	8	9	9	9
LUC ABSOLUTE (thous/uL)				
WEEK 13 MEAN	0.05	0.03	0.04	0.05
% CHANGE		-40.0	-20.0	0.0
S.D.	0.018	0.024	0.016	0.027
N	8	9	9	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

None significantly different from control group

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
ALBUMIN (g/dL)				
WEEK 13 MEAN	4.4	4.4	4.4	4.3
% CHANGE		0.0	0.0	-2.3
S.D.	0.13	0.25	0.24	0.20
N	9	10	10	10
TOTAL PROTEIN (g/dL)				
WEEK 13 MEAN	7.0	6.8	6.8	6.4**
% CHANGE		-2.9	-2.9	-8.6
S.D.	0.24	0.27	0.30	0.22
N	9	10	10	10
GLOBULIN (g/dL)				
WEEK 13 MEAN	2.6	2.4	2.4	2.1**
% CHANGE		-7.7	-7.7	-19.2
S.D.	0.22	0.18	0.23	0.12
N	9	10	10	10
A/G RATIO				
WEEK 13 MEAN	1.69	1.84	1.88	2.03**
% CHANGE		8.9	11.2	20.1
S.D.	0.176	0.177	0.234	0.158
N	9	10	10	10

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** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
TOTAL BILI (mg/dL)				
WEEK 13 MEAN	0.1	0.1	0.1	0.1
% CHANGE		0.0	0.0	0.0
S.D.	0.05	0.05	0.04	0.03
N	9	10	10	10
UREA NITROGEN (mg/dL)				
WEEK 13 MEAN	10.8	11.4	11.8	11.7
% CHANGE		5.6	9.3	8.3
S.D.	1.22	1.09	1.44	1.69
N	9	10	10	10
CREATININE (mg/dL)				
WEEK 13 MEAN	0.3	0.3	0.3	0.2
% CHANGE		0.0	0.0	-33.3
S.D.	0.07	0.05	0.04	0.07
N	9	10	10	10
ALKALINEPHOS'TSE (U/L)				
WEEK 13 MEAN	91.	132.*	166.**	178.**
% CHANGE		45.1	82.4	95.6
S.D.	14.0	45.9	27.0	30.5
N	9	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

* = Significantly different from the control group at 0.05 using Dunnett's test
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TABLE 10
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
ALANINE TRANSFER (U/L)				
WEEK 13 MEAN	38.	44.	80.	248.**
% CHANGE		15.8	110.5	552.6
S.D.	5.2	12.8	12.9	77.5
N	9	10	10	10
ASPARTATTRANSFER (U/L)				
WEEK 13 MEAN	70.	71.	79.	122.**
% CHANGE		1.4	12.9	74.3
S.D.	8.5	8.0	8.7	16.6
N	9	10	10	10
GLUCOSE (mg/dL)				
WEEK 13 MEAN	124.	124.	128.	115.
% CHANGE		0.0	3.2	-7.3
S.D.	10.9	12.0	16.6	13.0
N	9	10	10	10
CHOLESTEROL (mg/dL)				
WEEK 13 MEAN	52.	64.	61.	60.
% CHANGE		23.1	17.3	15.4
S.D.	12.1	8.9	12.2	13.0
N	9	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES

SPONSOR NO.:06-012

		MALES			
ANALYSIS	GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
CALCIUM (mg/dL)					
WEEK 13	MEAN	10.9	10.8	10.8	10.7
	% CHANGE		-0.9	-0.9	-1.8
	S.D.	0.31	0.11	0.29	0.30
	N	9	10	10	10
CHLORIDE (mEq/L)					
WEEK 13	MEAN	103.	103.	103.	104.
	% CHANGE		0.0	0.0	1.0
	S.D.	1.6	0.7	1.6	1.6
	N	9	10	10	10
PHOSPHORUS (mg/dL)					
WEEK 13	MEAN	7.0	6.7	7.0	7.2
	% CHANGE		-4.3	0.0	2.9
	S.D.	0.49	0.55	0.45	0.44
	N	9	10	10	10
POTASSIUM (mEq/L)					
WEEK 13	MEAN	4.70	4.78	4.62	4.53
	% CHANGE		1.7	-1.7	-3.6
	S.D.	0.308	0.584	0.455	0.301
	N	9	10	10	10

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None significantly different from control group

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES

SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
SODIUM (mEq/L)				
WEEK 13 MEAN	144.	144.	144.	145.
% CHANGE		0.0	0.0	0.7
S.D.	1.9	0.8	1.7	1.3
N	9	10	10	10
TRIGLYCERIDE (mg/dL)				
WEEK 13 MEAN	62.	79.	91.	83.
% CHANGE		27.4	46.8	33.9
S.D.	18.5	29.5	21.5	35.9
N	9	10	10	10

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None significantly different from control group

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
ALBUMIN (g/dL)				
WEEK 13 MEAN	5.1	5.2	5.0	5.1
% CHANGE		2.0	-2.0	0.0
S.D.	0.36	0.34	0.32	0.43
N	10	10	9	10
TOTAL PROTEIN (g/dL)				
WEEK 13 MEAN	7.4	7.4	7.0	7.1
% CHANGE		0.0	-5.4	-4.1
S.D.	0.35	0.56	0.40	0.45
N	10	10	9	10
GLOBULIN (g/dL)				
WEEK 13 MEAN	2.3	2.2	2.1	2.0*
% CHANGE		-4.3	-8.7	-13.0
S.D.	0.19	0.28	0.24	0.19
N	10	10	9	10
A/G RATIO				
WEEK 13 MEAN	2.26	2.40	2.49	2.61
% CHANGE		6.2	10.2	15.5
S.D.	0.286	0.257	0.364	0.373
N	10	10	9	10

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	FEMALES 160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
TOTAL BILI (mg/dL)				
WEEK 13 MEAN	0.2	0.2	0.2	0.1
% CHANGE		0.0	0.0	-50.0
S.D.	0.05	0.05	0.05	0.05
N	10	10	9	10
UREA NITROGEN (mg/dL)				
WEEK 13 MEAN	12.5	14.1	13.4	15.9
% CHANGE		12.8	7.2	27.2
S.D.	1.63	1.80	1.23	5.57
N	10	10	9	10
CREATININE (mg/dL)				
WEEK 13 MEAN	0.3	0.3	0.3	0.4
% CHANGE		0.0	0.0	33.3
S.D.	0.08	0.06	0.03	0.07
N	10	10	9	10
ALKALINEPHOS'TSE (U/L)				
WEEK 13 MEAN	47.	79.*	81.*	122.**
% CHANGE		68.1	72.3	159.6
S.D.	8.4	26.5	14.7	38.7
N	10	10	9	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
ALANINE TRANSFER (U/L)				
WEEK 13 MEAN	32.	37.	55.	181.**
% CHANGE		15.6	71.9	465.6
S.D.	10.2	9.6	15.4	113.5
N	10	10	9	10
ASPARTATTRANSFER (U/L)				
WEEK 13 MEAN	68.	77.	79.	112.**
% CHANGE		13.2	16.2	64.7
S.D.	15.9	16.0	17.1	32.5
N	10	10	9	10
GLUCOSE (mg/dL)				
WEEK 13 MEAN	112.	110.	110.	110.
% CHANGE		-1.8	-1.8	-1.8
S.D.	11.3	8.6	11.1	6.3
N	10	10	9	10
CHOLESTEROL (mg/dL)				
WEEK 13 MEAN	73.	72.	60.	57.*
% CHANGE		-1.4	-17.8	-21.9
S.D.	5.5	19.1	8.7	7.7
N	10	10	9	10

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* = Significantly different from the control group at 0.05 using Dunnett's test
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TABLE 10

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 9
SPONSOR: [redacted] SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	FEMALES 160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
CALCIUM (mg/dL)				
WEEK 13 MEAN	11.1	11.1	10.9	10.9
% CHANGE		0.0	-1.8	-1.8
S.D.	0.35	0.26	0.31	0.33
N	10	10	9	10
CHLORIDE (mEq/L)				
WEEK 13 MEAN	104.	103.	104.	105.
% CHANGE		-1.0	0.0	1.0
S.D.	1.6	2.0	1.0	1.0
N	10	10	9	10
PHOSPHORUS (mg/dL)				
WEEK 13 MEAN	6.1	6.1	6.1	6.2
% CHANGE		0.0	0.0	1.6
S.D.	0.82	0.55	0.69	0.85
N	10	10	9	10
POTASSIUM (mEq/L)				
WEEK 13 MEAN	4.40	4.52	4.44	4.48
% CHANGE		2.7	0.9	1.8
S.D.	0.417	0.312	0.337	0.384
N	10	10	9	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

None significantly different from control group

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TABLE 10

SPONSOR:[redacted]
SUMMARY OF SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANALYSIS GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
SODIUM (mEq/L)				
WEEK 13 MEAN	144.	144.	144.	145.
% CHANGE		0.0	0.0	0.7
S.D.	1.3	1.2	1.5	0.9
N	10	10	9	10
TRIGLYCERIDE (mg/dL)				
WEEK 13 MEAN	45.	57.	52.	55.
% CHANGE		26.7	15.6	22.2
S.D.	9.6	19.6	9.3	11.4
N	10	10	9	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

None significantly different from control group

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TABLE 11 (WEEK -1 PRETEST EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF OPHTHALMIC EXAMINATION FINDINGS
SPONSOR NO.:06-012

	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10	10	10	10	10
NUMBER OF ANIMALS EXAMINED EXAM 1(WEEK -1)	10	10	10	10	10	10	10	10
-NO OCULAR LESIONS - BILATERAL	8	9	8	8	8	6	10	7
-CORNEAL CRYSTALS - BILATERAL	2	1	2	2	2	4	0	3

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 12 (WEEK 12 EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF OPHTHALMIC EXAMINATION FINDINGS

	MALE				FEMALE			
GROUP:	1	2	3	4	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10	10	10	10	10
NUMBER OF ANIMALS EXAMINED EXAM 2(WEEK 12)	9	10	10	10	10	10	9	10
-NO OCULAR LESIONS - BILATERAL	6	9	10	9	10	10	9	10
-CORNEAL CRYSTALS - BILATERAL	3	1	0	1	0	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

POPSIv4.01
07/25/2006

Audited Draft

Modified: 8/30/2006

TABLE 13 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:06-012

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
CECUM				
-DISTENDED	1	0	0	0
ILEUM				
-DISTENDED	1	0	0	0
SKIN				
-MATTING, RED	1	0	0	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	0	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

Audited Draft

Modified: 8/30/2006

TABLE 13 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
SUMMARY OF MACROSCOPIC FINDINGS
SPONSOR NO.:06-012

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- F E M A L E -----			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

PGRSI2v4.07
08/14/2006

187054 AD

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Modified: 8/30/2006

TABLE 14 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:06-012

SCHEDULED NECROPSY

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	10	10	10
KIDNEYS				
-AREA(S), DEPRESSED	0	0	0	1
-DILATED PELVIS	0	0	1	0
L.N. POP, RT				
-SMALL	0	0	1	0
LUNGS				
-AREA(S), DARK RED	0	1	0	0
LYMPH NODE, MAND				
-DISCOLORATION, DARK RED	0	2	1	1
SEMINAL VESICLES				
-SMALL	0	0	1	0
SKIN				
-OPEN SORE(S)	1	0	0	0
TEETH				
-FRACTURED	0	1	0	0
-MALALIGNED	1	0	0	1
-MISSING	0	1	0	0
TESTES				
-SMALL	0	1	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

187054 AD

Audited Draft

Modified: 8/30/2006

TABLE 14 (SCHEDULED NECROPSY)

SPONSOR: [redacted]
SUMMARY OF MACROSCOPIC FINDINGS
SPONSOR NO.:06-012

SCHEDULED NECROPSY

	MALE			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	10	10	10
THYMUS				
-AREA(S), DARK RED	2	0	0	2
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	7	5	6	6

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

Audited Draft

Modified: 8/30/2006

TABLE 14 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SUMMARY OF MACROSCOPIC FINDINGS
SPONSOR NO.:06-012

SCHEDULED NECROPSY

	----- FEMALE -----			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	10	9	10
KIDNEYS				
-AREA(S), DEPRESSED	0	1	0	0
L.N. POP, LT				
-DISCOLORATION, DARK RED	1	0	0	0
L.N. POP, RT				
-DISCOLORATION, DARK RED	1	0	0	0
LYMPH NODE, MAND				
-DISCOLORATION, DARK RED	2	1	2	0
LYMPH NODE, MES				
-DISCOLORATION, DARK RED	1	0	0	0
SPLEEN				
-ROUGH SURFACE	0	0	1	0
STOMACH				
-AREA(S), DARK RED	1	0	0	0
TEETH				
-FRACTURED	0	1	0	0
-MALALIGNED	0	0	0	1
THYMUS				
-AREA(S), DARK RED	1	0	2	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

Audited Draft

Modified: 8/30/2006

TABLE 14 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:06-012

SCHEDULED NECROPSY

	----- FEMALE -----			
GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	10	9	10
UTERUS				
-CONTENTS, CLEAR FLUID	2	2	0	2
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	4	6	6	7

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

PGRSI2v4.07
08/14/2006

Audited Draft

Modified: 8/30/2006

TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
FINAL BODY WT (G)				
MEAN	540.	521.	529.	468.*
% CHANGE		-3.5	-2.0	-13.3
S.D.	52.4	67.9	46.2	37.3
N	9	10	10	10
ADRENAL GLANDS (G)				
MEAN	0.0658	0.0611	0.0641	0.0619
% CHANGE		-7.1	-2.6	-5.9
S.D.	0.01108	0.00818	0.00637	0.00763
N	9	10	10	9
ADRENAL GLANDS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.012	0.012	0.012	0.013
% CHANGE		0.0	0.0	8.3
S.D.	0.0010	0.0009	0.0014	0.0018
N	9	10	10	9
ADRENAL GLANDS (G/100 G BRAIN)				
MEAN	3.162	2.856	3.080	3.031
% CHANGE		-9.7	-2.6	-4.1
S.D.	0.4459	0.3315	0.3439	0.3566
N	9	10	10	9
BRAIN (G)				
MEAN	2.08	2.14	2.08	2.03
% CHANGE		2.9	0.0	-2.4
S.D.	0.117	0.064	0.045	0.072
N	9	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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Modified: 8/30/2006

TABLE 15

SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BRAIN (G/100 G FINAL BODY WEIGHT)				
MEAN	0.387	0.416	0.397	0.435*
% CHANGE		7.5	2.6	12.4
S.D.	0.0338	0.0494	0.0343	0.0242
N	9	10	10	10
EPIDIDYMIDES (G)				
MEAN	1.40	1.31	1.35	1.34
% CHANGE		-6.4	-3.6	-4.3
S.D.	0.145	0.100	0.084	0.088
N	9	10	10	10
EPIDIDYMIDES (G/100 G FINAL BODY WEIGHT)				
MEAN	0.260	0.255	0.258	0.289
% CHANGE		-1.9	-0.8	11.2
S.D.	0.0213	0.0325	0.0322	0.0298
N	9	10	10	10
EPIDIDYMIDES (G/100 G BRAIN)				
MEAN	67.338	61.351	64.861	66.331
% CHANGE		-8.9	-3.7	-1.5
S.D.	6.5066	4.6615	4.6381	5.1503
N	9	10	10	10
HEART (G)				
MEAN	1.73	1.74	1.74	1.51*
% CHANGE		0.6	0.6	-12.7
S.D.	0.248	0.208	0.194	0.106
N	9	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-012 SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
HEART (G/100 G FINAL BODY WEIGHT)				
MEAN	0.319	0.335	0.329	0.324
% CHANGE		5.0	3.1	1.6
S.D.	0.0269	0.0258	0.0243	0.0419
N	9	10	10	10
HEART (G/100 G BRAIN)				
MEAN	83.102	81.173	83.393	74.413
% CHANGE		-2.3	0.4	-10.5
S.D.	10.9013	8.4354	9.7809	6.8341
N	9	10	10	10
KIDNEYS (G)				
MEAN	3.95	3.80	3.98	3.88
% CHANGE		-3.8	0.8	-1.8
S.D.	0.334	0.337	0.368	0.260
N	9	10	10	10
KIDNEYS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.733	0.736	0.755	0.831**
% CHANGE		0.4	3.0	13.4
S.D.	0.0432	0.0618	0.0639	0.0541
N	9	10	10	10
KIDNEYS (G/100 G BRAIN)				
MEAN	189.948	177.796	191.225	191.128
% CHANGE		-6.4	0.7	0.6
S.D.	12.9704	13.8781	18.5734	8.5662
N	9	10	10	10

** = Significantly different from the control group at 0.01 using Dunnett's test

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Modified: 8/30/2006

TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		MALES		
L.N. POP, LT (G)				
MEAN	0.0103	0.0106	0.0122	0.0089
% CHANGE		2.9	18.4	-13.6
S.D.	0.00256	0.00448	0.00405	0.00350
N	9	10	10	10
L.N. POP, LT (G/100 G FINAL BODY WEIGHT)				
MEAN	0.002	0.002	0.002	0.002
% CHANGE		0.0	0.0	0.0
S.D.	0.0007	0.0010	0.0007	0.0009
N	9	10	10	10
L.N. POP, LT (G/100 G BRAIN)				
MEAN	0.498	0.497	0.588	0.439
% CHANGE		-0.2	18.1	-11.8
S.D.	0.1332	0.2125	0.1959	0.1787
N	9	10	10	10
L.N. POP, RT (G)				
MEAN	0.0121	0.0111	0.0142	0.0102
% CHANGE		-8.3	17.4	-15.7
S.D.	0.00512	0.00607	0.00582	0.00425
N	9	10	10	10
L.N. POP, RT (G/100 G FINAL BODY WEIGHT)				
MEAN	0.002	0.002	0.003	0.002
% CHANGE		0.0	50.0	0.0
S.D.	0.0010	0.0015	0.0011	0.0009
N	9	10	10	10

None significantly different from control group

Audited Draft

Modified: 8/30/2006

TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
L.N. POP, RT (G/100 G BRAIN)				
MEAN	0.584	0.520	0.685	0.505
% CHANGE		-11.0	17.3	-13.5
S.D.	0.2521	0.2878	0.2828	0.2117
N	9	10	10	10
LIVER (G)				
MEAN	16.10	15.50	16.99	14.43
% CHANGE		-3.7	5.5	-10.4
S.D.	1.983	2.235	2.472	1.545
N	9	10	10	10
LIVER (G/100 G FINAL BODY WEIGHT)				
MEAN	2.979	2.976	3.204	3.084
% CHANGE		-0.1	7.6	3.5
S.D.	0.1814	0.1633	0.2346	0.2633
N	9	10	10	10
LIVER (G/100 G BRAIN)				
MEAN	774.528	724.482	816.702	710.615
% CHANGE		-6.5	5.4	-8.3
S.D.	85.1301	93.5736	126.6916	63.6134
N	9	10	10	10
PROSTATE (G)				
MEAN	0.90	0.76	0.84	0.83
% CHANGE		-15.6	-6.7	-7.8
S.D.	0.146	0.230	0.177	0.203
N	9	10	10	10

None significantly different from control group

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Modified: 8/30/2006

TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
PROSTATE (G/100 G FINAL BODY WEIGHT)				
MEAN	0.168	0.147	0.158	0.179
% CHANGE		-12.5	-6.0	6.5
S.D.	0.0319	0.0469	0.0318	0.0500
N	9	10	10	10
PROSTATE (G/100 G BRAIN)				
MEAN	43.422	35.218	40.167	40.877
% CHANGE		-18.9	-7.5	-5.9
S.D.	7.4664	10.2114	8.5922	10.3056
N	9	10	10	10
SEM VES/CG (G)				
MEAN	2.18	1.94	2.01	2.12
% CHANGE		-11.0	-7.8	-2.8
S.D.	0.428	0.243	0.280	0.232
N	9	10	10	10
SEM VES/CG (G/100 G FINAL BODY WEIGHT)				
MEAN	0.404	0.377	0.382	0.456
% CHANGE		-6.7	-5.4	12.9
S.D.	0.0707	0.0580	0.0594	0.0741
N	9	10	10	10
SEM VES/CG (G/100 G BRAIN)				
MEAN	104.635	90.607	96.478	104.558
% CHANGE		-13.4	-7.8	-0.1
S.D.	17.9857	10.1725	13.4445	13.2353
N	9	10	10	10

None significantly different from control group

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SPLEEN (G)				
MEAN	0.76	0.73	0.77	0.73
% CHANGE		-3.9	1.3	-3.9
S.D.	0.119	0.158	0.106	0.090
N	9	10	10	10
SPLEEN (G/100 G FINAL BODY WEIGHT)				
MEAN	0.140	0.139	0.144	0.158
% CHANGE		-0.7	2.9	12.9
S.D.	0.0169	0.0221	0.0138	0.0222
N	9	10	10	10
SPLEEN (G/100 G BRAIN)				
MEAN	36.349	33.958	36.742	36.197
% CHANGE		-6.6	1.1	-0.4
S.D.	4.8923	7.0992	5.2322	4.3843
N	9	10	10	10
TESTES (G)				
MEAN	3.59	3.67	3.49	3.56
% CHANGE		2.2	-2.8	-0.8
S.D.	0.302	0.368	0.195	0.281
N	9	10	10	10
TESTES (G/100 G FINAL BODY WEIGHT)				
MEAN	0.669	0.713	0.664	0.764*
% CHANGE		6.6	-0.7	14.2
S.D.	0.0616	0.0894	0.0684	0.0878
N	9	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 8
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
TESTES (G/100 G BRAIN)				
MEAN	173.025	171.838	167.542	175.586
% CHANGE		-0.7	-3.2	1.5
S.D.	12.8406	15.4325	11.2630	14.8344
N	9	10	10	10
THYMUS (G)				
MEAN	0.2669	0.2754	0.3017	0.2381
% CHANGE		3.2	13.0	-10.8
S.D.	0.02969	0.04774	0.07467	0.04094
N	9	10	10	10
THYMUS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.050	0.053	0.057	0.051
% CHANGE		6.0	14.0	2.0
S.D.	0.0055	0.0105	0.0106	0.0087
N	9	10	10	10
THYMUS (G/100 G BRAIN)				
MEAN	12.878	12.884	14.491	11.730
% CHANGE		0.0	12.5	-8.9
S.D.	1.6272	2.1355	3.6239	1.9540
N	9	10	10	10
THYROIDS/PARA. (G)				
MEAN	0.0243	0.0254	0.0237	0.0217
% CHANGE		4.5	-2.5	-10.7
S.D.	0.00337	0.00403	0.00373	0.00441
N	9	10	10	10

None significantly different from control group

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS

SPONSOR NO.:06-012

MALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
THYROIDS/PARA. (G/100 G FINAL BODY WEIGHT)				
MEAN	0.004	0.005	0.004	0.005
% CHANGE		25.0	0.0	25.0
S.D.	0.0009	0.0008	0.0007	0.0012
N	9	10	10	10
THYROIDS/PARA. (G/100 G BRAIN)				
MEAN	1.171	1.188	1.136	1.069
% CHANGE		1.5	-3.0	-8.7
S.D.	0.1504	0.1865	0.1740	0.2258
N	9	10	10	10

None significantly different from control group

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
FINAL BODY WT (G)				
MEAN	273.	279.	266.	268.
% CHANGE		2.2	-2.6	-1.8
S.D.	27.1	19.1	15.7	21.3
N	10	10	9	10
ADRENAL GLANDS (G)				
MEAN	0.0651	0.0707	0.0793*	0.0822**
% CHANGE		8.6	21.8	26.3
S.D.	0.00869	0.01547	0.01121	0.01075
N	10	10	9	10
ADRENAL GLANDS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.024	0.026	0.030*	0.031**
% CHANGE		8.3	25.0	29.2
S.D.	0.0038	0.0060	0.0041	0.0028
N	10	10	9	10
ADRENAL GLANDS (G/100 G BRAIN)				
MEAN	3.429	3.650	4.026	4.305**
% CHANGE		6.4	17.4	25.5
S.D.	0.5014	0.6786	0.5348	0.5460
N	10	10	9	10
BRAIN (G)				
MEAN	1.90	1.93	1.97	1.91
% CHANGE		1.6	3.7	0.5
S.D.	0.075	0.099	0.094	0.052
N	10	10	9	10

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 15

SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
BRAIN (G/100 G FINAL BODY WEIGHT)				
MEAN	0.703	0.693	0.742	0.718
% CHANGE		-1.4	5.5	2.1
S.D.	0.0704	0.0620	0.0504	0.0592
N	10	10	9	10
HEART (G)				
MEAN	1.05	1.09	1.01	1.05
% CHANGE		3.8	-3.8	0.0
S.D.	0.086	0.115	0.093	0.061
N	10	10	9	10
HEART (G/100 G FINAL BODY WEIGHT)				
MEAN	0.386	0.392	0.379	0.393
% CHANGE		1.6	-1.8	1.8
S.D.	0.0483	0.0394	0.0353	0.0239
N	10	10	9	10
HEART (G/100 G BRAIN)				
MEAN	55.101	56.934	51.128	54.973
% CHANGE		3.3	-7.2	-0.2
S.D.	6.1295	6.7726	3.6408	3.2773
N	10	10	9	10
KIDNEYS (G)				
MEAN	2.06	2.08	2.15	2.24*
% CHANGE		1.0	4.4	8.7
S.D.	0.176	0.134	0.149	0.148
N	10	10	9	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 12
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
KIDNEYS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.758	0.745	0.808	0.842*
% CHANGE		-1.7	6.6	11.1
S.D.	0.0659	0.0500	0.0571	0.0763
N	10	10	9	10
KIDNEYS (G/100 G BRAIN)				
MEAN	108.474	108.000	109.189	117.436
% CHANGE		-0.4	0.7	8.3
S.D.	10.3268	8.2990	10.0249	7.8975
N	10	10	9	10
L.N. POP, LT (G)				
MEAN	0.0092	0.0066	0.0094	0.0085
% CHANGE		-28.3	2.2	-7.6
S.D.	0.00448	0.00231	0.00263	0.00278
N	10	10	9	10
L.N. POP, LT (G/100 G FINAL BODY WEIGHT)				
MEAN	0.003	0.002	0.004	0.003
% CHANGE		-33.3	33.3	0.0
S.D.	0.0016	0.0008	0.0009	0.0012
N	10	10	9	10
L.N. POP, LT (G/100 G BRAIN)				
MEAN	0.482	0.343	0.474	0.443
% CHANGE		-28.8	-1.7	-8.1
S.D.	0.2264	0.1219	0.1280	0.1448
N	10	10	9	10

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
L.N. POP, RT (G)				
MEAN	0.0088	0.0073	0.0082	0.0080
% CHANGE		-17.0	-6.8	-9.1
S.D.	0.00303	0.00193	0.00347	0.00350
N	10	10	9	10
L.N. POP, RT (G/100 G FINAL BODY WEIGHT)				
MEAN	0.003	0.003	0.003	0.003
% CHANGE		0.0	0.0	0.0
S.D.	0.0013	0.0007	0.0011	0.0010
N	10	10	9	10
L.N. POP, RT (G/100 G BRAIN)				
MEAN	0.463	0.376	0.416	0.415
% CHANGE		-18.8	-10.2	-10.4
S.D.	0.1519	0.0920	0.1796	0.1756
N	10	10	9	10
LIVER (G)				
MEAN	8.25	8.75	8.69	9.19
% CHANGE		6.1	5.3	11.4
S.D.	0.680	1.113	0.630	0.722
N	10	10	9	10
LIVER (G/100 G FINAL BODY WEIGHT)				
MEAN	3.036	3.144	3.263	3.440**
% CHANGE		3.6	7.5	13.3
S.D.	0.2372	0.4332	0.0840	0.2196
N	10	10	9	10

** = Significantly different from the control group at 0.01 using Dunnett's test

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GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
LIVER (G/100 G BRAIN)				
MEAN	434.701	454.775	441.518	481.452
% CHANGE		4.6	1.6	10.8
S.D.	45.6380	56.0065	34.7092	39.8057
N	10	10	9	10
OVARIES/OVIDUCTS (G)				
MEAN	0.1281	0.1387	0.1454	0.1507
% CHANGE		8.3	13.5	17.6
S.D.	0.01403	0.02168	0.02512	0.01424
N	10	10	9	10
OVARIES/OVIDUCTS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.047	0.050	0.055	0.057**
% CHANGE		6.4	17.0	21.3
S.D.	0.0044	0.0078	0.0086	0.0057
N	10	10	9	10
OVARIES/OVIDUCTS (G/100 G BRAIN)				
MEAN	6.756	7.205	7.400	7.902
% CHANGE		6.6	9.5	17.0
S.D.	0.9204	1.1320	1.3430	0.7958
N	10	10	9	10
SPLEEN (G)				
MEAN	0.51	0.52	0.56	0.54
% CHANGE		2.0	9.8	5.9
S.D.	0.055	0.043	0.076	0.067
N	10	10	9	10

** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 15
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
SPLEEN (G/100 G FINAL BODY WEIGHT)				
MEAN	0.189	0.188	0.210	0.204
% CHANGE		-0.5	11.1	7.9
S.D.	0.0202	0.0157	0.0259	0.0266
N	10	10	9	10
SPLEEN (G/100 G BRAIN)				
MEAN	27.137	27.214	28.415	28.485
% CHANGE		0.3	4.7	5.0
S.D.	3.8019	2.7789	3.6350	3.8598
N	10	10	9	10
THYMUS (G)				
MEAN	0.2834	0.2857	0.3161	0.2538
% CHANGE		0.8	11.5	-10.4
S.D.	0.06201	0.06523	0.09186	0.04810
N	10	10	9	10
THYMUS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.104	0.103	0.120	0.095
% CHANGE		-1.0	15.4	-8.7
S.D.	0.0199	0.0230	0.0374	0.0168
N	10	10	9	10
THYMUS (G/100 G BRAIN)				
MEAN	14.948	14.992	16.104	13.302
% CHANGE		0.3	7.7	-11.0
S.D.	3.4429	4.1322	4.7863	2.5340
N	10	10	9	10

None significantly different from control group

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TABLE 15

FEMALES

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
THYROIDS/PARA. (G)				
MEAN	0.0209	0.0198	0.0218	0.0208
% CHANGE		-5.3	4.3	-0.5
S.D.	0.00317	0.00241	0.00330	0.00357
N	10	10	9	9
THYROIDS/PARA. (G/100 G FINAL BODY WEIGHT)				
MEAN	0.008	0.007	0.008	0.008
% CHANGE		-12.5	0.0	0.0
S.D.	0.0008	0.0012	0.0012	0.0011
N	10	10	9	9
THYROIDS/PARA. (G/100 G BRAIN)				
MEAN	1.100	1.029	1.106	1.094
% CHANGE		-6.5	0.5	-0.5
S.D.	0.1767	0.1222	0.1701	0.1718
N	10	10	9	9
UTERUS (G)				
MEAN	0.61	0.65	0.53	0.72
% CHANGE		6.6	-13.1	18.0
S.D.	0.190	0.217	0.084	0.254
N	10	10	9	10
UTERUS (G/100 G FINAL BODY WEIGHT)				
MEAN	0.224	0.233	0.198	0.270
% CHANGE		4.0	-11.6	20.5
S.D.	0.0707	0.0826	0.0299	0.0859
N	10	10	9	10

None significantly different from control group

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TABLE 15

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 17
SPONSOR:[redacted] SUMMARY OF ORGAN WEIGHTS AND RELATIVE ORGAN WEIGHTS
SPONSOR NO.:06-012

GROUP:	0 MG/KG/DAY	160 MG/KG/DAY	400 MG/KG/DAY	1000 MG/KG/DAY
		FEMALES		
UTERUS (G/100 G BRAIN)				
MEAN	31.905	33.621	26.720	38.007
% CHANGE		5.4	-16.3	19.1
S.D.	9.9490	11.0014	3.7294	13.7652
N	10	10	9	10

None significantly different from control group

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted]
SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
AORTA				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
BRAIN				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
CAUSE OF DEATH				
TOTAL NUMBER EXAMINED	1	NA	NA	NA
EXAMINED, UNREMARKABLE	0	NA	NA	NA
-UNDETERMINED	1	NA	NA	NA
PRESENT	1	NA	NA	NA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
CECUM				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-DILATATION	1	0	0	0
MODERATE	1	NONE	NONE	NONE
COLON				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-DILATATION, CRYPTS	1	0	0	0
MILD	1	NONE	NONE	NONE
DUODENUM				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
EAR CANAL				
TOTAL NUMBER EXAMINED	1	NA	NA	NA
EXAMINED, UNREMARKABLE	0	NA	NA	NA
-INFILTRATE, LYMPHOCYTE	1	NA	NA	NA
MILD	1	NA	NA	NA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
EPIDIDYMIDES				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
ESOPHAGUS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
HARDERIAN GLANDS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
HEART				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-INFILTRATE, MONONUCLEAR	1	0	0	0
MINIMAL	1	NONE	NONE	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
ILEUM				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-DILATATION	1	0	0	0
SEVERE	1	NONE	NONE	NONE
JEJUNUM				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
KIDNEYS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-MINERALIZATION	1	0	0	0
MINIMAL	1	NONE	NONE	NONE
-PROTEINOSIS, TUBULAR	1	0	0	0
MINIMAL	1	NONE	NONE	NONE
L.N. POP, LT				
TOTAL NUMBER EXAMINED	0	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
NOT EXAMINED	1	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
L.N. POP, RT				
TOTAL NUMBER EXAMINED	0	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
NOT EXAMINED	1	0	0	0
LAC. GLAND EXOR				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
LARYNX				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
LIVER				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
LUNGS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-HEMORRHAGE	1	0	0	0
MINIMAL	1	NONE	NONE	NONE
MARROW, STERN				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
NASAL LEVEL I				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-LUMINAL DEBRIS	1	0	0	0
MODERATE	1	NONE	NONE	NONE
-HEMORRHAGE	1	0	0	0
MILD	1	NONE	NONE	NONE
-INFLAMMATION, ACUTE	1	0	0	0
MILD	1	NONE	NONE	NONE
-ULCERATION	1	0	0	0
SEVERE	1	NONE	NONE	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 7

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
NASAL LEVEL III				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-MINERALIZATION, MUCOSAL	1	0	0	0
MINIMAL	1	NONE	NONE	NONE
-HEMORRHAGE	1	0	0	0
MILD	1	NONE	NONE	NONE
-LUMINAL DEBRIS	1	0	0	0
MILD	1	NONE	NONE	NONE
-ATROPHY	1	0	0	0
MILD	1	NONE	NONE	NONE
-ULCERATION	1	0	0	0
MODERATE	1	NONE	NONE	NONE
-INFLAMMATION, ACUTE	1	0	0	0
MODERATE	1	NONE	NONE	NONE
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
PANCREAS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
PARATHYROIDS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
PEYER'S PATCHES				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
PHARYNX				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
PITUITARY				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
PROSTATE				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-INFILTRATE, NEUTROPHIL	1	0	0	0
MILD	1	NONE	NONE	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
RECTUM				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-ULCERATION	1	0	0	0
MINIMAL	1	NONE	NONE	NONE
-INFLAMMATION, ACUTE	1	0	0	0
MINIMAL	1	NONE	NONE	NONE
SAL. GLAND MAND				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
SEMINAL VESICLES				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
SKELETAL MUSCLE				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
SKIN				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 10
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF MICROSCOPIC FINDINGS

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
SPINAL CORD				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
SPLEEN				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
STERNUM				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
STOMACH, NON				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
TESTES				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	1	0	0	0
THYMUS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-ATROPHY	1	0	0	0
MODERATE	1	NONE	NONE	NONE
THYROID GLANDS				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
-CYST, ULTIMOBRANCHIAL	1	0	0	0
PRESENT	1	NONE	NONE	NONE
TRACHEA				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0
URINARY BLADDER				
TOTAL NUMBER EXAMINED	1	0	0	0
EXAMINED, UNREMARKABLE	1	0	0	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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Modified: 8/30/2006

TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
AORTA				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
BRAIN				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
CAUSE OF DEATH				
TOTAL NUMBER EXAMINED	NA	NA	1	NA
EXAMINED, UNREMARKABLE	NA	NA	0	NA
-UNDETERMINED	NA	NA	1	NA
PRESENT	NA	NA	1	NA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
CECUM				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
CERVIX				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
COLON				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
DUODENUM				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
EAR CANAL				
TOTAL NUMBER EXAMINED	NA	NA	1	NA
EXAMINED, UNREMARKABLE	NA	NA	0	NA
-INFILTRATE, LYMPHOCYTE	NA	NA	1	NA
MINIMAL	NA	NA	1	NA

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 16 (UNSCHEDULED DEATHS)

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
ESOPHAGUS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
HARDERIAN GLANDS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
HEART				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
ILEUM				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
JEJUNUM				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
KIDNEYS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
L.N. POP, LT				
TOTAL NUMBER EXAMINED	0	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
NOT EXAMINED	0	0	1	0
L.N. POP, RT				
TOTAL NUMBER EXAMINED	0	0	0	0
EXAMINED, UNREMARKABLE	0	0	0	0
NOT EXAMINED	0	0	1	0
LAC. GLAND EXOR				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
LARYNX				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
LIVER				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
LUNGS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	0	0
-MINERALIZATION, VASCULAR	0	0	1	0
MINIMAL	NONE	NONE	1	NONE
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	0	0
-DEPLETION, LYMPHOID	0	0	1	0
MINIMAL	NONE	NONE	1	NONE
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
MAMMARY GLAND				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
MARROW, STERN				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
NASAL LEVEL I				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
NASAL LEVEL III				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
OVARIES				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
OVIDUCTS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
PANCREAS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
PARATHYROIDS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
PEYER'S PATCHES				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
PHARYNX				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
PITUITARY				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
RECTUM				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
SAL. GLAND MAND				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
SKELETAL MUSCLE				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
SKIN				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
SPINAL CORD				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
SPLEEN				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	0	0
-DEPLETION, LYMPHOID	0	0	1	0
MINIMAL	NONE	NONE	1	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 16 (UNSCHEDULED DEATHS)
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
STERNUM				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
STOMACH, NON				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
THYMUS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
THYROID GLANDS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
TRACHEA				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 16 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 21
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED	0	0	1	0
URINARY BLADDER				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0
UTERUS				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	0	0
-DILATATION	0	0	1	0
MILD	NONE	NONE	1	NONE
VAGINA				
TOTAL NUMBER EXAMINED	0	0	1	0
EXAMINED, UNREMARKABLE	0	0	1	0

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	9	NA	NA	9
EXAMINED, UNREMARKABLE	9	NA	NA	9
NOT EXAMINED	0	NA	NA	1
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	9	NA	NA	9
EXAMINED, UNREMARKABLE	9	NA	NA	9
NOT EXAMINED	0	NA	NA	1
AORTA				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
BRAIN				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
CECUM				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF MICROSCOPIC FINDINGS

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
COLON				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	9
-EDEMA, SUBMUCOSAL	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
DUODENUM				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
EAR CANAL				
TOTAL NUMBER EXAMINED	7	NA	NA	8
EXAMINED, UNREMARKABLE	0	NA	NA	0
-INFILTRATE, LYMPHOCYTE	7	NA	NA	8
MINIMAL	5	NA	NA	5
MILD	2	NA	NA	3
EPIDIDYMIDES				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	10
-INFILTRATE, LYMPHOCYTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF MICROSCOPIC FINDINGS

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
ESOPHAGUS				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	6
-INFLAMMATION, ACUTE	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
-INFLAMMATION, SUBACUTE	2	NA	NA	3
MINIMAL	2	NA	NA	NONE
MILD	NONE	NA	NA	3
HARDERIAN GLANDS				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	6
-HEMORRHAGE	2	NA	NA	4
MINIMAL	1	NA	NA	1
MILD	NONE	NA	NA	3
MODERATE	1	NA	NA	NONE
-INFILTRATE, LYMPHOCYTE	1	NA	NA	1
MINIMAL	1	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
HEART				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	8
-INFILTRATE, MONONUCLEAR	1	NA	NA	2
MINIMAL	1	NA	NA	2
-HEMORRHAGE	1	NA	NA	0
MODERATE	1	NA	NA	NONE
-EXUDATE, FIBRINOUS	1	NA	NA	0
MILD	1	NA	NA	NONE
-VASCULITIS	1	NA	NA	0
MODERATE	1	NA	NA	NONE
ILEUM				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
JEJUNUM				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
KIDNEYS				
TOTAL NUMBER EXAMINED	9	NA	1	10
EXAMINED, UNREMARKABLE	1	NA	0	2
-MINERALIZATION	1	NA	0	1
MINIMAL	1	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)
PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:06-012
SUMMARY OF MICROSCOPIC FINDINGS

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
KIDNEYS - CONTINUED				
-DILATATION, TUBULAR	2	NA	0	0
MINIMAL	2	NA	NA	NONE
-INFILTRATE, LYMPHOCYTE	5	NA	0	2
MINIMAL	5	NA	NA	2
-FIBROSIS, INTERSTITIAL	1	NA	0	1
MINIMAL	1	NA	NA	1
-CYST, MEDULLARY	1	NA	0	1
PRESENT	1	NA	NA	1
-PROTEINOSIS, TUBULAR	3	NA	0	4
MINIMAL	3	NA	NA	4
-BASOPHILIC TUBULES	4	NA	0	4
MINIMAL	4	NA	NA	4
-DILATATION, PELVIS	0	NA	1	0
MINIMAL	NONE	NA	1	NONE
-DROPLET, HYALINE	1	NA	0	2
MINIMAL	1	NA	NA	NONE
MILD	NONE	NA	NA	2
-CYST, CORTICAL	0	NA	0	1
PRESENT	NONE	NA	NA	1
L.N. POP, LT				
TOTAL NUMBER EXAMINED	9	NA	NA	9
EXAMINED, UNREMARKABLE	9	NA	NA	8
NOT EXAMINED	0	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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Modified: 8/30/2006

TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
L.N. POP, LT - CONTINUED				
-HYPERPLASIA, LYMPHOID	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
L.N. POP, RT				
TOTAL NUMBER EXAMINED	9	NA	1	9
EXAMINED, UNREMARKABLE	9	NA	1	8
NOT EXAMINED	0	NA	0	1
-HYPERPLASIA, LYMPHOID	0	NA	0	1
MINIMAL	NONE	NA	NA	1
LAC. GLAND EXOR				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	9
-DEPLETION, SECRETORY GRANULES	0	NA	NA	1
MILD	NONE	NA	NA	1
LARYNX				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	3	NA	NA	8
-INFILTRATE, MONONUCLEAR	2	NA	NA	0
MINIMAL	2	NA	NA	NONE
-INFLAMMATION, CHRONIC	3	NA	NA	0
MINIMAL	1	NA	NA	NONE
MILD	2	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
LARYNX - CONTINUED				
-DEGENERATION, CARTILAGE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
-DILATATION, GLANDULAR	1	NA	NA	1
MINIMAL	1	NA	NA	1
-MINERALIZATION, MUCOSAL	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
LIVER				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	6	NA	NA	7
-INFILTRATE, MONONUCLEAR	2	NA	NA	2
MINIMAL	2	NA	NA	2
-VACUOLATION, HEPATOCELLULAR	2	NA	NA	0
MINIMAL	2	NA	NA	NONE
-FIBROSIS	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
LUNGS				
TOTAL NUMBER EXAMINED	9	1	NA	10
EXAMINED, UNREMARKABLE	1	0	NA	1
-MINERALIZATION, VASCULAR	7	0	NA	7
MINIMAL	7	NA	NA	7
-INFILTRATE, MONONUCLEAR	5	0	NA	2
MINIMAL	4	NA	NA	2
MILD	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
LUNGS - CONTINUED				
-CONGESTION	0	1	NA	0
MILD	NONE	1	NA	NONE
-HEMORRHAGE	0	0	NA	1
MINIMAL	NONE	NA	NA	1
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	9	2	1	10
EXAMINED, UNREMARKABLE	6	0	0	9
-HEMORRHAGE	1	2	1	1
MINIMAL	NONE	2	NA	1
MILD	1	NA	1	NONE
-DEPLETION, LYMPHOID	1	0	0	0
MILD	1	NA	NA	NONE
-HYPERPLASIA, LYMPHOID	1	0	0	0
MINIMAL	1	NA	NA	NONE
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
MARROW, STERN				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 9

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
NASAL LEVEL I				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	10
-INFLAMMATION	1	NA	NA	0
MILD	1	NA	NA	NONE
-EROSION, EPITHELIAL	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
NASAL LEVEL III				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	3	NA	NA	3
-ATROPHY, GLANDULAR	0	NA	NA	1
SEVERE	NONE	NA	NA	1
-MINERALIZATION, MUCOSAL	6	NA	NA	7
MINIMAL	6	NA	NA	7
-HEMORRHAGE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
NASOLACRIMAL DUC				
TOTAL NUMBER EXAMINED	3	NA	NA	2
EXAMINED, UNREMARKABLE	0	NA	NA	0
-LUMINAL DEBRIS	3	NA	NA	2
MINIMAL	1	NA	NA	1
MILD	2	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
PANCREAS				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	10
-FIBROSIS	1	NA	NA	0
MILD	1	NA	NA	NONE
PARATHYROIDS				
TOTAL NUMBER EXAMINED	7	NA	NA	7
EXAMINED, UNREMARKABLE	7	NA	NA	7
NOT EXAMINED	2	NA	NA	3
PEYER'S PATCHES				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
PHARYNX				
TOTAL NUMBER EXAMINED	7	NA	NA	6
EXAMINED, UNREMARKABLE	7	NA	NA	6
NOT EXAMINED	2	NA	NA	4

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
PITUITARY				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	10
-CYST, PARS DISTALIS	2	NA	NA	0
PRESENT	2	NA	NA	NONE
PROSTATE				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	9
-INFILTRATE, LYMPHOCYTE	1	NA	NA	1
MINIMAL	1	NA	NA	1
-DECREASED SECRETION	0	NA	NA	1
MILD	NONE	NA	NA	1
RECTUM				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	10
-PARASITES, NEMATODES	2	NA	NA	0
PRESENT	2	NA	NA	NONE
SAL. GLAND MAND				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
SEMINAL VESICLES				
TOTAL NUMBER EXAMINED	9	NA	1	10
EXAMINED, UNREMARKABLE	9	NA	0	10
-DECREASED SECRETION	0	NA	1	0
MODERATE	NONE	NA	1	NONE
SKELETAL MUSCLE				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	8
-NECROSIS	1	NA	NA	2
MINIMAL	1	NA	NA	2
SKIN				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
SPINAL CORD				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
SPLEEN				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
STERNUM				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
STOMACH, NON				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
TEETH				
TOTAL NUMBER EXAMINED	NA	NA	NA	3
EXAMINED, UNREMARKABLE	NA	NA	NA	0
-NECROSIS	NA	NA	NA	3
PRESENT	NA	NA	NA	3
-INFLAMMATION, CHRONIC	NA	NA	NA	1
MILD	NA	NA	NA	1
TESTES				
TOTAL NUMBER EXAMINED	9	1	NA	10
EXAMINED, UNREMARKABLE	9	1	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	9	4	4	10
THYMUS				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	9
-HEMORRHAGE	1	NA	NA	1
MINIMAL	1	NA	NA	1
THYROID GLANDS				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	4	NA	NA	3
-CYST, ULTIMOBRANCHIAL	5	NA	NA	7
PRESENT	5	NA	NA	7
TRACHEA				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
URINARY BLADDER				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	10
-INFILTRATE, LYMPHOCYTE	2	NA	NA	0
MINIMAL	2	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
AORTA				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
BRAIN				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
CECUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
CERVIX				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
COLON				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
DUODENUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
EAR CANAL				
TOTAL NUMBER EXAMINED	5	NA	NA	9
EXAMINED, UNREMARKABLE	0	NA	NA	0
-INFILTRATE, LYMPHOCYTE	5	NA	NA	9
MINIMAL	3	NA	NA	3
MILD	2	NA	NA	6
-CYST, KERATIN	0	NA	NA	1
PRESENT	NA	NA	NA	1
ESOPHAGUS				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
-INFILTRATE, MONONUCLEAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	9
-INFLAMMATION, SUBACUTE	1	NA	NA	1
MINIMAL	1	NA	NA	1
HARDERIAN GLANDS				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	3	NA	NA	5
-HEMORRHAGE	5	NA	NA	5
MINIMAL	3	NA	NA	3
MILD	1	NA	NA	1
MODERATE	NONE	NA	NA	1
SEVERE	1	NA	NA	NONE
-INFILTRATE, LYMPHOCYTE	3	NA	NA	1
MINIMAL	3	NA	NA	1
-INFLAMMATION, SUBACUTE	0	NA	NA	1
MILD	NONE	NA	NA	1
HEART				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
-INFILTRATE, MONONUCLEAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
ILEUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
JEJUNUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
KIDNEYS				
TOTAL NUMBER EXAMINED	10	1	NA	10
EXAMINED, UNREMARKABLE	3	0	NA	4
-MINERALIZATION	4	1	NA	3
MINIMAL	4	1	NA	3
-DILATATION, TUBULAR	1	0	NA	2
MINIMAL	1	NA	NA	1
MILD	NONE	NA	NA	1
-INFILTRATE, LYMPHOCYTE	2	0	NA	1
MINIMAL	2	NA	NA	1
-FIBROSIS, INTERSTITIAL	1	0	NA	0
MINIMAL	1	NA	NA	NONE
-CYST, MEDULLARY	0	0	NA	1
PRESENT	NONE	NA	NA	1
-PROTEINOSIS, TUBULAR	0	0	NA	4
MINIMAL	NONE	NA	NA	3
MILD	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
KIDNEYS - CONTINUED				
-BASOPHILIC TUBULES	0	0	NA	1
MINIMAL	NONE	NA	NA	1
L.N. POP, LT				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	10
NOT EXAMINED	1	NA	NA	0
-HEMORRHAGE	1	NA	NA	0
MODERATE	1	NA	NA	NONE
L.N. POP, RT				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	10
NOT EXAMINED	1	NA	NA	0
-HEMORRHAGE	1	NA	NA	0
MILD	1	NA	NA	NONE
LAC. GLAND EXOR				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	9
-INFILTRATE, LYMPHOCYTE	0	NA	NA	1
MINIMAL	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
LARYNX				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	8
-INFILTRATE, MONONUCLEAR	2	NA	NA	1
MINIMAL	2	NA	NA	1
-INFLAMMATION, CHRONIC	1	NA	NA	1
MILD	NONE	NA	NA	1
MODERATE	1	NA	NA	NONE
-DEGENERATION, CARTILAGE	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
LIVER				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	5	NA	NA	9
-INFILTRATE, MONONUCLEAR	5	NA	NA	1
MINIMAL	5	NA	NA	1
LUNGS				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	6	NA	NA	3
-MINERALIZATION, VASCULAR	3	NA	NA	5
MINIMAL	3	NA	NA	5
-INFILTRATE, MONONUCLEAR	2	NA	NA	4
MINIMAL	2	NA	NA	3
MILD	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
LUNGS - CONTINUED				
-METAPLASIA, OSSEOUS	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	10	1	2	10
EXAMINED, UNREMARKABLE	8	0	0	9
-HEMORRHAGE	2	1	2	1
MINIMAL	1	1	1	NONE
MILD	1	NA	1	1
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
-HEMORRHAGE	1	NA	NA	0
SEVERE	1	NA	NA	NONE
MAMMARY GLAND				
TOTAL NUMBER EXAMINED	9	NA	NA	7
EXAMINED, UNREMARKABLE	9	NA	NA	7
NOT EXAMINED	1	NA	NA	3

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
MARROW, STERN				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
NASAL LEVEL I				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	9
-INFLAMMATION	3	NA	NA	1
MINIMAL	1	NA	NA	1
MILD	2	NA	NA	NONE
-EROSION, EPITHELIAL	2	NA	NA	1
MINIMAL	1	NA	NA	NONE
MILD	1	NA	NA	1
-METAPLASIA, SQUAMOUS	1	NA	NA	0
PRESENT	1	NA	NA	NONE
-LUMINAL DEBRIS	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
NASAL LEVEL III				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	5
-HYPERPLASIA, LYMPHOID	1	NA	NA	0
MILD	1	NA	NA	NONE
-ATROPHY, GLANDULAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)
PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
NASAL LEVEL III - CONTINUED				
-MINERALIZATION, MUCOSAL	1	NA	NA	5
MINIMAL	1	NA	NA	5
NASOLACRIMAL DUC				
TOTAL NUMBER EXAMINED	4	NA	NA	1
EXAMINED, UNREMARKABLE	0	NA	NA	0
-LUMINAL DEBRIS	4	NA	NA	1
MINIMAL	4	NA	NA	NA
MILD	NA	NA	NA	1
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
OVARIES				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
OVIDUCTS				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

SPONSOR: [redacted]

SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
PANCREAS				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
PARATHYROIDS				
TOTAL NUMBER EXAMINED	6	NA	NA	8
EXAMINED, UNREMARKABLE	6	NA	NA	8
NOT EXAMINED	4	NA	NA	2
PEYER'S PATCHES				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	9
-INFLAMMATION, GRANULOMATOUS	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
PHARYNX				
TOTAL NUMBER EXAMINED	7	NA	NA	6
EXAMINED, UNREMARKABLE	7	NA	NA	6
NOT EXAMINED	3	NA	NA	4
PITUITARY				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	8
-CYST, PARS DISTALIS	1	NA	NA	2
PRESENT	1	NA	NA	2

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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Modified: 8/30/2006

TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
RECTUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	9
-DILATATION, FOLLICULAR	1	NA	NA	0
MILD	1	NA	NA	NONE
-CYST, KERATIN	0	NA	NA	1
PRESENT	NONE	NA	NA	1
SAL. GLAND MAND				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
SKELETAL MUSCLE				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	9
-NECROSIS	1	NA	NA	1
MINIMAL	1	NA	NA	1
SKIN				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

Audited Draft

Modified: 8/30/2006

TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
SPINAL CORD				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
SPLEEN				
TOTAL NUMBER EXAMINED	10	NA	1	10
EXAMINED, UNREMARKABLE	9	NA	0	10
-PIGMENT, BROWN	1	NA	0	0
MILD	1	NA	NA	NONE
-INFILTRATE, MONONUCLEAR	0	NA	1	0
MINIMAL	NONE	NA	1	NONE
STERNUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
STOMACH, NON				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
TEETH				
TOTAL NUMBER EXAMINED	NA	NA	NA	1
EXAMINED, UNREMARKABLE	NA	NA	NA	0
-INFLAMMATION, SUBACUTE	NA	NA	NA	1
MODERATE	NA	NA	NA	1
THYMUS				
TOTAL NUMBER EXAMINED	10	NA	2	10
EXAMINED, UNREMARKABLE	9	NA	2	9
-HEMORRHAGE	1	NA	0	1
MINIMAL	1	NA	NA	1
THYROID GLANDS				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	5	NA	NA	2
-CYST, ULTIMOBRANCHIAL	5	NA	NA	8
PRESENT	5	NA	NA	8
TRACHEA				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 17 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	4	3	10
URINARY BLADDER				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
-INFILTRATE, LYMPHOCYTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
UTERUS				
TOTAL NUMBER EXAMINED	10	2	NA	10
EXAMINED, UNREMARKABLE	8	0	NA	6
-DILATATION	2	2	NA	4
MINIMAL	1	NA	NA	2
MILD	1	NA	NA	1
MODERATE	NONE	2	NA	NONE
SEVERE	NONE	NA	NA	1
VAGINA				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	9
-DILATATION, GLANDULAR	0	NA	NA	1
MODERATE	NONE	NA	NA	1
-INFLAMMATION, CHRONIC	0	NA	NA	1
MILD	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 160 MG/KG/DAY 3- 400 MG/KG/DAY 4- 1000 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 18

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL SURVIVAL AND DISPOSITION

SPONSOR NO.:06-012

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
19623	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19626	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19630	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19636	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19639	M	0 MG/KG/DAY	EUTHANIZED IN EXTREMIS	16	15-MAY-06	70
19644	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19652	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19655	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19657	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19660	M	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19619	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19628	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19640	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19646	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19647	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19648	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19650	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19654	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19659	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19663	M	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19621	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19622	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19631	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19632	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19634	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19635	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19645	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19656	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (6)

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TABLE 18

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL SURVIVAL AND DISPOSITION

SPONSOR NO.:06-012

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
19658	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19661	M	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19618	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19620	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19624	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19625	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19633	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19641	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19643	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19649	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19653	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19662	M	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (6)

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TABLE 18

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL SURVIVAL AND DISPOSITION

SPONSOR NO.:06-012

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
19668	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19670	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19675	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19683	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19687	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19692	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19696	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19698	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19703	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19709	F	0 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19664	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19669	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19672	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19674	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19676	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19690	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19694	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19699	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19706	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19707	F	160 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19665	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19666	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19667	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19673	F	400 MG/KG/DAY	FOUND DEAD	15	10-MAY-06	65
19677	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19685	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19686	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19689	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (6)

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TABLE 18

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL SURVIVAL AND DISPOSITION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
19693	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19705	F	400 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19671	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19678	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19679	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19680	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19681	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19688	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19691	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	05-JUN-06	91
19695	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19700	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92
19701	F	1000 MG/KG/DAY	SCHEDULED EUTHANASIA	19	06-JUN-06	92

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (6)

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19623	124.	184.	212.	253.	300.	329.	369.	395.
19626	120.	178.	218.	287.	348.	392.	442.	473.
19630	123.	178.	209.	258.	300.	321.	349.	380.
19636	130.	190.	229.	285.	330.	363.	401.	428.
19639	117.	182.	215.	260.	303.	323.	356.	390.
19644	117.	171.	204.	252.	298.	323.	367.	392.
19652	121.	181.	215.	270.	328.	371.	418.	449.
19655	130.	195.	234.	296.	353.	394.	444.	492.
19657	115.	174.	211.	264.	305.	343.	374.	405.
19660	122.	180.	217.	257.	298.	332.	376.	403.
MEAN	122.	181.	216.	268.	316.	349.	390.	421.
S.D.	5.1	7.1	9.0	15.7	21.6	28.7	34.6	38.5
N	10	10	10	10	10	10	10	10

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 19
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 160 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19619	123.	180.	205.	251.	294.	329.	373.	405.
19628	115.	174.	207.	253.	310.	339.	378.	391.
19640	115.	175.	207.	267.	314.	345.	378.	410.
19646	117.	180.	219.	282.	340.	375.	414.	444.
19647	126.	185.	219.	271.	307.	321.	335.	360.
19648	123.	186.	224.	291.	346.	392.	436.	474.
19650	123.	183.	213.	272.	327.	365.	408.	439.
19654	123.	177.	204.	250.	289.	315.	343.	369.
19659	127.	194.	236.	298.	353.	395.	438.	468.
19663	125.	181.	206.	240.	272.	294.	323.	350.
MEAN	122.	182.	214.	268.	315.	347.	383.	411.
S.D.	4.4	5.9	10.4	19.1	26.3	33.9	40.9	44.2
N	10	10	10	10	10	10	10	10

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 400 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19621	120.	177.	209.	259.	296.	330.	364.	404.
19622	127.	192.	225.	288.	341.	381.	430.	471.
19631	108.	171.	204.	257.	303.	328.	361.	380.
19632	124.	182.	212.	265.	318.	358.	396.	417.
19634	124.	180.	217.	267.	316.	353.	392.	422.
19635	121.	182.	214.	268.	325.	360.	398.	425.
19645	125.	179.	206.	272.	317.	356.	358.	400.
19656	119.	177.	211.	262.	312.	345.	379.	408.
19658	130.	188.	226.	268.	308.	332.	367.	403.
19661	121.	184.	217.	278.	339.	381.	422.	462.
MEAN	122.	181.	214.	268.	318.	352.	387.	419.
S.D.	5.9	5.9	7.3	9.2	14.4	19.2	25.4	28.1
N	10	10	10	10	10	10	10	10

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 19
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 1000 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19618	131.	192.	226.	279.	330.	364.	388.	432.
19620	123.	185.	218.	277.	331.	363.	399.	421.
19624	120.	177.	206.	260.	310.	336.	367.	400.
19625	119.	179.	208.	262.	322.	352.	382.	414.
19633	119.	180.	216.	266.	314.	347.	374.	412.
19641	121.	176.	208.	261.	281.	323.	357.	382.
19643	126.	183.	211.	251.	281.	296.	317.	345.
19649	126.	181.	210.	257.	292.	315.	332.	360.
19653	116.	174.	212.	257.	292.	312.	341.	371.
19662	129.	189.	223.	274.	297.	338.	368.	390.
MEAN	123.	182.	214.	264.	305.	335.	363.	393.
S.D.	4.9	5.7	6.7	9.4	19.0	22.8	25.9	28.2
N	10	10	10	10	10	10	10	10

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 19
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19623	418.	446.	465.	485.	509.	517.	522.	530.	SCHEDULED EUTH WEEK 13
19626	508.	543.	567.	585.	595.	609.	623.	635.	SCHEDULED EUTH WEEK 13
19630	405.	424.	450.	468.	481.	498.	508.	512.	SCHEDULED EUTH WEEK 13
19636	457.	470.	492.	509.	523.	538.	543.	548.	SCHEDULED EUTH WEEK 13
19639	404.	422.	428.	441.	339.	EUTH IN EXTREMIS WEEK 10			
19644	424.	440.	462.	474.	488.	506.	512.	518.	SCHEDULED EUTH WEEK 13
19652	486.	500.	536.	563.	575.	602.	599.	614.	SCHEDULED EUTH WEEK 13
19655	517.	553.	580.	598.	621.	631.	641.	655.	SCHEDULED EUTH WEEK 13
19657	430.	446.	462.	478.	497.	514.	519.	525.	SCHEDULED EUTH WEEK 13
19660	427.	449.	472.	490.	502.	521.	532.	545.	SCHEDULED EUTH WEEK 13
MEAN	448.	469.	491.	509.	513.	548.	555.	565.	
S.D.	42.0	47.2	51.7	53.8	77.9	50.9	51.3	54.7	
N	10	10	10	10	10	9	9	9	

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 160 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19619	431.	460.	483.	507.	525.	539.	551.	563.	SCHEDULED EUTH WEEK 13
19628	411.	424.	425.	434.	451.	465.	467.	476.	SCHEDULED EUTH WEEK 13
19640	438.	457.	477.	495.	509.	528.	529.	544.	SCHEDULED EUTH WEEK 13
19646	465.	490.	520.	530.	551.	558.	570.	577.	SCHEDULED EUTH WEEK 13
19647	367.	385.	355.	396.	411.	432.	429.	444.	SCHEDULED EUTH WEEK 13
19648	508.	539.	560.	581.	599.	627.	631.	649.	SCHEDULED EUTH WEEK 13
19650	475.	503.	517.	548.	565.	592.	592.	606.	SCHEDULED EUTH WEEK 13
19654	388.	402.	419.	434.	448.	460.	469.	483.	SCHEDULED EUTH WEEK 13
19659	490.	508.	540.	572.	574.	598.	606.	619.	SCHEDULED EUTH WEEK 13
19663	377.	396.	415.	427.	442.	466.	471.	479.	SCHEDULED EUTH WEEK 13
MEAN	435.	456.	471.	492.	508.	527.	532.	544.	
S.D.	49.0	53.3	65.7	66.1	65.5	67.9	69.3	70.3	
N	10	10	10	10	10	10	10	10	

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Modified: 8/30/2006

PROJECT NO.:WIL-187054
SPONSOR:[redacted]
SPONSOR NO.:06-012

TABLE 19
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 400 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19621	437.	456.	484.	500.	505.	510.	518.	527.	SCHEDULED EUTH WEEK 13
19622	505.	538.	565.	587.	615.	637.	659.	671.	SCHEDULED EUTH WEEK 13
19631	412.	424.	440.	446.	468.	480.	478.	481.	SCHEDULED EUTH WEEK 13
19632	444.	468.	480.	463.	489.	510.	523.	535.	SCHEDULED EUTH WEEK 13
19634	454.	479.	466.	492.	509.	519.	533.	536.	SCHEDULED EUTH WEEK 13
19635	444.	470.	494.	509.	523.	543.	547.	560.	SCHEDULED EUTH WEEK 13
19645	416.	444.	465.	490.	505.	514.	520.	529.	SCHEDULED EUTH WEEK 13
19656	434.	461.	482.	499.	514.	513.	530.	530.	SCHEDULED EUTH WEEK 13
19658	433.	452.	476.	494.	520.	538.	555.	573.	SCHEDULED EUTH WEEK 13
19661	491.	521.	515.	542.	558.	580.	585.	595.	SCHEDULED EUTH WEEK 13
MEAN	447.	471.	487.	502.	521.	534.	545.	554.	
S.D.	29.8	34.5	33.8	39.2	40.5	44.7	48.8	51.3	
N	10	10	10	10	10	10	10	10	

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Modified: 8/30/2006

TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 1000 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19618	451.	458.	491.	513.	529.	544.	542.	550.	SCHEDULED EUTH WEEK 13
19620	443.	455.	469.	446.	473.	497.	500.	514.	SCHEDULED EUTH WEEK 13
19624	420.	441.	451.	444.	459.	483.	477.	491.	SCHEDULED EUTH WEEK 13
19625	442.	461.	479.	501.	515.	509.	507.	517.	SCHEDULED EUTH WEEK 13
19633	429.	447.	462.	472.	489.	506.	517.	536.	SCHEDULED EUTH WEEK 13
19641	407.	422.	441.	432.	450.	464.	469.	488.	SCHEDULED EUTH WEEK 13
19643	365.	380.	400.	417.	415.	423.	433.	436.	SCHEDULED EUTH WEEK 13
19649	382.	398.	406.	420.	402.	427.	432.	441.	SCHEDULED EUTH WEEK 13
19653	397.	414.	440.	463.	468.	493.	506.	524.	SCHEDULED EUTH WEEK 13
19662	392.	404.	409.	427.	427.	446.	459.	463.	SCHEDULED EUTH WEEK 13
MEAN	413.	428.	445.	454.	463.	479.	484.	496.	
S.D.	28.8	28.4	31.7	33.3	41.3	38.8	36.4	39.3	
N	10	10	10	10	10	10	10	10	

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Modified: 8/30/2006

TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 0 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19668	113.	161.	183.	214.	229.	256.	276.	288.
19670	109.	149.	163.	180.	205.	215.	229.	233.
19675	102.	137.	151.	171.	190.	205.	219.	234.
19683	107.	154.	176.	197.	223.	225.	247.	245.
19687	104.	151.	170.	192.	216.	230.	248.	251.
19692	114.	156.	175.	205.	228.	246.	258.	265.
19696	102.	147.	165.	175.	199.	221.	236.	241.
19698	113.	149.	166.	180.	197.	202.	215.	223.
19703	113.	152.	167.	184.	207.	225.	235.	245.
19709	95.	140.	162.	187.	203.	220.	235.	241.
MEAN	107.	150.	168.	189.	210.	225.	240.	247.
S.D.	6.4	7.1	8.9	13.6	13.6	16.6	18.2	18.4
N	10	10	10	10	10	10	10	10

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 10

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19664	108.	149.	162.	182.	198.	203.	228.	232.
19669	116.	163.	183.	213.	241.	252.	279.	287.
19672	112.	156.	173.	196.	218.	231.	244.	255.
19674	104.	154.	169.	198.	224.	238.	258.	255.
19676	100.	144.	160.	183.	200.	221.	239.	254.
19690	108.	152.	168.	196.	215.	226.	238.	240.
19694	110.	158.	174.	185.	204.	217.	233.	245.
19699	101.	143.	160.	186.	193.	215.	237.	250.
19706	99.	135.	156.	183.	201.	214.	227.	246.
19707	112.	149.	156.	177.	201.	208.	224.	234.
MEAN	107.	150.	166.	190.	210.	223.	241.	250.
S.D.	5.8	8.2	8.8	10.7	14.8	14.7	16.6	15.5
N	10	10	10	10	10	10	10	10

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19665	107.	155.	171.	196.	215.	223.	241.	242.
19666	109.	148.	158.	167.	188.	186.	197.	202.
19667	120.	166.	184.	206.	227.	236.	251.	258.
19673	111.	149.	157.	169.	192.	220.	218.	248.
19677	112.	151.	168.	198.	223.	233.	249.	262.
19685	98.	139.	156.	177.	191.	208.	220.	230.
19686	113.	152.	172.	192.	219.	236.	242.	253.
19689	112.	157.	166.	185.	204.	215.	230.	246.
19693	103.	142.	161.	186.	206.	217.	233.	240.
19705	110.	153.	169.	202.	223.	246.	272.	273.
MEAN	110.	151.	166.	188.	209.	222.	235.	245.
S.D.	5.9	7.6	8.6	13.5	14.7	17.2	20.8	19.5
N	10	10	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	-2	-1	0	1	2	3	4	5
ANIMAL								
19671	107.	151.	161.	173.	177.	204.	202.	207.
19678	107.	146.	164.	176.	193.	200.	213.	222.
19679	116.	154.	169.	191.	211.	219.	242.	251.
19680	114.	153.	171.	205.	224.	246.	277.	266.
19681	109.	149.	165.	192.	216.	231.	236.	248.
19688	107.	152.	165.	193.	212.	219.	225.	236.
19691	106.	140.	151.	178.	190.	203.	225.	234.
19695	121.	159.	173.	207.	230.	243.	251.	272.
19700	112.	160.	178.	203.	217.	230.	246.	250.
19701	104.	143.	160.	181.	196.	211.	217.	232.
MEAN	110.	151.	166.	190.	207.	221.	233.	242.
S.D.	5.3	6.4	7.6	12.5	16.8	16.5	21.8	19.7
N	10	10	10	10	10	10	10	10

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 13

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 0 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19668	280.	294.	296.	304.	300.	314.	318.	316.	SCHEDULED EUTH WEEK 13
19670	243.	243.	257.	252.	266.	263.	268.	272.	SCHEDULED EUTH WEEK 13
19675	236.	249.	254.	255.	258.	270.	270.	274.	SCHEDULED EUTH WEEK 13
19683	263.	265.	270.	273.	281.	283.	283.	285.	SCHEDULED EUTH WEEK 13
19687	258.	266.	277.	276.	279.	284.	296.	291.	SCHEDULED EUTH WEEK 13
19692	274.	279.	280.	284.	290.	287.	299.	299.	SCHEDULED EUTH WEEK 13
19696	260.	275.	282.	281.	290.	298.	303.	303.	SCHEDULED EUTH WEEK 13
19698	241.	243.	250.	249.	261.	262.	264.	265.	SCHEDULED EUTH WEEK 13
19703	254.	254.	261.	267.	273.	275.	274.	276.	SCHEDULED EUTH WEEK 13
19709	247.	255.	263.	267.	270.	272.	277.	273.	SCHEDULED EUTH WEEK 13
MEAN	256.	262.	269.	271.	277.	281.	285.	285.	
S.D.	14.3	16.7	14.6	16.7	13.7	16.2	17.9	16.4	
N	10	10	10	10	10	10	10	10	

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 14
SPONSOR:[redacted]
SPONSOR NO.:06-012
INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19664	254.	265.	272.	273.	285.	299.	297.	302.	SCHEDULED EUTH WEEK 13
19669	299.	302.	306.	319.	330.	332.	340.	343.	SCHEDULED EUTH WEEK 13
19672	261.	267.	266.	270.	281.	281.	290.	290.	SCHEDULED EUTH WEEK 13
19674	279.	280.	288.	305.	307.	308.	303.	313.	SCHEDULED EUTH WEEK 13
19676	260.	270.	282.	293.	297.	293.	302.	308.	SCHEDULED EUTH WEEK 13
19690	254.	258.	257.	261.	263.	262.	273.	269.	SCHEDULED EUTH WEEK 13
19694	261.	277.	284.	277.	292.	301.	298.	300.	SCHEDULED EUTH WEEK 13
19699	252.	264.	272.	271.	278.	285.	290.	290.	SCHEDULED EUTH WEEK 13
19706	249.	252.	263.	276.	280.	279.	284.	288.	SCHEDULED EUTH WEEK 13
19707	254.	265.	263.	258.	267.	272.	279.	275.	SCHEDULED EUTH WEEK 13
MEAN	262.	270.	275.	280.	288.	291.	296.	298.	
S.D.	15.4	13.9	14.8	19.5	19.7	20.1	18.4	21.0	
N	10	10	10	10	10	10	10	10	

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 19
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHTS [G]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19665	260.	257.	267.	276.	277.	278.	281.	284.	SCHEDULED EUTH WEEK 13
19666	212.	227.	234.	227.	234.	252.	249.	253.	SCHEDULED EUTH WEEK 13
19667	259.	265.	274.	273.	274.	282.	284.	286.	SCHEDULED EUTH WEEK 13
19673	246.	263.	265.	270.	FOUND DEAD WEEK 9				
19677	273.	275.	283.	274.	298.	299.	295.	300.	SCHEDULED EUTH WEEK 13
19685	230.	245.	252.	256.	254.	268.	265.	266.	SCHEDULED EUTH WEEK 13
19686	263.	271.	273.	279.	278.	292.	290.	286.	SCHEDULED EUTH WEEK 13
19689	253.	264.	271.	274.	289.	296.	294.	301.	SCHEDULED EUTH WEEK 13
19693	250.	257.	262.	267.	273.	279.	276.	279.	SCHEDULED EUTH WEEK 13
19705	278.	284.	291.	293.	291.	303.	300.	306.	SCHEDULED EUTH WEEK 13
MEAN	252.	261.	267.	269.	274.	283.	282.	285.	
S.D.	19.6	16.0	15.9	17.4	19.7	16.3	16.3	17.1	
N	10	10	10	10	9	9	9	9	

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TABLE 19

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 16
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	6	7	8	9	10	11	12	13	
ANIMAL									
19671	219.	222.	228.	221.	241.	249.	252.	257.	SCHEDULED EUTH WEEK 13
19678	231.	237.	240.	240.	243.	252.	250.	252.	SCHEDULED EUTH WEEK 13
19679	258.	262.	279.	278.	287.	289.	288.	290.	SCHEDULED EUTH WEEK 13
19680	272.	280.	284.	283.	288.	302.	310.	303.	SCHEDULED EUTH WEEK 13
19681	256.	262.	269.	279.	287.	293.	295.	295.	SCHEDULED EUTH WEEK 13
19688	244.	245.	252.	260.	269.	268.	264.	270.	SCHEDULED EUTH WEEK 13
19691	249.	257.	267.	271.	279.	283.	277.	286.	SCHEDULED EUTH WEEK 13
19695	273.	279.	283.	297.	307.	312.	309.	320.	SCHEDULED EUTH WEEK 13
19700	262.	260.	277.	282.	291.	300.	299.	306.	SCHEDULED EUTH WEEK 13
19701	242.	251.	258.	257.	266.	274.	276.	284.	SCHEDULED EUTH WEEK 13
MEAN	251.	256.	264.	267.	276.	282.	282.	286.	
S.D.	17.2	17.8	19.0	22.7	21.2	21.2	21.9	21.6	
N	10	10	10	10	10	10	10	10	

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHT CHANGES (G)

MALE GROUP: 0 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19623	60.	28.	41.	47.	29.	40.	26.	23.
19626	58.	40.	69.	61.	44.	50.	31.	35.
19630	55.	31.	49.	42.	21.	28.	31.	25.
19636	60.	39.	56.	45.	33.	38.	27.	29.
19639	65.	33.	45.	43.	20.	33.	34.	14.
19644	54.	33.	48.	46.	25.	44.	25.	32.
19652	60.	34.	55.	58.	43.	47.	31.	37.
19655	65.	39.	62.	57.	41.	50.	48.	25.
19657	59.	37.	53.	41.	38.	31.	31.	25.
19660	58.	37.	40.	41.	34.	44.	27.	24.
MEAN	59.	35.	52.	48.	33.	41.	31.	27.
S.D.	3.6	3.9	9.2	7.6	8.8	7.9	6.6	6.7
N	10	10	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 20

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19619	57.	25.	46.	43.	35.	44.	32.	26.
19628	59.	33.	46.	57.	29.	39.	13.	20.
19640	60.	32.	60.	47.	31.	33.	32.	28.
19646	63.	39.	63.	58.	35.	39.	30.	21.
19647	59.	34.	52.	36.	14.	14.	25.	7.
19648	63.	38.	67.	55.	46.	44.	38.	34.
19650	60.	30.	59.	55.	38.	43.	31.	36.
19654	54.	27.	46.	39.	26.	28.	26.	19.
19659	67.	42.	62.	55.	42.	43.	30.	22.
19663	56.	25.	34.	32.	22.	29.	27.	27.
MEAN	60.	33.	54.	48.	32.	36.	28.	24.
S.D.	3.8	5.9	10.4	9.6	9.5	9.7	6.6	8.3
N	10	10	10	10	10	10	10	10

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19621	57.	32.	50.	37.	34.	34.	40.	33.
19622	65.	33.	63.	53.	40.	49.	41.	34.
19631	63.	33.	53.	46.	25.	33.	19.	32.
19632	58.	30.	53.	53.	40.	38.	21.	27.
19634	56.	37.	50.	49.	37.	39.	30.	32.
19635	61.	32.	54.	57.	35.	38.	27.	19.
19645	54.	27.	66.	45.	39.	2.	42.	16.
19656	58.	34.	51.	50.	33.	34.	29.	26.
19658	58.	38.	42.	40.	24.	35.	36.	30.
19661	63.	33.	61.	61.	42.	41.	40.	29.
MEAN	59.	33.	54.	49.	35.	34.	33.	28.
S.D.	3.5	3.1	7.1	7.4	6.2	12.3	8.5	6.0
N	10	10	10	10	10	10	10	10

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHT CHANGES [G]

MALE GROUP: 1000 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19618	61.	34.	53.	51.	34.	24.	44.	19.
19620	62.	33.	59.	54.	32.	36.	22.	22.
19624	57.	29.	54.	50.	26.	31.	33.	20.
19625	60.	29.	54.	60.	30.	30.	32.	28.
19633	61.	36.	50.	48.	33.	27.	38.	17.
19641	55.	32.	53.	20.	42.	34.	25.	25.
19643	57.	28.	40.	30.	15.	21.	28.	20.
19649	55.	29.	47.	35.	23.	17.	28.	22.
19653	58.	38.	45.	35.	20.	29.	30.	26.
19662	60.	34.	51.	23.	41.	30.	22.	2.
MEAN	59.	32.	51.	41.	30.	28.	30.	20.
S.D.	2.5	3.4	5.4	13.8	8.7	5.8	6.9	7.2
N	10	10	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHT CHANGES [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19623	28.	19.	20.	24.	8.	5.	8.	SCHEDULED EUTH WEEK 13
19626	35.	24.	18.	10.	14.	14.	12.	SCHEDULED EUTH WEEK 13
19630	19.	26.	18.	13.	17.	10.	4.	SCHEDULED EUTH WEEK 13
19636	13.	22.	17.	14.	15.	5.	5.	SCHEDULED EUTH WEEK 13
19639	18.	6.	13.	-102.	EUTH IN EXTREMIS WEEK 10			
19644	16.	22.	12.	14.	18.	6.	6.	SCHEDULED EUTH WEEK 13
19652	14.	36.	27.	12.	27.	-3.	15.	SCHEDULED EUTH WEEK 13
19655	36.	27.	18.	23.	10.	10.	14.	SCHEDULED EUTH WEEK 13
19657	16.	16.	16.	19.	17.	5.	6.	SCHEDULED EUTH WEEK 13
19660	22.	23.	18.	12.	19.	11.	13.	SCHEDULED EUTH WEEK 13
MEAN	22.	22.	18.	4.	16.	7.	9.	
S.D.	8.4	7.8	4.1	37.5	5.5	4.9	4.3	
N	10	10	10	10	9	9	9	

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Modified: 8/30/2006

TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19619	29.	23.	24.	18.	14.	12.	12.	SCHEDULED EUTH WEEK 13
19628	13.	1.	9.	17.	14.	2.	9.	SCHEDULED EUTH WEEK 13
19640	19.	20.	18.	14.	19.	1.	15.	SCHEDULED EUTH WEEK 13
19646	25.	30.	10.	21.	7.	12.	7.	SCHEDULED EUTH WEEK 13
19647	18.	-30.	41.	15.	21.	-3.	15.	SCHEDULED EUTH WEEK 13
19648	31.	21.	21.	18.	28.	4.	18.	SCHEDULED EUTH WEEK 13
19650	28.	14.	31.	17.	27.	0.	14.	SCHEDULED EUTH WEEK 13
19654	14.	17.	15.	14.	12.	9.	14.	SCHEDULED EUTH WEEK 13
19659	18.	32.	32.	2.	24.	8.	13.	SCHEDULED EUTH WEEK 13
19663	19.	19.	12.	15.	24.	5.	8.	SCHEDULED EUTH WEEK 13
MEAN	21.	15.	21.	15.	19.	5.	13.	
S.D.	6.4	17.9	10.6	5.1	7.0	5.1	3.5	
N	10	10	10	10	10	10	10	

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Modified: 8/30/2006

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 20
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL BODY WEIGHT CHANGES [G]

MALE GROUP: 400 MG/KG/DAY

WEEK / ANIMAL	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
19621	19.	28.	16.	5.	5.	8.	9.	SCHEDULED EUTH WEEK 13
19622	33.	27.	22.	28.	22.	22.	12.	SCHEDULED EUTH WEEK 13
19631	12.	16.	6.	22.	12.	-2.	3.	SCHEDULED EUTH WEEK 13
19632	24.	12.	-17.	26.	21.	13.	12.	SCHEDULED EUTH WEEK 13
19634	25.	-13.	26.	17.	10.	14.	3.	SCHEDULED EUTH WEEK 13
19635	26.	24.	15.	14.	20.	4.	13.	SCHEDULED EUTH WEEK 13
19645	28.	21.	25.	15.	9.	6.	9.	SCHEDULED EUTH WEEK 13
19656	27.	21.	17.	15.	-1.	17.	0.	SCHEDULED EUTH WEEK 13
19658	19.	24.	18.	26.	18.	17.	18.	SCHEDULED EUTH WEEK 13
19661	30.	-6.	27.	16.	22.	5.	10.	SCHEDULED EUTH WEEK 13
MEAN	24.	15.	16.	18.	14.	10.	9.	
S.D.	6.1	14.1	13.0	7.1	8.0	7.4	5.5	
N	10	10	10	10	10	10	10	

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Modified: 8/30/2006

TABLE 20

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 1000 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19618	7.	33.	22.	16.	15.	-2.	8.	SCHEDULED EUTH WEEK 13
19620	12.	14.	-23.	27.	24.	3.	14.	SCHEDULED EUTH WEEK 13
19624	21.	10.	-7.	15.	24.	-6.	14.	SCHEDULED EUTH WEEK 13
19625	19.	18.	22.	14.	-6.	-2.	10.	SCHEDULED EUTH WEEK 13
19633	18.	15.	10.	17.	17.	11.	19.	SCHEDULED EUTH WEEK 13
19641	15.	19.	-9.	18.	14.	5.	19.	SCHEDULED EUTH WEEK 13
19643	15.	20.	17.	-2.	8.	10.	3.	SCHEDULED EUTH WEEK 13
19649	16.	8.	14.	-18.	25.	5.	9.	SCHEDULED EUTH WEEK 13
19653	17.	26.	23.	5.	25.	13.	18.	SCHEDULED EUTH WEEK 13
19662	12.	5.	18.	0.	19.	13.	4.	SCHEDULED EUTH WEEK 13
MEAN	15.	17.	9.	9.	17.	5.	12.	
S.D.	4.0	8.4	16.0	13.0	9.7	6.8	5.9	
N	10	10	10	10	10	10	10	

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Modified: 8/30/2006

TABLE 20

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALE GROUP: 0 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19668	48.	22.	31.	15.	27.	20.	12.	-8.
19670	40.	14.	17.	25.	10.	14.	4.	10.
19675	35.	14.	20.	19.	15.	14.	15.	2.
19683	47.	22.	21.	26.	2.	22.	-2.	18.
19687	47.	19.	22.	24.	14.	18.	3.	7.
19692	42.	19.	30.	23.	18.	12.	7.	9.
19696	45.	18.	10.	24.	22.	15.	5.	19.
19698	36.	17.	14.	17.	5.	13.	8.	18.
19703	39.	15.	17.	23.	18.	10.	10.	9.
19709	45.	22.	25.	16.	17.	15.	6.	6.
MEAN	42.	18.	21.	21.	15.	15.	7.	9.
S.D.	4.7	3.2	6.7	4.0	7.5	3.7	4.8	8.3
N	10	10	10	10	10	10	10	10

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TABLE 20

SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19664	41.	13.	20.	16.	5.	25.	4.	22.
19669	47.	20.	30.	28.	11.	27.	8.	12.
19672	44.	17.	23.	22.	13.	13.	11.	6.
19674	50.	15.	29.	26.	14.	20.	-3.	24.
19676	44.	16.	23.	17.	21.	18.	15.	6.
19690	44.	16.	28.	19.	11.	12.	2.	14.
19694	48.	16.	11.	19.	13.	16.	12.	16.
19699	42.	17.	26.	7.	22.	22.	13.	2.
19706	36.	21.	27.	18.	13.	13.	19.	3.
19707	37.	7.	21.	24.	7.	16.	10.	20.
MEAN	43.	16.	24.	20.	13.	18.	9.	13.
S.D.	4.5	3.9	5.6	5.9	5.3	5.2	6.5	8.0
N	10	10	10	10	10	10	10	10

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TABLE 20

SPONSOR:[redacted]

INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19665	48.	16.	25.	19.	8.	18.	1.	18.
19666	39.	10.	9.	21.	-2.	11.	5.	10.
19667	46.	18.	22.	21.	9.	15.	7.	1.
19673	38.	8.	12.	23.	28.	-2.	30.	-2.
19677	39.	17.	30.	25.	10.	16.	13.	11.
19685	41.	17.	21.	14.	17.	12.	10.	0.
19686	39.	20.	20.	27.	17.	6.	11.	10.
19689	45.	9.	19.	19.	11.	15.	16.	7.
19693	39.	19.	25.	20.	11.	16.	7.	10.
19705	43.	16.	33.	21.	23.	26.	1.	5.
MEAN	42.	15.	22.	21.	13.	13.	10.	7.
S.D.	3.6	4.3	7.3	3.6	8.4	7.4	8.5	6.1
N	10	10	10	10	10	10	10	10

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	-2 TO -1	-1 TO 0	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6
ANIMAL								
19671	44.	10.	12.	4.	27.	-2.	5.	12.
19678	39.	18.	12.	17.	7.	13.	9.	9.
19679	38.	15.	22.	20.	8.	23.	9.	7.
19680	39.	18.	34.	19.	22.	31.	-11.	6.
19681	40.	16.	27.	24.	15.	5.	12.	8.
19688	45.	13.	28.	19.	7.	6.	11.	8.
19691	34.	11.	27.	12.	13.	22.	9.	15.
19695	38.	14.	34.	23.	13.	8.	21.	1.
19700	48.	18.	25.	14.	13.	16.	4.	12.
19701	39.	17.	21.	15.	15.	6.	15.	10.
MEAN	40.	15.	24.	17.	14.	13.	8.	9.
S.D.	4.1	2.9	7.7	5.9	6.4	10.1	8.4	3.9
N	10	10	10	10	10	10	10	10

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALE GROUP: 0 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19668	14.	2.	8.	-4.	14.	4.	-2.	SCHEDULED EUTH WEEK 13
19670	0.	14.	-5.	14.	-3.	5.	4.	SCHEDULED EUTH WEEK 13
19675	13.	5.	1.	3.	12.	0.	4.	SCHEDULED EUTH WEEK 13
19683	2.	5.	3.	8.	2.	0.	2.	SCHEDULED EUTH WEEK 13
19687	8.	11.	-1.	3.	5.	12.	-5.	SCHEDULED EUTH WEEK 13
19692	5.	1.	4.	6.	-3.	12.	0.	SCHEDULED EUTH WEEK 13
19696	15.	7.	-1.	9.	8.	5.	0.	SCHEDULED EUTH WEEK 13
19698	2.	7.	-1.	12.	1.	2.	1.	SCHEDULED EUTH WEEK 13
19703	0.	7.	6.	6.	2.	-1.	2.	SCHEDULED EUTH WEEK 13
19709	8.	8.	4.	3.	2.	5.	-4.	SCHEDULED EUTH WEEK 13
MEAN	7.	7.	2.	6.	4.	4.	0.	
S.D.	5.8	3.9	3.9	5.2	5.8	4.6	3.1	
N	10	10	10	10	10	10	10	

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 14
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19664	11.	7.	1.	12.	14.	-2.	5.	SCHEDULED EUTH WEEK 13
19669	3.	4.	13.	11.	2.	8.	3.	SCHEDULED EUTH WEEK 13
19672	6.	-1.	4.	11.	0.	9.	0.	SCHEDULED EUTH WEEK 13
19674	1.	8.	17.	2.	1.	-5.	10.	SCHEDULED EUTH WEEK 13
19676	10.	12.	11.	4.	-4.	9.	6.	SCHEDULED EUTH WEEK 13
19690	4.	-1.	4.	2.	-1.	11.	-4.	SCHEDULED EUTH WEEK 13
19694	16.	7.	-7.	15.	9.	-3.	2.	SCHEDULED EUTH WEEK 13
19699	12.	8.	-1.	7.	7.	5.	0.	SCHEDULED EUTH WEEK 13
19706	3.	11.	13.	4.	-1.	5.	4.	SCHEDULED EUTH WEEK 13
19707	11.	-2.	-5.	9.	5.	7.	-4.	SCHEDULED EUTH WEEK 13
MEAN	8.	5.	5.	8.	3.	4.	2.	
S.D.	4.9	5.1	8.2	4.6	5.5	5.7	4.4	
N	10	10	10	10	10	10	10	

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19665	-3.	10.	9.	1.	1.	3.	3.	SCHEDULED EUTH WEEK 13
19666	15.	7.	-7.	7.	18.	-3.	4.	SCHEDULED EUTH WEEK 13
19667	6.	9.	-1.	1.	8.	2.	2.	SCHEDULED EUTH WEEK 13
19673	17.	2.	5.	FOUND DEAD WEEK 9				
19677	2.	8.	-9.	24.	1.	-4.	5.	SCHEDULED EUTH WEEK 13
19685	15.	7.	4.	-2.	14.	-3.	1.	SCHEDULED EUTH WEEK 13
19686	8.	2.	6.	-1.	14.	-2.	-4.	SCHEDULED EUTH WEEK 13
19689	11.	7.	3.	15.	7.	-2.	7.	SCHEDULED EUTH WEEK 13
19693	7.	5.	5.	6.	6.	-3.	3.	SCHEDULED EUTH WEEK 13
19705	6.	7.	2.	-2.	12.	-3.	6.	SCHEDULED EUTH WEEK 13
MEAN	8.	6.	2.	5.	9.	-2.	3.	
S.D.	6.3	2.7	5.8	8.9	5.9	2.4	3.2	
N	10	10	10	9	9	9	9	

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TABLE 20

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	6 TO 7	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL								
19671	3.	6.	-7.	20.	8.	3.	5.	SCHEDULED EUTH WEEK 13
19678	6.	3.	0.	3.	9.	-2.	2.	SCHEDULED EUTH WEEK 13
19679	4.	17.	-1.	9.	2.	-1.	2.	SCHEDULED EUTH WEEK 13
19680	8.	4.	-1.	5.	14.	8.	-7.	SCHEDULED EUTH WEEK 13
19681	6.	7.	10.	8.	6.	2.	0.	SCHEDULED EUTH WEEK 13
19688	1.	7.	8.	9.	-1.	-4.	6.	SCHEDULED EUTH WEEK 13
19691	8.	10.	4.	8.	4.	-6.	9.	SCHEDULED EUTH WEEK 13
19695	6.	4.	14.	10.	5.	-3.	11.	SCHEDULED EUTH WEEK 13
19700	-2.	17.	5.	9.	9.	-1.	7.	SCHEDULED EUTH WEEK 13
19701	9.	7.	-1.	9.	8.	2.	8.	SCHEDULED EUTH WEEK 13
MEAN	5.	8.	3.	9.	6.	0.	4.	
S.D.	3.4	5.1	6.3	4.4	4.2	4.0	5.3	
N	10	10	10	10	10	10	10	

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TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 0 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19623	41.	88.	117.	157.	183.	206.	234.	253.
19626	69.	130.	174.	224.	255.	290.	325.	349.
19630	49.	91.	112.	140.	171.	196.	215.	241.
19636	56.	101.	134.	172.	199.	228.	241.	263.
19639	45.	88.	108.	141.	175.	189.	207.	213.
19644	48.	94.	119.	163.	188.	220.	236.	258.
19652	55.	113.	156.	203.	234.	271.	285.	321.
19655	62.	119.	160.	210.	258.	283.	319.	346.
19657	53.	94.	132.	163.	194.	219.	235.	251.
19660	40.	81.	115.	159.	186.	210.	232.	255.
MEAN	52.	100.	133.	173.	204.	231.	253.	275.
S.D.	9.2	15.8	23.1	29.1	32.5	36.7	41.7	46.6
N	10	10	10	10	10	10	10	10

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 21
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 160 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19619	46.	89.	124.	168.	200.	226.	255.	278.
19628	46.	103.	132.	171.	184.	204.	217.	218.
19640	60.	107.	138.	171.	203.	231.	250.	270.
19646	63.	121.	156.	195.	225.	246.	271.	301.
19647	52.	88.	102.	116.	141.	148.	166.	136.
19648	67.	122.	168.	212.	250.	284.	315.	336.
19650	59.	114.	152.	195.	226.	262.	290.	304.
19654	46.	85.	111.	139.	165.	184.	198.	215.
19659	62.	117.	159.	202.	232.	254.	272.	304.
19663	34.	66.	88.	117.	144.	171.	190.	209.
MEAN	54.	101.	133.	169.	197.	221.	242.	257.
S.D.	10.4	18.6	26.6	34.5	37.8	43.4	47.9	61.0
N	10	10	10	10	10	10	10	10

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TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19621	50.	87.	121.	155.	195.	228.	247.	275.
19622	63.	116.	156.	205.	246.	280.	313.	340.
19631	53.	99.	124.	157.	176.	208.	220.	236.
19632	53.	106.	146.	184.	205.	232.	256.	268.
19634	50.	99.	136.	175.	205.	237.	262.	249.
19635	54.	111.	146.	184.	211.	230.	256.	280.
19645	66.	111.	150.	152.	194.	210.	238.	259.
19656	51.	101.	134.	168.	197.	223.	250.	271.
19658	42.	82.	106.	141.	177.	207.	226.	250.
19661	61.	122.	164.	205.	245.	274.	304.	298.
MEAN	54.	103.	138.	173.	205.	233.	257.	273.
S.D.	7.1	12.5	17.6	22.0	24.1	25.5	30.2	29.6
N	10	10	10	10	10	10	10	10

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TABLE 21

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 1000 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19618	53.	104.	138.	162.	206.	225.	232.	265.
19620	59.	113.	145.	181.	203.	225.	237.	251.
19624	54.	104.	130.	161.	194.	214.	235.	245.
19625	54.	114.	144.	174.	206.	234.	253.	271.
19633	50.	98.	131.	158.	196.	213.	231.	246.
19641	53.	73.	115.	149.	174.	199.	214.	233.
19643	40.	70.	85.	106.	134.	154.	169.	189.
19649	47.	82.	105.	122.	150.	172.	188.	196.
19653	45.	80.	100.	129.	159.	185.	202.	228.
19662	51.	74.	115.	145.	167.	169.	181.	186.
MEAN	51.	91.	121.	149.	179.	199.	214.	231.
S.D.	5.4	17.2	20.1	23.7	25.8	27.6	28.0	30.9
N	10	10	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-012

MALE GROUP: 0 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19623	273.	297.	305.	310.	318.	SCHEDULED EUTH WEEK 13
19626	367.	377.	391.	405.	417.	SCHEDULED EUTH WEEK 13
19630	259.	272.	289.	299.	303.	SCHEDULED EUTH WEEK 13
19636	280.	294.	309.	314.	319.	SCHEDULED EUTH WEEK 13
19639	226.	124.	EUTH IN EXTREMIS WEEK 10			
19644	270.	284.	302.	308.	314.	SCHEDULED EUTH WEEK 13
19652	348.	360.	387.	384.	399.	SCHEDULED EUTH WEEK 13
19655	364.	387.	397.	407.	421.	SCHEDULED EUTH WEEK 13
19657	267.	286.	303.	308.	314.	SCHEDULED EUTH WEEK 13
19660	273.	285.	304.	315.	328.	SCHEDULED EUTH WEEK 13
MEAN	293.	297.	332.	339.	348.	
S.D.	48.7	74.1	45.2	45.5	49.0	
N	10	10	9	9	9	

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Modified: 8/30/2006

TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19619	302.	320.	334.	346.	358.	SCHEDULED EUTH WEEK 13
19628	227.	244.	258.	260.	269.	SCHEDULED EUTH WEEK 13
19640	288.	302.	321.	322.	337.	SCHEDULED EUTH WEEK 13
19646	311.	332.	339.	351.	358.	SCHEDULED EUTH WEEK 13
19647	177.	192.	213.	210.	225.	SCHEDULED EUTH WEEK 13
19648	357.	375.	403.	407.	425.	SCHEDULED EUTH WEEK 13
19650	335.	352.	379.	379.	393.	SCHEDULED EUTH WEEK 13
19654	230.	244.	256.	265.	279.	SCHEDULED EUTH WEEK 13
19659	336.	338.	362.	370.	383.	SCHEDULED EUTH WEEK 13
19663	221.	236.	260.	265.	273.	SCHEDULED EUTH WEEK 13
MEAN	278.	294.	313.	318.	330.	
S.D.	60.5	60.4	62.5	64.0	65.0	
N	10	10	10	10	10	

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TABLE 21

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

MALE GROUP: 400 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19621	291.	296.	301.	309.	318.	SCHEDULED EUTH WEEK 13
19622	362.	390.	412.	434.	446.	SCHEDULED EUTH WEEK 13
19631	242.	264.	276.	274.	277.	SCHEDULED EUTH WEEK 13
19632	251.	277.	298.	311.	323.	SCHEDULED EUTH WEEK 13
19634	275.	292.	302.	316.	319.	SCHEDULED EUTH WEEK 13
19635	295.	309.	329.	333.	346.	SCHEDULED EUTH WEEK 13
19645	284.	299.	308.	314.	323.	SCHEDULED EUTH WEEK 13
19656	288.	303.	302.	319.	319.	SCHEDULED EUTH WEEK 13
19658	268.	294.	312.	329.	347.	SCHEDULED EUTH WEEK 13
19661	325.	341.	363.	368.	378.	SCHEDULED EUTH WEEK 13
MEAN	288.	307.	320.	331.	340.	
S.D.	34.9	35.6	39.5	43.2	45.6	
N	10	10	10	10	10	

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TABLE 21

SPONSOR:[redacted]

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

MALE GROUP: 1000 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19618	287.	303.	318.	316.	324.	SCHEDULED EUTH WEEK 13
19620	228.	255.	279.	282.	296.	SCHEDULED EUTH WEEK 13
19624	238.	253.	277.	271.	285.	SCHEDULED EUTH WEEK 13
19625	293.	307.	301.	299.	309.	SCHEDULED EUTH WEEK 13
19633	256.	273.	290.	301.	320.	SCHEDULED EUTH WEEK 13
19641	224.	242.	256.	261.	280.	SCHEDULED EUTH WEEK 13
19643	206.	204.	212.	222.	225.	SCHEDULED EUTH WEEK 13
19649	210.	192.	217.	222.	231.	SCHEDULED EUTH WEEK 13
19653	251.	256.	281.	294.	312.	SCHEDULED EUTH WEEK 13
19662	204.	204.	223.	236.	240.	SCHEDULED EUTH WEEK 13
MEAN	240.	249.	265.	270.	282.	
S.D.	31.9	39.9	36.9	34.1	37.5	
N	10	10	10	10	10	

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TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 0 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19668	31.	46.	73.	93.	105.	97.	111.	113.
19670	17.	42.	52.	66.	70.	80.	80.	94.
19675	20.	39.	54.	68.	83.	85.	98.	103.
19683	21.	47.	49.	71.	69.	87.	89.	94.
19687	22.	46.	60.	78.	81.	88.	96.	107.
19692	30.	53.	71.	83.	90.	99.	104.	105.
19696	10.	34.	56.	71.	76.	95.	110.	117.
19698	14.	31.	36.	49.	57.	75.	77.	84.
19703	17.	40.	58.	68.	78.	87.	87.	94.
19709	25.	41.	58.	73.	79.	85.	93.	101.
MEAN	21.	42.	57.	72.	79.	88.	95.	101.
S.D.	6.7	6.5	10.6	11.5	12.9	7.5	11.7	10.0
N	10	10	10	10	10	10	10	10

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TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19664	20.	36.	41.	66.	70.	92.	103.	110.
19669	30.	58.	69.	96.	104.	116.	119.	123.
19672	23.	45.	58.	71.	82.	88.	94.	93.
19674	29.	55.	69.	89.	86.	110.	111.	119.
19676	23.	40.	61.	79.	94.	100.	110.	122.
19690	28.	47.	58.	70.	72.	86.	90.	89.
19694	11.	30.	43.	59.	71.	87.	103.	110.
19699	26.	33.	55.	77.	90.	92.	104.	112.
19706	27.	45.	58.	71.	90.	93.	96.	107.
19707	21.	45.	52.	68.	78.	98.	109.	107.
MEAN	24.	43.	56.	75.	84.	96.	104.	109.
S.D.	5.6	9.0	9.3	11.0	11.2	10.0	8.8	11.3
N	10	10	10	10	10	10	10	10

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TABLE 21
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 400 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19665	25.	44.	52.	70.	71.	89.	86.	96.
19666	9.	30.	28.	39.	44.	54.	69.	76.
19667	22.	43.	52.	67.	74.	75.	81.	90.
19673	12.	35.	63.	61.	91.	89.	106.	108.
19677	30.	55.	65.	81.	94.	105.	107.	115.
19685	21.	35.	52.	64.	74.	74.	89.	96.
19686	20.	47.	64.	70.	81.	91.	99.	101.
19689	19.	38.	49.	64.	80.	87.	98.	105.
19693	25.	45.	56.	72.	79.	89.	96.	101.
19705	33.	54.	77.	103.	104.	109.	115.	122.
MEAN	22.	43.	56.	69.	79.	86.	95.	101.
S.D.	7.3	8.2	13.0	16.1	16.1	15.7	13.7	12.9
N	10	10	10	10	10	10	10	10

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TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	0 TO 1	0 TO 2	0 TO 3	0 TO 4	0 TO 5	0 TO 6	0 TO 7	0 TO 8
ANIMAL								
19671	12.	16.	43.	41.	46.	58.	61.	67.
19678	12.	29.	36.	49.	58.	67.	73.	76.
19679	22.	42.	50.	73.	82.	89.	93.	110.
19680	34.	53.	75.	106.	95.	101.	109.	113.
19681	27.	51.	66.	71.	83.	91.	97.	104.
19688	28.	47.	54.	60.	71.	79.	80.	87.
19691	27.	39.	52.	74.	83.	98.	106.	116.
19695	34.	57.	70.	78.	99.	100.	106.	110.
19700	25.	39.	52.	68.	72.	84.	82.	99.
19701	21.	36.	51.	57.	72.	82.	91.	98.
MEAN	24.	41.	55.	68.	76.	85.	90.	98.
S.D.	7.7	12.2	12.1	17.9	16.0	14.1	15.7	16.5
N	10	10	10	10	10	10	10	10

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TABLE 21

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 13

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 0 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19668	121.	117.	131.	135.	133.	SCHEDULED EUTH WEEK 13
19670	89.	103.	100.	105.	109.	SCHEDULED EUTH WEEK 13
19675	104.	107.	119.	119.	123.	SCHEDULED EUTH WEEK 13
19683	97.	105.	107.	107.	109.	SCHEDULED EUTH WEEK 13
19687	106.	109.	114.	126.	121.	SCHEDULED EUTH WEEK 13
19692	109.	115.	112.	124.	124.	SCHEDULED EUTH WEEK 13
19696	116.	125.	133.	138.	138.	SCHEDULED EUTH WEEK 13
19698	83.	95.	96.	98.	99.	SCHEDULED EUTH WEEK 13
19703	100.	106.	108.	107.	109.	SCHEDULED EUTH WEEK 13
19709	105.	108.	110.	115.	111.	SCHEDULED EUTH WEEK 13
MEAN	103.	109.	113.	117.	118.	
S.D.	11.5	8.3	12.0	13.4	12.2	
N	10	10	10	10	10	

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PROJECT NO.:WIL-187054
SPONSOR:[redacted]
SPONSOR NO.:06-012

TABLE 21
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19664	111.	123.	137.	135.	140.	SCHEDULED EUTH WEEK 13
19669	136.	147.	149.	157.	160.	SCHEDULED EUTH WEEK 13
19672	97.	108.	108.	117.	117.	SCHEDULED EUTH WEEK 13
19674	136.	138.	139.	134.	144.	SCHEDULED EUTH WEEK 13
19676	133.	137.	133.	142.	148.	SCHEDULED EUTH WEEK 13
19690	93.	95.	94.	105.	101.	SCHEDULED EUTH WEEK 13
19694	103.	118.	127.	124.	126.	SCHEDULED EUTH WEEK 13
19699	111.	118.	125.	130.	130.	SCHEDULED EUTH WEEK 13
19706	120.	124.	123.	128.	132.	SCHEDULED EUTH WEEK 13
19707	102.	111.	116.	123.	119.	SCHEDULED EUTH WEEK 13
MEAN	114.	122.	125.	130.	132.	
S.D.	16.3	15.6	16.1	14.1	17.1	
N	10	10	10	10	10	

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TABLE 21

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19665	105.	106.	107.	110.	113.	SCHEDULED EUTH WEEK 13
19666	69.	76.	94.	91.	95.	SCHEDULED EUTH WEEK 13
19667	89.	90.	98.	100.	102.	SCHEDULED EUTH WEEK 13
19673	113.	FOUND DEAD WEEK 9				
19677	106.	130.	131.	127.	132.	SCHEDULED EUTH WEEK 13
19685	100.	98.	112.	109.	110.	SCHEDULED EUTH WEEK 13
19686	107.	106.	120.	118.	114.	SCHEDULED EUTH WEEK 13
19689	108.	123.	130.	128.	135.	SCHEDULED EUTH WEEK 13
19693	106.	112.	118.	115.	118.	SCHEDULED EUTH WEEK 13
19705	124.	122.	134.	131.	137.	SCHEDULED EUTH WEEK 13
MEAN	103.	107.	116.	114.	117.	
S.D.	14.8	17.2	14.4	13.4	14.7	
N	10	9	9	9	9	

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 21
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL CUMULATIVE BODY WEIGHT CHANGES [G]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	0 TO 9	0 TO 10	0 TO 11	0 TO 12	0 TO 13	
ANIMAL						
19671	60.	80.	88.	91.	96.	SCHEDULED EUTH WEEK 13
19678	76.	79.	88.	86.	88.	SCHEDULED EUTH WEEK 13
19679	109.	118.	120.	119.	121.	SCHEDULED EUTH WEEK 13
19680	112.	117.	131.	139.	132.	SCHEDULED EUTH WEEK 13
19681	114.	122.	128.	130.	130.	SCHEDULED EUTH WEEK 13
19688	95.	104.	103.	99.	105.	SCHEDULED EUTH WEEK 13
19691	120.	128.	132.	126.	135.	SCHEDULED EUTH WEEK 13
19695	124.	134.	139.	136.	147.	SCHEDULED EUTH WEEK 13
19700	104.	113.	122.	121.	128.	SCHEDULED EUTH WEEK 13
19701	97.	106.	114.	116.	124.	SCHEDULED EUTH WEEK 13
MEAN	101.	110.	117.	116.	121.	
S.D.	20.0	18.5	18.1	18.5	18.6	
N	10	10	10	10	10	

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 0 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19623	22.	21.	22.	23.	24.	23.	23.	23.
19626	22.	28.	30.	29.	29.	30.	31.	33.
19630	23.	26.	26.	23.	22.	23.	24.	24.
19636	22.	27.	25.	24.	24.	24.	24.	23.
19639	22.	26.	25.	24.	23.	24.	23.	22.
19644	21.	24.	23.	21.	22.	22.	23.	22.
19652	22.	25.	26.	27.	26.	26.	26.	26.
19655	21.	25.	26.	26.	25.	28.	27.	27.
19657	21.	27.	25.	25.	22.	NA	23.	22.
19660	21.	23.	21.	23.	23.	24.	24.	24.
MEAN	22.	25.	25.	25.	24.	25.	25.	25.
S.D.	0.7	2.1	2.5	2.3	2.2	2.6	2.6	3.4
N	10	10	10	10	10	9	10	10

NA = NOT APPLICABLE

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 2

SPONSOR:[redacted]

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19619	21.	23.	23.	24.	24.	25.	26.	25.
19628	21.	23.	25.	24.	21.	21.	20.	20.
19640	21.	25.	26.	24.	23.	24.	24.	24.
19646	22.	28.	29.	28.	26.	28.	26.	27.
19647	22.	25.	22.	21.	17.	22.	21.	22.
19648	22.	28.	28.	30.	28.	29.	29.	30.
19650	22.	26.	27.	27.	27.	28.	29.	29.
19654	22.	25.	24.	24.	20.	21.	21.	21.
19659	23.	27.	28.	28.	28.	28.	26.	26.
19663	21.	21.	23.	22.	20.	21.	23.	22.
MEAN	22.	25.	26.	25.	23.	25.	25.	25.
S.D.	0.7	2.3	2.5	2.9	3.8	3.3	3.2	3.4
N	10	10	10	10	10	10	10	10

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 400 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19621	20.	22.	22.	23.	22.	26.	24.	25.
19622	24.	27.	27.	28.	28.	31.	30.	30.
19631	21.	27.	25.	27.	25.	28.	27.	26.
19632	21.	24.	27.	27.	25.	25.	26.	26.
19634	21.	25.	24.	24.	25.	27.	27.	26.
19635	21.	22.	25.	25.	24.	26.	23.	25.
19645	22.	23.	26.	27.	17.	26.	25.	27.
19656	21.	23.	25.	25.	24.	24.	24.	24.
19658	22.	25.	25.	24.	24.	26.	26.	26.
19661	22.	26.	29.	28.	28.	30.	29.	29.
MEAN	22.	24.	26.	26.	24.	27.	26.	26.
S.D.	1.1	1.9	1.9	1.8	3.1	2.2	2.2	1.8
N	10	10	10	10	10	10	10	10

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 22
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 1000 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19618	23.	24.	31.	18.	30.	28.	26.	24.
19620	21.	24.	25.	25.	24.	25.	23.	24.
19624	22.	23.	25.	25.	23.	24.	23.	24.
19625	22.	24.	28.	29.	26.	27.	27.	31.
19633	22.	24.	27.	26.	25.	27.	26.	27.
19641	22.	23.	25.	24.	24.	24.	26.	25.
19643	21.	20.	20.	19.	18.	21.	21.	22.
19649	21.	22.	24.	25.	22.	23.	23.	23.
19653	21.	22.	25.	23.	23.	25.	26.	25.
19662	22.	22.	23.	22.	23.	23.	22.	21.
MEAN	22.	23.	25.	24.	24.	25.	24.	25.
S.D.	0.7	1.3	2.9	3.3	3.0	2.2	2.1	2.8
N	10	10	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 0 MG/KG/DAY

WEEK	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL							
19623	22.	24.	24.	22.	21.	22.	SCHEDULED EUTH WEEK 13
19626	30.	30.	27.	27.	29.	28.	SCHEDULED EUTH WEEK 13
19630	24.	22.	23.	22.	23.	23.	SCHEDULED EUTH WEEK 13
19636	24.	24.	23.	23.	22.	23.	SCHEDULED EUTH WEEK 13
19639	21.	22.	11.	EUTH IN EXTREMIS WEEK 10			
19644	23.	22.	23.	23.	22.	21.	SCHEDULED EUTH WEEK 13
19652	26.	25.	24.	26.	25.	26.	SCHEDULED EUTH WEEK 13
19655	26.	26.	26.	24.	25.	25.	SCHEDULED EUTH WEEK 13
19657	22.	22.	22.	23.	22.	22.	SCHEDULED EUTH WEEK 13
19660	23.	23.	26.	23.	23.	24.	SCHEDULED EUTH WEEK 13
MEAN	24.	24.	23.	24.	24.	24.	
S.D.	2.6	2.5	4.5	1.7	2.5	2.2	
N	10	10	10	9	9	9	

Audited Draft

Modified: 8/30/2006

TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 160 MG/KG/DAY

WEEK	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL							
19619	25.	25.	25.	24.	25.	23.	SCHEDULED EUTH WEEK 13
19628	19.	19.	19.	19.	19.	19.	SCHEDULED EUTH WEEK 13
19640	24.	24.	23.	24.	24.	24.	SCHEDULED EUTH WEEK 13
19646	26.	26.	26.	25.	25.	23.	SCHEDULED EUTH WEEK 13
19647	11.	24.	22.	21.	21.	21.	SCHEDULED EUTH WEEK 13
19648	29.	28.	28.	29.	28.	27.	SCHEDULED EUTH WEEK 13
19650	27.	29.	29.	27.	26.	26.	SCHEDULED EUTH WEEK 13
19654	21.	20.	20.	20.	20.	22.	SCHEDULED EUTH WEEK 13
19659	27.	26.	22.	25.	23.	24.	SCHEDULED EUTH WEEK 13
19663	20.	21.	21.	22.	21.	21.	SCHEDULED EUTH WEEK 13
MEAN	23.	24.	24.	24.	23.	23.	
S.D.	5.3	3.3	3.4	3.1	2.9	2.4	
N	10	10	10	10	10	10	

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TABLE 22
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 400 MG/KG/DAY

WEEK	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL							
19621	25.	25.	23.	22.	24.	25.	SCHEDULED EUTH WEEK 13
19622	28.	29.	29.	29.	30.	29.	SCHEDULED EUTH WEEK 13
19631	25.	25.	22.	21.	23.	24.	SCHEDULED EUTH WEEK 13
19632	25.	21.	24.	24.	23.	24.	SCHEDULED EUTH WEEK 13
19634	20.	23.	24.	22.	24.	22.	SCHEDULED EUTH WEEK 13
19635	26.	26.	26.	25.	25.	26.	SCHEDULED EUTH WEEK 13
19645	27.	28.	25.	24.	24.	23.	SCHEDULED EUTH WEEK 13
19656	24.	24.	23.	21.	23.	22.	SCHEDULED EUTH WEEK 13
19658	25.	25.	26.	26.	26.	27.	SCHEDULED EUTH WEEK 13
19661	24.	26.	27.	27.	28.	28.	SCHEDULED EUTH WEEK 13
MEAN	25.	25.	25.	24.	25.	25.	
S.D.	2.1	2.3	2.1	2.7	2.4	2.4	
N	10	10	10	10	10	10	

Audited Draft

Modified: 8/30/2006

TABLE 22

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

MALE GROUP: 1000 MG/KG/DAY

WEEK	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL							
19618	27.	28.	27.	26.	26.	26.	SCHEDULED EUTH WEEK 13
19620	24.	19.	23.	24.	22.	24.	SCHEDULED EUTH WEEK 13
19624	23.	23.	22.	24.	21.	24.	SCHEDULED EUTH WEEK 13
19625	26.	32.	29.	21.	25.	25.	SCHEDULED EUTH WEEK 13
19633	25.	26.	25.	25.	26.	27.	SCHEDULED EUTH WEEK 13
19641	25.	20.	24.	24.	24.	25.	SCHEDULED EUTH WEEK 13
19643	22.	23.	18.	20.	20.	20.	SCHEDULED EUTH WEEK 13
19649	22.	23.	18.	23.	22.	22.	SCHEDULED EUTH WEEK 13
19653	26.	26.	22.	26.	26.	26.	SCHEDULED EUTH WEEK 13
19662	21.	21.	19.	22.	24.	23.	SCHEDULED EUTH WEEK 13
MEAN	24.	24.	23.	24.	24.	24.	
S.D.	2.0	4.0	3.7	2.0	2.2	2.1	
N	10	10	10	10	10	10	

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALE GROUP: 0 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19668	20.	20.	19.	21.	19.	20.	16.	18.
19670	18.	17.	18.	19.	18.	17.	18.	17.
19675	17.	17.	16.	17.	15.	16.	15.	15.
19683	19.	22.	20.	18.	18.	17.	18.	17.
19687	20.	20.	20.	19.	18.	19.	18.	19.
19692	19.	19.	19.	20.	17.	18.	18.	17.
19696	20.	18.	19.	19.	17.	20.	21.	21.
19698	18.	17.	17.	16.	15.	17.	16.	15.
19703	19.	22.	19.	20.	18.	17.	17.	17.
19709	17.	17.	17.	17.	16.	16.	16.	17.
MEAN	19.	19.	18.	19.	17.	18.	17.	17.
S.D.	1.2	2.0	1.3	1.6	1.4	1.5	1.7	1.8
N	10	10	10	10	10	10	10	10

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19664	18.	17.	16.	18.	18.	18.	18.	17.
19669	21.	19.	20.	20.	20.	19.	20.	19.
19672	20.	18.	18.	19.	17.	17.	17.	17.
19674	19.	21.	NA	22.	20.	19.	21.	19.
19676	18.	17.	17.	18.	19.	19.	18.	17.
19690	18.	17.	17.	17.	17.	14.	16.	16.
19694	20.	17.	18.	18.	16.	18.	17.	19.
19699	17.	17.	16.	18.	17.	18.	17.	18.
19706	17.	18.	18.	18.	17.	18.	17.	18.
19707	17.	15.	17.	15.	15.	16.	17.	25.
MEAN	19.	18.	17.	18.	18.	18.	18.	19.
S.D.	1.4	1.6	1.2	1.8	1.6	1.6	1.5	2.5
N	10	10	9	10	10	10	10	10

NA = NOT APPLICABLE

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]
SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19665	17.	18.	16.	17.	17.	16.	18.	16.
19666	18.	15.	16.	15.	14.	14.	15.	17.
19667	20.	20.	19.	18.	18.	17.	15.	18.
19673	18.	15.	15.	23.	17.	17.	17.	NA
19677	19.	19.	19.	19.	19.	20.	20.	19.
19685	16.	17.	15.	16.	14.	14.	15.	15.
19686	17.	19.	17.	18.	15.	17.	16.	16.
19689	19.	16.	17.	19.	15.	16.	16.	16.
19693	17.	16.	16.	17.	16.	16.	16.	16.
19705	17.	18.	18.	20.	19.	18.	16.	18.
MEAN	18.	17.	17.	18.	16.	17.	16.	17.
S.D.	1.2	1.8	1.5	2.3	1.9	1.8	1.6	1.3
N	10	10	10	10	10	10	10	9

NA = NOT APPLICABLE

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TABLE 22

SPONSOR:[redacted]
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]
SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	-2 TO -1	0 TO 1	1 TO 2	2 TO 3	3 TO 4	4 TO 5	5 TO 6	6 TO 7
ANIMAL								
19671	18.	19.	16.	19.	22.	17.	18.	15.
19678	18.	16.	17.	23.	20.	22.	21.	22.
19679	19.	17.	22.	19.	19.	18.	18.	19.
19680	19.	19.	16.	25.	16.	18.	24.	21.
19681	19.	18.	20.	24.	18.	19.	19.	20.
19688	19.	20.	NA	24.	18.	19.	16.	17.
19691	16.	15.	17.	17.	17.	18.	19.	19.
19695	20.	20.	21.	20.	19.	21.	19.	20.
19700	22.	20.	16.	22.	20.	20.	17.	22.
19701	17.	17.	20.	19.	15.	19.	17.	19.
MEAN	19.	18.	18.	21.	18.	19.	19.	19.
S.D.	1.6	1.8	2.4	2.7	2.1	1.5	2.3	2.2
N	10	10	9	10	10	10	10	10

NA = NOT APPLICABLE

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALE GROUP: 0 MG/KG/DAY

WEEK / ANIMAL	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
19668	16.	17.	16.	17.	16.	17.	SCHEDULED EUTH WEEK 13
19670	17.	16.	16.	16.	17.	16.	SCHEDULED EUTH WEEK 13
19675	14.	13.	14.	15.	14.	15.	SCHEDULED EUTH WEEK 13
19683	16.	16.	17.	16.	17.	16.	SCHEDULED EUTH WEEK 13
19687	19.	18.	19.	19.	18.	17.	SCHEDULED EUTH WEEK 13
19692	16.	17.	16.	16.	18.	16.	SCHEDULED EUTH WEEK 13
19696	20.	18.	19.	18.	20.	20.	SCHEDULED EUTH WEEK 13
19698	15.	14.	16.	14.	16.	15.	SCHEDULED EUTH WEEK 13
19703	18.	18.	17.	16.	16.	17.	SCHEDULED EUTH WEEK 13
19709	16.	16.	17.	16.	16.	15.	SCHEDULED EUTH WEEK 13
MEAN	17.	16.	17.	16.	17.	16.	
S.D.	1.8	1.7	1.5	1.4	1.6	1.5	
N	10	10	10	10	10	10	

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TABLE 22

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-012
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALE GROUP: 160 MG/KG/DAY

WEEK	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL							
19664	17.	17.	17.	17.	16.	16.	SCHEDULED EUTH WEEK 13
19669	19.	19.	18.	18.	19.	17.	SCHEDULED EUTH WEEK 13
19672	16.	17.	16.	17.	17.	17.	SCHEDULED EUTH WEEK 13
19674	19.	19.	19.	19.	20.	19.	SCHEDULED EUTH WEEK 13
19676	17.	17.	16.	15.	17.	16.	SCHEDULED EUTH WEEK 13
19690	15.	14.	14.	14.	17.	14.	SCHEDULED EUTH WEEK 13
19694	16.	15.	17.	17.	16.	16.	SCHEDULED EUTH WEEK 13
19699	16.	16.	16.	17.	16.	15.	SCHEDULED EUTH WEEK 13
19706	19.	18.	16.	16.	17.	16.	SCHEDULED EUTH WEEK 13
19707	16.	14.	16.	16.	16.	15.	SCHEDULED EUTH WEEK 13
MEAN	17.	17.	17.	17.	17.	16.	
S.D.	1.5	1.8	1.4	1.4	1.4	1.4	
N	10	10	10	10	10	10	

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TABLE 22

SPONSOR:[redacted]
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]
SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

WEEK / ANIMAL	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
19665	17.	16.	15.	17.	19.	17.	SCHEDULED EUTH WEEK 13
19666	16.	15.	16.	16.	15.	17.	SCHEDULED EUTH WEEK 13
19667	18.	17.	16.	16.	17.	16.	SCHEDULED EUTH WEEK 13
19673	21.	17.	FOUND DEAD WEEK 9				
19677	20.	17.	21.	18.	18.	20.	SCHEDULED EUTH WEEK 13
19685	15.	15.	15.	16.	16.	16.	SCHEDULED EUTH WEEK 13
19686	15.	17.	15.	16.	14.	15.	SCHEDULED EUTH WEEK 13
19689	16.	15.	17.	17.	16.	17.	SCHEDULED EUTH WEEK 13
19693	16.	16.	16.	15.	15.	16.	SCHEDULED EUTH WEEK 13
19705	16.	16.	16.	17.	17.	16.	SCHEDULED EUTH WEEK 13
MEAN	17.	16.	16.	16.	16.	17.	
S.D.	2.1	0.9	1.9	0.9	1.6	1.4	
N	10	10	9	9	9	9	

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 22
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL FOOD CONSUMPTION [G/ANIMAL/DAY]

FEMALE GROUP: 1000 MG/KG/DAY

WEEK	7 TO 8	8 TO 9	9 TO 10	10 TO 11	11 TO 12	12 TO 13	
ANIMAL							
19671	18.	16.	18.	17.	16.	15.	SCHEDULED EUTH WEEK 13
19678	18.	16.	13.	18.	16.	16.	SCHEDULED EUTH WEEK 13
19679	23.	19.	19.	20.	19.	18.	SCHEDULED EUTH WEEK 13
19680	20.	22.	26.	26.	21.	19.	SCHEDULED EUTH WEEK 13
19681	20.	20.	18.	22.	20.	21.	SCHEDULED EUTH WEEK 13
19688	17.	NA	17.	19.	15.	15.	SCHEDULED EUTH WEEK 13
19691	18.	18.	17.	17.	16.	18.	SCHEDULED EUTH WEEK 13
19695	21.	23.	20.	20.	21.	21.	SCHEDULED EUTH WEEK 13
19700	21.	20.	19.	20.	19.	21.	SCHEDULED EUTH WEEK 13
19701	18.	19.	18.	18.	18.	20.	SCHEDULED EUTH WEEK 13
MEAN	19.	19.	19.	20.	18.	18.	
S.D.	1.9	2.4	3.2	2.7	2.2	2.4	
N	10	9	10	10	10	10	

NA = NOT APPLICABLE

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07/25/2006

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 0 MG/KG/DAY MALES										
19623	8.74	9.59	16.5	51.0	53.2	17.3	32.4	1097.	14.8	19.1
19626	15.07	9.35	15.6	48.5	51.9	16.7	32.1	747.	14.4	19.4
19630	7.67	9.72	16.4	49.7	51.2	16.9	32.9	996.	21.2	19.0
19636	7.64	8.87	16.6	50.2	56.6	18.7	33.0	767.	17.6	19.3
19644	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	18.1	19.0
19652	8.29	8.63	15.5	46.3	53.6	18.0	33.6	1319.	16.3	20.2
19655	6.98	8.70	16.3	51.8	59.5	18.7	31.4	871.	15.9	20.0
19657	6.62	9.30	16.4	49.7	53.5	17.6	33.0	884.	18.0	21.8
19660	7.54	8.88	16.8	51.4	57.9	19.0	32.8	602.	16.0	19.4
MEAN	8.57	9.13	16.3	49.8	54.7	17.9	32.7	910.	16.9	19.7
S.D.	2.710	0.414	0.47	1.78	2.97	0.88	0.67	224.8	2.08	0.90
N	8	8	8	8	8	8	8	8	9	9

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 0 MG/KG/DAY MALES								
19623	1.8	173.0	7.4	88.8	1.4	1.0	0.5	0.9
19626	1.6	149.4	23.8	70.6	2.5	1.5	0.4	1.2
19630	1.4	134.6	12.5	83.5	1.1	2.0	0.4	0.5
19636	1.5	130.8	11.2	84.8	1.8	1.2	0.4	0.5
19644	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19652	1.7	148.4	14.0	81.8	2.0	1.1	0.4	0.7
19655	1.9	169.2	16.1	76.7	2.5	3.4	0.3	1.0
19657	1.6	148.3	12.7	82.7	1.2	2.7	0.3	0.5
19660	1.7	152.0	23.1	71.7	2.2	1.9	0.3	0.7
MEAN	1.7	150.7	15.1	80.1	1.8	1.9	0.4	0.8
S.D.	0.16	14.68	5.72	6.45	0.56	0.84	0.07	0.26
N	8	8	8	8	8	8	8	8

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 0 MG/KG/DAY MALES								
19623	0.65	7.76	0.12	0.08	0.05	0.08	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19626	3.59	10.64	0.37	0.23	0.06	0.18	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19630	0.96	6.41	0.08	0.15	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19636	0.86	6.48	0.14	0.09	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19644	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19652	1.16	6.78	0.17	0.09	0.03	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19655	1.12	5.35	0.17	0.24	0.02	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19657	0.84	5.47	0.08	0.18	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19660	1.74	5.41	0.17	0.15	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.37	6.79	0.16	0.15	0.03	0.07		
S.D.	0.956	1.762	0.092	0.063	0.015	0.048		
N	8	8	8	8	8	8		

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

Audited Draft

Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 160 MG/KG/DAY MALES										
19619	10.71	9.42	16.8	52.6	55.8	17.8	31.9	1190.	17.0	22.3
19628	7.45	9.43	16.5	51.9	55.0	17.5	31.7	883.	15.1	23.2
19640	9.15	8.82	15.8	47.6	54.0	17.9	33.2	1041.	18.8	20.4
19646	8.25	9.21	17.1	50.1	54.4	18.6	34.2	1104.	17.6	22.9
19647	10.53	9.39	16.6	51.5	54.8	17.6	32.2	1108.	19.5	22.1
19648	6.26	8.86	16.3	48.7	55.0	18.4	33.4	974.	15.3	21.4
19650	10.59	8.97	16.4	50.0	55.7	18.3	32.8	1052.	16.7	20.7
19654	9.12	9.30	15.9	47.2	50.8	17.1	33.7	1124.	19.6	24.1
19659	11.06	9.41	15.6	49.0	52.0	16.6	31.9	731.	17.9	21.1
19663	5.10	9.69	16.5	51.4	53.0	17.0	32.1	891.	23.1	20.8
MEAN	8.82	9.25	16.4	50.0	54.1	17.7	32.7	1010.	18.1	21.9
S.D.	2.040	0.283	0.46	1.85	1.64	0.65	0.87	139.8	2.36	1.23
N	10	10	10	10	10	10	10	10	10	10

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 160 MG/KG/DAY MALES								
19619	1.7	159.9	9.2	86.7	1.5	1.5	0.7	0.3
19628	1.7	163.6	13.5	82.6	1.6	1.4	0.3	0.6
19640	1.3	110.7	11.7	85.1	1.0	1.1	0.4	0.7
19646	1.6	151.3	10.4	86.7	1.1	0.9	0.3	0.7
19647	1.7	157.3	14.7	81.4	1.4	1.3	0.5	0.8
19648	1.5	131.3	10.8	85.0	1.8	1.6	0.2	0.6
19650	1.9	172.9	15.2	81.2	1.4	1.2	0.2	0.8
19654	1.3	124.2	28.4	67.8	1.1	1.7	0.4	0.5
19659	1.8	166.0	16.0	79.4	1.1	2.5	0.4	0.6
19663	1.0	96.5	14.7	81.5	1.4	1.3	0.4	0.6
MEAN	1.6	143.4	14.5	81.7	1.3	1.5	0.4	0.6
S.D.	0.28	26.04	5.41	5.50	0.26	0.44	0.15	0.15
N	10	10	10	10	10	10	10	10

thous/uL = THOUSANDS/MICROLITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 160 MG/KG/DAY MALES								
19619	0.99	9.28	0.16	0.16	0.08	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19628	1.00	6.16	0.12	0.10	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19640	1.07	7.78	0.09	0.10	0.04	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19646	0.85	7.15	0.09	0.07	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19647	1.55	8.57	0.14	0.14	0.05	0.08	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19648	0.67	5.32	0.11	0.10	0.01	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19650	1.61	8.60	0.15	0.12	0.02	0.09	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19654	2.59	6.18	0.10	0.16	0.04	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19659	1.77	8.78	0.12	0.27	0.05	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19663	0.75	4.16	0.07	0.07	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.29	7.20	0.12	0.13	0.04	0.06		
S.D.	0.595	1.696	0.029	0.059	0.021	0.019		
N	10	10	10	10	10	10		

thous/uL = THOUSANDS/MICROLITER

Audited Draft

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 7
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 400 MG/KG/DAY MALES										
19621	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	16.4	20.3
19622	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	16.3	21.9
19631	6.98	9.41	17.2	51.1	54.3	18.3	33.6	955.	18.9	24.6
19632	6.49	8.83	16.3	49.6	56.2	18.4	32.8	1035.	17.0	22.4
19634	10.17	8.98	16.8	50.0	55.7	18.7	33.5	1228.	22.3	22.8
19635	6.39	9.09	16.0	48.1	53.0	17.6	33.3	889.	19.1	22.9
19645	12.60	8.26	15.1	46.4	56.1	18.3	32.6	949.	18.4	23.4
19656	8.14	9.07	15.9	48.3	53.2	17.5	32.9	1311.	24.7	25.1
19658	11.84	8.64	16.0	48.8	56.4	18.6	32.9	972.	17.7	23.6
19661	8.43	9.25	16.6	50.7	54.8	17.9	32.7	992.	20.4	24.3
MEAN	8.88	8.94	16.2	49.1	55.0	18.2	33.0	1041.	19.1	23.1
S.D.	2.406	0.363	0.64	1.54	1.36	0.45	0.38	148.3	2.69	1.41
N	8	8	8	8	8	8	8	8	10	10

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 8
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 400 MG/KG/DAY MALES								
19621	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19622	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19631	1.5	141.7	11.1	85.3	1.8	0.9	0.4	0.6
19632	2.0	172.4	21.7	73.7	1.6	2.0	0.5	0.5
19634	1.5	139.1	16.6	79.1	1.7	1.3	0.6	0.7
19635	1.3	117.1	22.9	70.9	2.6	2.3	0.3	1.0
19645	1.3	109.4	15.2	82.0	1.1	0.7	0.4	0.6
19656	1.0	95.2	12.3	84.4	1.7	0.8	0.2	0.6
19658	1.9	165.3	12.4	84.0	1.1	1.3	0.4	0.8
19661	1.8	165.6	11.0	84.0	3.0	2.0	0.0	0.0
MEAN	1.5	138.2	15.4	80.4	1.8	1.4	0.4	0.6
S.D.	0.34	28.76	4.69	5.42	0.67	0.62	0.19	0.29
N	8	8	8	8	8	8	8	8

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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TABLE 23

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —

SPONSOR:[redacted] — INDIVIDUAL HEMATOLOGY VALUES —

SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 400 MG/KG/DAY MALES								
19621	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19622	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19631	0.77	5.95	0.12	0.06	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19632	1.41	4.78	0.10	0.13	0.03	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19634	1.69	8.04	0.17	0.13	0.06	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19635	1.46	4.53	0.17	0.15	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19645	1.92	10.33	0.13	0.08	0.05	0.08	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19656	1.00	6.87	0.14	0.06	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19658	1.46	9.95	0.13	0.15	0.04	0.10	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19661	0.93	7.08	0.25	0.17	0.00	0.00	ADEQUATE 2-PLT CLUM	1-POL
MEAN	1.33	7.19	0.15	0.12	0.03	0.05		
S.D.	0.396	2.163	0.046	0.043	0.019	0.031		
N	8	8	8	8	8	8		

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

------ MORPHOLOGY CODE ------

1 = FEW, 2 = MODERATE, PLT CLUM = PLATELET CLUMPS, POL = POLYCHROMASIA

187054 AD

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 10
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 1000 MG/KG/DAY MALES										
19618	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	24.7	25.8
19620	6.70	8.63	15.5	45.4	52.6	17.9	34.1	1139.	27.0	28.1
19624	10.25	8.96	15.7	48.2	53.8	17.5	32.5	1037.	30.0	35.3
19625	15.27	8.85	15.6	46.7	52.8	17.6	33.4	1075.	23.6	26.2
19633	6.04	9.14	16.1	47.3	51.8	17.6	33.9	1236.	26.0	31.0
19641	10.11	8.45	15.8	47.3	56.0	18.6	33.3	1155.	19.2	24.0
19643	9.40	8.79	15.1	45.4	51.6	17.2	33.3	965.	24.8	29.1
19649	10.47	9.38	17.2	52.3	55.7	18.4	32.9	816.	33.6	30.0
19653	8.89	9.19	16.6	50.8	55.2	18.1	32.8	1121.	26.0	29.7
19662	9.23	9.00	15.4	46.9	52.1	17.1	32.9	1098.	24.3	26.2
MEAN	9.60	8.93	15.9	47.8	53.5	17.8	33.2	1071.	25.9	28.5
S.D.	2.630	0.289	0.65	2.33	1.73	0.51	0.52	122.3	3.84	3.25
N	9	9	9	9	9	9	9	9	10	10

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 11
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 1000 MG/KG/DAY MALES								
19618	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19620	1.4	116.9	9.6	86.3	1.8	1.4	0.3	0.7
19624	2.5	224.1	12.2	84.0	1.3	1.5	0.3	0.6
19625	1.7	147.1	12.4	83.7	1.5	1.1	0.5	0.9
19633	1.5	135.9	17.1	78.5	1.8	1.2	0.4	0.9
19641	1.8	149.0	13.2	82.9	1.4	1.5	0.5	0.6
19643	1.1	96.9	14.4	82.5	1.0	1.1	0.2	0.8
19649	1.7	156.2	10.8	85.3	0.7	2.3	0.3	0.6
19653	1.6	151.6	16.0	80.6	1.2	1.3	0.4	0.4
19662	1.1	97.0	23.0	72.4	1.9	1.7	0.4	0.6
MEAN	1.6	141.6	14.3	81.8	1.4	1.5	0.4	0.7
S.D.	0.42	38.46	4.03	4.23	0.40	0.37	0.10	0.16
N	9	9	9	9	9	9	9	9

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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TABLE 23

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —
SPONSOR:[redacted] — INDIVIDUAL HEMATOLOGY VALUES —
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 1000 MG/KG/DAY MALES								
19618	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19620	0.64	5.78	0.12	0.09	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19624	1.26	8.61	0.13	0.16	0.04	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19625	1.89	12.77	0.23	0.16	0.07	0.14	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19633	1.04	4.75	0.11	0.07	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19641	1.33	8.37	0.14	0.15	0.05	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19643	1.36	7.75	0.09	0.11	0.02	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19649	1.13	8.93	0.08	0.24	0.04	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19653	1.42	7.17	0.11	0.12	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19662	2.12	6.68	0.17	0.16	0.04	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	1.35	7.87	0.13	0.14	0.04	0.07		
S.D.	0.440	2.290	0.046	0.050	0.017	0.029		
N	9	9	9	9	9	9		

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 0 MG/KG/DAY FEMALES										
19668	7.31	8.71	15.8	49.0	56.3	18.1	32.2	938.	12.7	17.7
19670	6.20	8.37	15.9	47.6	56.9	19.0	33.3	1287.	13.3	19.0
19675	8.22	8.36	15.9	47.2	56.4	19.0	33.7	1096.	11.9	17.3
19683	6.02	8.07	15.7	48.6	60.3	19.4	32.2	646.	12.0	16.8
19687	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	12.4	18.7
19692	4.47	8.89	15.4	44.8	50.4	17.4	34.5	1032.	11.9	16.4
19696	4.69	8.26	15.8	47.2	57.1	19.1	33.4	790.	12.0	16.5
19698	3.81	8.42	15.3	45.4	53.9	18.2	33.7	948.	12.2	17.0
19703	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	12.2	18.4
19709	6.48	6.90	13.9	42.1	61.0	20.1	33.0	59.	11.6	16.8
MEAN	5.90	8.25	15.5	46.5	56.5	18.8	33.3	850.	12.2	17.5
S.D.	1.497	0.601	0.67	2.28	3.36	0.85	0.78	372.8	0.48	0.94
N	8	8	8	8	8	8	8	8	10	10

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 0 MG/KG/DAY	FEMALES							
19668	2.1	183.3	6.5	90.0	1.4	1.1	0.3	0.6
19670	1.9	161.8	10.1	86.1	1.2	1.5	0.2	0.9
19675	1.8	154.5	9.8	86.1	1.3	1.6	0.4	0.7
19683	1.6	126.6	14.6	80.1	1.2	2.9	0.4	0.7
19687	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19692	1.2	108.7	21.1	73.7	2.2	2.1	0.2	0.6
19696	2.0	162.5	21.1	74.3	0.8	2.9	0.4	0.5
19698	1.6	135.7	9.2	86.3	1.5	2.0	0.1	0.8
19703	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19709	1.9	133.8	15.1	81.0	2.0	0.5	0.4	1.1
MEAN	1.8	145.9	13.4	82.2	1.5	1.8	0.3	0.7
S.D.	0.29	23.93	5.50	5.96	0.45	0.83	0.12	0.19
N	8	8	8	8	8	8	8	8

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 0 MG/KG/DAY FEMALES								
19668	0.48	6.58	0.10	0.08	0.03	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19670	0.63	5.34	0.07	0.09	0.01	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19675	0.81	7.08	0.11	0.13	0.03	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19683	0.88	4.82	0.07	0.17	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19687	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19692	0.95	3.30	0.10	0.10	0.01	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19696	0.99	3.48	0.04	0.13	0.02	0.02	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19698	0.35	3.29	0.06	0.08	0.00	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19703	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19709	0.98	5.25	0.13	0.03	0.02	0.07	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	0.76	4.89	0.09	0.10	0.02	0.05		
S.D.	0.244	1.467	0.030	0.042	0.011	0.018		
N	8	8	8	8	8	8		

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

Audited Draft

Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 160 MG/KG/DAY FEMALES										
19664	7.48	8.16	15.8	46.4	56.9	19.4	34.1	1102.	12.7	14.0
19669	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	12.6	16.8
19672	5.79	7.93	15.2	45.2	57.0	19.2	33.6	1454.	11.6	16.5
19674	6.49	8.31	16.1	48.4	58.2	19.4	33.3	1017.	12.5	21.3
19676	6.74	8.35	15.5	45.4	54.4	18.6	34.2	1040.	11.6	18.6
19690	7.13	8.89	16.7	50.2	56.4	18.8	33.3	995.	11.9	20.1
19694	6.75	8.47	15.4	46.0	54.3	18.2	33.4	990.	12.5	17.6
19699	5.23	8.36	15.1	44.2	52.9	18.0	34.1	1171.	11.9	20.4
19706	6.98	8.35	15.9	48.4	58.0	19.0	32.8	1092.	12.1	17.7
19707	5.24	8.50	15.6	47.3	55.7	18.4	33.0	1082.	12.5	17.3
MEAN	6.43	8.37	15.7	46.8	56.0	18.8	33.5	1105.	12.2	18.0
S.D.	0.819	0.260	0.49	1.90	1.80	0.51	0.50	143.2	0.42	2.16
N	9	9	9	9	9	9	9	9	10	10

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 17
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 160 MG/KG/DAY	FEMALES							
19664	2.1	168.1	12.1	84.3	0.9	1.5	0.4	0.8
19669	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19672	1.9	148.4	13.1	82.2	1.8	1.7	0.2	0.9
19674	1.7	138.2	13.0	86.0	0.0	1.0	0.0	0.0
19676	1.6	133.5	11.6	85.0	1.2	1.4	0.4	0.4
19690	1.8	163.5	18.9	76.8	1.0	2.3	0.5	0.5
19694	1.4	118.9	9.8	86.7	1.3	1.1	0.4	0.6
19699	1.3	104.7	15.1	82.2	1.4	0.9	0.2	0.2
19706	1.3	110.2	6.0	90.6	0.9	1.4	0.3	0.9
19707	1.2	104.0	21.0	76.0	2.0	1.0	0.0	0.0
MEAN	1.6	132.2	13.4	83.3	1.2	1.4	0.3	0.5
S.D.	0.31	24.45	4.52	4.66	0.58	0.44	0.18	0.36
N	9	9	9	9	9	9	9	9

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 160 MG/KG/DAY FEMALES								
19664	0.90	6.30	0.07	0.11	0.03	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19669	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19672	0.76	4.76	0.11	0.10	0.01	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19674	0.84	5.58	0.00	0.06	0.00	0.00	ADEQUATE 2-PLT CLUM	
	1-POL							
19676	0.78	5.73	0.08	0.09	0.03	0.02	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19690	1.35	5.48	0.07	0.16	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19694	0.66	5.86	0.09	0.08	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19699	0.79	4.30	0.07	0.05	0.01	0.01	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19706	0.42	6.32	0.06	0.10	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19707	1.10	3.98	0.10	0.05	0.00	0.00	ADEQUATE 2-PLT CLUM	
	1-PKC 1-POL							
MEAN	0.84	5.37	0.07	0.09	0.02	0.03		
S.D.	0.263	0.840	0.032	0.035	0.013	0.024		
N	9	9	9	9	9	9		

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

------ MORPHOLOGY CODE ------

1 = FEW, 2 = MODERATE, PLT CLUM = PLATELET CLUMPS, PKC = POIKILOCYTOSIS, POL = POLYCHROMASIA

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 400 MG/KG/DAY	FEMALES									
19665	5.18	8.21	15.4	47.1	57.3	18.8	32.7	1077.	12.4	17.7
19666	5.62	8.16	15.3	44.3	54.3	18.8	34.6	1212.	12.4	18.3
19667	4.65	8.24	15.2	45.3	55.0	18.4	33.5	1401.	12.1	19.2
19677	5.99	7.96	14.8	43.1	54.1	18.6	34.4	1339.	11.9	17.9
19685	8.43	8.56	16.3	49.2	57.5	19.1	33.2	1160.	13.0	17.6
19686	6.14	8.02	15.0	45.6	56.8	18.7	32.8	1071.	11.9	18.4
19689	6.63	8.74	16.3	48.8	55.8	18.6	33.3	1098.	12.6	18.0
19693	5.85	8.10	15.8	46.6	57.5	19.5	34.0	848.	12.6	19.7
19705	6.68	8.26	15.0	44.8	54.3	18.2	33.5	954.	15.5	19.9
MEAN	6.13	8.25	15.5	46.1	55.8	18.7	33.6	1129.	12.7	18.5
S.D.	1.078	0.251	0.56	2.03	1.46	0.38	0.66	174.1	1.11	0.87
N	9	9	9	9	9	9	9	9	9	9

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 23
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL HEMATOLOGY VALUES

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 400 MG/KG/DAY	FEMALES							
19665	1.8	146.3	16.2	78.6	1.8	2.5	0.5	0.4
19666	1.3	110.0	12.9	82.9	1.6	1.3	0.3	1.0
19667	1.7	143.8	14.7	82.5	0.9	0.9	0.4	0.7
19677	1.4	110.4	19.2	75.9	2.2	1.3	0.4	0.9
19685	1.4	122.4	11.8	85.0	1.1	1.2	0.4	0.6
19686	1.4	113.9	8.9	87.6	1.2	1.5	0.4	0.4
19689	1.8	161.0	14.6	80.7	2.1	1.4	0.4	0.9
19693	2.1	173.9	17.6	78.3	0.9	2.3	0.3	0.6
19705	1.6	136.0	13.7	81.5	1.5	2.1	0.5	0.7
MEAN	1.6	135.3	14.4	81.4	1.5	1.6	0.4	0.7
S.D.	0.26	22.99	3.09	3.59	0.49	0.55	0.07	0.21
N	9	9	9	9	9	9	9	9

thous/uL = THOUSANDS/MICROLITER

Audited Draft

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 21
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 400 MG/KG/DAY FEMALES								
19665	0.84	4.07	0.09	0.13	0.02	0.02	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19666	0.72	4.66	0.09	0.07	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19667	0.68	3.84	0.04	0.04	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19677	1.15	4.55	0.13	0.08	0.02	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19685	0.99	7.16	0.09	0.10	0.03	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19686	0.55	5.38	0.07	0.10	0.02	0.02	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19689	0.97	5.35	0.14	0.09	0.02	0.06	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19693	1.03	4.58	0.05	0.13	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19705	0.91	5.44	0.10	0.14	0.03	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	0.87	5.00	0.09	0.10	0.02	0.04		
S.D.	0.191	0.989	0.033	0.032	0.004	0.016		
N	9	9	9	9	9	9		

thous/uL = THOUSANDS/MICROLITER

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TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES
SPONSOR NO.:06-012

ANIMAL	WHITE CELLS	RED CELLS	HEMO-GLOBIN	HEMATO-CRIT	MCV	MCH	MCHC	PLATELET	PROTIME	APTT
	thous/uL	mil/uL	g/dL	%	fL	pg	g/dL	thous/uL	seconds	seconds
GROUP: 1000 MG/KG/DAY FEMALES										
19671	4.23	7.72	15.5	47.3	61.3	20.0	32.7	994.	12.3	17.7
19678	5.05	7.43	14.4	44.0	59.3	19.4	32.7	1079.	12.8	17.5
19679	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT	12.7	19.3
19680	5.58	8.18	15.8	46.0	56.2	19.3	34.3	1240.	12.6	17.9
19681	4.75	8.40	15.6	46.3	55.1	18.5	33.7	1041.	12.7	16.1
19688	5.23	8.35	15.3	46.2	55.4	18.3	33.1	1135.	11.7	18.1
19691	5.19	8.08	15.4	45.7	56.5	19.0	33.7	1022.	12.8	18.3
19695	7.56	7.76	15.1	44.2	56.9	19.4	34.1	1079.	12.6	20.2
19700	9.69	8.43	15.8	46.5	55.2	18.8	34.0	1114.	12.4	17.4
19701	7.40	8.25	15.6	46.7	56.6	18.9	33.3	948.	11.8	19.5
MEAN	6.08	8.07	15.4	45.9	56.9	19.1	33.5	1072.	12.4	18.2
S.D.	1.767	0.352	0.43	1.10	2.07	0.52	0.59	85.9	0.40	1.19
N	9	9	9	9	9	9	9	9	10	10

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, fL = FEMTOLITERS, pg = PICOGRAMS, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 23
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	RETIC-ULOCYTE	RETIC ABSOLUTE	NEUTRO-PHIL	LYMPH-OCYTE	MONOCYTE	EOSIN-OPHIL	BASOPHIL	LG UNST-AIN CELL
	%	thous/uL	%	%	%	%	%	%
GROUP: 1000 MG/KG/DAY FEMALES								
19671	1.6	122.2	12.0	83.6	1.4	1.9	0.2	0.9
19678	1.5	114.1	11.3	85.8	0.9	1.2	0.3	0.6
19679	CLT	CLT	CLT	CLT	CLT	CLT	CLT	CLT
19680	1.3	103.5	9.6	87.0	1.4	1.2	0.4	0.5
19681	1.7	142.3	11.3	83.8	1.4	2.6	0.3	0.5
19688	2.8	236.7	22.7	71.4	1.1	3.6	0.4	0.9
19691	1.7	134.2	15.5	80.3	1.1	2.1	0.3	0.7
19695	1.6	121.8	9.2	88.1	1.0	0.6	0.4	0.7
19700	1.7	147.2	17.3	77.7	1.8	1.7	0.4	1.2
19701	1.4	115.7	8.2	88.8	1.2	0.5	0.2	1.1
MEAN	1.7	137.5	13.0	82.9	1.3	1.7	0.3	0.8
S.D.	0.44	39.73	4.67	5.64	0.27	0.99	0.08	0.25
N	9	9	9	9	9	9	9	9

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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Modified: 8/30/2006

TABLE 23

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 24
SPONSOR:[redacted] INDIVIDUAL HEMATOLOGY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	NEU ABSOLUTE	LYMPH ABSOLUTE	MONO ABSOLUTE	EOS ABSOLUTE	BASO ABSOLUTE	LUC ABSOLUTE	PLATELET ESTIMATE	RBC MORPHOLOGY
	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL	thous/uL		
GROUP: 1000 MG/KG/DAY FEMALES								
19671	0.51	3.53	0.06	0.08	0.01	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19678	0.57	4.34	0.05	0.06	0.01	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19679	CLT	CLT	CLT	CLT	CLT	CLT	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19680	0.53	4.85	0.08	0.07	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19681	0.54	3.99	0.07	0.12	0.02	0.03	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19688	1.18	3.73	0.06	0.19	0.02	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19691	0.81	4.17	0.06	0.11	0.02	0.04	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19695	0.69	6.66	0.08	0.04	0.03	0.05	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19700	1.67	7.53	0.17	0.16	0.04	0.11	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
19701	0.61	6.57	0.09	0.04	0.02	0.08	PLATELET ESTIMATE AND MORPHOLOGY NOT REVIEWED	
MEAN	0.79	5.04	0.08	0.10	0.02	0.05		
S.D.	0.392	1.481	0.036	0.053	0.009	0.027		
N	9	9	9	9	9	9		

CLT = CLOTTED

thous/uL = THOUSANDS/MICROLITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 1
SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13
SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 0 MG/KG/DAY		MALES								
19623	4.5	7.3	2.7	1.67	0.1	12.3	0.2	96.	37.	68.
19626	4.3	7.1	2.8	1.51	0.1	11.1	0.3	75.	41.	57.
19630	4.4	7.0	2.7	1.62	0.1	10.2	0.2	94.	37.	77.
19636	4.3	6.9	2.6	1.64	0.1	10.0	0.3	101.	39.	67.
19644	4.5	6.7	2.2	2.03	0.1	9.2	0.3	101.	41.	87.
19652	4.1	6.7	2.6	1.55	0.2	11.0	0.3	68.	45.	66.
19655	4.4	7.3	2.9	1.53	0.2	12.6	0.4	85.	40.	72.
19657	4.5	6.9	2.4	1.89	0.1	11.5	0.3	113.	37.	73.
19660	4.3	6.7	2.4	1.78	0.2	9.3	0.2	86.	26.	65.
MEAN	4.4	7.0	2.6	1.69	0.1	10.8	0.3	91.	38.	70.
S.D.	0.13	0.24	0.22	0.176	0.05	1.22	0.07	14.0	5.2	8.5
N	9	9	9	9	9	9	9	9	9	9

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 2
SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13
SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 0 MG/KG/DAY		MALES						
19623	129.	73.	11.1	100.	6.5	4.95	141.	96.
19626	144.	65.	11.2	102.	7.0	4.55	143.	64.
19630	116.	35.	10.3	103.	6.3	4.74	143.	39.
19636	118.	50.	10.9	104.	7.0	4.57	147.	61.
19644	119.	43.	10.6	105.	7.4	5.01	146.	40.
19652	114.	61.	11.2	102.	6.9	4.16	143.	72.
19655	138.	49.	11.0	103.	8.0	5.03	146.	60.
19657	118.	54.	10.9	104.	7.2	4.92	145.	48.
19660	116.	42.	11.2	105.	7.1	4.37	145.	78.
MEAN	124.	52.	10.9	103.	7.0	4.70	144.	62.
S.D.	10.9	12.1	0.31	1.6	0.49	0.308	1.9	18.5
N	9	9	9	9	9	9	9	9

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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Modified: 8/30/2006

TABLE 24

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 160 MG/KG/DAY		MALES								
19619	4.5	6.8	2.3	2.01	0.2	11.3	0.3	226.	72.	80.
19628	4.6	6.9	2.3	2.03	0.1	12.0	0.3	113.	49.	74.
19640	4.1	6.4	2.3	1.76	0.1	11.9	0.2	109.	45.	66.
19646	4.5	6.8	2.3	2.00	0.1	10.1	0.3	90.	32.	67.
19647	4.3	6.6	2.3	1.88	0.2	13.5	0.3	118.	49.	88.
19648	4.2	6.5	2.3	1.82	0.1	11.0	0.3	76.	29.	69.
19650	4.4	7.0	2.6	1.69	0.1	10.8	0.2	118.	51.	60.
19654	4.6	7.1	2.5	1.82	0.2	10.4	0.2	169.	39.	66.
19659	4.0	6.8	2.8	1.46	0.1	12.6	0.3	116.	30.	69.
19663	4.8	7.3	2.5	1.96	0.2	10.4	0.3	180.	42.	72.
MEAN	4.4	6.8	2.4	1.84	0.1	11.4	0.3	132.	44.	71.
S.D.	0.25	0.27	0.18	0.177	0.05	1.09	0.05	45.9	12.8	8.0
N	10	10	10	10	10	10	10	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 24

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 160 MG/KG/DAY		MALES						
19619	119.	69.	10.8	103.	7.1	6.06	144.	109.
19628	136.	76.	10.7	102.	7.3	5.08	145.	92.
19640	108.	50.	10.6	102.	6.2	4.28	144.	53.
19646	136.	58.	10.7	102.	6.0	4.23	144.	122.
19647	120.	67.	10.8	103.	7.7	5.32	145.	39.
19648	108.	71.	10.8	102.	6.6	4.65	144.	100.
19650	124.	63.	10.8	103.	6.6	4.38	144.	55.
19654	119.	56.	10.9	102.	6.2	4.57	143.	81.
19659	129.	72.	10.8	103.	7.0	4.98	144.	42.
19663	144.	53.	11.0	104.	6.4	4.29	146.	95.
MEAN	124.	64.	10.8	103.	6.7	4.78	144.	79.
S.D.	12.0	8.9	0.11	0.7	0.55	0.584	0.8	29.5
N	10	10	10	10	10	10	10	10

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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Modified: 8/30/2006

TABLE 24

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES
SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 400 MG/KG/DAY		MALES								
19621	4.4	6.6	2.2	1.98	0.1	13.4	0.3	191.	73.	91.
19622	4.1	6.6	2.5	1.62	0.1	11.2	0.3	142.	78.	81.
19631	4.9	6.9	2.1	2.34	0.2	11.4	0.2	152.	79.	79.
19632	4.5	7.3	2.8	1.61	0.1	11.6	0.3	165.	71.	69.
19634	4.1	6.3	2.2	1.89	0.1	10.4	0.2	131.	56.	66.
19635	4.5	7.1	2.6	1.77	0.2	12.6	0.3	197.	97.	79.
19645	4.6	6.7	2.1	2.18	0.1	12.9	0.3	158.	87.	88.
19656	4.3	6.5	2.3	1.87	0.1	11.2	0.3	209.	99.	70.
19658	4.3	6.7	2.5	1.72	0.1	13.8	0.3	176.	87.	79.
19661	4.5	7.0	2.5	1.84	0.1	9.1	0.3	135.	74.	89.
MEAN	4.4	6.8	2.4	1.88	0.1	11.8	0.3	166.	80.	79.
S.D.	0.24	0.30	0.23	0.234	0.04	1.44	0.04	27.0	12.9	8.7
N	10	10	10	10	10	10	10	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 24

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 400 MG/KG/DAY		MALES						
19621	161.	56.	10.3	105.	6.6	5.52	142.	71.
19622	128.	65.	10.8	99.	6.7	4.86	140.	79.
19631	113.	55.	10.9	102.	7.3	4.24	144.	75.
19632	147.	82.	10.7	102.	6.2	4.42	144.	90.
19634	115.	64.	10.8	104.	6.7	3.90	145.	115.
19635	127.	49.	11.3	102.	7.5	4.27	144.	130.
19645	137.	42.	10.5	103.	6.7	4.51	144.	58.
19656	126.	59.	10.9	103.	7.6	4.80	146.	96.
19658	112.	64.	10.8	103.	7.2	4.94	145.	103.
19661	111.	78.	11.2	103.	7.1	4.77	145.	95.
MEAN	128.	61.	10.8	103.	7.0	4.62	144.	91.
S.D.	16.6	12.2	0.29	1.6	0.45	0.455	1.7	21.5
N	10	10	10	10	10	10	10	10

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13

SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 1000 MG/KG/DAY		MALES								
19618	4.3	6.5	2.2	2.00	0.1	13.7	0.3	182.	270.	134.
19620	4.2	6.2	2.0	2.16	0.1	10.8	0.2	198.	151.	108.
19624	4.5	6.7	2.2	2.09	0.1	8.6	0.2	240.	397.	146.
19625	4.0	6.1	2.1	1.91	0.1	11.2	0.2	197.	239.	113.
19633	4.1	6.6	2.4	1.70	0.1	13.5	0.2	176.	205.	114.
19641	4.4	6.5	2.1	2.07	0.1	14.0	0.3	150.	272.	137.
19643	4.1	6.2	2.1	1.95	0.1	11.8	0.2	152.	169.	92.
19649	4.6	6.7	2.1	2.18	0.1	11.1	0.2	161.	294.	121.
19653	4.5	6.5	2.0	2.24	0.1	12.1	0.4	187.	317.	138.
19662	4.2	6.3	2.1	1.96	0.2	10.3	0.2	134.	168.	117.
MEAN	4.3	6.4	2.1	2.03	0.1	11.7	0.2	178.	248.	122.
S.D.	0.20	0.22	0.12	0.158	0.03	1.69	0.07	30.5	77.5	16.6
N	10	10	10	10	10	10	10	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 8

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13

SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 1000 MG/KG/DAY		MALES						
19618	113.	55.	10.2	103.	6.8	4.72	143.	70.
19620	104.	44.	10.6	105.	6.7	5.02	144.	72.
19624	120.	79.	11.3	102.	7.6	4.28	145.	177.
19625	111.	46.	10.8	105.	7.8	4.28	145.	76.
19633	124.	66.	10.6	104.	6.9	4.18	145.	58.
19641	143.	65.	10.8	102.	6.9	4.53	143.	96.
19643	114.	78.	10.4	104.	6.8	4.28	145.	48.
19649	104.	48.	10.8	105.	7.3	4.36	146.	82.
19653	122.	69.	10.7	103.	7.3	4.88	146.	84.
19662	97.	51.	10.4	107.	7.9	4.81	147.	63.
MEAN	115.	60.	10.7	104.	7.2	4.53	145.	83.
S.D.	13.0	13.0	0.30	1.6	0.44	0.301	1.3	35.9
N	10	10	10	10	10	10	10	10

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 9

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13

SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 0 MG/KG/DAY FEMALES										
19668	5.2	7.5	2.2	2.33	0.2	11.3	0.3	37.	30.	65.
19670	5.4	7.5	2.2	2.47	0.1	15.3	0.3	41.	33.	57.
19675	5.1	7.5	2.3	2.19	0.2	13.2	0.2	52.	22.	53.
19683	5.1	7.2	2.2	2.33	0.2	12.0	0.4	40.	24.	79.
19687	5.5	7.9	2.4	2.24	0.2	14.6	0.4	61.	41.	104.
19692	4.7	7.1	2.4	1.95	0.2	12.3	0.2	48.	34.	59.
19696	5.2	7.2	2.0	2.64	0.1	10.5	0.4	48.	23.	69.
19698	4.9	6.9	2.0	2.51	0.1	10.2	0.3	40.	24.	52.
19703	5.4	7.8	2.4	2.27	0.1	12.7	0.4	41.	29.	60.
19709	4.3	6.9	2.6	1.65	0.2	12.8	0.3	59.	55.	78.
MEAN	5.1	7.4	2.3	2.26	0.2	12.5	0.3	47.	32.	68.
S.D.	0.36	0.35	0.19	0.286	0.05	1.63	0.08	8.4	10.2	15.9
N	10	10	10	10	10	10	10	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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TABLE 24

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 10
SPONSOR:[redacted] INDIVIDUAL SERUM CHEMISTRY VALUES WEEK 13
SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 0 MG/KG/DAY FEMALES								
19668	124.	80.	11.4	104.	5.9	4.64	144.	58.
19670	107.	75.	10.9	103.	5.6	4.47	144.	57.
19675	122.	70.	11.6	103.	6.3	4.39	142.	38.
19683	104.	66.	10.9	104.	5.7	4.40	145.	39.
19687	93.	70.	11.4	102.	7.8	5.18	145.	36.
19692	105.	66.	10.8	103.	6.1	4.27	143.	32.
19696	127.	81.	10.5	107.	5.9	3.88	146.	43.
19698	103.	72.	11.3	106.	6.7	4.82	146.	58.
19703	122.	79.	10.8	103.	4.6	4.07	143.	45.
19709	112.	71.	11.0	105.	6.2	3.83	144.	41.
MEAN	112.	73.	11.1	104.	6.1	4.40	144.	45.
S.D.	11.3	5.5	0.35	1.6	0.82	0.417	1.3	9.6
N	10	10	10	10	10	10	10	10

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 11

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13

SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 160 MG/KG/DAY FEMALES										
19664	5.2	7.1	1.9	2.65	0.2	14.1	0.2	94.	33.	66.
19669	4.9	7.1	2.2	2.29	0.1	11.8	0.3	71.	35.	93.
19672	5.7	8.3	2.6	2.15	0.2	18.1	0.4	72.	60.	103.
19674	4.9	7.4	2.5	2.00	0.1	15.7	0.3	53.	34.	89.
19676	5.4	7.8	2.4	2.28	0.1	14.0	0.3	69.	26.	52.
19690	5.5	7.8	2.3	2.38	0.2	12.4	0.4	65.	40.	68.
19694	4.8	6.6	1.8	2.73	0.2	14.7	0.3	119.	31.	58.
19699	4.9	6.7	1.8	2.78	0.2	12.9	0.3	130.	34.	80.
19706	5.6	7.9	2.3	2.49	0.2	13.8	0.4	55.	45.	83.
19707	4.9	7.1	2.2	2.26	0.1	13.3	0.3	64.	32.	74.
MEAN	5.2	7.4	2.2	2.40	0.2	14.1	0.3	79.	37.	77.
S.D.	0.34	0.56	0.28	0.257	0.05	1.80	0.06	26.5	9.6	16.0
N	10	10	10	10	10	10	10	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 12

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13

SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 160 MG/KG/DAY FEMALES								
19664	112.	72.	11.1	104.	6.3	4.75	142.	60.
19669	106.	65.	10.7	106.	6.2	4.78	145.	52.
19672	118.	106.	11.2	101.	5.1	4.41	143.	56.
19674	122.	63.	10.9	101.	5.5	3.89	144.	108.
19676	113.	76.	11.4	102.	5.9	4.38	144.	67.
19690	101.	88.	11.4	103.	6.3	4.67	145.	53.
19694	123.	48.	10.8	103.	6.1	4.21	143.	47.
19699	100.	53.	11.0	106.	7.0	4.43	146.	44.
19706	107.	92.	11.3	102.	6.6	4.85	145.	49.
19707	102.	52.	10.8	106.	5.7	4.82	145.	38.
MEAN	110.	72.	11.1	103.	6.1	4.52	144.	57.
S.D.	8.6	19.1	0.26	2.0	0.55	0.312	1.2	19.6
N	10	10	10	10	10	10	10	10

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 13
SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13
SPONSOR NO.:06-012

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 400 MG/KG/DAY FEMALES										
19665	5.2	7.3	2.1	2.53	0.2	13.8	0.3	75.	64.	105.
19666	4.9	7.0	2.1	2.30	0.2	13.2	0.3	101.	58.	91.
19667	5.3	7.1	1.9	2.84	0.2	14.5	0.3	95.	49.	64.
19677	4.4	6.3	2.0	2.21	0.2	11.6	0.3	91.	35.	64.
19685	4.7	7.0	2.4	1.97	0.1	14.0	0.3	62.	69.	104.
19686	5.2	6.8	1.7	3.10	0.2	15.4	0.3	59.	39.	63.
19689	5.2	7.0	1.8	2.80	0.2	12.4	0.3	89.	83.	79.
19693	5.1	7.1	2.1	2.44	0.1	13.7	0.3	82.	47.	66.
19705	5.4	7.8	2.4	2.21	0.1	12.0	0.2	71.	47.	74.
MEAN	5.0	7.0	2.1	2.49	0.2	13.4	0.3	81.	55.	79.
S.D.	0.32	0.40	0.24	0.364	0.05	1.23	0.03	14.7	15.4	17.1
N	9	9	9	9	9	9	9	9	9	9

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —

SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES —

SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 400 MG/KG/DAY FEMALES								
19665	105.	59.	10.8	104.	5.7	4.38	144.	59.
19666	102.	52.	10.7	103.	6.5	4.72	141.	52.
19667	106.	60.	11.0	104.	5.6	4.14	145.	57.
19677	93.	55.	10.4	105.	6.0	4.17	144.	34.
19685	116.	74.	10.7	105.	6.6	5.08	146.	54.
19686	111.	53.	11.1	104.	6.8	4.51	144.	39.
19689	131.	59.	10.8	103.	6.6	4.58	143.	52.
19693	119.	76.	10.8	106.	4.6	3.96	145.	54.
19705	104.	56.	11.5	104.	6.3	4.43	143.	63.
MEAN	110.	60.	10.9	104.	6.1	4.44	144.	52.
S.D.	11.1	8.7	0.31	1.0	0.69	0.337	1.5	9.3
N	9	9	9	9	9	9	9	9

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 24

ANIMAL	ALBUMIN	TOTAL PROTEIN	GLOBULIN	A/G RATIO	TOTAL BILI	UREA NITROGEN	CREAT-ININE	ALKALINE PHOS'TSE	ALANINE TRANSFER	ASPARTAT TRANSFER
	g/dL	g/dL	g/dL		mg/dL	mg/dL	mg/dL	U/L	U/L	U/L
GROUP: 1000 MG/KG/DAY FEMALES										
19671	5.8	7.9	2.1	2.76	0.1	10.7	0.3	140.	128.	112.
19678	5.5	7.1	1.7	3.30	0.1	13.9	0.3	218.	393.	188.
19679	5.1	6.8	1.7	3.07	0.1	16.4	0.4	84.	204.	105.
19680	4.4	6.5	2.1	2.16	0.1	16.6	0.3	128.	376.	147.
19681	5.1	7.2	2.1	2.42	0.1	12.9	0.3	90.	86.	84.
19688	4.9	7.0	2.2	2.24	0.1	30.2	0.5	115.	76.	84.
19691	5.6	7.7	2.0	2.81	0.1	16.9	0.4	108.	107.	93.
19695	4.9	7.1	2.2	2.27	0.2	11.0	0.4	112.	170.	112.
19700	4.7	6.5	1.8	2.56	0.2	17.1	0.3	132.	142.	101.
19701	5.0	7.0	2.0	2.51	0.2	13.2	0.3	91.	132.	92.
MEAN	5.1	7.1	2.0	2.61	0.1	15.9	0.4	122.	181.	112.
S.D.	0.43	0.45	0.19	0.373	0.05	5.57	0.07	38.7	113.5	32.5
N	10	10	10	10	10	10	10	10	10	10

U/L = INTERNATIONAL UNIT/LITER, mg/dL = MILLIGRAMS/DECILITER, g/dL = GRAMS/DECILITER

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Modified: 8/30/2006

TABLE 24

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 16
SPONSOR:[redacted] — INDIVIDUAL SERUM CHEMISTRY VALUES — WEEK 13
SPONSOR NO.:06-012

ANIMAL	GLUCOSE	CHOL-ESTEROL	CALCIUM	CHLORIDE	PHOS-PHORUS	POTAS-SIUM	SODIUM	TRIGLY-CERIDE
	mg/dL	mg/dL	mg/dL	mEq/L	mg/dL	mEq/L	mEq/L	mg/dL
GROUP: 1000 MG/KG/DAY FEMALES								
19671	98.	63.	11.2	104.	5.3	4.89	145.	75.
19678	116.	54.	10.5	106.	5.1	4.42	144.	64.
19679	110.	55.	10.8	106.	7.5	4.76	146.	49.
19680	109.	52.	10.6	104.	6.6	4.88	143.	49.
19681	120.	51.	10.7	106.	5.1	4.10	144.	37.
19688	106.	61.	10.9	105.	6.4	4.27	145.	54.
19691	112.	45.	11.6	104.	6.8	4.77	146.	69.
19695	107.	73.	10.6	103.	7.2	4.78	144.	49.
19700	117.	58.	10.9	105.	6.2	3.84	145.	53.
19701	108.	58.	10.9	105.	6.0	4.10	145.	48.
MEAN	110.	57.	10.9	105.	6.2	4.48	145.	55.
S.D.	6.3	7.7	0.33	1.0	0.85	0.384	0.9	11.4
N	10	10	10	10	10	10	10	10

mg/dL = MILLIGRAMS/DECILITER, mEq/L = MILLIEQUIVALENTS/LITER

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TABLE 25 (WEEK -1 PRETEST EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS

SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: LMH EXAM 1(WEEK -1)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19623	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19626	0 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19630	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19636	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19639	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19644	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19652	0 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19655	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19657	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19660	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19619	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19628	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19640	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19646	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19647	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19648	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19650	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19654	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19659	160 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19663	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19621	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19622	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19631	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19632	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

Audited Draft

TABLE 25 (WEEK -1 PRETEST EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS

SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: LMH EXAM 1(WEEK -1)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19634	400 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19635	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19645	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19656	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19658	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19661	400 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19618	1000 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19620	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19624	1000 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19625	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19633	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19641	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19643	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19649	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19653	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19662	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19668	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19670	0 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19675	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19683	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19687	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19692	0 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19696	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19698	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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Modified: 8/30/2006

EXAMINER: DAW INPUT BY: LMH EXAM 1(WEEK -1)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19703	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19709	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19664	160 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19669	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19672	160 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19674	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19676	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19690	160 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19694	160 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19699	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19706	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19707	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19665	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19666	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19667	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19673	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19677	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19685	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19686	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19689	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19693	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19705	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19671	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19678	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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TABLE 25 (WEEK -1 PRETEST EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS

SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: LMH EXAM 1(WEEK -1)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19679	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19680	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19681	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19688	1000 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19691	1000 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19695	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19700	1000 MG/KG/DAY	FEMALE	CORNEAL CRYSTALS - BILATERAL	1
19701	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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TABLE 26 (WEEK 12 EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS

SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: JLK3 EXAM 2(WEEK 12)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19623	0 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19626	0 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19630	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19636	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19644	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19652	0 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19655	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19657	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19660	0 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19619	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19628	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19640	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19646	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19647	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19648	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19650	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19654	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19659	160 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19663	160 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19621	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19622	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19631	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19632	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19634	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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TABLE 26 (WEEK 12 EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS

SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: JLK3 EXAM 2(WEEK 12)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19635	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19645	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19656	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19658	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19661	400 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19618	1000 MG/KG/DAY	MALE	CORNEAL CRYSTALS - BILATERAL	1
19620	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19624	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19625	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19633	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19641	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19643	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19649	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19653	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19662	1000 MG/KG/DAY	MALE	NO OCULAR LESIONS - BILATERAL	P
19668	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19670	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19675	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19683	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19687	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19692	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19696	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19698	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19703	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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TABLE 26 (WEEK 12 EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS

SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: JLK3 EXAM 2(WEEK 12)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19709	0 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19664	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19669	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19672	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19674	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19676	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19690	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19694	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19699	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19706	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19707	160 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19665	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19666	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19667	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19677	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19685	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19686	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19689	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19693	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19705	400 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19671	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19678	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19679	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19680	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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TABLE 26 (WEEK 12 EXAMINATION)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL OPHTHALMIC EXAMINATION FINDINGS
SPONSOR NO.:06-012

EXAMINER: DAW INPUT BY: JLK3 EXAM 2(WEEK 12)

ANIMAL NO.	DOSE GROUP	SEX	FINDING	GRADE
19681	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19688	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19691	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19695	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19700	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P
19701	1000 MG/KG/DAY	FEMALE	NO OCULAR LESIONS - BILATERAL	P

CODE: 1-SLIGHT, 2-MODERATE, 3-SEVERE, P-PRESENT, O.D.-RIGHT EYE, O.S.-LEFT EYE

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07/25/2006

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TABLE 27 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19639 GROUP 1: 0 MG/KG/DAY MALE EUTH IN EXTREMIS 05/15/06 DATE OF DEATH: 05/15/06 STUDY DAY: 70

			GRADE
CECUM	GROSS:	DISTENDED GAS FILLED	P
CECUM	MICRO:	DILATATION GROSS OBSERVATION CONFIRMED	3
COLON	MICRO:	DILATATION, CRYPTS DIFFUSE	2
HEART	MICRO:	INFILTRATE, MONONUCLEAR MULTIFOCAL	1
ILEUM	GROSS:	DISTENDED GAS FILLED	P
ILEUM	MICRO:	DILATATION GROSS OBSERVATION CONFIRMED	4
KIDNEYS	MICRO:	PROTEINOSIS, TUBULAR MULTIFOCAL, BILATERAL	1
		MINERALIZATION FOCAL, UNILATERAL	1
LYMPH NODE, MES	MICRO:	HEMORRHAGE	1
PROSTATE	MICRO:	INFILTRATE, NEUTROPHIL MULTIFOCAL; INTRA-TUBULAR	2
RECTUM	MICRO:	ULCERATION FOCAL; HAIRED SKIN PORTION	1
		INFLAMMATION, ACUTE FOCAL; HAIRED SKIN PORTION	1

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TABLE 27 (UNSCHEDULED DEATHS)

ANIMAL NO. 19639 GROUP 1: 0 MG/KG/DAY MALE EUTH IN EXTREMIS 05/15/06 DATE OF DEATH: 05/15/06 STUDY DAY: 70

			GRADE
SKIN	GROSS:	MATTING, RED NASAL; BUCCAL; OCULAR, BILATERAL	P
NASAL LEVEL I	MICRO:	LUMINAL DEBRIS BILATERAL	3
		HEMORRHAGE MULTIFOCAL, BILATERAL; SUBMUCOSA	2
		INFLAMMATION, ACUTE MULTIFOCAL, BILATERAL; SUBMUCOSA	2
		ULCERATION MULTIFOCAL, BILATERAL	4
THYROID GLANDS	MICRO:	CYST, ULTIMOBRANCHIAL	P
THYMUS	MICRO:	ATROPHY	3
NASAL LEVEL III	MICRO:	LUMINAL DEBRIS BILATERAL	2
		MINERALIZATION, MUCOSAL MULTIFOCAL	1
		ATROPHY OLFACTORY EPITHELIUM; MULTIFOCAL, BILATERAL	2
		HEMORRHAGE FOCAL	2
		ULCERATION FOCAL	3
		INFLAMMATION, ACUTE	3

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ANIMAL NO. 19639 GROUP 1: 0 MG/KG/DAY MALE EUTH IN EXTREMIS 05/15/06 DATE OF DEATH: 05/15/06 STUDY DAY: 70

		GRADE
	FOCAL	
L.N. POP, LT	MICRO: NOT EXAMINED	
	LYMPH NODE NOT EXAMINED, NOT PRESENT AT TRIMMING	
L.N. POP, RT	MICRO: NOT EXAMINED	
	LYMPH NODE NOT EXAMINED, NOT PRESENT AT TRIMMING	
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE	2
	BILATERAL	
CAUSE OF DEATH	MICRO: UNDETERMINED	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	COLON	DUODENUM	EPIDIDYMIDES	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	LUNGS	LARYNX
	NERVE, SCIATIC	PANCREAS	PHARYNX	PITUITARY
	PROSTATE	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH	SKELETAL MUSCLE	SPLEEN	SEMINAL VESICLES
	TESTES	THYROID GLANDS	THYMUS	TRACHEA
	URINARY BLADDER	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	HARDERIAN GLANDS	JEJUNUM
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LUNGS
	LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX
	PITUITARY	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
	STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN
	SEMINAL VESICLES	TESTES	PARATHYROIDS	TRACHEA
	URINARY BLADDER	PEYER'S PATCHES		

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Modified: 8/30/2006

TABLE 27 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19639 GROUP 1: 0 MG/KG/DAY MALE EUTH IN EXTREMIS 05/15/06 DATE OF DEATH: 05/15/06 STUDY DAY: 70

	GRADE
NOT EXAMINED	
MICRO:L.N. POP, LT	
L.N. POP, RT	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 27 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19673 GROUP 3: 400 MG/KG/DAY FEMALE FOUND DEAD 05/10/06 DATE OF DEATH: 05/10/06 STUDY DAY: 65

			GRADE
	LYMPH NODE, MAND	MICRO: DEPLETION, LYMPHOID	1
	LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
	SPLEEN	MICRO: DEPLETION, LYMPHOID	1
	UTERUS	MICRO: DILATATION	2
	L.N. POP, LT	MICRO: NOT EXAMINED LYMPH NODE NOT EXAMINED, NOT PRESENT AT TRIMMING	
	L.N. POP, RT	MICRO: NOT EXAMINED LYMPH NODE NOT EXAMINED, NOT PRESENT AT TRIMMING	
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1
	CAUSE OF DEATH	MICRO: UNDETERMINED	P
	NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART

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TABLE 27 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19673 GROUP 3: 400 MG/KG/DAY FEMALE FOUND DEAD 05/10/06 DATE OF DEATH: 05/10/06 STUDY DAY: 65

GRADE

HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LARYNX
MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
PANCREAS	PHARYNX	PITUITARY	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
SKELETAL MUSCLE	SKIN	NASAL LEVEL I	THYROID GLANDS
PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
VAGINA	CERVIX	NASAL LEVEL III	PEYER'S PATCHES

NOT EXAMINED

MICRO:L.N. POP, LT L.N. POP, RT

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.54
08/14/2006

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19623 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.96	0.388
LIVER	13.93	2.758
KIDNEYS	3.37	0.667
SPLEEN	0.79	0.156
HEART	1.58	0.313
SEM VES/CG	1.77	0.350
PROSTATE	0.80	0.158
EPIDIDYMIDES	1.23	0.244
TESTES	3.46	0.685
THYMUS	0.2920	0.058
ADRENAL GLANDS	0.0541	0.011
L.N. POP, LT	0.0135	0.003
L.N. POP, RT	0.0195	0.004
THYROIDS/PARA.	0.0240	0.005
FINAL BODY WT(G)	505.	

		GRADE
KIDNEYS	MICRO: MINERALIZATION	
	FOCAL, UNILATERAL	1
	BASOPHILIC TUBULES	
	MULTIFOCAL, BILATERAL	1
	INFILTRATE, LYMPHOCYTE	
	MULTIFOCAL, UNILATERAL	1
LIVER	MICRO: INFILTRATE, MONONUCLEAR	
	FOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR	
	FOCAL	1
	INFILTRATE, MONONUCLEAR	
	MULTIFOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL	
	MULTIFOCAL	1

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19623 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	HARDERIAN GLANDS	ILEUM	JEJUNUM
	LYMPH NODE, MAND	LAC. GLAND EXOR	LYMPH NODE, MES	LARYNX
	NERVE, SCIATIC	PANCREAS	PHARYNX	PITUITARY
	PROSTATE	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	SEMINAL VESICLES	TESTES	NASAL LEVEL I
	PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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ANIMAL NO. 19626 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	2.23	0.365	KIDNEYS	MICRO: BASOPHILIC TUBULES MULTIFOCAL, BILATERAL	1
LIVER	19.87	3.252		INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
KIDNEYS	4.46	0.730	LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
SPLEEN	0.87	0.142		INFILTRATE, MONONUCLEAR MULTIFOCAL	2
HEART	2.06	0.337	PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
SEM VES/CG	3.07	0.502	RECTUM	MICRO: PARASITES, NEMATODES	P
PROSTATE	0.76	0.124	SKELETAL MUSCLE	MICRO: NECROSIS FOCAL	1
EPIDIDYMIDES	1.44	0.236	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
TESTES	3.65	0.597	THYMUS	GROSS: AREA(S), DARK RED MULTIPLE, IRREGULARLY SHAPED	P
THYMUS	0.3078	0.050	THYMUS	MICRO: HEMORRHAGE MULTIFOCAL; GROSS OBSERVATION CONFIRMED	1
ADRENAL GLANDS	0.0766	0.013	URINARY BLADDER	MICRO: INFILTRATE, LYMPHOCYTE FOCAL	1
L.N. POP, LT	0.0078	0.001	NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL MULTIFOCAL	1
L.N. POP, RT	0.0137	0.002			
THYROIDS/PARA.	0.0274	0.004			
FINAL BODY WT(G)	611.				

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19626 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

			GRADE
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1

NO SIGNIFICANT CHANGES OBSERVED

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	TRACHEA	URINARY BLADDER	L.N. POP, LT
	L.N. POP, RT	PEYER'S PATCHES		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	HARDERIAN GLANDS	ILEUM	JEJUNUM
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LARYNX	NERVE, SCIATIC	PANCREAS	PITUITARY
	PROSTATE	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
	STOMACH, NON	SKIN	SPLEEN	SEMINAL VESICLES
	TESTES	NASAL LEVEL I	PARATHYROIDS	TRACHEA
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

NOT EXAMINED

MICRO: PHARYNX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 5
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19630 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.08	0.425
LIVER	15.28	3.125
KIDNEYS	3.88	0.793
SPLEEN	0.80	0.164
HEART	1.82	0.372
SEM VES/CG	2.64	0.540
PROSTATE	0.97	0.198
EPIDIDYMIDES	1.38	0.282
TESTES	3.44	0.703
THYMUS	0.2530	0.052
ADRENAL GLANDS	0.0595	0.012
L.N. POP, LT	0.0151	0.003
L.N. POP, RT	0.0112	0.002
THYROIDS/PARA.	0.0297	0.006
FINAL BODY WT(G)	489.	

			GRADE
ADRENAL MEDULLA	MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE ADRENAL MEDULLA NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
HARDERIAN GLANDS	MICRO:	HEMORRHAGE UNILATERAL	3
KIDNEYS	MICRO:	DILATATION, TUBULAR FOCAL, UNILATERAL	1
		DROPLET, HYALINE	1
		PROTEINOSIS, TUBULAR FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO:	HEMORRHAGE BILATERAL	2
LARYNX	MICRO:	INFILTRATE, MONONUCLEAR FOCAL	1
PANCREAS	MICRO:	FIBROSIS FOCAL	2
THYROID GLANDS	MICRO:	CYST, ULTIMOBRANCHIAL	P
NASOLACRIMAL DUC	MICRO:	LUMINAL DEBRIS UNILATERAL	2
EAR CANAL	MICRO:	INFILTRATE, LYMPHOCYTE BILATERAL	1

NO SIGNIFICANT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19630 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

CHANGES OBSERVED	GRADE			
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	ILEUM	JEJUNUM	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	LUNGS	NERVE, SCIATIC
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
	SKELETAL MUSCLE	SKIN	SPLEEN	SEMINAL VESICLES
	TESTES	NASAL LEVEL I	PARATHYROIDS	THYMUS
	TRACHEA	URINARY BLADDER	NASAL LEVEL III	L.N. POP, LT
	L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19636 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.	GENERAL COMMENT	GRADE
BRAIN	2.07	0.393		
LIVER	14.66	2.782	KIDNEYS	
KIDNEYS	4.00	0.759		
SPLEEN	0.60	0.114		
HEART	1.61	0.306		
SEM VES/CG	1.77	0.336	LUNGS	
PROSTATE	0.64	0.121		
EPIDIDYMIDES	1.27	0.241	LARYNX	
TESTES	3.26	0.619		
THYMUS	0.3008	0.057	NASAL LEVEL III	
ADRENAL GLANDS	0.0587	0.011		
L.N. POP, LT	0.0102	0.002	EAR CANAL	
L.N. POP, RT	0.0073	0.001		
THYROIDS/PARA.	0.0228	0.004	NO SIGNIFICANT	
FINAL BODY WT(G)	527.		CHANGES OBSERVED	

GROSS: SEMINAL FLUID LOST PRIOR TO WEIGHING P
SEMINAL VESICLE, BILATERAL

MICRO: PROTEINOSIS, TUBULAR 1
FOCAL, UNILATERAL
INFILTRATE, LYMPHOCYTE 1
FOCAL, UNILATERAL

MICRO: MINERALIZATION, VASCULAR 1
FOCAL

MICRO: INFLAMMATION, CHRONIC 2
FOCALLY EXTENSIVE

MICRO: MINERALIZATION, MUCOSAL 1
MULTIFOCAL

MICRO: INFILTRATE, LYMPHOCYTE 1
BILATERAL

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19636 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

				GRADE
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	HARDERIAN GLANDS	ILEUM	JEJUNUM
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	NERVE, SCIATIC	PANCREAS	PHARYNX	PITUITARY
	PROSTATE	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	SEMINAL VESICLES	TESTES	NASAL LEVEL I
	THYROID GLANDS	PARATHYROIDS	THYMUS	TRACHEA
	URINARY BLADDER	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19644 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.99	0.402	HEART	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
LIVER	15.78	3.188	LYMPH NODE, MAND	MICRO: DEPLETION, LYMPHOID BILATERAL	2
KIDNEYS	3.61	0.729	LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
SPLEEN	0.61	0.123	LARYNX	MICRO: DEGENERATION, CARTILAGE MULTIFOCAL	1
HEART	1.45	0.293		INFLAMMATION, CHRONIC FOCALLY EXTENSIVE	2
SEM VES/CG	1.99	0.402	PITUITARY	MICRO: CYST, PARS DISTALIS	P
PROSTATE	0.98	0.198	SKIN	GROSS: OPEN SORE(S) ONE, BUCCAL	P
EPIDIDYMIDES	1.22	0.246	SKIN	MICRO: NO SIGNIFICANT CHANGES OBSERVED GROSS OBSERVATION NOT CONFIRMED	
TESTES	3.25	0.657	THYMUS	GROSS: AREA(S), DARK RED ONE, IRREGULARLY SHAPED	P
THYMUS	0.2443	0.049	THYMUS	MICRO: NO SIGNIFICANT CHANGES OBSERVED GROSS OBSERVATION NOT CONFIRMED	
ADRENAL GLANDS	0.0583	0.012	TEETH	GROSS: MALALIGNED LOWER INCISOR, BILATERAL	P
L.N. POP, LT	0.0092	0.002	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	2
L.N. POP, RT	0.0089	0.002			
THYROIDS/PARA.	0.0257	0.005			
FINAL BODY WT(G)	495.				

NO SIGNIFICANT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19644 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

CHANGES OBSERVED	GRADE			
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SPLEEN	SEMINAL VESICLES	TESTES	THYROID GLANDS
	TRACHEA	URINARY BLADDER	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	NERVE, SCIATIC
	PANCREAS	PHARYNX	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
	SKELETAL MUSCLE	SKIN	SPLEEN	SEMINAL VESICLES
	TESTES	NASAL LEVEL I	THYROID GLANDS	PARATHYROIDS
	THYMUS	TRACHEA	URINARY BLADDER	NASAL LEVEL III
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19652 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.95	0.331
LIVER	17.93	3.044
KIDNEYS	4.04	0.686
SPLEEN	0.76	0.129
HEART	1.99	0.338
SEM VES/CG	2.14	0.363
PROSTATE	0.89	0.151
EPIDIDYMIDES	1.47	0.250
TESTES	3.46	0.587
THYMUS	0.2836	0.048
ADRENAL GLANDS	0.0702	0.012
L.N. POP, LT	0.0104	0.002
L.N. POP, RT	0.0160	0.003
THYROIDS/PARA.	0.0224	0.004
FINAL BODY WT(G)	589.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
KIDNEYS	MICRO: BASOPHILIC TUBULES MULTIFOCAL, BILATERAL	1
	PROTEINOSIS, TUBULAR MULTIFOCAL, BILATERAL	1
LIVER	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
	VACUOLATION, HEPATOCELLULAR MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
LARYNX	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL MULTIFOCAL	1
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	1

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19652 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

				GRADE
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	HARDERIAN GLANDS	ILEUM	JEJUNUM
	LYMPH NODE, MAND	LAC. GLAND EXOR	LYMPH NODE, MES	NERVE, SCIATIC
	PANCREAS	PHARYNX	PITUITARY	PROSTATE
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
	STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN
	SEMINAL VESICLES	TESTES	NASAL LEVEL I	THYROID GLANDS
	PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19655 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.22	0.357
LIVER	17.83	2.867
KIDNEYS	4.32	0.695
SPLEEN	0.97	0.156
HEART	2.03	0.326
SEM VES/CG	2.23	0.359
PROSTATE	1.07	0.172
EPIDIDYMIDES	1.65	0.265
TESTES	4.13	0.664
THYMUS	0.2564	0.041
ADRENAL GLANDS	0.0890	0.014
L.N. POP, LT	0.0099	0.002
L.N. POP, RT	0.0188	0.003
THYROIDS/PARA.	0.0228	0.004
FINAL BODY WT(G)	622.	

		GRADE
EPIDIDYMIDES	MICRO: INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
HEART	MICRO: HEMORRHAGE HEART BASE	3
	EXUDATE, FIBRINOUS HEART BASE	2
	VASCULITIS HEART BASE	3
KIDNEYS	MICRO: FIBROSIS, INTERSTITIAL FOCAL, UNILATERAL	1
	DILATATION, TUBULAR FOCAL, UNILATERAL	1
	INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: HYPERPLASIA, LYMPHOID BILATERAL	1
LIVER	MICRO: VACUOLATION, HEPATOCELLULAR MULTIFOCAL	1
LUNGS	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
LARYNX	MICRO: DILATATION, GLANDULAR FOCAL	1

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19655 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

			GRADE
	RECTUM	MICRO: PARASITES, NEMATODES	P
	NASAL LEVEL I	MICRO: EROSION, EPITHELIAL	1
		FOCAL, UNILATERAL	
		INFLAMMATION	2
		FOCAL, UNILATERAL	
	PARATHYROIDS	MICRO: NOT EXAMINED	
		PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
	URINARY BLADDER	MICRO: INFILTRATE, LYMPHOCYTE	1
		MULTIFOCAL	
	NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL	1
		MULTIFOCAL	
		HEMORRHAGE	1
		MULTIFOCAL; SUBMUCOSA	
	NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS	2
		UNILATERAL	
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE	2
		UNILATERAL	
	NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
CECUM	COLON	DUODENUM	EPIDIDYMIDES	
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART	
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS	
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS	

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19655 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

GRADE

	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HARDERIAN GLANDS
	ILEUM	JEJUNUM	LAC. GLAND EXOR	LYMPH NODE, MES
	NERVE, SCIATIC	PANCREAS	PHARYNX	PITUITARY
	PROSTATE	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
	STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN
	SEMINAL VESICLES	TESTES	THYROID GLANDS	THYMUS
	TRACHEA	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19657 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.22	0.441
LIVER	14.86	2.954
KIDNEYS	3.81	0.757
SPLEEN	0.73	0.145
HEART	1.53	0.304
SEM VES/CG	1.90	0.378
PROSTATE	0.91	0.181
EPIDIDYMIDES	1.39	0.276
TESTES	3.76	0.748
THYMUS	0.2262	0.045
ADRENAL GLANDS	0.0608	0.012
L.N. POP, LT	0.0095	0.002
L.N. POP, RT	0.0077	0.002
THYROIDS/PARA.	0.0262	0.005
FINAL BODY WT(G)	503.	

			GRADE
EYES/OPTIC N.	MICRO:	INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	1
KIDNEYS	MICRO:	BASOPHILIC TUBULES MULTIFOCAL, BILATERAL	1
		CYST, MEDULLARY FOCAL, UNILATERAL	P
LUNGS	MICRO:	INFILTRATE, MONONUCLEAR MULTIFOCAL	1
		MINERALIZATION, VASCULAR MULTIFOCAL	1
PITUITARY	MICRO:	CYST, PARS DISTALIS	P
PROSTATE	MICRO:	INFILTRATE, LYMPHOCYTE MULTIFOCAL	1
THYROID GLANDS	MICRO:	CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO:	NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
NASAL LEVEL III	MICRO:	MINERALIZATION, MUCOSAL MULTIFOCAL	1
NASOLACRIMAL DUC	MICRO:	LUMINAL DEBRIS BILATERAL	1

NO SIGNIFICANT CHANGES OBSERVED

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19657 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

GRADE

	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LARYNX
	NERVE, SCIATIC	PANCREAS	PHARYNX	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
	SKELETAL MUSCLE	SKIN	SPLEEN	SEMINAL VESICLES
	TESTES	NASAL LEVEL I	THYMUS	TRACHEA
	URINARY BLADDER	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19660 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.99	0.383
LIVER	14.75	2.842
KIDNEYS	4.04	0.778
SPLEEN	0.68	0.131
HEART	1.48	0.285
SEM VES/CG	2.10	0.405
PROSTATE	1.08	0.208
EPIDIDYMIDES	1.54	0.297
TESTES	3.94	0.759
THYMUS	0.2377	0.046
ADRENAL GLANDS	0.0654	0.013
L.N. POP, LT	0.0070	0.001
L.N. POP, RT	0.0059	0.001
THYROIDS/PARA.	0.0181	0.003
FINAL BODY WT(G)	519.	

		GRADE
EYES/OPTIC N.	MICRO: INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	1
HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	1
	INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
KIDNEYS	MICRO: INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
	INFILTRATE, MONONUCLEAR MULTIFOCAL	1
LARYNX	MICRO: INFLAMMATION, CHRONIC FOCAL	1
PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1
NO SIGNIFICANT CHANGES OBSERVED	GROSS:ADRENAL GLANDS AORTA STERNUM BRAIN	

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19660 GROUP 1: 0 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

GRADE

	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	HEART
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	NERVE, SCIATIC	PANCREAS
	PITUITARY	PROSTATE	RECTUM	SPINAL CORD
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	NASAL LEVEL I	PARATHYROIDS	THYMUS	TRACHEA
	URINARY BLADDER	NASAL LEVEL III	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			

NOT EXAMINED

MICRO:PHARYNX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19619 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.15	0.397
LIVER	15.66	2.895
KIDNEYS	3.79	0.701
SPLEEN	0.63	0.116
HEART	1.63	0.301
SEM VES/CG	1.74	0.322
PROSTATE	0.89	0.165
EPIDIDYMIDES	1.21	0.224
TESTES	3.18	0.588
THYMUS	0.3300	0.061
ADRENAL GLANDS	0.0570	0.011
L.N. POP, LT	0.0084	0.002
L.N. POP, RT	0.0093	0.002
THYROIDS/PARA.	0.0205	0.004
FINAL BODY WT(G)	541.	

		GRADE
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	1
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX
PITUITARY	PROSTATE	RECTUM	SPINAL CORD
SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	SKIN
SPLEEN	SEMINAL VESICLES	TESTES	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19628 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.05	0.450
LIVER	13.36	2.930
KIDNEYS	3.40	0.746
SPLEEN	0.68	0.149
HEART	1.47	0.322
SEM VES/CG	1.78	0.390
PROSTATE	0.87	0.191
EPIDIDYMIDES	1.27	0.279
TESTES	3.37	0.739
THYMUS	0.2711	0.059
ADRENAL GLANDS	0.0533	0.012
L.N. POP, LT	0.0108	0.002
L.N. POP, RT	0.0073	0.002
THYROIDS/PARA.	0.0220	0.005
FINAL BODY WT(G)	456.	

GENERAL COMMENT: NO SIGNIFICANT CHANGES OBSERVED

GROSS: SEMINAL FLUID LOST PRIOR TO WEIGHING URETHRA

GRADE: P

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19640 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.11	0.407
LIVER	14.33	2.761
KIDNEYS	4.09	0.788
SPLEEN	0.64	0.123
HEART	1.65	0.318
SEM VES/CG	2.27	0.437
PROSTATE	0.78	0.150
EPIDIDYMIDES	1.14	0.220
TESTES	3.29	0.634
THYMUS	0.2100	0.040
ADRENAL GLANDS	0.0578	0.011
L.N. POP, LT	0.0114	0.002
L.N. POP, RT	0.0076	0.001
THYROIDS/PARA.	0.0242	0.005
FINAL BODY WT(G)	519.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19646 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.06	0.373
LIVER	16.68	3.022
KIDNEYS	3.72	0.674
SPLEEN	0.77	0.139
HEART	1.86	0.337
SEM VES/CG	1.71	0.310
PROSTATE	0.43	0.078
EPIDIDYMIDES	1.37	0.248
TESTES	3.91	0.708
THYMUS	0.2199	0.040
ADRENAL GLANDS	0.0581	0.011
L.N. POP, LT	0.0095	0.002
L.N. POP, RT	0.0119	0.002
THYROIDS/PARA.	0.0308	0.006
FINAL BODY WT(G)	552.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19647 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.12	0.506
LIVER	11.83	2.823
KIDNEYS	3.51	0.838
SPLEEN	0.68	0.162
HEART	1.66	0.396
SEM VES/CG	1.97	0.470
PROSTATE	0.92	0.220
EPIDIDYMIDES	1.26	0.301
TESTES	3.48	0.831
THYMUS	0.2942	0.070
ADRENAL GLANDS	0.0564	0.013
L.N. POP, LT	0.0183	0.004
L.N. POP, RT	0.0271	0.006
THYROIDS/PARA.	0.0247	0.006
FINAL BODY WT(G)	419.	

			GRADE
TEETH	GROSS: MISSING	UPPER INCISOR, RIGHT	P
TEETH	GROSS: FRACTURED	UPPER INCISOR, LEFT	P
NO SIGNIFICANT CHANGES OBSERVED			

GROSS:				
	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19648 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.22	0.359
LIVER	17.96	2.906
KIDNEYS	4.39	0.710
SPLEEN	0.79	0.128
HEART	1.97	0.319
SEM VES/CG	1.78	0.288
PROSTATE	0.77	0.125
EPIDIDYMIDES	1.40	0.227
TESTES	3.77	0.610
THYMUS	0.2759	0.045
ADRENAL GLANDS	0.0721	0.012
L.N. POP, LT	0.0121	0.002
L.N. POP, RT	0.0104	0.002
THYROIDS/PARA.	0.0315	0.005
FINAL BODY WT(G)	618.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19650 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.25	0.389
LIVER	17.70	3.057
KIDNEYS	3.67	0.634
SPLEEN	0.74	0.128
HEART	1.92	0.332
SEM VES/CG	2.40	0.415
PROSTATE	1.14	0.197
EPIDIDYMIDES	1.33	0.230
TESTES	4.35	0.751
THYMUS	0.2804	0.048
ADRENAL GLANDS	0.0650	0.011
L.N. POP, LT	0.0046	0.001
L.N. POP, RT	0.0073	0.001
THYROIDS/PARA.	0.0261	0.005
FINAL BODY WT(G)	579.	

TESTES
NO SIGNIFICANT
CHANGES OBSERVED

GRADE

GROSS: SMALL P
LEFT
MICRO: NO SIGNIFICANT CHANGES OBSERVED
GROSS OBSERVATION NOT CONFIRMED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
L.N. POP, RT	PEYER'S PATCHES		

MICRO:TESTES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19654 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	2.10	0.450	
LIVER	15.60	3.340	
KIDNEYS	3.73	0.799	
SPLEEN	0.64	0.137	
HEART	1.53	0.328	
SEM VES/CG	1.83	0.392	
PROSTATE	0.40	0.086	
EPIDIDYMIDES	1.43	0.306	
TESTES	3.95	0.846	
THYMUS	0.2978	0.064	
ADRENAL GLANDS	0.0609	0.013	
L.N. POP, LT	0.0071	0.002	
L.N. POP, RT	0.0122	0.003	
THYROIDS/PARA.	0.0277	0.006	
FINAL BODY WT(G)	467.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19659 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.17	0.363
LIVER	18.46	3.092
KIDNEYS	4.24	0.710
SPLEEN	1.13	0.189
HEART	2.09	0.350
SEM VES/CG	2.11	0.353
PROSTATE	0.78	0.131
EPIDIDYMIDES	1.44	0.241
TESTES	3.93	0.658
THYMUS	0.3545	0.059
ADRENAL GLANDS	0.0777	0.013
L.N. POP, LT	0.0062	0.001
L.N. POP, RT	0.0120	0.002
THYROIDS/PARA.	0.0268	0.004
FINAL BODY WT(G)	597.	

		GRADE
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	1
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX
PITUITARY	PROSTATE	RECTUM	SPINAL CORD
SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	SKIN
SPLEEN	SEMINAL VESICLES	TESTES	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19663 GROUP 2: 160 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.13	0.466
LIVER	13.39	2.930
KIDNEYS	3.45	0.755
SPLEEN	0.56	0.123
HEART	1.58	0.346
SEM VES/CG	1.78	0.389
PROSTATE	0.57	0.125
EPIDIDYMIDES	1.25	0.274
TESTES	3.49	0.764
THYMUS	0.2205	0.048
ADRENAL GLANDS	0.0527	0.012
L.N. POP, LT	0.0173	0.004
L.N. POP, RT	0.0058	0.001
THYROIDS/PARA.	0.0195	0.004
FINAL BODY WT(G)	457.	

		GRADE
LUNGS	GROSS: AREA(S), DARK RED ONE, 15 X 10 MM, RIGHT DIAPHRAGMATIC LOBE	P
LUNGS	MICRO: CONGESTION FOCALLY EXTENSIVE; GROSS OBSERVATION CONFIRMED	2
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX
PITUITARY	PROSTATE	RECTUM	SPINAL CORD
SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	SKIN
SPLEEN	SEMINAL VESICLES	TESTES	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19621 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.	GENERAL COMMENT	GROSS: NOT POSITIVELY IDENTIFIED POPLITEAL LYMPH NODE, LEFT	GRADE
BRAIN	2.12	0.416			
LIVER	16.62	3.259	LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
KIDNEYS	3.62	0.710			
SPLEEN	0.73	0.143	LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	P
HEART	1.94	0.380			2
SEM VES/CG	1.82	0.357	NO SIGNIFICANT		
PROSTATE	0.60	0.118	CHANGES OBSERVED		
EPIDIDYMIDES	1.41	0.276			
TESTES	3.39	0.665			
THYMUS	0.2527	0.050			
ADRENAL GLANDS	0.0524	0.010			
L.N. POP, LT	0.0091	0.002			
L.N. POP, RT	0.0123	0.002			
THYROIDS/PARA.	0.0248	0.005			
FINAL BODY WT(G)	510.				

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX
PITUITARY	PROSTATE	RECTUM	SPINAL CORD
SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	SKIN
SPLEEN	SEMINAL VESICLES	TESTES	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19622 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.02	0.319
LIVER	22.88	3.609
KIDNEYS	4.44	0.700
SPLEEN	0.94	0.148
HEART	2.14	0.338
SEM VES/CG	1.97	0.311
PROSTATE	0.85	0.134
EPIDIDYMIDES	1.34	0.211
TESTES	3.71	0.585
THYMUS	0.4242	0.067
ADRENAL GLANDS	0.0662	0.010
L.N. POP, LT	0.0141	0.002
L.N. POP, RT	0.0183	0.003
THYROIDS/PARA.	0.0264	0.004
FINAL BODY WT(G)	634.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19631 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.08	0.452
LIVER	12.91	2.807
KIDNEYS	3.56	0.774
SPLEEN	0.61	0.133
HEART	1.51	0.328
SEM VES/CG	1.94	0.422
PROSTATE	0.70	0.152
EPIDIDYMIDES	1.42	0.309
TESTES	3.63	0.789
THYMUS	0.1748	0.038
ADRENAL GLANDS	0.0590	0.013
L.N. POP, LT	0.0025	0.001
L.N. POP, RT	0.0069	0.002
THYROIDS/PARA.	0.0229	0.005
FINAL BODY WT(G)	460.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19632 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.12	0.414
LIVER	17.72	3.461
KIDNEYS	3.80	0.742
SPLEEN	0.76	0.148
HEART	1.71	0.334
SEM VES/CG	1.70	0.332
PROSTATE	0.66	0.129
EPIDIDYMIDES	1.34	0.262
TESTES	3.49	0.682
THYMUS	0.3717	0.073
ADRENAL GLANDS	0.0608	0.012
L.N. POP, LT	0.0140	0.003
L.N. POP, RT	0.0159	0.003
THYROIDS/PARA.	0.0240	0.005
FINAL BODY WT(G)	512.	

			GRADE
KIDNEYS	GROSS: DILATED PELVIS RIGHT		2
KIDNEYS	MICRO: DILATATION, PELVIS GROSS OBSERVATION CONFIRMED		1
NO SIGNIFICANT CHANGES OBSERVED			

GROSS:				
ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
CECUM	COLON	DUODENUM	EPIDIDYMIDES	
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART	
HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND	
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS	
LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX	
PITUITARY	PROSTATE	RECTUM	SPINAL CORD	
SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	SKIN	
SPLEEN	SEMINAL VESICLES	TESTES	THYROID GLANDS	
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT	
L.N. POP, RT	PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19634 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.09	0.406
LIVER	16.28	3.161
KIDNEYS	4.41	0.856
SPLEEN	0.91	0.177
HEART	1.60	0.311
SEM VES/CG	2.48	0.482
PROSTATE	1.01	0.196
EPIDIDYMIDES	1.34	0.260
TESTES	3.70	0.718
THYMUS	0.2729	0.053
ADRENAL GLANDS	0.0636	0.012
L.N. POP, LT	0.0109	0.002
L.N. POP, RT	0.0051	0.001
THYROIDS/PARA.	0.0152	0.003
FINAL BODY WT(G)	515.	

L.N. POP, RT NO SIGNIFICANT CHANGES OBSERVED

L.N. POP, RT

	GRADE
GROSS: SMALL	P
MICRO: NO SIGNIFICANT CHANGES OBSERVED	
GROSS OBSERVATION NOT CONFIRMED	

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	PEYER'S PATCHES		

MICRO:L.N. POP, RT

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19635 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.08	0.398
LIVER	16.09	3.076
KIDNEYS	3.84	0.734
SPLEEN	0.68	0.130
HEART	1.52	0.291
SEM VES/CG	1.93	0.369
PROSTATE	1.06	0.203
EPIDIDYMIDES	1.27	0.243
TESTES	3.35	0.641
THYMUS	0.2442	0.047
ADRENAL GLANDS	0.0616	0.012
L.N. POP, LT	0.0173	0.003
L.N. POP, RT	0.0260	0.005
THYROIDS/PARA.	0.0228	0.004
FINAL BODY WT(G)	523.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19645 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.08	0.411
LIVER	17.11	3.381
KIDNEYS	4.28	0.846
SPLEEN	0.70	0.138
HEART	1.77	0.350
SEM VES/CG	2.10	0.415
PROSTATE	0.68	0.134
EPIDIDYMIDES	1.48	0.292
TESTES	3.57	0.706
THYMUS	0.2798	0.055
ADRENAL GLANDS	0.0682	0.013
L.N. POP, LT	0.0135	0.003
L.N. POP, RT	0.0157	0.003
THYROIDS/PARA.	0.0265	0.005
FINAL BODY WT(G)	506.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19656 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.00	0.389
LIVER	15.78	3.070
KIDNEYS	3.55	0.691
SPLEEN	0.68	0.132
HEART	1.65	0.321
SEM VES/CG	1.76	0.342
PROSTATE	0.81	0.158
EPIDIDYMIDES	1.42	0.276
TESTES	3.55	0.691
THYMUS	0.2789	0.054
ADRENAL GLANDS	0.0712	0.014
L.N. POP, LT	0.0135	0.003
L.N. POP, RT	0.0150	0.003
THYROIDS/PARA.	0.0216	0.004
FINAL BODY WT(G)	514.	

		GRADE
SEMINAL VESICLES	GROSS: SMALL	P
	RIGHT	
SEMINAL VESICLES	MICRO: DECREASED SECRETION	3
	GROSS OBSERVATION CONFIRMED	

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	TESTES	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19658 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	2.09	0.385	
LIVER	17.41	3.206	
KIDNEYS	4.41	0.812	
SPLEEN	0.83	0.153	
HEART	1.70	0.313	
SEM VES/CG	2.51	0.462	
PROSTATE	1.10	0.203	
EPIDIDYMIDES	1.21	0.223	
TESTES	3.06	0.564	
THYMUS	0.3524	0.065	
ADRENAL GLANDS	0.0747	0.014	
L.N. POP, LT	0.0130	0.002	
L.N. POP, RT	0.0124	0.002	
THYROIDS/PARA.	0.0233	0.004	
FINAL BODY WT(G)	543.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19661 GROUP 3: 400 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.15	0.378
LIVER	17.13	3.011
KIDNEYS	3.90	0.685
SPLEEN	0.81	0.142
HEART	1.82	0.320
SEM VES/CG	1.88	0.330
PROSTATE	0.89	0.156
EPIDIDYMIDES	1.27	0.223
TESTES	3.42	0.601
THYMUS	0.3655	0.064
ADRENAL GLANDS	0.0630	0.011
L.N. POP, LT	0.0145	0.003
L.N. POP, RT	0.0148	0.003
THYROIDS/PARA.	0.0292	0.005
FINAL BODY WT(G)	569.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 40
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19618 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.03	0.387
LIVER	14.48	2.763
KIDNEYS	3.68	0.702
SPLEEN	0.59	0.113
HEART	1.47	0.281
SEM VES/CG	1.91	0.365
PROSTATE	0.75	0.143
EPIDIDYMIDES	1.39	0.265
TESTES	3.49	0.666
THYMUS	0.2446	0.047
ADRENAL GLANDS	0.0501	0.010
L.N. POP, LT	0.0081	0.002
L.N. POP, RT	0.0194	0.004
THYROIDS/PARA.	0.0178	0.003
FINAL BODY WT(G)	524.	

			GRADE
COLON	MICRO:	EDEMA, SUBMUCOSAL	1
EYES/OPTIC N.	MICRO:	INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	2
HARDERIAN GLANDS	MICRO:	INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
		HEMORRHAGE UNILATERAL	2
KIDNEYS	MICRO:	BASOPHILIC TUBULES MULTIFOCAL, UNILATERAL	1
LUNGS	MICRO:	MINERALIZATION, VASCULAR FOCAL	1
SKELETAL MUSCLE	MICRO:	NECROSIS FOCAL	1
THYROID GLANDS	MICRO:	CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO:	NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
THYMUS	GROSS:	AREA(S), DARK RED FEW, PINPOINT	P
THYMUS	MICRO:	HEMORRHAGE MULTIFOCAL; GROSS OBSERVATION CONFIRMED	1
NASAL LEVEL III	MICRO:	MINERALIZATION, MUCOSAL FOCAL	1
EAR CANAL	MICRO:	INFILTRATE, LYMPHOCYTE	2

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ANIMAL NO. 19618 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

			GRADE		
			UNILATERAL		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
		CECUM	COLON	DUODENUM	EPIDIDYMIDES
		ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
		HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
		LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
		LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
		PHARYNX	PITUITARY	PROSTATE	RECTUM
		SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
		SKIN	SPLEEN	SEMINAL VESICLES	TESTES
		THYROID GLANDS	TRACHEA	URINARY BLADDER	L.N. POP, LT
		L.N. POP, RT	PEYER'S PATCHES		
	MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
		MARROW, STERN	BRAIN	CECUM	DUODENUM
		EPIDIDYMIDES	ESOPHAGUS	HEART	ILEUM
		JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER
		LYMPH NODE, MES	LARYNX	NERVE, SCIATIC	PANCREAS
		PHARYNX	PITUITARY	PROSTATE	RECTUM
		SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
		SKIN	SPLEEN	SEMINAL VESICLES	TESTES
		NASAL LEVEL I	TRACHEA	URINARY BLADDER	L.N. POP, LT
		L.N. POP, RT	PEYER'S PATCHES		
NOT EXAMINED	MICRO:	PARATHYROIDS			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19620 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	2.12	0.432	EYES/OPTIC N.	MICRO: INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	2
LIVER	15.50	3.157	KIDNEYS	MICRO: PROTEINOSIS, TUBULAR FOCAL, UNILATERAL	1
KIDNEYS	4.19	0.853	LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
SPLEEN	0.78	0.159		INFILTRATE, MONONUCLEAR MULTIFOCAL	1
HEART	1.50	0.305	LARYNX	MICRO: DILATATION, GLANDULAR MULTIFOCAL	1
SEM VES/CG	1.80	0.367	PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
PROSTATE	0.87	0.177	SKELETAL MUSCLE	MICRO: NECROSIS FOCAL	1
EPIDIDYMIDES	1.39	0.283	PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
TESTES	3.57	0.727	L.N. POP, LT	MICRO: NOT EXAMINED LYMPH NODE NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYMUS	0.2288	0.047	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE	1
ADRENAL GLANDS	0.0538	0.011			
L.N. POP, LT	0.0060	0.001			
L.N. POP, RT	0.0050	0.001			
THYROIDS/PARA.	0.0186	0.004			
FINAL BODY WT(G)	491.				

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19620 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

UNILATERAL

NO SIGNIFICANT CHANGES OBSERVED

GRADE				
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	NERVE, SCIATIC
	PANCREAS	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	NASAL LEVEL I	THYROID GLANDS	PARATHYROIDS	THYMUS
	TRACHEA	URINARY BLADDER	NASAL LEVEL III	L.N. POP, RT
	PEYER'S PATCHES			

NOT EXAMINED

MICRO:	PHARYNX	L.N. POP, LT

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19624 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.98	0.427
LIVER	14.37	3.097
KIDNEYS	3.80	0.819
SPLEEN	0.78	0.168
HEART	1.54	0.332
SEM VES/CG	2.02	0.435
PROSTATE	0.92	0.198
EPIDIDYMIDES	1.38	0.297
TESTES	3.65	0.787
THYMUS	0.2273	0.049
ADRENAL GLANDS	0.0609	0.013
L.N. POP, LT	0.0070	0.002
L.N. POP, RT	0.0083	0.002
THYROIDS/PARA.	0.0241	0.005
FINAL BODY WT(G)	464.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
LAC. GLAND EXOR	MICRO: DEPLETION, SECRETORY GRANULES DIFFUSE, BILATERAL	2
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
TEETH	GROSS: MALALIGNED UPPER INCISOR, BILATERAL; CEO MALALIGNED	P
TEETH	MICRO: NECROSIS BILATERAL; GROSS OBSERVATION CONFIRMED	P
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	1

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	SEMINAL VESICLES	TESTES
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19624 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	HARDERIAN GLANDS	ILEUM	JEJUNUM
	KIDNEYS	LYMPH NODE, MAND	LIVER	LYMPH NODE, MES
	LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX
	PITUITARY	PROSTATE	RECTUM	SPINAL CORD
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	NASAL LEVEL I	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

NOT EXAMINED

MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19625 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.08	0.431
LIVER	14.31	2.963
KIDNEYS	3.96	0.820
SPLEEN	0.70	0.145
HEART	1.47	0.304
SEM VES/CG	2.45	0.507
PROSTATE	0.72	0.149
EPIDIDYMIDES	1.22	0.253
TESTES	3.13	0.648
THYMUS	0.2067	0.043
ADRENAL GLANDS	0.0667	0.014
L.N. POP, LT	0.0090	0.002
L.N. POP, RT	0.0112	0.002
THYROIDS/PARA.	0.0212	0.004
FINAL BODY WT(G)	483.	

			GRADE
HARDERIAN GLANDS	MICRO:	HEMORRHAGE	1
		UNILATERAL	
KIDNEYS	MICRO:	BASOPHILIC TUBULES	1
		FOCAL, BILATERAL	
		INFILTRATE, LYMPHOCYTE	1
		FOCAL, UNILATERAL	
LIVER	MICRO:	INFILTRATE, MONONUCLEAR	1
		FOCAL	
LUNGS	MICRO:	MINERALIZATION, VASCULAR	1
		MULTIFOCAL	
PHARYNX	MICRO:	NOT EXAMINED	
		PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
PROSTATE	MICRO:	INFILTRATE, LYMPHOCYTE	1
		MULTIFOCAL	
		DECREASED SECRETION	2
NASAL LEVEL III	MICRO:	MINERALIZATION, MUCOSAL	1
		MULTIFOCAL	
		ATROPHY, GLANDULAR	4
		UNILATERAL	
TEETH	MICRO:	NECROSIS	P
		BILATERAL	

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ANIMAL NO. 19625 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
		CECUM	COLON	DUODENUM	EPIDIDYMIDES
		ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
		HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
		LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
		LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
		PHARYNX	PITUITARY	PROSTATE	RECTUM
		SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
		SKIN	SPLEEN	SEMINAL VESICLES	TESTES
		THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
		L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
	MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
		MARROW, STERN	BRAIN	CECUM	COLON
		DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
		HEART	ILEUM	JEJUNUM	LYMPH NODE, MAND
		LAC. GLAND EXOR	LYMPH NODE, MES	LARYNX	NERVE, SCIATIC
		PANCREAS	PITUITARY	RECTUM	SPINAL CORD
		SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
		SKIN	SPLEEN	SEMINAL VESICLES	TESTES
		NASAL LEVEL I	THYROID GLANDS	PARATHYROIDS	THYMUS
		TRACHEA	URINARY BLADDER	L.N. POP, LT	L.N. POP, RT
		PEYER'S PATCHES			
NOT EXAMINED	MICRO:	PHARYNX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 48

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19633 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.	ESOPHAGUS	MICRO: NO SIGNIFICANT CHANGES OBSERVED MUCOSAL SURFACE NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	GRADE
BRAIN	2.11	0.422			
LIVER	17.60	3.520			
KIDNEYS	4.31	0.862	KIDNEYS	MICRO: PROTEINOSIS, TUBULAR MULTIFOCAL, UNILATERAL	1
SPLEEN	0.65	0.130			
HEART	1.50	0.300		FIBROSIS, INTERSTITIAL MULTIFOCAL, UNILATERAL	1
SEM VES/CG	1.77	0.354			
PROSTATE	0.47	0.094	LIVER	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
EPIDIDYMIDES	1.35	0.270			
TESTES	3.98	0.796	LUNGS	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
THYMUS	0.2438	0.049			
ADRENAL GLANDS	0.0762	0.015	PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
L.N. POP, LT	0.0095	0.002			
L.N. POP, RT	0.0108	0.002	NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
THYROIDS/PARA.	0.0180	0.004			
FINAL BODY WT(G)	500.		NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
PHARYNX	PITUITARY	PROSTATE	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19633 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

				GRADE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	HEART	HARDERIAN GLANDS	ILEUM	JEJUNUM
	LYMPH NODE, MAND	LAC. GLAND EXOR	LYMPH NODE, MES	LARYNX
	NERVE, SCIATIC	PANCREAS	PHARYNX	PITUITARY
	PROSTATE	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	SEMINAL VESICLES	TESTES	NASAL LEVEL I
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

NOT EXAMINED
MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19641 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.05	0.443
LIVER	14.42	3.114
KIDNEYS	3.67	0.793
SPLEEN	0.79	0.171
HEART	1.45	0.313
SEM VES/CG	2.19	0.473
PROSTATE	0.73	0.158
EPIDIDYMIDES	1.16	0.251
TESTES	3.24	0.700
THYMUS	0.3173	0.069
ADRENAL GLANDS	0.0629	0.014
L.N. POP, LT	0.0144	0.003
L.N. POP, RT	0.0096	0.002
THYROIDS/PARA.	0.0304	0.007
FINAL BODY WT(G)	463.	

		GRADE
HEART	MICRO: INFILTRATE, MONONUCLEAR	
	FOCAL	1
HARDERIAN GLANDS	MICRO: HEMORRHAGE	
	UNILATERAL	2
KIDNEYS	MICRO: CYST, MEDULLARY	
	FOCAL, UNILATERAL	P
	MINERALIZATION	
	FOCAL, UNILATERAL	1
	PROTEINOSIS, TUBULAR	
	FOCAL, UNILATERAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR	
	MULTIFOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
THYMUS	GROSS: AREA(S), DARK RED	
	MULTIPLE, IRREGULARLY SHAPED	P
THYMUS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	GROSS OBSERVATION NOT CONFIRMED	
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE	
	BILATERAL	2

NO SIGNIFICANT CHANGES OBSERVED GROSS:ADRENAL GLANDS AORTA STERNUM BRAIN

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19641 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES
	THYROID GLANDS	TRACHEA	URINARY BLADDER	L.N. POP, LT
	L.N. POP, RT	PEYER'S PATCHES		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	LARYNX	NERVE, SCIATIC
	PANCREAS	PHARYNX	PITUITARY	PROSTATE
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
	STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN
	SEMINAL VESICLES	TESTES	NASAL LEVEL I	PARATHYROIDS
	THYMUS	TRACHEA	URINARY BLADDER	NASAL LEVEL III
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19643 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.92	0.464
LIVER	13.60	3.285
KIDNEYS	3.59	0.867
SPLEEN	0.72	0.174
HEART	1.37	0.331
SEM VES/CG	2.32	0.560
PROSTATE	0.79	0.191
EPIDIDYMIDES	1.32	0.319
TESTES	3.31	0.800
THYMUS	0.2578	0.062
L.N. POP, LT	0.0148	0.004
L.N. POP, RT	0.0109	0.003
THYROIDS/PARA.	0.0192	0.005
FINAL BODY WT(G)	414.	

GENERAL COMMENT	GRADE
ADRENAL CORTEX	
ADRENAL MEDULLA	
PHARYNX	
THYROID GLANDS	
NASAL LEVEL III	
L.N. POP, LT	
L.N. POP, RT	
EAR CANAL	
NO SIGNIFICANT CHANGES OBSERVED	

				GRADE
GROSS:	ORGAN LOST AT NECROPSY			P
	ADRENAL GLAND, BILATERAL			
MICRO:	NOT EXAMINED			
	ADRENAL GLANDS NOT EXAMINED, LOST AT NECROPSY			
MICRO:	NOT EXAMINED			
	ADRENAL GLANDS NOT EXAMINED, LOST AT NECROPSY			
MICRO:	NOT EXAMINED			
	PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED			
MICRO:	CYST, ULTIMOBRANCHIAL			P
MICRO:	MINERALIZATION, MUCOSAL			1
	FOCAL			
MICRO:	HYPERPLASIA, LYMPHOID			1
MICRO:	HYPERPLASIA, LYMPHOID			1
MICRO:	INFILTRATE, LYMPHOCYTE			1
	UNILATERAL			
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
	PHARYNX	PITUITARY	PROSTATE	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19643 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

				GRADE
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	AORTA	STERNUM	MARROW, STERN	BRAIN
	CECUM	COLON	DUODENUM	EPIDIDYMIDES
	ESOPHAGUS	EYES/OPTIC N.	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	NERVE, SCIATIC	PANCREAS	PITUITARY
	PROSTATE	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	SEMINAL VESICLES	TESTES	NASAL LEVEL I
	PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
	PEYER'S PATCHES			

NOT EXAMINED

MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	PHARYNX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19649 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.92	0.464
LIVER	13.72	3.314
KIDNEYS	3.73	0.901
SPLEEN	0.70	0.169
HEART	1.78	0.430
SEM VES/CG	2.24	0.541
PROSTATE	0.79	0.191
EPIDIDYMIDES	1.38	0.333
TESTES	3.69	0.891
THYMUS	0.1732	0.042
ADRENAL GLANDS	0.0588	0.014
L.N. POP, LT	0.0046	0.001
L.N. POP, RT	0.0092	0.002
THYROIDS/PARA.	0.0254	0.006
FINAL BODY WT(G)	414.	

		GRADE
EYES/OPTIC N.	MICRO: INFLAMMATION, ACUTE FOCAL; CORNEOSCLERAL JUNCTION	1
KIDNEYS	GROSS: AREA(S), DEPRESSED ONE, 2 MM IN DIAMETER, IN CORTEX, LEFT	P
KIDNEYS	MICRO: INFILTRATE, LYMPHOCYTE FOCAL; GROSS OBSERVATION NOT CONFIRMED	1
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
LYMPH NODE, MAND	MICRO: NO SIGNIFICANT CHANGES OBSERVED GROSS OBSERVATION NOT CONFIRMED	
LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
LARYNX	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL MULTIFOCAL	1
NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS UNILATERAL	2
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19649 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
		CECUM	COLON	DUODENUM	EPIDIDYMIDES
		ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
		HARDERIAN GLANDS	ILEUM	JEJUNUM	LAC. GLAND EXOR
		LIVER	LYMPH NODE, MES	LUNGS	LARYNX
		NERVE, SCIATIC	PANCREAS	PHARYNX	PITUITARY
		PROSTATE	RECTUM	SPINAL CORD	SAL. GLAND MAND
		STOMACH	SKELETAL MUSCLE	SKIN	SPLEEN
		SEMINAL VESICLES	TESTES	THYROID GLANDS	THYMUS
		TRACHEA	URINARY BLADDER	L.N. POP, LT	L.N. POP, RT
		PEYER'S PATCHES			
	MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
		MARROW, STERN	BRAIN	CECUM	COLON
		DUODENUM	EPIDIDYMIDES	ESOPHAGUS	HEART
		HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
		LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	NERVE, SCIATIC
		PANCREAS	PHARYNX	PITUITARY	PROSTATE
		RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
		STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN
		SEMINAL VESICLES	TESTES	NASAL LEVEL I	PARATHYROIDS
		THYMUS	TRACHEA	URINARY BLADDER	L.N. POP, LT
		L.N. POP, RT	PEYER'S PATCHES		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19653 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	2.07	0.418	EYES/OPTIC N.	MICRO: INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	2
LIVER	14.86	3.002	HEART	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
KIDNEYS	4.18	0.844	KIDNEYS	MICRO: DROPLET, HYALINE	2
SPLEEN	0.92	0.186		BASOPHILIC TUBULES	1
HEART	1.48	0.299		MULTIFOCAL, BILATERAL	
SEM VES/CG	2.31	0.467		CYST, CORTICAL	P
PROSTATE	0.98	0.198		FOCAL, UNILATERAL	
EPIDIDYMIDES	1.43	0.289	LYMPH NODE, MAND	MICRO: HEMORRHAGE	1
TESTES	3.58	0.723		BILATERAL	
THYMUS	0.2791	0.056	LIVER	MICRO: FIBROSIS	1
ADRENAL GLANDS	0.0608	0.012		FOCAL	
L.N. POP, LT	0.0054	0.001	LUNGS	MICRO: HEMORRHAGE	1
L.N. POP, RT	0.0043	0.001		FOCAL	
THYROIDS/PARA.	0.0250	0.005	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
FINAL BODY WT(G)	495.		PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
			NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
			L.N. POP, RT	MICRO: NOT EXAMINED LYMPH NODE NOT EXAMINED, NOT PRESENT AT TRIMMING	

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19653 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

					GRADE
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL				2
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
	CECUM	COLON	DUODENUM	EPIDIDYMIDES	
	ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART	
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS	
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	
	LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS	
	PHARYNX	PITUITARY	PROSTATE	RECTUM	
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES	
	THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER	
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES		
	MICRO: ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM	
	MARROW, STERN	BRAIN	CECUM	COLON	
	DUODENUM	EPIDIDYMIDES	ESOPHAGUS	HARDERIAN GLANDS	
	ILEUM	JEJUNUM	LAC. GLAND EXOR	LYMPH NODE, MES	
	LARYNX	NERVE, SCIATIC	PANCREAS	PHARYNX	
	PITUITARY	PROSTATE	RECTUM	SPINAL CORD	
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	
	SKIN	SPLEEN	SEMINAL VESICLES	TESTES	
	NASAL LEVEL I	PARATHYROIDS	THYMUS	TRACHEA	
	URINARY BLADDER	L.N. POP, LT	PEYER'S PATCHES		
NOT EXAMINED	MICRO:L.N. POP, RT				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19662 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	2.01	0.461	HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	2
LIVER	11.45	2.626	KIDNEYS	MICRO: PROTEINOSIS, TUBULAR FOCAL, UNILATERAL	1
KIDNEYS	3.69	0.846		BASOPHILIC TUBULES FOCAL, UNILATERAL	1
SPLEEN	0.71	0.163		DROPLET, HYALINE	2
HEART	1.51	0.346	LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
SEM VES/CG	2.15	0.493	PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
PROSTATE	1.25	0.287	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
EPIDIDYMIDES	1.42	0.326	PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
TESTES	3.95	0.906	TEETH	MICRO: NECROSIS BILATERAL	P
THYMUS	0.2025	0.046		INFLAMMATION, CHRONIC UNILATERAL	2
ADRENAL GLANDS	0.0665	0.015	NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS UNILATERAL	1
L.N. POP, LT	0.0100	0.002	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE	1
L.N. POP, RT	0.0133	0.003			
THYROIDS/PARA.	0.0168	0.004			
FINAL BODY WT(G)	436.				

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19662 GROUP 4: 1000 MG/KG/DAY MALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

		GRADE			
		BILATERAL			
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
		CECUM	COLON	DUODENUM	EPIDIDYMIDES
		ESOPHAGUS	EYES/OPTIC N.	NASAL TISSUES	HEART
		HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
		LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
		LUNGS	LARYNX	NERVE, SCIATIC	PANCREAS
		PHARYNX	PITUITARY	PROSTATE	RECTUM
		SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
		SKIN	SPLEEN	SEMINAL VESICLES	TESTES
		THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER
		L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
	MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
		MARROW, STERN	BRAIN	CECUM	COLON
		DUODENUM	EPIDIDYMIDES	ESOPHAGUS	EYES/OPTIC N.
		HEART	ILEUM	JEJUNUM	LYMPH NODE, MAND
		LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LARYNX
		NERVE, SCIATIC	PANCREAS	PITUITARY	PROSTATE
		RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN
		STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN
		SEMINAL VESICLES	TESTES	NASAL LEVEL I	PARATHYROIDS
		THYMUS	TRACHEA	URINARY BLADDER	NASAL LEVEL III
		L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
NOT EXAMINED	MICRO:	PHARYNX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19668 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.90	0.556
LIVER	8.99	2.629
KIDNEYS	2.32	0.678
SPLEEN	0.57	0.167
HEART	0.98	0.287
UTERUS	0.48	0.140
THYMUS	0.3974	0.116
OVARIES/OVIDUCTS	0.1407	0.041
ADRENAL GLANDS	0.0514	0.015
L.N. POP, LT	0.0171	0.005
L.N. POP, RT	0.0097	0.003
THYROIDS/PARA.	0.0258	0.008
FINAL BODY WT(G)	342.	

		GRADE
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
	INFILTRATE, MONONUCLEAR MULTIFOCAL	1
LARYNX	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
MAMMARY GLAND	MICRO: NOT EXAMINED MAMMARY GLAND NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
PITUITARY	MICRO: CYST, PARS DISTALIS	P
SKELETAL MUSCLE	MICRO: NECROSIS FOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
L.N. POP, RT	GROSS: DISCOLORATION, DARK RED	P
L.N. POP, RT	MICRO: HEMORRHAGE GROSS OBSERVATION CONFIRMED	2

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19668 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	PEYER'S PATCHES
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PHARYNX	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKIN	SPLEEN
	NASAL LEVEL I	PARATHYROIDS	THYMUS	TRACHEA
	URINARY BLADDER	UTERUS	VAGINA	CERVIX
	NASAL LEVEL III	L.N. POP, LT	PEYER'S PATCHES	

NOT EXAMINED
MICRO:MAMMARY GLAND

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19670 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.95	0.768
LIVER	7.71	3.035
KIDNEYS	2.02	0.795
SPLEEN	0.48	0.189
HEART	1.09	0.429
UTERUS	0.66	0.260
THYMUS	0.2370	0.093
OVARIES/OVIDUCTS	0.1125	0.044
ADRENAL GLANDS	0.0640	0.025
L.N. POP, LT	0.0119	0.005
L.N. POP, RT	0.0154	0.006
THYROIDS/PARA.	0.0169	0.007
FINAL BODY WT(G)	254.	

			GRADE
HARDERIAN GLANDS	MICRO:	HEMORRHAGE UNILATERAL	1
KIDNEYS	MICRO:	MINERALIZATION FOCAL, UNILATERAL	1
LIVER	MICRO:	INFILTRATE, MONONUCLEAR FOCAL	1
LARYNX	MICRO:	INFILTRATE, MONONUCLEAR FOCAL	1
NASAL LEVEL I	MICRO:	INFLAMMATION FOCAL, UNILATERAL	2
		EROSION, EPITHELIAL FOCAL, UNILATERAL	1
		METAPLASIA, SQUAMOUS FOCAL, UNILATERAL	P
UTERUS	GROSS:	CONTENTS, CLEAR FLUID BOTH HORNS	P
UTERUS	MICRO:	DILATATION GROSS OBSERVATION CONFIRMED	1
NASAL LEVEL III	MICRO:	HYPERPLASIA, LYMPHOID FOCAL; NASOPHARYNGEAL DUCT	2

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS AORTA STERNUM BRAIN
CECUM COLON DUODENUM ESOPHAGUS

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19670 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	VAGINA
	CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PHARYNX
	PITUITARY	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	THYROID GLANDS	PARATHYROIDS	THYMUS
	TRACHEA	URINARY BLADDER	VAGINA	CERVIX
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19675 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.81	0.702
LIVER	8.10	3.140
KIDNEYS	2.06	0.798
SPLEEN	0.57	0.221
HEART	1.03	0.399
UTERUS	0.52	0.202
THYMUS	0.3542	0.137
OVARIES/OVIDUCTS	0.1174	0.046
ADRENAL GLANDS	0.0581	0.023
L.N. POP, LT	0.0033	0.001
L.N. POP, RT	0.0068	0.003
THYROIDS/PARA.	0.0233	0.009
FINAL BODY WT(G)	258.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
KIDNEYS	MICRO: MINERALIZATION MULTIFOCAL, BILATERAL	1
LIVER	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS BILATERAL	1

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

MICRO:

ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19675 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

GRADE

MARROW, STERN	BRAIN	CECUM	COLON
DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
LAC. GLAND EXOR	LYMPH NODE, MES	LUNGS	LARYNX
MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	RECTUM	SPINAL CORD
SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
SKIN	SPLEEN	NASAL LEVEL I	THYMUS
TRACHEA	URINARY BLADDER	UTERUS	VAGINA
CERVIX	NASAL LEVEL III	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

NOT EXAMINED

MICRO:PHARYNX PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19683 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.91	0.723
LIVER	7.37	2.792
KIDNEYS	1.95	0.739
SPLEEN	0.50	0.189
HEART	0.92	0.348
UTERUS	0.45	0.170
THYMUS	0.2884	0.109
OVARIES/OVIDUCTS	0.1248	0.047
ADRENAL GLANDS	0.0606	0.023
L.N. POP, LT	0.0060	0.002
L.N. POP, RT	0.0097	0.004
THYROIDS/PARA.	0.0185	0.007
FINAL BODY WT(G)	264.	

		GRADE
HEART	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
KIDNEYS	MICRO: DILATATION, TUBULAR FOCAL, UNILATERAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
NASAL LEVEL III	MICRO: ATROPHY, GLANDULAR BILATERAL	1
L.N. POP, LT	GROSS: DISCOLORATION, DARK RED	P
L.N. POP, LT	MICRO: HEMORRHAGE GROSS OBSERVATION CONFIRMED	3
NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS UNILATERAL	1

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19683 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

GRADE

	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, RT	PEYER'S PATCHES
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HARDERIAN GLANDS
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	LARYNX	MAMMARY GLAND
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PHARYNX	PITUITARY	RECTUM	SPINAL CORD
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
	SKIN	SPLEEN	NASAL LEVEL I	PARATHYROIDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19687 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.97	0.719
LIVER	8.99	3.281
KIDNEYS	2.08	0.759
SPLEEN	0.52	0.190
HEART	1.03	0.376
UTERUS	0.50	0.182
THYMUS	0.2212	0.081
OVARIES/OVIDUCTS	0.1301	0.047
ADRENAL GLANDS	0.0754	0.028
L.N. POP, LT	0.0094	0.003
L.N. POP, RT	0.0085	0.003
THYROIDS/PARA.	0.0257	0.009
FINAL BODY WT(G)	274.	

		GRADE
ESOPHAGUS	MICRO: INFILTRATE, MONONUCLEAR FOCAL; MUSCULARIS	1
HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	1
KIDNEYS	MICRO: INFILTRATE, LYMPHOCYTE MULTIFOCAL, UNILATERAL	1
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	1
LIVER	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
STOMACH	GROSS: AREA(S), DARK RED ONE, IRREGULARLY SHAPED, GLANDULAR PORTION	P
STOMACH, GLAN	MICRO: NO SIGNIFICANT CHANGES OBSERVED GROSS OBSERVATION NOT CONFIRMED	
PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
URINARY BLADDER	MICRO: INFILTRATE, LYMPHOCYTE FOCAL	1
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1
NO SIGNIFICANT		

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19687 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

CHANGES OBSERVED					GRADE
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
	CECUM	COLON	DUODENUM	ESOPHAGUS	
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS	
	ILEUM	JEJUNUM	KIDNEYS	LAC. GLAND EXOR	
	LIVER	LYMPH NODE, MES	LUNGS	LARYNX	
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES	
	PANCREAS	PHARYNX	PITUITARY	RECTUM	
	SPINAL CORD	SAL. GLAND MAND	SKELETAL MUSCLE	SKIN	
	SPLEEN	THYROID GLANDS	THYMUS	TRACHEA	
	URINARY BLADDER	UTERUS	VAGINA	CERVIX	
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES		
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM	
	MARROW, STERN	BRAIN	CECUM	COLON	
	DUODENUM	EYES/OPTIC N.	HEART	ILEUM	
	JEJUNUM	LAC. GLAND EXOR	LYMPH NODE, MES	LUNGS	
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	
	OVARIES	PANCREAS	PHARYNX	PITUITARY	
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	
	STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN	
	NASAL LEVEL I	THYROID GLANDS	THYMUS	TRACHEA	
	UTERUS	VAGINA	CERVIX	NASAL LEVEL III	
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES		

NOT EXAMINED
MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19692 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.99	0.721
LIVER	7.80	2.826
KIDNEYS	2.06	0.746
SPLEEN	0.45	0.163
HEART	1.01	0.366
UTERUS	0.97	0.351
THYMUS	0.2522	0.091
OVARIES/OVIDUCTS	0.1275	0.046
ADRENAL GLANDS	0.0728	0.026
L.N. POP, LT	0.0160	0.006
L.N. POP, RT	0.0094	0.003
THYROIDS/PARA.	0.0190	0.007
FINAL BODY WT(G)	276.	

		GRADE
HARDERIAN GLANDS	MICRO: INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
KIDNEYS	MICRO: MINERALIZATION FOCAL, UNILATERAL	1
LIVER	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
LUNGS	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
NASAL LEVEL I	MICRO: INFLAMMATION FOCAL, UNILATERAL	1
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
UTERUS	MICRO: DILATATION	2
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
L.N. POP, LT	MICRO: NOT EXAMINED UNABLE TO READ TISSUE DUE TO PROCESSING ARTIFACT; RECUT MADE AND EXAMINED	
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	2
NO SIGNIFICANT		

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19692 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

CHANGES OBSERVED	GRADE			
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	LYMPH NODE, MES	LARYNX	MAMMARY GLAND	NERVE, SCIATIC
	OVIDUCTS	OVARIES	PANCREAS	PHARYNX
	PITUITARY	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	PARATHYROIDS	THYMUS	TRACHEA
	URINARY BLADDER	VAGINA	CERVIX	L.N. POP, RT
	PEYER'S PATCHES			

NOT EXAMINED
MICRO:L.N. POP, LT

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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ANIMAL NO. 19696 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.74	0.604
LIVER	8.99	3.122
KIDNEYS	2.02	0.701
SPLEEN	0.59	0.205
HEART	1.21	0.420
UTERUS	0.75	0.260
THYMUS	0.2337	0.081
OVARIES/OVIDUCTS	0.1525	0.053
ADRENAL GLANDS	0.0790	0.027
L.N. POP, LT	0.0072	0.003
L.N. POP, RT	0.0071	0.002
THYROIDS/PARA.	0.0204	0.007
FINAL BODY WT(G)	288.	

HARDERIAN GLANDS
NASAL LEVEL I
PARATHYROIDS
NASOLACRIMAL DUC
NO SIGNIFICANT CHANGES OBSERVED

	GRADE
MICRO: INFILTRATE, LYMPHOCYTE	
MULTIFOCAL, UNILATERAL	1
MICRO: LUMINAL DEBRIS	
BILATERAL	1
EROSION, EPITHELIAL	
MULTIFOCAL, BILATERAL	2
INFLAMMATION	
MULTIFOCAL, BILATERAL	2
MICRO: NOT EXAMINED	
PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
MICRO: LUMINAL DEBRIS	
UNILATERAL	1

GROSS:ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			
MICRO:ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19696 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
MARROW, STERN	BRAIN	CECUM	COLON	
DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART	
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS	
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	
OVARIES	PANCREAS	PHARYNX	PITUITARY	
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	
STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN	
THYROID GLANDS	THYMUS	TRACHEA	URINARY BLADDER	
UTERUS	VAGINA	CERVIX	NASAL LEVEL III	
L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES		

NOT EXAMINED
MICRO:PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19698 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.94	0.785
LIVER	7.60	3.077
KIDNEYS	1.92	0.777
SPLEEN	0.48	0.194
HEART	1.13	0.457
UTERUS	0.48	0.194
THYMUS	0.2288	0.093
OVARIES/OVIDUCTS	0.1145	0.046
ADRENAL GLANDS	0.0691	0.028
L.N. POP, LT	0.0079	0.003
L.N. POP, RT	0.0034	0.001
THYROIDS/PARA.	0.0181	0.007
FINAL BODY WT(G)	247.	

		GRADE
GENERAL COMMENT	GROSS: ORGAN DAMAGED AT NECROPSY BRAIN	P
EYES/OPTIC N.	MICRO: INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	1
HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	2
KIDNEYS	MICRO: FIBROSIS, INTERSTITIAL FOCAL, UNILATERAL	1
	INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19698 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

				GRADE
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	HEART	ILEUM
	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER
	LYMPH NODE, MES	LUNGS	LARYNX	MAMMARY GLAND
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PITUITARY	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	NASAL LEVEL I	THYMUS	TRACHEA
	URINARY BLADDER	UTERUS	VAGINA	CERVIX
	NASAL LEVEL III	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

NOT EXAMINED

MICRO:	PHARYNX	PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19703 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.90	0.720	HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	4
LIVER	9.06	3.432		INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
KIDNEYS	2.38	0.902			
SPLEEN	0.43	0.163	LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
HEART	1.09	0.413			
UTERUS	0.84	0.318	LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	2
THYMUS	0.2745	0.104			
OVARIES/OVIDUCTS	0.1154	0.044	RECTUM	MICRO: DILATATION, FOLLICULAR FOCAL; HAIRED SKIN PORTION	2
ADRENAL GLANDS	0.0596	0.023			
L.N. POP, LT	0.0079	0.003	THYMUS	GROSS: AREA(S), DARK RED ONE, IRREGULARLY SHAPED	P
L.N. POP, RT	0.0086	0.003			
THYROIDS/PARA.	0.0219	0.008	THYMUS	MICRO: HEMORRHAGE FOCALLY EXTENSIVE; GROSS OBSERVATION CONFIRMED	1
FINAL BODY WT(G)	264.				
			UTERUS	GROSS: CONTENTS, CLEAR FLUID BOTH HORNS	P
			UTERUS	MICRO: NO SIGNIFICANT CHANGES OBSERVED GROSS OBSERVATION NOT CONFIRMED	
			L.N. POP, RT	MICRO: NOT EXAMINED UNABLE TO READ TISSUE DUE TO PROCESSING ARTIFACT; RECUT MADE AND EXAMINED	
			NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS UNILATERAL	1

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ANIMAL NO. 19703 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

					GRADE
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL			2
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
	CECUM	COLON	DUODENUM	ESOPHAGUS	
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS	
	ILEUM	JEJUNUM	KIDNEYS	LAC. GLAND EXOR	
	LIVER	LYMPH NODE, MES	LUNGS	LARYNX	
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES	
	PANCREAS	PHARYNX	PITUITARY	RECTUM	
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE	
	SKIN	SPLEEN	THYROID GLANDS	TRACHEA	
	URINARY BLADDER	VAGINA	CERVIX	L.N. POP, LT	
	L.N. POP, RT	PEYER'S PATCHES			
	MICRO: ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM	
	MARROW, STERN	BRAIN	CECUM	COLON	
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART	
	ILEUM	JEJUNUM	KIDNEYS	LAC. GLAND EXOR	
	LIVER	LYMPH NODE, MES	LUNGS	LARYNX	
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES	
	PANCREAS	PHARYNX	PITUITARY	SPINAL CORD	
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	
	SKIN	SPLEEN	NASAL LEVEL I	THYROID GLANDS	
	PARATHYROIDS	TRACHEA	URINARY BLADDER	UTERUS	
	VAGINA	CERVIX	NASAL LEVEL III	L.N. POP, LT	
	PEYER'S PATCHES				
NOT EXAMINED	MICRO: L.N. POP, RT				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19709 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.91	0.735
LIVER	7.86	3.023
KIDNEYS	1.79	0.688
SPLEEN	0.55	0.212
HEART	0.96	0.369
UTERUS	0.41	0.158
THYMUS	0.3470	0.133
OVARIES/OVIDUCTS	0.1454	0.056
ADRENAL GLANDS	0.0610	0.023
L.N. POP, LT	0.0057	0.002
L.N. POP, RT	0.0096	0.004
THYROIDS/PARA.	0.0192	0.007
FINAL BODY WT(G)	260.	

		GRADE
HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	1
KIDNEYS	MICRO: MINERALIZATION FOCAL, UNILATERAL	1
LIVER	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
LYMPH NODE, MES	GROSS: DISCOLORATION, DARK RED	P
LYMPH NODE, MES	MICRO: HEMORRHAGE GROSS OBSERVATION CONFIRMED	4
LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
LARYNX	MICRO: INFLAMMATION, CHRONIC FOCALLY EXTENSIVE	3
PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
SPLEEN	MICRO: PIGMENT, BROWN	2
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1
NO SIGNIFICANT		

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19709 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

CHANGES OBSERVED	GRADE			
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LUNGS	LARYNX
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
	PANCREAS	PHARYNX	PITUITARY	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
	SKIN	SPLEEN	THYROID GLANDS	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
	PANCREAS	PITUITARY	RECTUM	SPINAL CORD
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
	SKIN	NASAL LEVEL I	THYROID GLANDS	PARATHYROIDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	NASAL LEVEL III	L.N. POP, LT
	L.N. POP, RT	PEYER'S PATCHES		

NOT EXAMINED
MICRO:PHARYNX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19664 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.76	0.622
LIVER	8.52	3.011
KIDNEYS	2.11	0.746
SPLEEN	0.53	0.187
HEART	1.13	0.399
UTERUS	0.56	0.198
THYMUS	0.3905	0.138
OVARIES/OVIDUCTS	0.1457	0.051
ADRENAL GLANDS	0.0503	0.018
L.N. POP, LT	0.0080	0.003
L.N. POP, RT	0.0055	0.002
THYROIDS/PARA.	0.0205	0.007
FINAL BODY WT(G)	283.	

KIDNEYS NO SIGNIFICANT CHANGES OBSERVED

		GRADE
KIDNEYS	GROSS: AREA(S), DEPRESSED ONE, 2 MM IN DIAMETER, IN CORTEX, RIGHT	P
KIDNEYS	MICRO: MINERALIZATION FOCAL; GROSS OBSERVATION NOT CONFIRMED	1

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
LIVER	LYMPH NODE, MES	LUNGS	LARYNX
MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
PANCREAS	PHARYNX	PITUITARY	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	THYROID GLANDS	THYMUS
TRACHEA	URINARY BLADDER	UTERUS	VAGINA
CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19669 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.99	0.626
LIVER	8.91	2.802
KIDNEYS	2.17	0.682
SPLEEN	0.58	0.182
HEART	1.27	0.399
UTERUS	0.50	0.157
THYMUS	0.2507	0.079
OVARIES/OVIDUCTS	0.1623	0.051
ADRENAL GLANDS	0.0788	0.025
L.N. POP, LT	0.0036	0.001
L.N. POP, RT	0.0103	0.003
THYROIDS/PARA.	0.0198	0.006
FINAL BODY WT(G)	318.	

		GRADE
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	1
TEETH	GROSS: FRACTURED UPPER INCISOR, RIGHT; CEO BROKEN	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LAC. GLAND EXOR
LIVER	LYMPH NODE, MES	LUNGS	LARYNX
MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
PANCREAS	PHARYNX	PITUITARY	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	THYROID GLANDS	THYMUS
TRACHEA	URINARY BLADDER	UTERUS	VAGINA
CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19672 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.97	0.727
LIVER	11.36	4.192
KIDNEYS	2.21	0.815
SPLEEN	0.52	0.192
HEART	1.24	0.458
UTERUS	1.21	0.446
THYMUS	0.2190	0.081
OVARIES/OVIDUCTS	0.1122	0.041
ADRENAL GLANDS	0.0863	0.032
L.N. POP, LT	0.0091	0.003
L.N. POP, RT	0.0110	0.004
THYROIDS/PARA.	0.0261	0.010
FINAL BODY WT(G)	271.	

		GRADE
UTERUS	GROSS: CONTENTS, CLEAR FLUID BOTH HORNS	P
UTERUS	MICRO: DILATATION GROSS OBSERVATION CONFIRMED	3
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	VAGINA
CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19674 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.98	0.669
LIVER	9.70	3.277
KIDNEYS	2.32	0.784
SPLEEN	0.56	0.189
HEART	1.12	0.378
UTERUS	0.62	0.209
THYMUS	0.2565	0.087
OVARIES/OVIDUCTS	0.1547	0.052
ADRENAL GLANDS	0.0936	0.032
L.N. POP, LT	0.0103	0.003
L.N. POP, RT	0.0068	0.002
THYROIDS/PARA.	0.0190	0.006
FINAL BODY WT(G)	296.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, STERNUM, BRAIN; CECUM, COLON, DUODENUM, ESOPHAGUS; EYES/OPTIC N., NASAL TISSUES, HEART, HARDERIAN GLANDS; ILEUM, JEJUNUM, KIDNEYS, LYMPH NODE, MAND; LAC. GLAND EXOR, LIVER, LYMPH NODE, MES, LUNGS; LARYNX, MAMMARY GLAND, NERVE, SCIATIC, OVIDUCTS; OVARIES, PANCREAS, PHARYNX, PITUITARY; RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH; SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER, UTERUS; VAGINA, CERVIX, L.N. POP, LT, L.N. POP, RT; PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19676 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.95	0.679
LIVER	8.80	3.066
KIDNEYS	1.88	0.655
SPLEEN	0.50	0.174
HEART	1.01	0.352
UTERUS	0.77	0.268
THYMUS	0.3586	0.125
OVARIES/OVIDUCTS	0.1443	0.050
ADRENAL GLANDS	0.0635	0.022
L.N. POP, LT	0.0067	0.002
L.N. POP, RT	0.0057	0.002
THYROIDS/PARA.	0.0187	0.007
FINAL BODY WT(G)	287.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
UTERUS	GROSS: CONTENTS, CLEAR FLUID BOTH HORNS	P
UTERUS	MICRO: DILATATION GROSS OBSERVATION CONFIRMED	3

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	VAGINA
CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19690 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	1.95	0.777	
LIVER	8.84	3.522	
KIDNEYS	1.92	0.765	
SPLEEN	0.55	0.219	
HEART	1.15	0.458	
UTERUS	0.66	0.263	
THYMUS	0.2613	0.104	
OVARIES/OVIDUCTS	0.1494	0.060	
ADRENAL GLANDS	0.0793	0.032	
L.N. POP, LT	0.0077	0.003	
L.N. POP, RT	0.0067	0.003	
THYROIDS/PARA.	0.0180	0.007	
FINAL BODY WT(G)	251.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19694 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.78	0.631
LIVER	8.13	2.883
KIDNEYS	2.07	0.734
SPLEEN	0.57	0.202
HEART	1.13	0.401
UTERUS	0.59	0.209
THYMUS	0.3535	0.125
OVARIES/OVIDUCTS	0.1475	0.052
ADRENAL GLANDS	0.0608	0.022
L.N. POP, LT	0.0069	0.002
L.N. POP, RT	0.0066	0.002
THYROIDS/PARA.	0.0176	0.006
FINAL BODY WT(G)	282.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19699 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.97	0.711
LIVER	7.69	2.776
KIDNEYS	2.05	0.740
SPLEEN	0.47	0.170
HEART	0.99	0.357
UTERUS	0.53	0.191
THYMUS	0.2010	0.073
OVARIES/OVIDUCTS	0.1216	0.044
ADRENAL GLANDS	0.0589	0.021
L.N. POP, LT	0.0033	0.001
L.N. POP, RT	0.0055	0.002
THYROIDS/PARA.	0.0196	0.007
FINAL BODY WT(G)	277.	

GENERAL COMMENT: NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ORGAN DAMAGED AT NECROPSY P
VAGINA

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19706 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.85	0.685
LIVER	7.75	2.870
KIDNEYS	1.97	0.730
SPLEEN	0.45	0.167
HEART	0.96	0.356
UTERUS	0.59	0.219
THYMUS	0.3225	0.119
OVARIES/OVIDUCTS	0.0950	0.035
ADRENAL GLANDS	0.0516	0.019
L.N. POP, LT	0.0046	0.002
L.N. POP, RT	0.0066	0.002
THYROIDS/PARA.	0.0184	0.007
FINAL BODY WT(G)	270.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19707 GROUP 2: 160 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.07	0.802
LIVER	7.84	3.039
KIDNEYS	2.07	0.802
SPLEEN	0.50	0.194
HEART	0.94	0.364
UTERUS	0.44	0.171
THYMUS	0.2438	0.094
OVARIES/OVIDUCTS	0.1542	0.060
ADRENAL GLANDS	0.0840	0.033
L.N. POP, LT	0.0056	0.002
L.N. POP, RT	0.0079	0.003
THYROIDS/PARA.	0.0203	0.008
FINAL BODY WT(G)	258.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, STERNUM, BRAIN; CECUM, COLON, DUODENUM, ESOPHAGUS; EYES/OPTIC N., NASAL TISSUES, HEART, HARDERIAN GLANDS; ILEUM, JEJUNUM, KIDNEYS, LYMPH NODE, MAND; LAC. GLAND EXOR, LIVER, LYMPH NODE, MES, LUNGS; LARYNX, MAMMARY GLAND, NERVE, SCIATIC, OVIDUCTS; OVARIES, PANCREAS, PHARYNX, PITUITARY; RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH; SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS; THYMUS, TRACHEA, URINARY BLADDER, UTERUS; VAGINA, CERVIX, L.N. POP, LT, L.N. POP, RT; PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19665 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	1.94	0.738	
LIVER	8.55	3.251	
KIDNEYS	2.03	0.772	
SPLEEN	0.54	0.205	
HEART	0.89	0.338	
UTERUS	0.49	0.186	
THYMUS	0.2083	0.079	
OVARIES/OVIDUCTS	0.1432	0.054	
ADRENAL GLANDS	0.0665	0.025	
L.N. POP, LT	0.0108	0.004	
L.N. POP, RT	0.0118	0.004	
THYROIDS/PARA.	0.0169	0.006	
FINAL BODY WT(G)	263.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19666 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.83	0.782
LIVER	7.48	3.197
KIDNEYS	2.10	0.897
SPLEEN	0.43	0.184
HEART	0.89	0.380
UTERUS	0.50	0.214
THYMUS	0.3630	0.155
OVARIES/OVIDUCTS	0.1313	0.056
ADRENAL GLANDS	0.0769	0.033
L.N. POP, LT	0.0082	0.004
L.N. POP, RT	0.0039	0.002
THYROIDS/PARA.	0.0220	0.009
FINAL BODY WT(G)	234.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19667 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.10	0.781
LIVER	8.99	3.342
KIDNEYS	2.08	0.773
SPLEEN	0.57	0.212
HEART	1.15	0.428
UTERUS	0.73	0.271
THYMUS	0.2296	0.085
OVARIES/OVIDUCTS	0.1089	0.040
ADRENAL GLANDS	0.0833	0.031
L.N. POP, LT	0.0083	0.003
L.N. POP, RT	0.0088	0.003
THYROIDS/PARA.	0.0255	0.009
FINAL BODY WT(G)	269.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
CECUM	COLON	DUODENUM	ESOPHAGUS	
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS	
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS	
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	
OVARIES	PANCREAS	PHARYNX	PITUITARY	
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH	
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS	
THYMUS	TRACHEA	URINARY BLADDER	UTERUS	
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT	
PEYER'S PATCHES				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19677 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.98	0.717
LIVER	8.65	3.134
KIDNEYS	1.99	0.721
SPLEEN	0.51	0.185
HEART	1.02	0.370
UTERUS	0.54	0.196
THYMUS	0.2074	0.075
OVARIES/OVIDUCTS	0.1299	0.047
ADRENAL GLANDS	0.0965	0.035
L.N. POP, LT	0.0144	0.005
L.N. POP, RT	0.0069	0.002
THYROIDS/PARA.	0.0225	0.008
FINAL BODY WT(G)	276.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, AORTA, BRAIN, CECUM, COLON, DUODENUM, ESOPHAGUS, EYES/OPTIC N., NASAL TISSUES, HARDERIAN GLANDS, HEART, ILEUM, JEJUNUM, KIDNEYS, LYMPH NODE, MAND, LAC. GLAND EXOR, LIVER, LYMPH NODE, MES, LUNGS, LARYNX, MAMMARY GLAND, NERVE, SCIATIC, OVIDUCTS, OVARIES, PANCREAS, PHARYNX, PITUITARY, RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH, SKELETAL MUSCLE, SKIN, SPLEEN, THYROID GLANDS, THYMUS, TRACHEA, URINARY BLADDER, UTERUS, VAGINA, CERVIX, L.N. POP, LT, L.N. POP, RT, PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19685 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.06	0.811
LIVER	8.41	3.311
KIDNEYS	2.21	0.870
SPLEEN	0.67	0.264
HEART	1.09	0.429
UTERUS	0.46	0.181
THYMUS	0.4557	0.179
OVARIES/OVIDUCTS	0.1630	0.064
ADRENAL GLANDS	0.0868	0.034
L.N. POP, LT	0.0097	0.004
L.N. POP, RT	0.0050	0.002
THYROIDS/PARA.	0.0197	0.008
FINAL BODY WT(G)	254.	

		GRADE
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED	P
	BILATERAL	
LYMPH NODE, MAND	MICRO: HEMORRHAGE	2
	BILATERAL; GROSS OBSERVATION CONFIRMED	
SPLEEN	GROSS: ROUGH SURFACE	P
SPLEEN	MICRO: INFILTRATE, MONONUCLEAR	1
	MULTIFOCAL, SUBCAPSULAR; GROSS OBSERVATION CONFIRMED	
THYMUS	GROSS: AREA(S), DARK RED	P
	FEW, IRREGULARLY SHAPED	
THYMUS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	GROSS OBSERVATION NOT CONFIRMED	
NO SIGNIFICANT CHANGES OBSERVED		

GROSS: ADRENAL GLANDS, AORTA, BRAIN, CECUM, COLON, DUODENUM, ESOPHAGUS, EYES/OPTIC N., NASAL TISSUES, HEART, HARDERIAN GLANDS, ILEUM, JEJUNUM, KIDNEYS, LAC. GLAND EXOR, LIVER, LYMPH NODE, MES, LUNGS, LARYNX, MAMMARY GLAND, NERVE, SCIATIC, OVIDUCTS, OVARIES, PANCREAS, PHARYNX, PITUITARY, RECTUM, SPINAL CORD, SAL. GLAND MAND, STOMACH, SKELETAL MUSCLE, SKIN, THYROID GLANDS, TRACHEA, URINARY BLADDER, UTERUS, VAGINA, CERVIX, L.N. POP, LT, L.N. POP, RT, PEYER'S PATCHES, STERNUM

MICRO: THYMUS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-012

ANIMAL NO. 19686 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.95	0.725
LIVER	8.80	3.271
KIDNEYS	2.06	0.766
SPLEEN	0.49	0.182
HEART	0.91	0.338
UTERUS	0.50	0.186
THYMUS	0.2545	0.095
OVARIES/OVIDUCTS	0.1308	0.049
ADRENAL GLANDS	0.0662	0.025
L.N. POP, LT	0.0074	0.003
L.N. POP, RT	0.0072	0.003
THYROIDS/PARA.	0.0259	0.010
FINAL BODY WT(G)	269.	

		GRADE
THYMUS	GROSS: AREA(S), DARK RED	P
	FEW, PINPOINT TO 1 MM IN DIAMETER	
THYMUS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	GROSS OBSERVATION NOT CONFIRMED	
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES
MICRO:	THYMUS			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19689 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
BRAIN	1.83	0.647	
LIVER	9.31	3.290	
KIDNEYS	2.36	0.834	
SPLEEN	0.63	0.223	
HEART	1.04	0.367	
UTERUS	0.51	0.180	
THYMUS	0.3904	0.138	
OVARIES/OVIDUCTS	0.1670	0.059	
ADRENAL GLANDS	0.0758	0.027	
L.N. POP, LT	0.0053	0.002	
L.N. POP, RT	0.0118	0.004	
THYROIDS/PARA.	0.0216	0.008	
FINAL BODY WT(G)	283.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19693 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	2.03	0.775
LIVER	8.31	3.172
KIDNEYS	2.07	0.790
SPLEEN	0.57	0.218
HEART	1.07	0.408
UTERUS	0.45	0.172
THYMUS	0.3773	0.144
OVARIES/OVIDUCTS	0.1411	0.054
ADRENAL GLANDS	0.0691	0.026
L.N. POP, LT	0.0115	0.004
L.N. POP, RT	0.0134	0.005
THYROIDS/PARA.	0.0173	0.007
FINAL BODY WT(G)	262.	

		GRADE
LYMPH NODE, MAND	GROSS: DISCOLORATION, DARK RED BILATERAL	P
LYMPH NODE, MAND	MICRO: HEMORRHAGE BILATERAL; GROSS OBSERVATION CONFIRMED	1
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LAC. GLAND EXOR
LIVER	LYMPH NODE, MES	LUNGS	LARYNX
MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
PANCREAS	PHARYNX	PITUITARY	RECTUM
SPINAL CORD	SAL. GLAND MAND	STOMACH	SKELETAL MUSCLE
SKIN	SPLEEN	THYROID GLANDS	THYMUS
TRACHEA	URINARY BLADDER	UTERUS	VAGINA
CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19705 GROUP 3: 400 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
BRAIN	2.01	0.705		
LIVER	9.68	3.396		
KIDNEYS	2.41	0.846		
SPLEEN	0.63	0.221		
HEART	1.01	0.354		
UTERUS	0.56	0.196		
THYMUS	0.3590	0.126		
OVARIES/OVIDUCTS	0.1930	0.068		
ADRENAL GLANDS	0.0927	0.033		
L.N. POP, LT	0.0087	0.003		
L.N. POP, RT	0.0048	0.002		
THYROIDS/PARA.	0.0245	0.009		
FINAL BODY WT(G)	285.			

GROSS:				
ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
CECUM	COLON	DUODENUM	ESOPHAGUS	
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS	
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS	
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	
OVARIES	PANCREAS	PHARYNX	PITUITARY	
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH	
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS	
THYMUS	TRACHEA	URINARY BLADDER	UTERUS	
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT	
PEYER'S PATCHES				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19671 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.91	0.806
LIVER	8.10	3.418
KIDNEYS	2.23	0.941
SPLEEN	0.44	0.186
HEART	0.97	0.409
UTERUS	0.62	0.262
THYMUS	0.2270	0.096
OVARIES/OVIDUCTS	0.1590	0.067
ADRENAL GLANDS	0.0696	0.029
L.N. POP, LT	0.0141	0.006
L.N. POP, RT	0.0094	0.004
THYROIDS/PARA.	0.0159	0.007
FINAL BODY WT(G)	237.	

NO SIGNIFICANT CHANGES OBSERVED

			GRADE
ADRENAL MEDULLA	MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE ADRENAL MEDULLA NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
LARYNX	MICRO:	INFILTRATE, MONONUCLEAR FOCAL	1
PITUITARY	MICRO:	CYST, PARS DISTALIS	P
THYROID GLANDS	MICRO:	CYST, ULTIMOBRANCHIAL	P
PEYER'S PATCHES	MICRO:	INFLAMMATION, GRANULOMATOUS FOCAL	1
EAR CANAL	MICRO:	INFILTRATE, LYMPHOCYTE UNILATERAL	2
		CYST, KERATIN UNILATERAL	P

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19671 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	KIDNEYS
	LYMPH NODE, MAND	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES
	LUNGS	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
	SKELETAL MUSCLE	SKIN	SPLEEN	NASAL LEVEL I
	PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
	UTERUS	VAGINA	CERVIX	NASAL LEVEL III
	L.N. POP, LT	L.N. POP, RT		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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ANIMAL NO. 19678 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.88	0.797
LIVER	8.50	3.602
KIDNEYS	2.03	0.860
SPLEEN	0.53	0.225
HEART	1.00	0.424
UTERUS	0.73	0.309
THYMUS	0.2515	0.107
OVARIES/OVIDUCTS	0.1158	0.049
ADRENAL GLANDS	0.0695	0.029
L.N. POP, LT	0.0078	0.003
L.N. POP, RT	0.0039	0.002
THYROIDS/PARA.	0.0158	0.007
FINAL BODY WT(G)	236.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
HARDERIAN GLANDS	MICRO: HEMORRHAGE	
	UNILATERAL	1
KIDNEYS	MICRO: MINERALIZATION	
	FOCAL, UNILATERAL	1
	CYST, MEDULLARY	
	FOCAL, UNILATERAL	P
	PROTEINOSIS, TUBULAR	
	FOCAL, UNILATERAL	1
LYMPH NODE, MAND	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE LYMPH NODE NOT EXAMINED; LOST AT MICROTOMY	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE	
	BILATERAL	2

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
THYMUS	TRACHEA	URINARY BLADDER	UTERUS
VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
PEYER'S PATCHES			

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19678 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

GRADE

MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	LUNGS	LARYNX
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
	PANCREAS	PHARYNX	PITUITARY	RECTUM
	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON
	SKELETAL MUSCLE	SKIN	SPLEEN	NASAL LEVEL I
	PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
	UTERUS	VAGINA	CERVIX	NASAL LEVEL III
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 103
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19679 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.87	0.685	KIDNEYS	MICRO: PROTEINOSIS, TUBULAR MULTIFOCAL, UNILATERAL	1
LIVER	10.26	3.758		INFILTRATE, LYMPHOCYTE FOCAL, UNILATERAL	1
KIDNEYS	2.48	0.908		DILATATION, TUBULAR FOCAL, UNILATERAL	1
SPLEEN	0.50	0.183	LYMPH NODE, MAND	MICRO: HEMORRHAGE UNILATERAL	2
HEART	1.10	0.403	LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
UTERUS	0.55	0.201		METAPLASIA, OSSEOUS FOCAL	1
THYMUS	0.2693	0.099		INFILTRATE, MONONUCLEAR MULTIFOCAL	1
OVARIES/OVIDUCTS	0.1465	0.054	RECTUM	MICRO: CYST, KERATIN FOCAL; HAIRED SKIN PORTION	P
ADRENAL GLANDS	0.0827	0.030	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
L.N. POP, LT	0.0034	0.001	NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
L.N. POP, RT	0.0055	0.002	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	1
THYROIDS/PARA.	0.0207	0.008			
FINAL BODY WT(G)	273.				

NO SIGNIFICANT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19679 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

CHANGES OBSERVED	GRADE			
GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	LAC. GLAND EXOR
	LIVER	LYMPH NODE, MES	LARYNX	MAMMARY GLAND
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PHARYNX	PITUITARY	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	NASAL LEVEL I	PARATHYROIDS	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19680 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.93	0.666
LIVER	9.31	3.210
KIDNEYS	2.32	0.800
SPLEEN	0.51	0.176
HEART	1.16	0.400
UTERUS	0.43	0.148
THYMUS	0.2176	0.075
OVARIES/OVIDUCTS	0.1559	0.054
ADRENAL GLANDS	0.0761	0.026
L.N. POP, LT	0.0098	0.003
L.N. POP, RT	0.0073	0.003
THYROIDS/PARA.	0.0241	0.008
FINAL BODY WT(G)	290.	

		GRADE
HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	2
	INFLAMMATION, SUBACUTE UNILATERAL	2
LIVER	MICRO: INFILTRATE, MONONUCLEAR MULTIFOCAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	1
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY

187054 AD

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19680 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

				GRADE
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LYMPH NODE, MES	LARYNX	MAMMARY GLAND
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PITUITARY	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	NASAL LEVEL I	PARATHYROIDS	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX	NASAL LEVEL III	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			

NOT EXAMINED

MICRO:PHARYNX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19681 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.92	0.698
LIVER	8.82	3.207
KIDNEYS	2.05	0.745
SPLEEN	0.46	0.167
HEART	1.00	0.364
UTERUS	0.88	0.320
THYMUS	0.2069	0.075
OVARIES/OVIDUCTS	0.1459	0.053
ADRENAL GLANDS	0.0953	0.035
L.N. POP, LT	0.0089	0.003
L.N. POP, RT	0.0095	0.003
THYROIDS/PARA.	0.0210	0.008
FINAL BODY WT(G)	275.	

		GRADE
KIDNEYS	MICRO: MINERALIZATION FOCAL, UNILATERAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR MULTIFOCAL	1
PITUITARY	MICRO: CYST, PARS DISTALIS	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
UTERUS	MICRO: DILATATION	1
VAGINA	MICRO: DILATATION, GLANDULAR FOCAL; HAIRED SKIN PORTION	3
	INFLAMMATION, CHRONIC MULTIFOCAL	2
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL MULTIFOCAL	1
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	2
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY
RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH

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Modified: 8/30/2006

ANIMAL NO. 19681 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LARYNX
	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
	PANCREAS	PHARYNX	RECTUM	SPINAL CORD
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
	SKIN	SPLEEN	NASAL LEVEL I	THYROID GLANDS
	PARATHYROIDS	THYMUS	TRACHEA	URINARY BLADDER
	CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Audited Draft

Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19688 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.99	0.787	EYES/OPTIC N.	MICRO: INFLAMMATION, SUBACUTE UNILATERAL; PERIOCULAR	1
LIVER	8.59	3.395	HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	1
KIDNEYS	2.30	0.909	LUNGS	MICRO: INFILTRATE, MONONUCLEAR FOCAL	2
SPLEEN	0.57	0.225	LARYNX	MICRO: DEGENERATION, CARTILAGE FOCAL	1
HEART	1.02	0.403		INFLAMMATION, CHRONIC FOCAL	2
UTERUS	0.67	0.265	MAMMARY GLAND	MICRO: NOT EXAMINED MAMMARY GLAND NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYMUS	0.2097	0.083	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
OVARIES/OVIDUCTS	0.1490	0.059	UTERUS	MICRO: DILATATION	1
ADRENAL GLANDS	0.0754	0.030	NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
L.N. POP, LT	0.0074	0.003	TEETH	GROSS: MALALIGNED UPPER INCISOR, BILATERAL; CEO MALALIGNED	P
L.N. POP, RT	0.0062	0.002	TEETH	MICRO: INFLAMMATION, SUBACUTE UNILATERAL; GROSS OBSERVATION NOT CONFIRMED	3
THYROIDS/PARA.	0.0257	0.010	NASOLACRIMAL DUC	MICRO: LUMINAL DEBRIS UNILATERAL	2
FINAL BODY WT(G)	253.				

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TABLE 28 (SCHEDULED NECROPSY)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO. 19688 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

					GRADE
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL			2
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS	AORTA	STERNUM	BRAIN	
	CECUM	COLON	DUODENUM	ESOPHAGUS	
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS	
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS	
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	
	OVARIES	PANCREAS	PHARYNX	PITUITARY	
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH	
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS	
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS	
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT	
	PEYER'S PATCHES				
	MICRO: ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM	
	MARROW, STERN	BRAIN	CECUM	COLON	
	DUODENUM	ESOPHAGUS	HEART	ILEUM	
	JEJUNUM	KIDNEYS	LYMPH NODE, MAND	LAC. GLAND EXOR	
	LIVER	LYMPH NODE, MES	NERVE, SCIATIC	OVIDUCTS	
	OVARIES	PANCREAS	PHARYNX	PITUITARY	
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH, GLAN	
	STOMACH, NON	SKELETAL MUSCLE	SKIN	SPLEEN	
	NASAL LEVEL I	PARATHYROIDS	THYMUS	TRACHEA	
	URINARY BLADDER	VAGINA	CERVIX	L.N. POP, LT	
	L.N. POP, RT	PEYER'S PATCHES			
NOT EXAMINED	MICRO: MAMMARY GLAND				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187054 AD

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19691 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.93	0.726
LIVER	9.79	3.680
KIDNEYS	2.44	0.917
SPLEEN	0.58	0.218
HEART	1.12	0.421
UTERUS	0.54	0.203
THYMUS	0.3379	0.127
OVARIES/OVIDUCTS	0.1522	0.057
ADRENAL GLANDS	0.0868	0.033
L.N. POP, LT	0.0060	0.002
L.N. POP, RT	0.0051	0.002
THYROIDS/PARA.	0.0244	0.009
FINAL BODY WT(G)	266.	

		GRADE
KIDNEYS	MICRO: MINERALIZATION FOCAL, UNILATERAL	1
	PROTEINOSIS, TUBULAR MULTIFOCAL, UNILATERAL	1
LUNGS	MICRO: INFILTRATE, MONONUCLEAR FOCAL	1
MAMMARY GLAND	MICRO: NOT EXAMINED MAMMARY GLAND NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL MULTIFOCAL	1
EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL	2

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	AORTA	STERNUM	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
OVARIES	PANCREAS	PHARYNX	PITUITARY

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19691 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/05/06 DATE OF DEATH: 06/05/06 STUDY DAY: 91

				GRADE
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	THYMUS	TRACHEA	URINARY BLADDER	UTERUS
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
	PEYER'S PATCHES			
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LARYNX
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PHARYNX	PITUITARY	RECTUM	SPINAL CORD
	SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE
	SKIN	SPLEEN	NASAL LEVEL I	THYMUS
	TRACHEA	URINARY BLADDER	UTERUS	VAGINA
	CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES

NOT EXAMINED

MICRO:	MAMMARY GLAND	PARATHYROIDS

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19695 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.98	0.662	GENERAL COMMENT	GROSS: ORGAN WEIGHT THYROID/PARATHYROID GLAND, RIGHT: 0.0161 G	P
LIVER	10.11	3.381	GENERAL COMMENT	GROSS: ORGAN LOST AT NECROPSY THYROID/PARATHYROID GLAND, LEFT	P
KIDNEYS	2.21	0.739			
SPLEEN	0.57	0.191	HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	3
HEART	1.07	0.358			
UTERUS	0.95	0.318	LAC. GLAND EXOR	MICRO: INFILTRATE, LYMPHOCYTE FOCAL	1
THYMUS	0.3073	0.103			
OVARIES/OVIDUCTS	0.1572	0.053	LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
ADRENAL GLANDS	0.1005	0.034			
L.N. POP, LT	0.0101	0.003		INFILTRATE, MONONUCLEAR MULTIFOCAL	1
L.N. POP, RT	0.0164	0.005			
FINAL BODY WT(G)	299.		PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
			THYROID GLANDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE THYROID GLAND NOT EXAMINED, LOST AT MICROTOMY	
			PARATHYROIDS	MICRO: NOT EXAMINED PARATHYROID GLANDS NOT EXAMINED, NOT IN PLANE OF SECTION	
			UTERUS	GROSS: CONTENTS, CLEAR FLUID BOTH HORNS	P
			UTERUS	MICRO: DILATATION GROSS OBSERVATION CONFIRMED	2

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ANIMAL NO. 19695 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

					GRADE
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE BILATERAL			2
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
		CECUM	COLON	DUODENUM	ESOPHAGUS
		EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
		ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
		LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
		LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
		OVARIES	PANCREAS	PHARYNX	PITUITARY
		RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
		SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
		THYMUS	TRACHEA	URINARY BLADDER	VAGINA
		CERVIX	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES
	MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
		MARROW, STERN	BRAIN	CECUM	COLON
		DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
		ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
		LIVER	LYMPH NODE, MES	LARYNX	MAMMARY GLAND
		NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
		PITUITARY	RECTUM	SPINAL CORD	SAL. GLAND MAND
		STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
		SPLEEN	NASAL LEVEL I	THYROID GLANDS	THYMUS
		TRACHEA	URINARY BLADDER	VAGINA	CERVIX
		NASAL LEVEL III	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES
NOT EXAMINED	MICRO:	PHARYNX	PARATHYROIDS		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 28 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-012

ANIMAL NO. 19700 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.
BRAIN	1.84	0.646
LIVER	8.90	3.123
KIDNEYS	2.18	0.765
SPLEEN	0.62	0.218
HEART	1.04	0.365
UTERUS	1.29	0.453
THYMUS	0.3024	0.106
OVARIES/OVIDUCTS	0.1551	0.054
ADRENAL GLANDS	0.0903	0.032
L.N. POP, LT	0.0087	0.003
L.N. POP, RT	0.0084	0.003
THYROIDS/PARA.	0.0213	0.007
FINAL BODY WT(G)	285.	

		GRADE
KIDNEYS	MICRO: BASOPHILIC TUBULES FOCAL, UNILATERAL	1
LUNGS	MICRO: MINERALIZATION, VASCULAR FOCAL	1
MAMMARY GLAND	MICRO: NOT EXAMINED MAMMARY GLAND NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
NASAL LEVEL I	MICRO: INFLAMMATION MULTIFOCAL, BILATERAL	1
	EROSION, EPITHELIAL FOCAL, UNILATERAL	2
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION	
THYMUS	GROSS: AREA(S), DARK RED MULTIPLE, IRREGULARLY SHAPED	P
THYMUS	MICRO: HEMORRHAGE MULTIFOCAL; GROSS OBSERVATION CONFIRMED	1
UTERUS	GROSS: CONTENTS, CLEAR FLUID	P

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19700 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

			GRADE
		BOTH HORNS	
	UTERUS	MICRO: DILATATION GROSS OBSERVATION CONFIRMED	4
	NASAL LEVEL III	MICRO: MINERALIZATION, MUCOSAL FOCAL	1
	EAR CANAL	MICRO: INFILTRATE, LYMPHOCYTE UNILATERAL	1

NO SIGNIFICANT CHANGES OBSERVED

GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
	CECUM	COLON	DUODENUM	ESOPHAGUS
	EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
	ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
	LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
	OVARIES	PANCREAS	PHARYNX	PITUITARY
	RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
	SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
	TRACHEA	URINARY BLADDER	VAGINA	CERVIX
	L.N. POP, LT	L.N. POP, RT	PEYER'S PATCHES	
MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
	MARROW, STERN	BRAIN	CECUM	COLON
	DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
	HARDERIAN GLANDS	ILEUM	JEJUNUM	LYMPH NODE, MAND
	LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LARYNX
	NERVE, SCIATIC	OVIDUCTS	OVARIES	PANCREAS
	PITUITARY	RECTUM	SPINAL CORD	SAL. GLAND MAND
	STOMACH, GLAN	STOMACH, NON	SKELETAL MUSCLE	SKIN
	SPLEEN	PARATHYROIDS	TRACHEA	URINARY BLADDER
	VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT

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TABLE 28 (SCHEDULED NECROPSY)
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PROJECT NO.:WIL-187054
SPONSOR:[redacted]
SPONSOR NO.:06-012

ANIMAL NO. 19700 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

GRADE

PEYER'S PATCHES

NOT EXAMINED

MICRO:MAMMARY GLAND PHARYNX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 8/30/2006

TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19701 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
BRAIN	1.84	0.705	GENERAL COMMENT	GROSS: ORGAN DAMAGED AT NECROPSY BRAIN	P
LIVER	9.47	3.628	GENERAL COMMENT	GROSS: ORGAN LOST AT NECROPSY ADRENAL GLAND, SIDE DESIGNATION UNKNOWN	P
KIDNEYS	2.17	0.831			
SPLEEN	0.65	0.249	ADRENAL CORTEX	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE ADRENAL GLAND NOT EXAMINED, LOST AT NECROPSY	
HEART	1.01	0.387			
UTERUS	0.58	0.222	ADRENAL MEDULLA	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE ADRENAL GLAND NOT EXAMINED, LOST AT NECROPSY	
THYMUS	0.2079	0.080			
OVARIES/OVIDUCTS	0.1708	0.065	HARDERIAN GLANDS	MICRO: HEMORRHAGE UNILATERAL	1
ADRENAL GLANDS	0.0757	0.029			
L.N. POP, LT	0.0084	0.003		INFILTRATE, LYMPHOCYTE FOCAL, BILATERAL	1
L.N. POP, RT	0.0078	0.003			
THYROIDS/PARA.	0.0186	0.007	KIDNEYS	MICRO: PROTEINOSIS, TUBULAR FOCAL, UNILATERAL	2
FINAL BODY WT(G)	261.			DILATATION, TUBULAR FOCAL, UNILATERAL	2
			PHARYNX	MICRO: NOT EXAMINED PHARYNX NOT EXAMINED, NOT IN PLANE OF SECTION, RECUT MADE AND EXAMINED	
			SKELETAL MUSCLE	MICRO: NECROSIS FOCAL	1
			THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
			PARATHYROIDS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	

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TABLE 28 (SCHEDULED NECROPSY)

ANIMAL NO. 19701 GROUP 4: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 06/06/06 DATE OF DEATH: 06/06/06 STUDY DAY: 92

		GRADE			
ONE PARATHYROID GLAND NOT EXAMINED, NOT IN PLANE OF SECTION					
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	AORTA	STERNUM	BRAIN
		CECUM	COLON	DUODENUM	ESOPHAGUS
		EYES/OPTIC N.	NASAL TISSUES	HEART	HARDERIAN GLANDS
		ILEUM	JEJUNUM	KIDNEYS	LYMPH NODE, MAND
		LAC. GLAND EXOR	LIVER	LYMPH NODE, MES	LUNGS
		LARYNX	MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS
		OVARIES	PANCREAS	PHARYNX	PITUITARY
		RECTUM	SPINAL CORD	SAL. GLAND MAND	STOMACH
		SKELETAL MUSCLE	SKIN	SPLEEN	THYROID GLANDS
		THYMUS	TRACHEA	URINARY BLADDER	UTERUS
		VAGINA	CERVIX	L.N. POP, LT	L.N. POP, RT
		PEYER'S PATCHES			
	MICRO:	ADRENAL CORTEX	ADRENAL MEDULLA	AORTA	STERNUM
		MARROW, STERN	BRAIN	CECUM	COLON
		DUODENUM	ESOPHAGUS	EYES/OPTIC N.	HEART
		ILEUM	JEJUNUM	LYMPH NODE, MAND	LAC. GLAND EXOR
		LIVER	LYMPH NODE, MES	LUNGS	LARYNX
		MAMMARY GLAND	NERVE, SCIATIC	OVIDUCTS	OVARIES
		PANCREAS	PITUITARY	RECTUM	SPINAL CORD
		SAL. GLAND MAND	STOMACH, GLAN	STOMACH, NON	SKIN
		SPLEEN	NASAL LEVEL I	PARATHYROIDS	THYMUS
		TRACHEA	URINARY BLADDER	UTERUS	VAGINA
		CERVIX	NASAL LEVEL III	L.N. POP, LT	L.N. POP, RT
		PEYER'S PATCHES			
NOT EXAMINED	MICRO:	PHARYNX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.54
08/14/2006

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Modified: 8/30/2006

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 29
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19623	505.	1.96	13.93	3.37	0.79	1.58	1.77	0.80
19626	611.	2.23	19.87	4.46	0.87	2.06	3.07	0.76
19630	489.	2.08	15.28	3.88	0.80	1.82	2.64	0.97
19636	527.	2.07	14.66	4.00	0.60	1.61	1.77	0.64
19644	495.	1.99	15.78	3.61	0.61	1.45	1.99	0.98
19652	589.	1.95	17.93	4.04	0.76	1.99	2.14	0.89
19655	622.	2.22	17.83	4.32	0.97	2.03	2.23	1.07
19657	503.	2.22	14.86	3.81	0.73	1.53	1.90	0.91
19660	519.	1.99	14.75	4.04	0.68	1.48	2.10	1.08
MEAN	540.	2.08	16.10	3.95	0.76	1.73	2.18	0.90
S.D.	52.4	0.117	1.983	0.334	0.119	0.248	0.428	0.146
N	9	9	9	9	9	9	9	9

FBW = FINAL BODY WEIGHT

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Modified: 8/30/2006

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 29
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19619	541.	2.15	15.66	3.79	0.63	1.63	1.74	0.89
19628	456.	2.05	13.36	3.40	0.68	1.47	1.78	0.87
19640	519.	2.11	14.33	4.09	0.64	1.65	2.27	0.78
19646	552.	2.06	16.68	3.72	0.77	1.86	1.71	0.43
19647	419.	2.12	11.83	3.51	0.68	1.66	1.97	0.92
19648	618.	2.22	17.96	4.39	0.79	1.97	1.78	0.77
19650	579.	2.25	17.70	3.67	0.74	1.92	2.40	1.14
19654	467.	2.10	15.60	3.73	0.64	1.53	1.83	0.40
19659	597.	2.17	18.46	4.24	1.13	2.09	2.11	0.78
19663	457.	2.13	13.39	3.45	0.56	1.58	1.78	0.57
MEAN	521.	2.14	15.50	3.80	0.73	1.74	1.94	0.76
S.D.	67.9	0.064	2.235	0.337	0.158	0.208	0.243	0.230
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 3

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19621	510.	2.12	16.62	3.62	0.73	1.94	1.82	0.60
19622	634.	2.02	22.88	4.44	0.94	2.14	1.97	0.85
19631	460.	2.08	12.91	3.56	0.61	1.51	1.94	0.70
19632	512.	2.12	17.72	3.80	0.76	1.71	1.70	0.66
19634	515.	2.09	16.28	4.41	0.91	1.60	2.48	1.01
19635	523.	2.08	16.09	3.84	0.68	1.52	1.93	1.06
19645	506.	2.08	17.11	4.28	0.70	1.77	2.10	0.68
19656	514.	2.00	15.78	3.55	0.68	1.65	1.76	0.81
19658	543.	2.09	17.41	4.41	0.83	1.70	2.51	1.10
19661	569.	2.15	17.13	3.90	0.81	1.82	1.88	0.89
MEAN	529.	2.08	16.99	3.98	0.77	1.74	2.01	0.84
S.D.	46.2	0.045	2.472	0.368	0.106	0.194	0.280	0.177
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 29
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19618	524.	2.03	14.48	3.68	0.59	1.47	1.91	0.75
19620	491.	2.12	15.50	4.19	0.78	1.50	1.80	0.87
19624	464.	1.98	14.37	3.80	0.78	1.54	2.02	0.92
19625	483.	2.08	14.31	3.96	0.70	1.47	2.45	0.72
19633	500.	2.11	17.60	4.31	0.65	1.50	1.77	0.47
19641	463.	2.05	14.42	3.67	0.79	1.45	2.19	0.73
19643	414.	1.92	13.60	3.59	0.72	1.37	2.32	0.79
19649	414.	1.92	13.72	3.73	0.70	1.78	2.24	0.79
19653	495.	2.07	14.86	4.18	0.92	1.48	2.31	0.98
19662	436.	2.01	11.45	3.69	0.71	1.51	2.15	1.25
MEAN	468.	2.03	14.43	3.88	0.73	1.51	2.12	0.83
S.D.	37.3	0.072	1.545	0.260	0.090	0.106	0.232	0.203
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 0 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROIDS/PARA.
19623	1.23	3.46	0.2920	0.0541	0.0135	0.0195	0.0240
19626	1.44	3.65	0.3078	0.0766	0.0078	0.0137	0.0274
19630	1.38	3.44	0.2530	0.0595	0.0151	0.0112	0.0297
19636	1.27	3.26	0.3008	0.0587	0.0102	0.0073	0.0228
19644	1.22	3.25	0.2443	0.0583	0.0092	0.0089	0.0257
19652	1.47	3.46	0.2836	0.0702	0.0104	0.0160	0.0224
19655	1.65	4.13	0.2564	0.0890	0.0099	0.0188	0.0228
19657	1.39	3.76	0.2262	0.0608	0.0095	0.0077	0.0262
19660	1.54	3.94	0.2377	0.0654	0.0070	0.0059	0.0181
MEAN	1.40	3.59	0.2669	0.0658	0.0103	0.0121	0.0243
S.D.	0.145	0.302	0.02969	0.01108	0.00256	0.00512	0.00337
N	9	9	9	9	9	9	9

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19619	1.21	3.18	0.3300	0.0570	0.0084	0.0093	0.0205
19628	1.27	3.37	0.2711	0.0533	0.0108	0.0073	0.0220
19640	1.14	3.29	0.2100	0.0578	0.0114	0.0076	0.0242
19646	1.37	3.91	0.2199	0.0581	0.0095	0.0119	0.0308
19647	1.26	3.48	0.2942	0.0564	0.0183	0.0271	0.0247
19648	1.40	3.77	0.2759	0.0721	0.0121	0.0104	0.0315
19650	1.33	4.35	0.2804	0.0650	0.0046	0.0073	0.0261
19654	1.43	3.95	0.2978	0.0609	0.0071	0.0122	0.0277
19659	1.44	3.93	0.3545	0.0777	0.0062	0.0120	0.0268
19663	1.25	3.49	0.2205	0.0527	0.0173	0.0058	0.0195
MEAN	1.31	3.67	0.2754	0.0611	0.0106	0.0111	0.0254
S.D.	0.100	0.368	0.04774	0.00818	0.00448	0.00607	0.00403
N	10	10	10	10	10	10	10

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR: [redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19621	1.41	3.39	0.2527	0.0524	0.0091	0.0123	0.0248
19622	1.34	3.71	0.4242	0.0662	0.0141	0.0183	0.0264
19631	1.42	3.63	0.1748	0.0590	0.0025	0.0069	0.0229
19632	1.34	3.49	0.3717	0.0608	0.0140	0.0159	0.0240
19634	1.34	3.70	0.2729	0.0636	0.0109	0.0051	0.0152
19635	1.27	3.35	0.2442	0.0616	0.0173	0.0260	0.0228
19645	1.48	3.57	0.2798	0.0682	0.0135	0.0157	0.0265
19656	1.42	3.55	0.2789	0.0712	0.0135	0.0150	0.0216
19658	1.21	3.06	0.3524	0.0747	0.0130	0.0124	0.0233
19661	1.27	3.42	0.3655	0.0630	0.0145	0.0148	0.0292
MEAN	1.35	3.49	0.3017	0.0641	0.0122	0.0142	0.0237
S.D.	0.084	0.195	0.07467	0.00637	0.00405	0.00582	0.00373
N	10	10	10	10	10	10	10

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PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 29
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19618	1.39	3.49	0.2446	0.0501	0.0081	0.0194	0.0178
19620	1.39	3.57	0.2288	0.0538	0.0060	0.0050	0.0186
19624	1.38	3.65	0.2273	0.0609	0.0070	0.0083	0.0241
19625	1.22	3.13	0.2067	0.0667	0.0090	0.0112	0.0212
19633	1.35	3.98	0.2438	0.0762	0.0095	0.0108	0.0180
19641	1.16	3.24	0.3173	0.0629	0.0144	0.0096	0.0304
19643	1.32	3.31	0.2578	A	0.0148	0.0109	0.0192
19649	1.38	3.69	0.1732	0.0588	0.0046	0.0092	0.0254
19653	1.43	3.58	0.2791	0.0608	0.0054	0.0043	0.0250
19662	1.42	3.95	0.2025	0.0665	0.0100	0.0133	0.0168
MEAN	1.34	3.56	0.2381	0.0619	0.0089	0.0102	0.0217
S.D.	0.088	0.281	0.04094	0.00763	0.00350	0.00425	0.00441
N	10	10	10	9	10	10	10

A = ORGAN LOST AT NECROPSY

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 9
SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19668	342.	1.90	8.99	2.32	0.57	0.98	0.48
19670	254.	1.95	7.71	2.02	0.48	1.09	0.66
19675	258.	1.81	8.10	2.06	0.57	1.03	0.52
19683	264.	1.91	7.37	1.95	0.50	0.92	0.45
19687	274.	1.97	8.99	2.08	0.52	1.03	0.50
19692	276.	1.99	7.80	2.06	0.45	1.01	0.97
19696	288.	1.74	8.99	2.02	0.59	1.21	0.75
19698	247.	1.94	7.60	1.92	0.48	1.13	0.48
19703	264.	1.90	9.06	2.38	0.43	1.09	0.84
19709	260.	1.91	7.86	1.79	0.55	0.96	0.41
MEAN	273.	1.90	8.25	2.06	0.51	1.05	0.61
S.D.	27.1	0.075	0.680	0.176	0.055	0.086	0.190
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 10
SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19664	283.	1.76	8.52	2.11	0.53	1.13	0.56
19669	318.	1.99	8.91	2.17	0.58	1.27	0.50
19672	271.	1.97	11.36	2.21	0.52	1.24	1.21
19674	296.	1.98	9.70	2.32	0.56	1.12	0.62
19676	287.	1.95	8.80	1.88	0.50	1.01	0.77
19690	251.	1.95	8.84	1.92	0.55	1.15	0.66
19694	282.	1.78	8.13	2.07	0.57	1.13	0.59
19699	277.	1.97	7.69	2.05	0.47	0.99	0.53
19706	270.	1.85	7.75	1.97	0.45	0.96	0.59
19707	258.	2.07	7.84	2.07	0.50	0.94	0.44
MEAN	279.	1.93	8.75	2.08	0.52	1.09	0.65
S.D.	19.1	0.099	1.113	0.134	0.043	0.115	0.217
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 11

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13

SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19665	263.	1.94	8.55	2.03	0.54	0.89	0.49
19666	234.	1.83	7.48	2.10	0.43	0.89	0.50
19667	269.	2.10	8.99	2.08	0.57	1.15	0.73
19677	276.	1.98	8.65	1.99	0.51	1.02	0.54
19685	254.	2.06	8.41	2.21	0.67	1.09	0.46
19686	269.	1.95	8.80	2.06	0.49	0.91	0.50
19689	283.	1.83	9.31	2.36	0.63	1.04	0.51
19693	262.	2.03	8.31	2.07	0.57	1.07	0.45
19705	285.	2.01	9.68	2.41	0.63	1.01	0.56
MEAN	266.	1.97	8.69	2.15	0.56	1.01	0.53
S.D.	15.7	0.094	0.630	0.149	0.076	0.093	0.084
N	9	9	9	9	9	9	9

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 29

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 12
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19671	237.	1.91	8.10	2.23	0.44	0.97	0.62
19678	236.	1.88	8.50	2.03	0.53	1.00	0.73
19679	273.	1.87	10.26	2.48	0.50	1.10	0.55
19680	290.	1.93	9.31	2.32	0.51	1.16	0.43
19681	275.	1.92	8.82	2.05	0.46	1.00	0.88
19688	253.	1.99	8.59	2.30	0.57	1.02	0.67
19691	266.	1.93	9.79	2.44	0.58	1.12	0.54
19695	299.	1.98	10.11	2.21	0.57	1.07	0.95
19700	285.	1.84	8.90	2.18	0.62	1.04	1.29
19701	261.	1.84	9.47	2.17	0.65	1.01	0.58
MEAN	268.	1.91	9.19	2.24	0.54	1.05	0.72
S.D.	21.3	0.052	0.722	0.148	0.067	0.061	0.254
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 29

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 13
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19668	0.3974	0.1407	0.0514	0.0171	0.0097	0.0258
19670	0.2370	0.1125	0.0640	0.0119	0.0154	0.0169
19675	0.3542	0.1174	0.0581	0.0033	0.0068	0.0233
19683	0.2884	0.1248	0.0606	0.0060	0.0097	0.0185
19687	0.2212	0.1301	0.0754	0.0094	0.0085	0.0257
19692	0.2522	0.1275	0.0728	0.0160	0.0094	0.0190
19696	0.2337	0.1525	0.0790	0.0072	0.0071	0.0204
19698	0.2288	0.1145	0.0691	0.0079	0.0034	0.0181
19703	0.2745	0.1154	0.0596	0.0079	0.0086	0.0219
19709	0.3470	0.1454	0.0610	0.0057	0.0096	0.0192
MEAN	0.2834	0.1281	0.0651	0.0092	0.0088	0.0209
S.D.	0.06201	0.01403	0.00869	0.00448	0.00303	0.00317
N	10	10	10	10	10	10

Audited Draft

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 29
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19664	0.3905	0.1457	0.0503	0.0080	0.0055	0.0205
19669	0.2507	0.1623	0.0788	0.0036	0.0103	0.0198
19672	0.2190	0.1122	0.0863	0.0091	0.0110	0.0261
19674	0.2565	0.1547	0.0936	0.0103	0.0068	0.0190
19676	0.3586	0.1443	0.0635	0.0067	0.0057	0.0187
19690	0.2613	0.1494	0.0793	0.0077	0.0067	0.0180
19694	0.3535	0.1475	0.0608	0.0069	0.0066	0.0176
19699	0.2010	0.1216	0.0589	0.0033	0.0055	0.0196
19706	0.3225	0.0950	0.0516	0.0046	0.0066	0.0184
19707	0.2438	0.1542	0.0840	0.0056	0.0079	0.0203
MEAN	0.2857	0.1387	0.0707	0.0066	0.0073	0.0198
S.D.	0.06523	0.02168	0.01547	0.00231	0.00193	0.00241
N	10	10	10	10	10	10

Audited Draft

TABLE 29

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 15
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19665	0.2083	0.1432	0.0665	0.0108	0.0118	0.0169
19666	0.3630	0.1313	0.0769	0.0082	0.0039	0.0220
19667	0.2296	0.1089	0.0833	0.0083	0.0088	0.0255
19677	0.2074	0.1299	0.0965	0.0144	0.0069	0.0225
19685	0.4557	0.1630	0.0868	0.0097	0.0050	0.0197
19686	0.2545	0.1308	0.0662	0.0074	0.0072	0.0259
19689	0.3904	0.1670	0.0758	0.0053	0.0118	0.0216
19693	0.3773	0.1411	0.0691	0.0115	0.0134	0.0173
19705	0.3590	0.1930	0.0927	0.0087	0.0048	0.0245
MEAN	0.3161	0.1454	0.0793	0.0094	0.0082	0.0218
S.D.	0.09186	0.02512	0.01121	0.00263	0.00347	0.00330
N	9	9	9	9	9	9

Audited Draft

TABLE 29

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 16
SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS AND FINAL BODY WEIGHTS [G] — WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19671	0.2270	0.1590	0.0696	0.0141	0.0094	0.0159
19678	0.2515	0.1158	0.0695	0.0078	0.0039	0.0158
19679	0.2693	0.1465	0.0827	0.0034	0.0055	0.0207
19680	0.2176	0.1559	0.0761	0.0098	0.0073	0.0241
19681	0.2069	0.1459	0.0953	0.0089	0.0095	0.0210
19688	0.2097	0.1490	0.0754	0.0074	0.0062	0.0257
19691	0.3379	0.1522	0.0868	0.0060	0.0051	0.0244
19695	0.3073	0.1572	0.1005	0.0101	0.0164	0.0161-A
19700	0.3024	0.1551	0.0903	0.0087	0.0084	0.0213
19701	0.2079	0.1708	0.0757	0.0084	0.0078	0.0186
MEAN	0.2538	0.1507	0.0822	0.0085	0.0080	0.0208
S.D.	0.04810	0.01424	0.01075	0.00278	0.00350	0.00357
N	10	10	10	10	10	9

A = SINGLE ORGAN WEIGHT, NOT INCLUDED IN CALCULATION OF MEAN

POFBWv4.14
07/25/2006
R:08/07/2006

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Modified: 8/30/2006

TABLE 30

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] WEEK 13
SPONSOR NO.:06-012

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19623	505.	0.388	2.758	0.667	0.156	0.313	0.350	0.158
19626	611.	0.365	3.252	0.730	0.142	0.337	0.502	0.124
19630	489.	0.425	3.125	0.793	0.164	0.372	0.540	0.198
19636	527.	0.393	2.782	0.759	0.114	0.306	0.336	0.121
19644	495.	0.402	3.188	0.729	0.123	0.293	0.402	0.198
19652	589.	0.331	3.044	0.686	0.129	0.338	0.363	0.151
19655	622.	0.357	2.867	0.695	0.156	0.326	0.359	0.172
19657	503.	0.441	2.954	0.757	0.145	0.304	0.378	0.181
19660	519.	0.383	2.842	0.778	0.131	0.285	0.405	0.208
MEAN	540.	0.387	2.979	0.733	0.140	0.319	0.404	0.168
S.D.	52.4	0.0338	0.1814	0.0432	0.0169	0.0269	0.0707	0.0319
N	9	9	9	9	9	9	9	9

FBW = FINAL BODY WEIGHT

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Modified: 8/30/2006

TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 2
SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13
SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19619	541.	0.397	2.895	0.701	0.116	0.301	0.322	0.165
19628	456.	0.450	2.930	0.746	0.149	0.322	0.390	0.191
19640	519.	0.407	2.761	0.788	0.123	0.318	0.437	0.150
19646	552.	0.373	3.022	0.674	0.139	0.337	0.310	0.078
19647	419.	0.506	2.823	0.838	0.162	0.396	0.470	0.220
19648	618.	0.359	2.906	0.710	0.128	0.319	0.288	0.125
19650	579.	0.389	3.057	0.634	0.128	0.332	0.415	0.197
19654	467.	0.450	3.340	0.799	0.137	0.328	0.392	0.086
19659	597.	0.363	3.092	0.710	0.189	0.350	0.353	0.131
19663	457.	0.466	2.930	0.755	0.123	0.346	0.389	0.125
MEAN	521.	0.416	2.976	0.736	0.139	0.335	0.377	0.147
S.D.	67.9	0.0494	0.1633	0.0618	0.0221	0.0258	0.0580	0.0469
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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Modified: 8/30/2006

TABLE 30

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19621	510.	0.416	3.259	0.710	0.143	0.380	0.357	0.118
19622	634.	0.319	3.609	0.700	0.148	0.338	0.311	0.134
19631	460.	0.452	2.807	0.774	0.133	0.328	0.422	0.152
19632	512.	0.414	3.461	0.742	0.148	0.334	0.332	0.129
19634	515.	0.406	3.161	0.856	0.177	0.311	0.482	0.196
19635	523.	0.398	3.076	0.734	0.130	0.291	0.369	0.203
19645	506.	0.411	3.381	0.846	0.138	0.350	0.415	0.134
19656	514.	0.389	3.070	0.691	0.132	0.321	0.342	0.158
19658	543.	0.385	3.206	0.812	0.153	0.313	0.462	0.203
19661	569.	0.378	3.011	0.685	0.142	0.320	0.330	0.156
MEAN	529.	0.397	3.204	0.755	0.144	0.329	0.382	0.158
S.D.	46.2	0.0343	0.2346	0.0639	0.0138	0.0243	0.0594	0.0318
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	SEMVES/CG	PROSTATE
19618	524.	0.387	2.763	0.702	0.113	0.281	0.365	0.143
19620	491.	0.432	3.157	0.853	0.159	0.305	0.367	0.177
19624	464.	0.427	3.097	0.819	0.168	0.332	0.435	0.198
19625	483.	0.431	2.963	0.820	0.145	0.304	0.507	0.149
19633	500.	0.422	3.520	0.862	0.130	0.300	0.354	0.094
19641	463.	0.443	3.114	0.793	0.171	0.313	0.473	0.158
19643	414.	0.464	3.285	0.867	0.174	0.331	0.560	0.191
19649	414.	0.464	3.314	0.901	0.169	0.430	0.541	0.191
19653	495.	0.418	3.002	0.844	0.186	0.299	0.467	0.198
19662	436.	0.461	2.626	0.846	0.163	0.346	0.493	0.287
MEAN	468.	0.435	3.084	0.831	0.158	0.324	0.456	0.179
S.D.	37.3	0.0242	0.2633	0.0541	0.0222	0.0419	0.0741	0.0500
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 5

SPONSOR: [redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 0 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19623	0.244	0.685	0.058	0.011	0.003	0.004	0.005
19626	0.236	0.597	0.050	0.013	0.001	0.002	0.004
19630	0.282	0.703	0.052	0.012	0.003	0.002	0.006
19636	0.241	0.619	0.057	0.011	0.002	0.001	0.004
19644	0.246	0.657	0.049	0.012	0.002	0.002	0.005
19652	0.250	0.587	0.048	0.012	0.002	0.003	0.004
19655	0.265	0.664	0.041	0.014	0.002	0.003	0.004
19657	0.276	0.748	0.045	0.012	0.002	0.002	0.005
19660	0.297	0.759	0.046	0.013	0.001	0.001	0.003
MEAN	0.260	0.669	0.050	0.012	0.002	0.002	0.004
S.D.	0.0213	0.0616	0.0055	0.0010	0.0007	0.0010	0.0009
N	9	9	9	9	9	9	9

Audited Draft

PROJECT NO.:WIL-187054
SPONSOR: [redacted]
SPONSOR NO.:06-012

TABLE 30
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

MALE GROUP: 160 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19619	0.224	0.588	0.061	0.011	0.002	0.002	0.004
19628	0.279	0.739	0.059	0.012	0.002	0.002	0.005
19640	0.220	0.634	0.040	0.011	0.002	0.001	0.005
19646	0.248	0.708	0.040	0.011	0.002	0.002	0.006
19647	0.301	0.831	0.070	0.013	0.004	0.006	0.006
19648	0.227	0.610	0.045	0.012	0.002	0.002	0.005
19650	0.230	0.751	0.048	0.011	0.001	0.001	0.005
19654	0.306	0.846	0.064	0.013	0.002	0.003	0.006
19659	0.241	0.658	0.059	0.013	0.001	0.002	0.004
19663	0.274	0.764	0.048	0.012	0.004	0.001	0.004
MEAN	0.255	0.713	0.053	0.012	0.002	0.002	0.005
S.D.	0.0325	0.0894	0.0105	0.0009	0.0010	0.0015	0.0008
N	10	10	10	10	10	10	10

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19621	0.276	0.665	0.050	0.010	0.002	0.002	0.005
19622	0.211	0.585	0.067	0.010	0.002	0.003	0.004
19631	0.309	0.789	0.038	0.013	0.001	0.002	0.005
19632	0.262	0.682	0.073	0.012	0.003	0.003	0.005
19634	0.260	0.718	0.053	0.012	0.002	0.001	0.003
19635	0.243	0.641	0.047	0.012	0.003	0.005	0.004
19645	0.292	0.706	0.055	0.013	0.003	0.003	0.005
19656	0.276	0.691	0.054	0.014	0.003	0.003	0.004
19658	0.223	0.564	0.065	0.014	0.002	0.002	0.004
19661	0.223	0.601	0.064	0.011	0.003	0.003	0.005
MEAN	0.258	0.664	0.057	0.012	0.002	0.003	0.004
S.D.	0.0322	0.0684	0.0106	0.0014	0.0007	0.0011	0.0007
N	10	10	10	10	10	10	10

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 8

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19618	0.265	0.666	0.047	0.010	0.002	0.004	0.003
19620	0.283	0.727	0.047	0.011	0.001	0.001	0.004
19624	0.297	0.787	0.049	0.013	0.002	0.002	0.005
19625	0.253	0.648	0.043	0.014	0.002	0.002	0.004
19633	0.270	0.796	0.049	0.015	0.002	0.002	0.004
19641	0.251	0.700	0.069	0.014	0.003	0.002	0.007
19643	0.319	0.800	0.062	A	0.004	0.003	0.005
19649	0.333	0.891	0.042	0.014	0.001	0.002	0.006
19653	0.289	0.723	0.056	0.012	0.001	0.001	0.005
19662	0.326	0.906	0.046	0.015	0.002	0.003	0.004
MEAN	0.289	0.764	0.051	0.013	0.002	0.002	0.005
S.D.	0.0298	0.0878	0.0087	0.0018	0.0009	0.0009	0.0012
N	10	10	10	9	10	10	10

A = ORGAN LOST AT NECROPSY

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Modified: 8/30/2006

TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] —

SPONSOR NO.:06-012

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19668	342.	0.556	2.629	0.678	0.167	0.287	0.140
19670	254.	0.768	3.035	0.795	0.189	0.429	0.260
19675	258.	0.702	3.140	0.798	0.221	0.399	0.202
19683	264.	0.723	2.792	0.739	0.189	0.348	0.170
19687	274.	0.719	3.281	0.759	0.190	0.376	0.182
19692	276.	0.721	2.826	0.746	0.163	0.366	0.351
19696	288.	0.604	3.122	0.701	0.205	0.420	0.260
19698	247.	0.785	3.077	0.777	0.194	0.457	0.194
19703	264.	0.720	3.432	0.902	0.163	0.413	0.318
19709	260.	0.735	3.023	0.688	0.212	0.369	0.158
MEAN	273.	0.703	3.036	0.758	0.189	0.386	0.224
S.D.	27.1	0.0704	0.2372	0.0659	0.0202	0.0483	0.0707
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

187054 AD

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TABLE 30

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19664	283.	0.622	3.011	0.746	0.187	0.399	0.198
19669	318.	0.626	2.802	0.682	0.182	0.399	0.157
19672	271.	0.727	4.192	0.815	0.192	0.458	0.446
19674	296.	0.669	3.277	0.784	0.189	0.378	0.209
19676	287.	0.679	3.066	0.655	0.174	0.352	0.268
19690	251.	0.777	3.522	0.765	0.219	0.458	0.263
19694	282.	0.631	2.883	0.734	0.202	0.401	0.209
19699	277.	0.711	2.776	0.740	0.170	0.357	0.191
19706	270.	0.685	2.870	0.730	0.167	0.356	0.219
19707	258.	0.802	3.039	0.802	0.194	0.364	0.171
MEAN	279.	0.693	3.144	0.745	0.188	0.392	0.233
S.D.	19.1	0.0620	0.4332	0.0500	0.0157	0.0394	0.0826
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 11

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13

SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19665	263.	0.738	3.251	0.772	0.205	0.338	0.186
19666	234.	0.782	3.197	0.897	0.184	0.380	0.214
19667	269.	0.781	3.342	0.773	0.212	0.428	0.271
19677	276.	0.717	3.134	0.721	0.185	0.370	0.196
19685	254.	0.811	3.311	0.870	0.264	0.429	0.181
19686	269.	0.725	3.271	0.766	0.182	0.338	0.186
19689	283.	0.647	3.290	0.834	0.223	0.367	0.180
19693	262.	0.775	3.172	0.790	0.218	0.408	0.172
19705	285.	0.705	3.396	0.846	0.221	0.354	0.196
MEAN	266.	0.742	3.263	0.808	0.210	0.379	0.198
S.D.	15.7	0.0504	0.0840	0.0571	0.0259	0.0353	0.0299
N	9	9	9	9	9	9	9

FBW = FINAL BODY WEIGHT

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 12
SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19671	237.	0.806	3.418	0.941	0.186	0.409	0.262
19678	236.	0.797	3.602	0.860	0.225	0.424	0.309
19679	273.	0.685	3.758	0.908	0.183	0.403	0.201
19680	290.	0.666	3.210	0.800	0.176	0.400	0.148
19681	275.	0.698	3.207	0.745	0.167	0.364	0.320
19688	253.	0.787	3.395	0.909	0.225	0.403	0.265
19691	266.	0.726	3.680	0.917	0.218	0.421	0.203
19695	299.	0.662	3.381	0.739	0.191	0.358	0.318
19700	285.	0.646	3.123	0.765	0.218	0.365	0.453
19701	261.	0.705	3.628	0.831	0.249	0.387	0.222
MEAN	268.	0.718	3.440	0.842	0.204	0.393	0.270
S.D.	21.3	0.0592	0.2196	0.0763	0.0266	0.0239	0.0859
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 30

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 13
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19668	0.116	0.041	0.015	0.005	0.003	0.008
19670	0.093	0.044	0.025	0.005	0.006	0.007
19675	0.137	0.046	0.023	0.001	0.003	0.009
19683	0.109	0.047	0.023	0.002	0.004	0.007
19687	0.081	0.047	0.028	0.003	0.003	0.009
19692	0.091	0.046	0.026	0.006	0.003	0.007
19696	0.081	0.053	0.027	0.003	0.002	0.007
19698	0.093	0.046	0.028	0.003	0.001	0.007
19703	0.104	0.044	0.023	0.003	0.003	0.008
19709	0.133	0.056	0.023	0.002	0.004	0.007
MEAN	0.104	0.047	0.024	0.003	0.003	0.008
S.D.	0.0199	0.0044	0.0038	0.0016	0.0013	0.0008
N	10	10	10	10	10	10

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 14

SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13

SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19664	0.138	0.051	0.018	0.003	0.002	0.007
19669	0.079	0.051	0.025	0.001	0.003	0.006
19672	0.081	0.041	0.032	0.003	0.004	0.010
19674	0.087	0.052	0.032	0.003	0.002	0.006
19676	0.125	0.050	0.022	0.002	0.002	0.007
19690	0.104	0.060	0.032	0.003	0.003	0.007
19694	0.125	0.052	0.022	0.002	0.002	0.006
19699	0.073	0.044	0.021	0.001	0.002	0.007
19706	0.119	0.035	0.019	0.002	0.002	0.007
19707	0.094	0.060	0.033	0.002	0.003	0.008
MEAN	0.103	0.050	0.026	0.002	0.003	0.007
S.D.	0.0230	0.0078	0.0060	0.0008	0.0007	0.0012
N	10	10	10	10	10	10

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 15
SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19665	0.079	0.054	0.025	0.004	0.004	0.006
19666	0.155	0.056	0.033	0.004	0.002	0.009
19667	0.085	0.040	0.031	0.003	0.003	0.009
19677	0.075	0.047	0.035	0.005	0.003	0.008
19685	0.179	0.064	0.034	0.004	0.002	0.008
19686	0.095	0.049	0.025	0.003	0.003	0.010
19689	0.138	0.059	0.027	0.002	0.004	0.008
19693	0.144	0.054	0.026	0.004	0.005	0.007
19705	0.126	0.068	0.033	0.003	0.002	0.009
MEAN	0.120	0.055	0.030	0.004	0.003	0.008
S.D.	0.0374	0.0086	0.0041	0.0009	0.0011	0.0012
N	9	9	9	9	9	9

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TABLE 30

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 16
SPONSOR:[redacted] — INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G] — WEEK 13
SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19671	0.096	0.067	0.029	0.006	0.004	0.007
19678	0.107	0.049	0.029	0.003	0.002	0.007
19679	0.099	0.054	0.030	0.001	0.002	0.008
19680	0.075	0.054	0.026	0.003	0.003	0.008
19681	0.075	0.053	0.035	0.003	0.003	0.008
19688	0.083	0.059	0.030	0.003	0.002	0.010
19691	0.127	0.057	0.033	0.002	0.002	0.009
19695	0.103	0.053	0.034	0.003	0.005	0.005-A
19700	0.106	0.054	0.032	0.003	0.003	0.007
19701	0.080	0.065	0.029	0.003	0.003	0.007
MEAN	0.095	0.057	0.031	0.003	0.003	0.008
S.D.	0.0168	0.0057	0.0028	0.0012	0.0010	0.0011
N	10	10	10	10	10	9

A = SINGLE ORGAN WEIGHT, NOT INCLUDED IN CALCULATION OF MEAN

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TABLE 31

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

SPONSOR NO.:06-012

MALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	SEMINAL VESICLES/CG	PROSTATE
19623	505.	1.96	710.714	171.939	40.306	80.612	90.306	40.816
19626	611.	2.23	891.031	200.000	39.013	92.377	137.668	34.081
19630	489.	2.08	734.615	186.538	38.462	87.500	126.923	46.635
19636	527.	2.07	708.213	193.237	28.986	77.778	85.507	30.918
19644	495.	1.99	792.965	181.407	30.653	72.864	100.000	49.246
19652	589.	1.95	919.487	207.179	38.974	102.051	109.744	45.641
19655	622.	2.22	803.153	194.595	43.694	91.441	100.450	48.198
19657	503.	2.22	669.369	171.622	32.883	68.919	85.586	40.991
19660	519.	1.99	741.206	203.015	34.171	74.372	105.528	54.271
MEAN	540.	2.08	774.528	189.948	36.349	83.102	104.635	43.422
S.D.	52.4	0.117	85.1301	12.9704	4.8923	10.9013	17.9857	7.4664
N	9	9	9	9	9	9	9	9

FBW = FINAL BODY WEIGHT

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MALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	SEMINAL VESICLES/CG	PROSTATE
19619	541.	2.15	728.372	176.279	29.302	75.814	80.930	41.395
19628	456.	2.05	651.707	165.854	33.171	71.707	86.829	42.439
19640	519.	2.11	679.147	193.839	30.332	78.199	107.583	36.967
19646	552.	2.06	809.709	180.583	37.379	90.291	83.010	20.874
19647	419.	2.12	558.019	165.566	32.075	78.302	92.925	43.396
19648	618.	2.22	809.009	197.748	35.586	88.739	80.180	34.685
19650	579.	2.25	786.667	163.111	32.889	85.333	106.667	50.667
19654	467.	2.10	742.857	177.619	30.476	72.857	87.143	19.048
19659	597.	2.17	850.691	195.392	52.074	96.313	97.235	35.945
19663	457.	2.13	628.639	161.972	26.291	74.178	83.568	26.761
MEAN	521.	2.14	724.482	177.796	33.958	81.173	90.607	35.218
S.D.	67.9	0.064	93.5736	13.8781	7.0992	8.4354	10.1725	10.2114
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 31

MALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	SEMINAL VESICLES/CG	PROSTATE
19621	510.	2.12	783.962	170.755	34.434	91.509	85.849	28.302
19622	634.	2.02	1132.673	219.802	46.535	105.941	97.525	42.079
19631	460.	2.08	620.673	171.154	29.327	72.596	93.269	33.654
19632	512.	2.12	835.849	179.245	35.849	80.660	80.189	31.132
19634	515.	2.09	778.947	211.005	43.541	76.555	118.660	48.325
19635	523.	2.08	773.558	184.615	32.692	73.077	92.788	50.962
19645	506.	2.08	822.596	205.769	33.654	85.096	100.962	32.692
19656	514.	2.00	789.000	177.500	34.000	82.500	88.000	40.500
19658	543.	2.09	833.014	211.005	39.713	81.340	120.096	52.632
19661	569.	2.15	796.744	181.395	37.674	84.651	87.442	41.395
MEAN	529.	2.08	816.702	191.225	36.742	83.393	96.478	40.167
S.D.	46.2	0.045	126.6916	18.5734	5.2322	9.7809	13.4445	8.5922
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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TABLE 31

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 4

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	SEMINAL VESICLES/CG	PROSTATE
19618	524.	2.03	713.301	181.281	29.064	72.414	94.089	36.946
19620	491.	2.12	731.132	197.642	36.792	70.755	84.906	41.038
19624	464.	1.98	725.758	191.919	39.394	77.778	102.020	46.465
19625	483.	2.08	687.981	190.385	33.654	70.673	117.788	34.615
19633	500.	2.11	834.123	204.265	30.806	71.090	83.886	22.275
19641	463.	2.05	703.415	179.024	38.537	70.732	106.829	35.610
19643	414.	1.92	708.333	186.979	37.500	71.354	120.833	41.146
19649	414.	1.92	714.583	194.271	36.458	92.708	116.667	41.146
19653	495.	2.07	717.874	201.932	44.444	71.498	111.594	47.343
19662	436.	2.01	569.652	183.582	35.323	75.124	106.965	62.189
MEAN	468.	2.03	710.615	191.128	36.197	74.413	104.558	40.877
S.D.	37.3	0.072	63.6134	8.5662	4.3843	6.8341	13.2353	10.3056
N	10	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

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MALE GROUP: 0 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19623	62.755	176.531	14.898	2.760	0.689	0.995	1.224
19626	64.574	163.677	13.803	3.435	0.350	0.614	1.229
19630	66.346	165.385	12.163	2.861	0.726	0.538	1.428
19636	61.353	157.488	14.531	2.836	0.493	0.353	1.101
19644	61.307	163.317	12.276	2.930	0.462	0.447	1.291
19652	75.385	177.436	14.544	3.600	0.533	0.821	1.149
19655	74.324	186.036	11.550	4.009	0.446	0.847	1.027
19657	62.613	169.369	10.189	2.739	0.428	0.347	1.180
19660	77.387	197.990	11.945	3.286	0.352	0.296	0.910
MEAN	67.338	173.025	12.878	3.162	0.498	0.584	1.171
S.D.	6.5066	12.8406	1.6272	0.4459	0.1332	0.2521	0.1504
N	9	9	9	9	9	9	9

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TABLE 31

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 6

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 160 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19619	56.279	147.907	15.349	2.651	0.391	0.433	0.953
19628	61.951	164.390	13.224	2.600	0.527	0.356	1.073
19640	54.028	155.924	9.953	2.739	0.540	0.360	1.147
19646	66.505	189.806	10.675	2.820	0.461	0.578	1.495
19647	59.434	164.151	13.877	2.660	0.863	1.278	1.165
19648	63.063	169.820	12.428	3.248	0.545	0.468	1.419
19650	59.111	193.333	12.462	2.889	0.204	0.324	1.160
19654	68.095	188.095	14.181	2.900	0.338	0.581	1.319
19659	66.359	181.106	16.336	3.581	0.286	0.553	1.235
19663	58.685	163.850	10.352	2.474	0.812	0.272	0.915
MEAN	61.351	171.838	12.884	2.856	0.497	0.520	1.188
S.D.	4.6615	15.4325	2.1355	0.3315	0.2125	0.2878	0.1865
N	10	10	10	10	10	10	10

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TABLE 31

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 7

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 13

SPONSOR NO.:06-012

MALE GROUP: 400 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19621	66.509	159.906	11.920	2.472	0.429	0.580	1.170
19622	66.337	183.663	21.000	3.277	0.698	0.906	1.307
19631	68.269	174.519	8.404	2.837	0.120	0.332	1.101
19632	63.208	164.623	17.533	2.868	0.660	0.750	1.132
19634	64.115	177.034	13.057	3.043	0.522	0.244	0.727
19635	61.058	161.058	11.740	2.962	0.832	1.250	1.096
19645	71.154	171.635	13.452	3.279	0.649	0.755	1.274
19656	71.000	177.500	13.945	3.560	0.675	0.750	1.080
19658	57.895	146.412	16.861	3.574	0.622	0.593	1.115
19661	59.070	159.070	17.000	2.930	0.674	0.688	1.358
MEAN	64.861	167.542	14.491	3.080	0.588	0.685	1.136
S.D.	4.6381	11.2630	3.6239	0.3439	0.1959	0.2828	0.1740
N	10	10	10	10	10	10	10

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TABLE 31

MALE GROUP: 1000 MG/KG/DAY

ANIMAL	EPIDIDYMIDES	TESTES	THYMUS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19618	68.473	171.921	12.049	2.468	0.399	0.956	0.877
19620	65.566	168.396	10.792	2.538	0.283	0.236	0.877
19624	69.697	184.343	11.480	3.076	0.354	0.419	1.217
19625	58.654	150.481	9.938	3.207	0.433	0.538	1.019
19633	63.981	188.626	11.555	3.611	0.450	0.512	0.853
19641	56.585	158.049	15.478	3.068	0.702	0.468	1.483
19643	68.750	172.396	13.427	A	0.771	0.568	1.000
19649	71.875	192.188	9.021	3.063	0.240	0.479	1.323
19653	69.082	172.947	13.483	2.937	0.261	0.208	1.208
19662	70.647	196.517	10.075	3.308	0.498	0.662	0.836
MEAN	66.331	175.586	11.730	3.031	0.439	0.505	1.069
S.D.	5.1503	14.8344	1.9540	0.3566	0.1787	0.2117	0.2258
N	10	10	10	9	10	10	10

A = ORGAN LOST AT NECROPSY

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Modified: 8/30/2006

TABLE 31

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19668	342.	1.90	473.158	122.105	30.000	51.579	25.263
19670	254.	1.95	395.385	103.590	24.615	55.897	33.846
19675	258.	1.81	447.514	113.812	31.492	56.906	28.729
19683	264.	1.91	385.864	102.094	26.178	48.168	23.560
19687	274.	1.97	456.345	105.584	26.396	52.284	25.381
19692	276.	1.99	391.960	103.518	22.613	50.754	48.744
19696	288.	1.74	516.667	116.092	33.908	69.540	43.103
19698	247.	1.94	391.753	98.969	24.742	58.247	24.742
19703	264.	1.90	476.842	125.263	22.632	57.368	44.211
19709	260.	1.91	411.518	93.717	28.796	50.262	21.466
MEAN	273.	1.90	434.701	108.474	27.137	55.101	31.905
S.D.	27.1	0.075	45.6380	10.3268	3.8019	6.1295	9.9490
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 31

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 10

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 13

SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19664	283.	1.76	484.091	119.886	30.114	64.205	31.818
19669	318.	1.99	447.739	109.045	29.146	63.819	25.126
19672	271.	1.97	576.650	112.183	26.396	62.944	61.421
19674	296.	1.98	489.899	117.172	28.283	56.566	31.313
19676	287.	1.95	451.282	96.410	25.641	51.795	39.487
19690	251.	1.95	453.333	98.462	28.205	58.974	33.846
19694	282.	1.78	456.742	116.292	32.022	63.483	33.146
19699	277.	1.97	390.355	104.061	23.858	50.254	26.904
19706	270.	1.85	418.919	106.486	24.324	51.892	31.892
19707	258.	2.07	378.744	100.000	24.155	45.411	21.256
MEAN	279.	1.93	454.775	108.000	27.214	56.934	33.621
S.D.	19.1	0.099	56.0065	8.2990	2.7789	6.7726	11.0014
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 31

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19665	263.	1.94	440.722	104.639	27.835	45.876	25.258
19666	234.	1.83	408.743	114.754	23.497	48.634	27.322
19667	269.	2.10	428.095	99.048	27.143	54.762	34.762
19677	276.	1.98	436.869	100.505	25.758	51.515	27.273
19685	254.	2.06	408.252	107.282	32.524	52.913	22.330
19686	269.	1.95	451.282	105.641	25.128	46.667	25.641
19689	283.	1.83	508.743	128.962	34.426	56.831	27.869
19693	262.	2.03	409.360	101.970	28.079	52.709	22.167
19705	285.	2.01	481.592	119.901	31.343	50.249	27.861
MEAN	266.	1.97	441.518	109.189	28.415	51.128	26.720
S.D.	15.7	0.094	34.7092	10.0249	3.6350	3.6408	3.7294
N	9	9	9	9	9	9	9

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 31

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 12

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 13

SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	FBW(G)	BRAIN WT (GRAMS)	LIVER	KIDNEYS	SPLEEN	HEART	UTERUS
19671	237.	1.91	424.084	116.754	23.037	50.785	32.461
19678	236.	1.88	452.128	107.979	28.191	53.191	38.830
19679	273.	1.87	548.663	132.620	26.738	58.824	29.412
19680	290.	1.93	482.383	120.207	26.425	60.104	22.280
19681	275.	1.92	459.375	106.771	23.958	52.083	45.833
19688	253.	1.99	431.658	115.578	28.643	51.256	33.668
19691	266.	1.93	507.254	126.425	30.052	58.031	27.979
19695	299.	1.98	510.606	111.616	28.788	54.040	47.980
19700	285.	1.84	483.696	118.478	33.696	56.522	70.109
19701	261.	1.84	514.674	117.935	35.326	54.891	31.522
MEAN	268.	1.91	481.452	117.436	28.485	54.973	38.007
S.D.	21.3	0.052	39.8057	7.8975	3.8598	3.2773	13.7652
N	10	10	10	10	10	10	10

FBW = FINAL BODY WEIGHT

Audited Draft

Modified: 8/30/2006

TABLE 31

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19668	20.916	7.405	2.705	0.900	0.511	1.358
19670	12.154	5.769	3.282	0.610	0.790	0.867
19675	19.569	6.486	3.210	0.182	0.376	1.287
19683	15.099	6.534	3.173	0.314	0.508	0.969
19687	11.228	6.604	3.827	0.477	0.431	1.305
19692	12.673	6.407	3.658	0.804	0.472	0.955
19696	13.431	8.764	4.540	0.414	0.408	1.172
19698	11.794	5.902	3.562	0.407	0.175	0.933
19703	14.447	6.074	3.137	0.416	0.453	1.153
19709	18.168	7.613	3.194	0.298	0.503	1.005
MEAN	14.948	6.756	3.429	0.482	0.463	1.100
S.D.	3.4429	0.9204	0.5014	0.2264	0.1519	0.1767
N	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 31

SPONSOR: [redacted]
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

SPONSOR NO.:06-012

FEMALE GROUP: 160 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19664	22.188	8.278	2.858	0.455	0.313	1.165
19669	12.598	8.156	3.960	0.181	0.518	0.995
19672	11.117	5.695	4.381	0.462	0.558	1.325
19674	12.955	7.813	4.727	0.520	0.343	0.960
19676	18.390	7.400	3.256	0.344	0.292	0.959
19690	13.400	7.662	4.067	0.395	0.344	0.923
19694	19.860	8.287	3.416	0.388	0.371	0.989
19699	10.203	6.173	2.990	0.168	0.279	0.995
19706	17.432	5.135	2.789	0.249	0.357	0.995
19707	11.778	7.449	4.058	0.271	0.382	0.981
MEAN	14.992	7.205	3.650	0.343	0.376	1.029
S.D.	4.1322	1.1320	0.6786	0.1219	0.0920	0.1222
N	10	10	10	10	10	10

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Modified: 8/30/2006

TABLE 31

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 15

SPONSOR:[redacted] — INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G] — WEEK 13

SPONSOR NO.:06-012

FEMALE GROUP: 400 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19665	10.737	7.381	3.428	0.557	0.608	0.871
19666	19.836	7.175	4.202	0.448	0.213	1.202
19667	10.933	5.186	3.967	0.395	0.419	1.214
19677	10.475	6.561	4.874	0.727	0.348	1.136
19685	22.121	7.913	4.214	0.471	0.243	0.956
19686	13.051	6.708	3.395	0.379	0.369	1.328
19689	21.333	9.126	4.142	0.290	0.645	1.180
19693	18.586	6.951	3.404	0.567	0.660	0.852
19705	17.861	9.602	4.612	0.433	0.239	1.219
MEAN	16.104	7.400	4.026	0.474	0.416	1.106
S.D.	4.7863	1.3430	0.5348	0.1280	0.1796	0.1701
N	9	9	9	9	9	9

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Modified: 8/30/2006

TABLE 31

SPONSOR: [redacted]
A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
INDIVIDUAL ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

SPONSOR NO.:06-012

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	L.N. P OP, LT	L.N. P OP, RT	THYROID S/PARA.
19671	11.885	8.325	3.644	0.738	0.492	0.832
19678	13.378	6.160	3.697	0.415	0.207	0.840
19679	14.401	7.834	4.422	0.182	0.294	1.107
19680	11.275	8.078	3.943	0.508	0.378	1.249
19681	10.776	7.599	4.964	0.464	0.495	1.094
19688	10.538	7.487	3.789	0.372	0.312	1.291
19691	17.508	7.886	4.497	0.311	0.264	1.264
19695	15.520	7.939	5.076	0.510	0.828	0.813-A
19700	16.435	8.429	4.908	0.473	0.457	1.158
19701	11.299	9.283	4.114	0.457	0.424	1.011
MEAN	13.302	7.902	4.305	0.443	0.415	1.094
S.D.	2.5340	0.7958	0.5460	0.1448	0.1756	0.1718
N	10	10	10	10	10	9

A = SINGLE ORGAN WEIGHT, NOT INCLUDED IN CALCULATION OF MEAN

POFBWv4.14
07/25/2006
R:08/07/2006

AUDITED DRAFT

Volume 2 of 2
(Appendices A-J)

STUDY TITLE

A 90-DAY REPEATED DOSE
ORAL (GAVAGE) TOXICITY STUDY OF [redacted] IN RATS

STUDY NUMBER

WIL-187054

DATA REQUIREMENT

OECD Guideline 408

STUDY DIRECTOR

[redacted]

STUDY INITIATION DATE

20 February 2006

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

06-012

SPONSOR

[redacted]

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APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

Audited Draft

[redacted]

Test Substance Certificate

Audited Draft

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown viscous liquid

Storage Conditions
Ambient

Expiration Date
1 August 2006

Additional Comments
None

[redacted]

25 July 2005
Date

[redacted]

Audited Draft

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown viscous liquid

Storage Conditions
Ambient

Expiration Date
1 August 2006

Additional Comments
None

[redacted]

5 May 2006
Date

APPENDIX B

Analyses Of Dosing Formulations (Sponsor-Provided Data)

Audited Draft

APPENDIX C

Pretest Clinical Observations

Audited Draft

Audited Draft

Modified: 8/30/2006

PRETEST CLINICAL OBSERVATIONS

PROJECT NO.:WIL-187054P A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-012

----- M A L E -----

TABLE RANGE:	02-24-06 TO 03-05-06
GROUP:	1
NORMAL	
-NO SIGNIFICANT CLINICAL OBSERVATIONS	92/46
1- PRETEST	

187054 AD

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PRETEST CLINICAL OBSERVATIONS

PROJECT NO.:WIL-187054P — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS — PAGE 2

SPONSOR:[redacted]

SPONSOR NO.:06-012

SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE: 02-24-06 TO 03-05-06

GROUP: 1

NORMAL

-NO SIGNIFICANT CLINICAL OBSERVATIONS 92/46

1- PRETEST

PCSUv4.07
07/25/2006

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APPENDIX D

Animal Room Environmental Conditions

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Audited Draft

Modified: 7/28/2006

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMAR[redacted]T BY STUDY

PROJECT NO [redacted] 187054
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187054

DATE IN: 02/21/06 TIME IN: 7:00
DATE OUT: 06/06/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 74
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
21-Feb-06	70.5	21.4	28.1 -
22-Feb-06	70.5	21.4	34.2
23-Feb-06	70.5	21.4	36.5
24-Feb-06	70.6	21.4	38.0
25-Feb-06	70.6	21.4	37.4
26-Feb-06	70.5	21.4	37.9
27-Feb-06	70.5	21.4	36.2
28-Feb-06	70.4	21.3	36.1
01-Mar-06	70.5	21.4	36.6
02-Mar-06	70.5	21.4	35.8
03-Mar-06	70.5	21.4	36.5
04-Mar-06	70.5	21.4	36.7
05-Mar-06	70.5	21.4	35.7
06-Mar-06	70.4	21.3	35.2
07-Mar-06	70.5	21.4	35.6
08-Mar-06	70.5	21.4	35.4
09-Mar-06	70.4	21.3	41.1
10-Mar-06	70.5	21.4	39.1
11-Mar-06	70.5	21.4	38.2
12-Mar-06	70.5	21.4	51.9
13-Mar-06	70.6	21.4	49.0
14-Mar-06	70.5	21.4	36.2
15-Mar-06	70.4	21.3	35.9

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/28/2006 09:51

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A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMAR[redacted]T BY STUDY

PROJECT NO [redacted] 187054
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187054

DATE IN: 02/21/06 TIME IN: 7:00
DATE OUT: 06/06/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 74
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
16-Mar-06	70.4	21.3	35.4
17-Mar-06	70.5	21.4	36.4
18-Mar-06	70.6	21.5	36.3
19-Mar-06	70.5	21.4	36.2
20-Mar-06	70.4	21.4	36.0
21-Mar-06	70.6	21.4	36.3
22-Mar-06	70.6	21.4	35.9
23-Mar-06	70.4	21.3	36.7
24-Mar-06	70.6	21.4	35.8
25-Mar-06	70.5	21.4	37.3
26-Mar-06	70.6	21.4	35.8
27-Mar-06	70.5	21.4	36.4
28-Mar-06	70.5	21.4	34.7
29-Mar-06	70.4	21.3	35.8
30-Mar-06	70.5	21.4	36.6
31-Mar-06	70.4	21.3	41.3
01-Apr-06	70.4	21.4	37.1
02-Apr-06	70.5	21.4	35.5
03-Apr-06	70.5	21.4	39.7
04-Apr-06	70.4	21.4	35.8
05-Apr-06	70.6	21.4	34.6
06-Apr-06	71.0	21.7	34.1
07-Apr-06	70.4	21.3	44.4

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/28/2006 09:51

Modified: 7/28/2006

187054 AD

Audited Draft

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMAR T BY STUDY

PROJECT NO [redacted] 187054
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187054

DATE IN: 02/21/06 TIME IN: 7:00
DATE OUT: 06/06/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 74
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
08-Apr-06	70.6	21.4	34.8
09-Apr-06	70.4	21.4	35.5
10-Apr-06	70.5	21.4	35.7
11-Apr-06	70.6	21.4	34.0
12-Apr-06	70.6	21.4	36.0
13-Apr-06	70.4	21.3	34.5
14-Apr-06	70.6	21.4	37.2
15-Apr-06	70.6	21.5	35.6
16-Apr-06	70.5	21.4	35.5
17-Apr-06	70.6	21.4	36.0
18-Apr-06	70.5	21.4	35.0
19-Apr-06	70.6	21.4	34.6
20-Apr-06	70.7	21.5	34.2
21-Apr-06	70.6	21.4	44.1
22-Apr-06	70.5	21.4	39.8
23-Apr-06	70.5	21.4	37.4
24-Apr-06	70.5	21.4	36.7
25-Apr-06	70.5	21.4	34.5
26-Apr-06	70.6	21.5	38.2
27-Apr-06	70.6	21.4	34.6
28-Apr-06	70.5	21.4	35.9
29-Apr-06	70.5	21.4	34.7
30-Apr-06	71.2	21.8	33.5

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/28/2006 09:51

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Modified: 7/28/2006

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMAR[redacted]T BY STUDY

PROJECT NO [redacted] 187054
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187054

DATE IN: 02/21/06 TIME IN: 7:00
DATE OUT: 06/06/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 74
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
01-May-06	70.6	21.4	37.2
02-May-06	70.5	21.4	37.7
03-May-06	70.5	21.4	45.1
04-May-06	70.4	21.3	41.0
05-May-06	70.5	21.4	34.2
06-May-06	70.5	21.4	35.4
07-May-06	70.5	21.4	31.7
08-May-06	70.5	21.4	33.4
09-May-06	70.5	21.4	35.6
10-May-06	70.6	21.5	37.7
11-May-06	70.6	21.4	37.1
12-May-06	70.5	21.4	37.6
13-May-06	70.6	21.4	35.8
14-May-06	70.5	21.4	38.0
15-May-06	70.6	21.4	41.4
16-May-06	70.6	21.4	38.4
17-May-06	70.6	21.4	36.1
18-May-06	70.6	21.4	36.0
19-May-06	70.6	21.4	37.1
20-May-06	70.5	21.4	35.7
21-May-06	70.6	21.4	34.9
22-May-06	70.7	21.5	36.0
23-May-06	70.4	21.3	34.1

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/28/2006 09:51

Audited Draft

Modified: 7/28/2006

A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMAR[redacted]T BY STUDY

PROJECT NO [redacted] 187054
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187054

DATE IN: 02/21/06 TIME IN: 7:00
DATE OUT: 06/06/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 74
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
24-May-06	70.5	21.4	39.2
25-May-06	70.5	21.4	46.6
26-May-06	70.5	21.4	47.7
27-May-06	70.5	21.4	46.9
28-May-06	70.6	21.5	47.8
29-May-06	70.7	21.5	51.6
30-May-06	70.5	21.4	50.6
31-May-06	70.6	21.4	54.6
01-Jun-06	70.6	21.4	51.4
02-Jun-06	70.6	21.4	45.4
03-Jun-06	70.5	21.4	45.2
04-Jun-06	70.6	21.5	40.9
05-Jun-06	70.5	21.4	41.7
06-Jun-06	70.6	21.5	44.8

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.4	71.2
TEMPERATURE °C	21.4	21.3	21.8
HUMIDITY (%RH)	38.1	28.1 -	54.6
N DAYS	106		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
7/28/2006 09:51

Audited Draft

ROOM SPECIFICATIONS:	B ROOM 74		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	02/21/06
HIGH TEMPERATURE:	76.0	TIME IN:	7:00
LOW HUMIDITY:	30.0	DATE OUT:	06/06/06
HIGH HUMIDITY:	70.0	TIME OUT:	16:00

ROOM B ROOM 74 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	38.1
MIN	67.1	5.3
MAX	76.4	85.8
SD	0.57	5.85
N SAMPLES	2520	2518
FIRST DAY	02/21/06	
LAST DAY	06/06/06	
N DAYS	106	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

Modified: 7/28/2006

187054 AD

Audited Draft

Modified: 7/28/2006

STUDY 187054 SUMMARY

MEAN	70.5	38.1
MIN	67.1	5.3
MAX	76.4	85.8
SD	0.57	5.85
N SAMPLES	2520	2518
FIRST DAY	02/21/06	
LAST DAY	06/06/06	
N DAYS	106	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

APPENDIX E

Unscheduled Clinical Observations

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UNSCHEDULED CLINICAL OBSERVATIONS

PROJECT NO.:WIL-187054U A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19639	M	0 MG/KG/DAY	CARDIO-PULMONARY	05-11-06	8:22	P	RALES
19639	M	0 MG/KG/DAY	EYES/EARS/NOSE	05-11-06	8:16	P	RED DISCHARGE LEFT EYE
				05-11-06	8:16	P	RED DISCHARGE RIGHT EYE
				05-11-06	8:16	P	RED NASAL DISCHARGE
				05-11-06	8:17	P	DRIED RED MATERIAL AROUND NOSE
19639	M	0 MG/KG/DAY	ORAL/DENTAL	05-11-06	8:18	P	UPPER INCISOR(S) MALALIGNED
				05-11-06	8:19	P	WET RED MATERIAL AROUND MOUTH
19639	M	0 MG/KG/DAY	SPECIAL	05-11-06	8:18	P	SWOLLEN FACIAL AREA
19640	M	160 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:49	P	DRIED YELLOW MATERIAL AROUND MOUTH
19631	M	400 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:51	P	DRIED RED MATERIAL AROUND MOUTH
19634	M	400 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:52	P	DRIED RED MATERIAL VENTRAL NECK
				03-31-06	9:52	P	WET CLEAR MATERIAL AROUND MOUTH
19618	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:55	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	9:55	P	WET CLEAR MATERIAL VENTRAL NECK
19624	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:55	P	DRIED CLEAR MATERIAL AROUND MOUTH
19633	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:53	P	DRIED RED MATERIAL AROUND MOUTH
19649	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:55	P	WET CLEAR MATERIAL AROUND MOUTH
19653	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:54	P	DRIED CLEAR MATERIAL AROUND MOUTH
19662	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:54	P	WET CLEAR MATERIAL AROUND MOUTH
19672	F	160 MG/KG/DAY	BODY/INTEGUMENT	06-05-06	7:28	P	HAIR LOSS FORELIMB(S)
19671	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:56	P	DRIED RED MATERIAL AROUND MOUTH
19679	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:57	P	DRIED YELLOW MATERIAL AROUND MOUTH
19695	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:57	P	WET CLEAR MATERIAL AROUND MOUTH
19701	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	9:58	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.11
08/30/2006

APPENDIX F

Clinical Pathology Methods, Procedures And References

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CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Serum Chemistry - Hitachi 912

Albumin - Bromcresol Green (BCG) Method, Modification of the Doumas reaction. Default unit: g/dL. Hitachi 912 Application Code 413. Roche Reagent, catalog number 11970569.

A/G Ratio - Calculated from Albumin and Globulin Results. Default unit: %.

Alkaline Phosphatase - based on the International Federation of Clinical Chemistry (IFCC) Method (Tietz *et al.* J Clin Chem Clin Biochem 1983; 21:731-748). Default unit: U/L. Hitachi 912 Application Code 158. Roche Reagent, catalog number 2172933.

Alanine Aminotransferase - Modification of the International Federation of Clinical Chemistry (IFCC) recommended method. Default unit: U/L. Hitachi 912 Application Code 706. Roche Reagent, catalog number 450065.

Aspartate Aminotransferase - Kinetic method based on the International Federation of Clinical Chemistry (IFCC) recommendations. Default unit: U/L. Hitachi 912 Application Code 715. Roche Reagent, catalog number 450064.

Bilirubin (Total) - Diazo method developed by Wahlefeld *et al.* Scand J Clin Lab Invest 1972; 29: Supplement 126. Default unit: mg/dL. Hitachi 912 Application Code 716. Roche Reagent, catalog number 1039034.

Blood Urea Nitrogen (BUN) - A urease-triggered methodology based upon the method of Talke and Schubert Klin Wschr, 1965; 43:174. Default unit: mg/dL. Hitachi 912 Application Code 427. Roche Reagent, catalog number 1489321.

Calcium - Modified method using a gamma-amino-butyric acid (GABA) buffer. Default unit: mg/dL. Hitachi 912 Application Code 180. Roche Reagent, catalog number 1125621.

Chloride - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog numbers 820638, 836246 and 820639.

Cholesterol - Enzymatic reaction as described by Trinder. Ann Clin Biochem 1974; 12:266. Default unit: mg/dL. Hitachi 912 Application Code 722. Roche Reagent, catalog number 450061.

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Creatinine - Modified Jaffe reaction based on the work of Poper *et al.* Biochem Z 1937; 291:354, and Seelig and Wuest. Aerztl Labor 1969; 15:34. Default unit: mg/dL. Hitachi 912 Application Code 727. Roche Reagent, catalog number 450019.

Globulin - Calculation obtained by subtracting Albumin from Total Protein. Default unit: g/dL.

Glucose - Glucose hexokinase method based on the work of Schmidt, Peterson and Young. Klin Wschr 1961; 39:1244. Methods of Enzymatic Analysis, 2nd Eng ed. New York, Academic Press, 1974; 1196. Anal Biochemistry 1958; 23:301. Default unit: mg/dL. Hitachi 912 Application Code 767. Roche Reagent, catalog number 450058.

Phosphorus - Method involves the formation of ammonium phosphomolybdate. Default unit: mg/dL. Hitachi 912 Application Code 714. Roche Reagent, catalog number 1040898.

Potassium - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog numbers 820638, 836246 and 820639.

Sodium - An ion-selective electrode that measures the electrical potential of the ions present in solution. Default unit: mEq/L. Hitachi 912 Application. Roche Reagent, catalog number 820638, 836246 and 820639.

Total Protein - Endpoint biuret method that utilizes a sample blank. Default unit: g/dL. Hitachi 912 Application Code 756. Roche Reagent, catalog number 1040901.

Triglycerides - Method that utilizes lipase from a microorganism to promote rapid and complete hydrolysis of triglycerides to glycerol. Default unit: mg/dL. Hitachi 912 Application Code 781. Roche Reagent, catalog number 1488899.

Hematology - Manual Methods

White Cell Differential - Manual method of counting 100 white cells stained with Wright Giemsa and entered on-line into the data files.

Reticulocyte Count - Manual method of counting the reticulocytes present in 1000 red blood cells stained with New Methylene Blue and entered on-line into the data files.

Red Blood Cell Morphology - Manual method of evaluating red blood cells on a Wright Giemsa-stained slide and entered on-line into the data files.

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Platelet Estimate- Manual method of evaluating platelets on a Wright Giemsa-stained slide. Platelet estimation is evaluated and entered on-line into the data files as decreased, adequate or increased. Platelet clumps present on the slide will be reported as part of the RBC morphology.

AMAX Destiny Amelung Coagulation

Mechanical (Ball Method) Measurement – Mechanical measurement methods depend on the physical formation of fibrin strands that attach to a moving mechanical device that either completes or opens and electrical circuit. The elapsed time from the addition of the starting reagent, up to the beginning of fibrin formation is measured.

Prothrombin Time (Protime-PT)- mechanical clot detection is used to measure and record the time required for plasma specimens to clot by adding an excess of thromboplastin reagent and an optional amount of calcium to citrated plasma. The PT measures from factor VII through fibrin formation (extrinsic and common pathways of coagulation). Default unit: sec.

Activated Partial Thromboplastin Time (APTT)- mechanical clot detection is used to measure and record clotting time in a one-stage procedure which consists of recalcifying plasma in the presence of an excess of platelet-like reagent (cephalin) containing a plasma activator. The APTT measures the clotting time from factor XII through fibrin formation (intrinsic and common pathways of coagulation) Default unit: sec.

Hematology-Bayer Advia® 120

WBC Count - The whole blood sample is mixed with ADVIA® 120 BASO reagent that contains acid and surfactant. The red cells are hemolyzed, and the white blood cells are then analyzed using two angle laser light scatter signals. Default unit: x 10^3 cells/μL

RBC / Platelet Count - Both red blood cells and platelets are analyzed by a single optical cytometer after appropriate dilution of the blood sample with ADVIA® 120 RBC/PLT reagent. The red blood cells are isovolumetrically sphered and lightly fixed with glutaraldehyde to preserve the spherical shape. Red cells and platelets are counted from the signals from a common detector with 2 different gain settings. Default unit RBC: x 10^6cells/μL. Default unit PLT: x 10^3 cells/μL

Hgb - Hemoglobin: The hemoglobin method is a modification of the manual cyanmethemoglobin method developed by the International Committee for standardization in Hematology (ICSH). Default unit: g/dL.

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Hematocrit - The percentage of blood volume that is occupied by red blood cells. Also referred to as the packed red cell volume. On the ADVIA® 120 Hematology System this parameter is derived from the measured red cell volume (MCV) and the red cell count (RBC). Default unit: %.

MCH - Mean Corpuscular Hemoglobin: the average weight of hemoglobin in the red blood cells, calculated from the RBC and Hgb measurements. Default unit: pg.

MCHC - Mean Corpuscular Hemoglobin Concentration: the average concentration of hemoglobin in the red blood cells. This parameter is computed from the measured hemoglobin and the computed hematocrit. Default unit: g/dL.

MCV - Mean Corpuscular Volume: the average volume of the red blood cells. Default unit: fL

White blood cell differential - The ADVIA® 120 Hematology System White Blood Cell Differential (WBC DIFF) methods, consists of both the Peroxidase method and the Basophil/Lobularity method. The ADVIA® 120 Hematology System performs a six-part differential that consists of basophils, eosinophils, large unstained cells, lymphocytes, monocytes, and neutrophils. The white blood cell differential count is reported in percent and the actual number of each type of cell per microliter of blood.

Reticulocyte - This method uses a nucleic acid dye (oxazine 750) to stain cellular RNA. The ADVIA® 120 autoRETIC reagent isovolumetrically spheres the erythroid cells and stains cellular RNA. Low-angle laser light scatter, high-angle laser light scatter, and absorption characteristics of all cells are counted and measured. The absorption data are used to classify each cell as a reticulocyte or mature red blood cell based on its RNA content. The reticulocyte is reported in percent and actual number x 10^9cells/Liter = thous/µl.

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References:

Bayer Reagent Strips, Multistix®. Bayer Corporation Diagnostics Division. Package Insert, 5/95.

ADVIA® 120 Hematology System Operator's Guide: Copyright© 1997, 1998 Bayer Corporation.

AMAX Destiny Operation Manual SW V 1.1.4, 31/08/05. Trinity Biotech Plc.

APPENDIX G

Ophthalmic Examinations ([redacted]

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Concluding Statement

Pertaining to

Ophthalmic Examinations

Performed During Conduct of

Study WIL-187054

All findings observed during the ophthalmic examinations for the above mentioned study are typical in prevalence and appearance for the species and strain or breed of animals examined. There were no significant differences within or among dose groups or compared to the pretest ophthalmic examinations to suggest a test article-related effect.

[redacted]

6/1/06
Date

T1-230

APPENDIX H

Pathology Report (WIL Research Laboratories, LLC)

Audited Draft

Audited Draft

A 90-DAY REPEATED DOSE ORAL (GAVAGE) TOXICITY STUDY OF [redacted] IN RATS

PATHOLOGY REPORT

Pathology Department

WIL Research Laboratories, LLC

Audited Draft

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1. INTRODUCTION

The objective of this study was to evaluate the possible toxic effects of the test article when administered orally to rats for at least 90 days.

2. STUDY DESIGN

Male and female Crl:CD(SD) rats, approximately 6 weeks of age at initiation of dosing, were administered [redacted] via oral gavage daily for a minimum of 90 consecutive days as indicated in the following table. The dosage volume was 5 mL/kg for all groups.

Group Number	Treatment	Dosage Level (mg/kg/day)	Number of Animals Males	Females
1	Vehicle [a]	0	10	10
2	[redacted]	160	10	10
3		400	10	10
4		1000	10	10

[a] = The vehicle was corn oil.

3. METHODS

3.1. CLINICAL PATHOLOGY

Hematology and serum chemistry parameters were evaluated on all surviving animals just prior to the scheduled necropsy. Animals were fasted overnight prior to blood collection. Blood for hematology and serum chemistry evaluations was collected prior to necropsy via the retro-orbital sinus of animals anesthetized by inhalation of isoflurane. Blood for coagulation parameters was collected from the vena cava at the time of necropsy. Anticoagulants were potassium EDTA for the hematology and sodium citrate for the coagulation tests. Anticoagulants were not used for serum chemistry samples.

The following parameters were evaluated:

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3.1.1. HEMATOLOGY

Total leukocyte count (White Cells)
Erythrocyte count (Red Cells)
Hemoglobin
Hematocrit
Mean corpuscular volume (MCV)
Mean corpuscular hemoglobin (MCH)
Mean corpuscular hemoglobin concentration (MCHC)
Platelet count (Platelet)
Prothrombin time (ProTime)
Activated partial thromboplastin time (APTT)
Reticulocyte count
  Percent (Reticulocyte)
  Absolute (Retic Absolute)

Differential leukocyte count -
  Percent and absolute
  -Neutrophil
  -Lymphocyte
  -Monocyte
  -Eosinophil
  -Basophil
  -Large unstained cell
Platelet estimate [a]
Red cell morphology (RBC Morphology) [a]

( ) - Designates tabular abbreviation
[a] - Presented on individual tables if the automated differential data were verified by manual review of slides

3.1.2. SERUM CHEMISTRY

Albumin
Total protein
Globulin [by calculation]
Albumin/globulin ratio (A/G Ratio) [by calculation]
Total bilirubin (Total Bili)
Urea nitrogen
Creatinine
Alkaline phosphatase (AlkalinePhos'tse)
Alanine aminotransferase (Alanine Transfer)

Aspartate aminotransferase (AspartatTransfer)
Glucose
Total cholesterol (Cholesterol)
Calcium
Chloride
Phosphorus
Potassium
Sodium
Triglycerides (Triglyceride)

( ) - Designates tabular abbreviation

3.2. ANATOMIC PATHOLOGY

3.2.1. MACROSCOPIC EXAMINATION

Complete postmortem examinations were performed on all animals found dead or at the scheduled necropsy. Animals were euthanized by carbon dioxide inhalation followed by exsanguination. At the time of necropsy, the following tissues and organs were collected and placed in 10% neutral buffered formalin fixative unless otherwise noted:

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Adrenal glands (2)
Aorta
Bone with marrow
  Sternum
Bone marrow smear (from femur)[a]
Brain with brainstem
  Cerebrum (2 levels)
  Cerebellum with medulla/pons
Cervix
Epididymides (2)[b]
Exorbital lacrimal glands (2)
Eyes (2) with optic nerves[c]
Gastrointestinal tract
  Esophagus
  Stomach
  Duodenum
  Jejunum with Peyer's patches
  Ileum
  Cecum
  Colon
  Rectum
Harderian glands (2)
Heart
Kidneys (2)
Larynx
Liver (sections of 2 lobes)
Lungs (including bronchi, fixed by inflation with fixative)
Lymph nodes
  Mandibular
  Mesenteric
  Popliteal[f]
Mammary gland (females only)
Nasal Tissues[d]
Ovaries (2) with oviducts[e]
Pancreas
Peripheral nerve (sciatic)
Pharynx
Pituitary
Prostate
Salivary glands [mandibular (2)]
Seminal vesicles (2)
Skeletal muscle (rectus femoris)
Skin
Spinal cord (cervical, thoracic, lumbar)
Spleen
Testes (2)[b]
Thymus
Thyroids with parathyroids[e]
Trachea
Urinary bladder
Uterus
Cervix
Vagina
Gross lesions (when possible)

[a] - Bone marrow smears were obtained at necropsy but not placed in formalin; smears were not microscopically examined.
[b] - Fixed in Bouin's solution.
[c] - Fixed in Davidson's solution.
[d] - Levels I and III according to the method of Young (Young, 1981) were examined.
[e] - Examined microscopically when in the plane of section and in all cases where a gross lesion was present.
[f] - As many per side as found were retained for microscopic evaluation.

3.2.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsy:

Adrenal glands	Prostate
Brain	Seminal vesicles / coagulating gland
Epididymides	Spleen
Heart	Testes
Kidneys	Thymus
Liver	Thyroid with parathyroids*
Ovaries (with oviducts)	Uterus
Popliteal lymph nodes	

Designated (*) organs were weighed following fixation in 10% neutral-buffered formalin. Paired organs were weighed together. Organ-to-final-body-weight and organ-to-brain-weight ratios were calculated.

3.2.3. MICROSCOPIC EXAMINATION

Microscopic examination of routinely prepared hematoxylin-eosin stained paraffin sections was performed on all tissues collected at necropsy from all animals that were found dead as well as all animals in the control and 1000 mg/kg/day groups. Additionally, all gross lesions were examined from animals in the 160 and 400 mg/kg/day groups. The stained histologic sections were examined by routine light microscopy and histologic observations were entered in the WIL Toxicology Data Management System (WTDMS™) by the pathologist at the time of examination. At the time of histologic examination, all gross necropsy observations were addressed and a cause-of-death/debility determination was made for all animals that died prior to scheduled study termination. Due to sectioning difficulties or minor laboratory errors, the number of tissues examined from each dosage group does not necessarily correlate with the number of animals included in the group. The number of missing tissues was small and did not interfere with detection of test article-related histologic alterations in the study. The histologic sections were of adequate size and quality for detailed histologic evaluation. The WTDMS™ histopathology tables contain a record of tissues

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examined and histologic findings and serve as the basis for this narrative report. Histopathologic lesions were classified using standard published terminology to the extent possible.

3.3. ABBREVIATIONS

The following abbreviations may apply to this report:

Interval - point in the study at which an animal died or was euthanized
FD - found dead
SN - scheduled necropsy
M - male
F - female

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3.4. DATA INTERPRETATION

In the discussion of clinical pathology parameters, values derived from the control group animals provided a 'normal' range for the present study. In addition, historical control values for this laboratory were consulted to refine data interpretation. Unless otherwise stated in this report, the 'normal' historical control range was considered to be the mean value ± 2 standard deviations. This narrative report addresses all clinical pathology values that were identified as statistically significantly different from control group values on the clinical pathology data tables.

In the discussion of organ weight changes, the indication of higher or lower mean organ weights refers to a statistically significant ($p<0.05$ or 0.01 using Dunnett's test) difference between test article-treated versus control group animals in the present study. In addition, historical control values for this laboratory were consulted to refine data interpretation. This narrative report addresses all organ weight values that were identified as statistically significantly different from control group values on the organ weight data tables.

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4. RESULTS

4.1. SURVIVAL

A single control male (no. 19639) was euthanized in extremis on study day 70, and a single 400 mg/kg/day group female (no. 19673) was found dead on study day 65. Suppurative rhinitis with intralesional bacteria was noted in male no. 19639 and may have been associated with the death of the animal (i.e., blockage of nasal passages by debris), although an exact cause could not be determined; no significant histologic findings were observed in female no 19673. Both deaths were considered spontaneous and unrelated to test article exposure. All other rats survived to the scheduled necropsy (study day 91 or 92).

4.2. CLINICAL PATHOLOGY

4.2.1. HEMATOLOGY

The following alterations in coagulation parameters were considered to be related to test article administration:

Text Table 1
Toxicologically relevant hematological changes

Parameter	Direction and magnitude of change	Dosage Level(s) (mg/kg/day)	Sex	Interval
Prothrombin time	↑ 7.1%, 13.0%, 53.3%*	160, 400, 1000	M	SN
APTT	↑ 11.2%*, 17.3%*, 44.7%*	160, 400, 1000	M	SN

* = significantly ($p<0.05$ or $p<0.01$) different from the control group using Dunnett's test.

Mean prothrombin time and APTT values were higher in the test article-treated males as compared to the control group. A dose relationship was observed, and all prothrombin values (including the control group values) and the APTT value for the 1000 mg/kg/day group were above WIL historical control data ranges. Increases in both prothrombin time and APTT suggest a deficiency in the common pathway of the coagulation cascade or multiple defects involving the intrinsic, extrinsic and common pathways.

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There were no other test article-related effects on hematology data. However, platelet count was statistically significantly higher (32.8%; $p<0.05$ using Dunnett's test) in the 400 mg/kg/day group females as compared to the control group. This group mean difference was not considered to be test article-related because there was no dose response, the value was within WIL historical control data range and a low outlier in the control group contributed to a low mean control group value.

4.2.2. SERUM CHEMISTRY

The following alterations in serum chemistry parameters were considered to be related to test article administration:

Text Table 2
Toxicologically relevant serum chemistry changes

Parameter	Direction and magnitude of change	Dosage Level(s) (mg/kg/day)	Sex	Interval
Alkaline phosphatase	↑ 45.1%*, 82.4%*, 95.6%* ↑ 68.1%*, 72.3%*, 159.6%*	160, 400, 1000	M F	SN
Alanine aminotransferase	↑ 15.8%, 110.5%, 552.6%* ↑ 15.6%, 71.9%, 465.6%*	160, 400, 1000	M F	SN
Aspartate aminotransferase	↑ 1.4%, 12.9%, 74.3%* ↑ 13.2%, 16.2%, 64.7%*	160, 400, 1000	M F	SN
Total Protein	↓ 2.9%, 2.9%, 8.6%*	160, 400, 1000	M	SN
Globulin	↓ 7.7%, 7.7%, 19.2%* ↓ 4.3%, 8.7%, 13.0%*	160, 400, 1000	M F	SN
A/G ratio	↑ 8.9%, 11.2%, 20.1%* ↑ 6.2%, 10.2%, 15.5%	160, 400, 1000	M F	SN
Cholesterol	↓ 1.4%, 17.8%, 21.9%*	160, 400, 1000	F	SN

* = significantly ($p<0.05$ or $p<0.01$) different from the control group using Dunnett's test.

Several mean liver enzyme values (alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase) were higher in the test article-treated animals as compared to the control group, and this was observed in a dose-related manner in both males and

females. In addition, mean alkaline phosphatase and alanine aminotransferase values were above the WIL historical control data ranges for the 400 and 1000 mg/kg/day group males; these values were also above historical control ranges for the 1000 mg/kg/day group females.

Statistically significantly lower mean total protein and globulin values and higher A/G ratio were noted in the 1000 mg/kg/day group males as compared to the control group values. Lower globulin levels were primarily responsible for the altered A/G ratio, while the difference in total protein was minor. There was no clear dose response. Mean globulin values were also statistically significantly lower in the 1000 mg/kg/day group females as compared to the control group value, and a dose response was observed. The A/G ratios in the test article-treated females were also higher than the control group value, although the differences were not statistically significant for this parameter. In addition, mean cholesterol was statistically significantly lower in the 1000 mg/kg/day group females as compared to the control group value, and this occurred in a dose-related manner, although there were no statistically significant differences in the mid-dose groups.

There were no other test article-related effects on serum chemistry data.

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4.3. GROSS OBSERVATIONS

There were no test article-related macroscopic findings. All macroscopic changes were considered to be spontaneous and/or incidental in nature and unrelated to test article exposure.

4.4. ORGAN WEIGHTS

Mean final body weight was statistically significantly (13.3%) lower in the 1000 mg/kg/day group males as compared to the control group. There were no other statistically significant mean final body weight differences.

The following organ weight changes were considered to be test article-related:

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Text Table 3 Toxicologically relevant organ weight changes					
	Dosage Level(s) (mg/kg/day)				Histologic
Organ	**160**	**400**	**1000**	**Sex**	**Correlate**
Adrenal Glands					
absolute	↑ 8.6%	↑ 21.8%*	↑ 26.3%*	F	None
relative to body weight	↑ 8.3%	↑ 25.0%*	↑ 29.2%*		
relative to brain weight	↑ 6.4%	↑ 17.4%	↑ 25.5%*		
Ovaries/Oviducts					
absolute	↑ 8.3%	↑ 13.5%	↑ 17.6%	F	None
relative to body weight	↑ 6.4%	↑ 17.0%	↑ 21.3%*		
relative to brain weight	↑ 6.6%	↑ 9.5%	↑ 17.0%		

* = significantly ($p<0.05$ or $p<0.01$) different from the control group using Dunnett's test.

Mean adrenal gland weights were statistically significantly higher in the 400 and 1000 mg/kg/day group females as compared to the control group, and this occurred in a dose-related manner. A statistically significantly higher mean ovaries/oviducts weight (relative to body weight) was observed in the 1000 mg/kg/day group females. Although remaining group mean differences in ovaries/oviducts weights lacked statistical significance, a dose response was evident.

Brain, testes and kidney weights relative to final body weights were statistically significantly higher (12.4% to 14.2%) in the 1000 mg/kg/day group males when compared to the control group at the scheduled necropsy. However, these changes were considered to be a result of a test article-related effect on final body weight, not a direct effect on the organs.

There were no other test article-related effects on organ weights. However, statistically significant lower mean absolute heart weight (12.7%; $p<0.05$ using Dunnett's test) in the 1000 mg/kg/day group males, higher mean absolute and relative (to body weight) kidney weights (8.7% and 11.1%, respectively; $p<0.05$ using Dunnett's test) in the 1000 mg/kg/day group females and higher mean liver weight relative to body weight (13.3%; $p<0.01$ using Dunnett's test) in the 1000 mg/kg/day group females were observed as compared to the control group. These group mean differences were not considered to be toxicologically relevant because there was no dose response, the values were generally within WIL historical control data ranges (except for the mean liver weight relative to body weight in the females), and there were no histologic correlates observed.

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4.5. HISTOLOGIC CHANGES

There were no test article-related histologic changes. Histologic changes were considered to be incidental findings, manifestations of spontaneous diseases, or related to some aspect of experimental manipulation other than exposure to the test article. There was no test article-related alteration in the incidence, severity or histologic character of those incidental and spontaneous tissue alterations.

5. DISCUSSION

Administration of [redacted] to Crl:CD(SD) rats via daily oral gavage for a minimum of 90 consecutive days resulted in hepatic alteration manifested as higher liver enzyme values (alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase) in both males and females. Additionally, lower total protein, lower globulin and increased coagulation times in the males as well as lower globulin and cholesterol values in the females were also likely associated with hepatocyte alteration, although the lack of effect on albumin levels is atypical. These differences were considered to be test article-related but not adverse as no related clinical signs were seen, correlating macroscopic or microscopic changes in the liver were not observed, and there was no effect on liver

weights. Higher adrenal gland and ovaries/oviduct weights had no microscopic correlates and were not considered adverse.

6. CONCLUSIONS

Administration of [redacted] to male and female Crl:CD(SD) rats via daily oral gavage for a minimum of 90 consecutive days resulted in the following alterations: higher prothrombin times and APTT values in the 160, 400 and 1000 mg/kg/day group males; higher alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase in the 160, 400 and 1000 mg/kg/day group males and females; lower globulin values and a correspondingly higher A/G ratio in test article-treated males and females as well as statistically significantly lower total protein values in the 1000 mg/kg/day males and lower cholesterol levels in the 1000 mg/kg/day females; lower mean final body weight in the 1000 mg/kg/day males; and higher mean adrenal gland and ovaries/oviducts weights in the test article-treated females. There were no test article-related histologic observations.

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7. REFERENCES

Young, J.T. Histopathological examination of the rat nasal cavity. *Fundamental and Applied Toxicology* **1981,** *1,* 309-312.

[redacted] A 28-Day Repeated Dose Oral (Gavage) Toxicity Study of [redacted] in Rats (with Functional Observational Battery and Motor Activity Determinations) (Study No. WIL-187051). WIL Research Laboratories, LLC. Revised Draft.

8. REPORT SUBMISSION

Report Submitted By:

[redacted] _____
Study Pathologist

_____
Date

Report Reviewed By:

[redacted] _____
Reviewing Pathologist

_____
Date

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APPENDIX I

Individual Clinical Observations

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DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS
PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19623	M	0 MG/KG/DAY	NORMAL	03-06-06	9:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	6:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19623	M	0 MG/KG/DAY	DISPOSITION	06-05-06	8:55	P	PRIMARY NECROPSY (WEEK 13)
19623	M	0 MG/KG/DAY	BODY/INTEGUMENT	04-17-06	7:48	P	HAIR LOSS FORELIMB(S)
				04-24-06	9:43	P	HAIR LOSS FORELIMB(S)
				05-01-06	9:35	P	HAIR LOSS FORELIMB(S)
				05-22-06	6:49	P	HAIR LOSS FORELIMB(S)
19626	M	0 MG/KG/DAY	NORMAL	03-06-06	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	6:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19626	M	0 MG/KG/DAY	DISPOSITION	06-06-06	9:27	P	PRIMARY NECROPSY (WEEK 13)
19630	M	0 MG/KG/DAY	NORMAL	03-06-06	9:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	6:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19630	M	0 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19630	M	0 MG/KG/DAY	ORAL/DENTAL	05-08-06	8:50	P	UPPER INCISOR(S) BROKEN
				05-15-06	7:40	P	UPPER INCISOR(S) BROKEN
				05-15-06	7:40	P	UPPER INCISOR(S) MALALIGNED
19636	M	0 MG/KG/DAY	NORMAL	03-06-06	9:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	6:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19636	M	0 MG/KG/DAY	NORMAL	05-29-06	10:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19636	M	0 MG/KG/DAY	DISPOSITION	06-06-06	9:27	P	PRIMARY NECROPSY (WEEK 13)
19636	M	0 MG/KG/DAY	BODY/INTEGUMENT	06-06-06	6:39	P	HAIR LOSS FORELIMB(S)
19639	M	0 MG/KG/DAY	NORMAL	03-06-06	9:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	6:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19639	M	0 MG/KG/DAY	DISPOSITION	05-15-06	10:48	P	SENT TO NECROPSY TO BE EUTHANIZED IN EXTREMIS-PHYSICAL CONDITION
19639	M	0 MG/KG/DAY	BEHAVIOR/CNS	05-15-06	7:53	P	UNKEMPT APPEARANCE
				05-15-06	7:53	P	HYPOACTIVITY
19639	M	0 MG/KG/DAY	CARDIO-PULMONARY	05-15-06	7:53	P	RALES
				05-15-06	7:53	P	RESPIRATION SHALLOW
19639	M	0 MG/KG/DAY	EYES/EARS/NOSE	05-15-06	7:51	P	DRIED RED MATERIAL AROUND LEFT EYE
				05-15-06	7:51	P	DRIED RED MATERIAL AROUND RIGHT EYE
				05-15-06	7:51	P	DRIED RED MATERIAL AROUND NOSE
19639	M	0 MG/KG/DAY	EXCRETA	05-15-06	7:44	P	DEFECATION DECREASED
19639	M	0 MG/KG/DAY	ORAL/DENTAL	05-15-06	7:44	P	DRIED YELLOW MATERIAL AROUND MOUTH
				05-15-06	7:50	P	LOWER INCISOR(S) LONG, TRIMMED
				05-15-06	7:51	P	UPPER INCISOR(S) MALALIGNED
19639	M	0 MG/KG/DAY	BODY INTEG III	05-15-06	7:52	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-15-06	7:52	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
				05-15-06	7:52	P	DRIED YELLOW MATERIAL VENTRAL TRUNK

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DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19644	M	0 MG/KG/DAY	NORMAL	03-06-06	9:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19644	M	0 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19652	M	0 MG/KG/DAY	NORMAL	03-06-06	9:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19652	M	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19655	M	0 MG/KG/DAY	NORMAL	03-06-06	9:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19655	M	0 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19655	M	0 MG/KG/DAY	SPECIAL	05-15-06	7:57	P	SWOLLEN LEFT EAR
				05-15-06	7:57	P	SWOLLEN RIGHT EAR
				05-22-06	6:57	P	SWOLLEN RIGHT EAR
				05-22-06	6:57	P	SWOLLEN LEFT EAR
				05-29-06	10:09	P	SWOLLEN LEFT EAR
19657	M	0 MG/KG/DAY	NORMAL	03-06-06	9:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 6

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19657	M	0 MG/KG/DAY	NORMAL	05-29-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19657	M	0 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19657	M	0 MG/KG/DAY	ORAL/DENTAL	05-01-06	9:43	P	LOWER INCISOR(S) LONG, TRIMMED
19660	M	0 MG/KG/DAY	NORMAL	03-06-06	9:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	6:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	6:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19660	M	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19619	M	160 MG/KG/DAY	NORMAL	03-06-06	9:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19619	M	160 MG/KG/DAY	NORMAL	05-15-06	8:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19619	M	160 MG/KG/DAY	DISPOSITION	06-05-06	8:55	P	PRIMARY NECROPSY (WEEK 13)
19628	M	160 MG/KG/DAY	NORMAL	03-06-06	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19628	M	160 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19640	M	160 MG/KG/DAY	NORMAL	03-06-06	9:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19640	M	160 MG/KG/DAY	NORMAL	05-08-06	9:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19640	M	160 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19646	M	160 MG/KG/DAY	NORMAL	03-06-06	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19646	M	160 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19647	M	160 MG/KG/DAY	NORMAL	03-06-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19647	M	160 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19647	M	160 MG/KG/DAY	EYES/EARS/NOSE	04-03-06	7:08	P	RED DISCHARGE RIGHT EYE
				04-10-06	9:31	P	DRIED RED MATERIAL AROUND RIGHT EYE
				05-08-06	9:08	P	DRIED RED MATERIAL AROUND RIGHT EYE

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

187054 AD

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —

SPONSOR: [redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19647	M	160 MG/KG/DAY	EYES/EARS/NOSE	05-22-06	7:13	P	DRIED RED MATERIAL AROUND RIGHT EYE
				05-29-06	10:18	P	DRIED RED MATERIAL AROUND RIGHT EYE
				06-05-06	7:25	P	DRIED RED MATERIAL AROUND RIGHT EYE
19647	M	160 MG/KG/DAY	EXCRETA	05-01-06	9:56	P	SOFT FECES
19647	M	160 MG/KG/DAY	ORAL/DENTAL	04-03-06	7:08	P	UPPER INCISOR(S) MALALIGNED
				04-03-06	7:08	P	LOWER INCISOR(S) LONG, TRIMMED
				04-10-06	9:31	P	UPPER INCISOR(S) MALALIGNED
				04-10-06	9:31	P	LOWER INCISOR(S) LONG, TRIMMED
				04-17-06	8:12	P	UPPER INCISOR(S) MALALIGNED
				04-17-06	8:13	P	LOWER INCISOR(S) LONG, TRIMMED
				04-24-06	10:02	P	UPPER INCISOR(S) BROKEN
				04-24-06	10:02	P	UPPER INCISOR(S) MALALIGNED
				04-24-06	10:04	P	LOWER INCISOR(S) LONG, TRIMMED
				05-01-06	9:57	P	UPPER INCISOR(S) MALALIGNED
				05-01-06	9:57	P	UPPER INCISOR(S) BROKEN
				05-01-06	9:58	P	LOWER INCISOR(S) LONG, TRIMMED
				05-08-06	9:08	P	UPPER INCISOR(S) BROKEN
				05-08-06	9:08	P	UPPER INCISOR(S) MISSING
				05-08-06	9:08	P	LOWER INCISOR(S) LONG, TRIMMED
				05-15-06	8:13	P	UPPER INCISOR(S) BROKEN
				05-22-06	7:13	P	UPPER INCISOR(S) BROKEN
				05-22-06	7:13	P	UPPER INCISOR(S) MALALIGNED
				05-22-06	7:14	P	LOWER INCISOR(S) LONG, TRIMMED
				05-29-06	10:19	P	UPPER INCISOR(S) BROKEN
				05-29-06	10:19	P	UPPER INCISOR(S) MALALIGNED
				05-29-06	10:19	P	LOWER INCISOR(S) LONG, TRIMMED
				06-05-06	7:25	P	UPPER INCISOR(S) MISSING
19647	M	160 MG/KG/DAY	BODY INTEG III	05-01-06	9:57	P	DRIED BROWN MATERIAL ANOGENITAL AREA
19648	M	160 MG/KG/DAY	NORMAL	03-06-06	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19648	M	160 MG/KG/DAY	NORMAL	03-13-06	8:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19648	M	160 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19648	M	160 MG/KG/DAY	EYES/EARS/NOSE	04-17-06	8:15	P	DRIED RED MATERIAL AROUND NOSE
19650	M	160 MG/KG/DAY	NORMAL	03-06-06	9:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19650	M	160 MG/KG/DAY	DISPOSITION	06-05-06	8:58	P	PRIMARY NECROPSY (WEEK 13)
19650	M	160 MG/KG/DAY	BODY/INTEGUMENT	03-27-06	11:07	P	HAIR LOSS FORELIMB(S)
				04-03-06	7:09	P	HAIR LOSS FORELIMB(S)
				04-10-06	9:33	P	HAIR LOSS FORELIMB(S)
				04-17-06	8:16	P	HAIR LOSS FORELIMB(S)
				04-24-06	10:06	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:00	P	HAIR LOSS FORELIMB(S)
				05-08-06	9:10	P	HAIR LOSS FORELIMB(S)
				05-22-06	7:16	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:21	P	HAIR LOSS FORELIMB(S)

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19654	M	160 MG/KG/DAY	NORMAL	03-06-06	9:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19654	M	160 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19659	M	160 MG/KG/DAY	NORMAL	03-06-06	9:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19659	M	160 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19663	M	160 MG/KG/DAY	NORMAL	03-06-06	9:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19663	M	160 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19621	M	400 MG/KG/DAY	NORMAL	03-06-06	10:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

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DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19621	M	400 MG/KG/DAY	NORMAL	06-05-06	7:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19621	M	400 MG/KG/DAY	DISPOSITION	06-05-06	8:55	P	PRIMARY NECROPSY (WEEK 13)
19622	M	400 MG/KG/DAY	NORMAL	03-06-06	10:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19622	M	400 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19622	M	400 MG/KG/DAY	BODY/INTEGUMENT	04-17-06	8:31	P	HAIR LOSS FORELIMB(S)
				05-22-06	7:31	P	HAIR LOSS FORELIMB(S)
19631	M	400 MG/KG/DAY	NORMAL	03-06-06	10:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19631	M	400 MG/KG/DAY	NORMAL	05-29-06	10:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19631	M	400 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19632	M	400 MG/KG/DAY	NORMAL	03-06-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19632	M	400 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19632	M	400 MG/KG/DAY	BODY/INTEGUMENT	03-13-06	8:55	P	HAIR LOSS FORELIMB(S)
				03-27-06	11:23	P	HAIR LOSS FORELIMB(S)
				04-17-06	8:33	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:13	P	HAIR LOSS FORELIMB(S)
				05-22-06	7:32	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:31	P	HAIR LOSS FORELIMB(S)
19634	M	400 MG/KG/DAY	NORMAL	03-06-06	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

187054 AD

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Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 — A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS —

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19634	M	400 MG/KG/DAY	NORMAL	05-22-06	7:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19634	M	400 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19635	M	400 MG/KG/DAY	NORMAL	03-06-06	10:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19635	M	400 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19635	M	400 MG/KG/DAY	EYES/EARS/NOSE	04-17-06	8:35	P	RED DISCHARGE RIGHT EYE
19645	M	400 MG/KG/DAY	NORMAL	03-06-06	10:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19645	M	400 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19645	M	400 MG/KG/DAY	BODY/INTEGUMENT	03-13-06	8:57	P	HAIR LOSS FORELIMB(S)
				03-27-06	11:25	P	HAIR LOSS FORELIMB(S)
				04-10-06	9:47	P	HAIR LOSS FORELIMB(S)
				04-17-06	8:37	P	HAIR LOSS FORELIMB(S)
				04-24-06	10:24	P	HAIR LOSS FORELIMB(S)

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19645	M	400 MG/KG/DAY	BODY/INTEGUMENT	05-01-06	10:16	P	HAIR LOSS FORELIMB(S)
				05-08-06	9:25	P	HAIR LOSS FORELIMB(S)
				05-22-06	7:35	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:33	P	HAIR LOSS FORELIMB(S)
				06-06-06	6:51	P	HAIR LOSS FORELIMB(S)
19656	M	400 MG/KG/DAY	NORMAL	03-06-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19656	M	400 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19658	M	400 MG/KG/DAY	NORMAL	03-06-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19658	M	400 MG/KG/DAY	NORMAL	05-08-06	9:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19658	M	400 MG/KG/DAY	DISPOSITION	06-05-06	8:58	P	PRIMARY NECROPSY (WEEK 13)
19661	M	400 MG/KG/DAY	NORMAL	03-06-06	10:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19661	M	400 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19618	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19618	M	1000 MG/KG/DAY	NORMAL	05-08-06	9:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19618	M	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19618	M	1000 MG/KG/DAY	BODY INTEG III	04-24-06	10:37	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				04-24-06	10:37	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
19620	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19620	M	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19624	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19624	M	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19624	M	1000 MG/KG/DAY	EYES/EARS/NOSE	04-03-06	7:28	P	DRIED RED MATERIAL AROUND RIGHT EYE

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19624	M	1000 MG/KG/DAY	EYES/EARS/NOSE	04-10-06	9:59	P	DRIED RED MATERIAL AROUND RIGHT EYE
19624	M	1000 MG/KG/DAY	ORAL/DENTAL	04-03-06	7:28	P	UPPER INCISOR(S) MALALIGNED
				04-10-06	10:00	P	UPPER INCISOR(S) MALALIGNED
				04-10-06	10:00	P	LOWER INCISOR(S) LONG, TRIMMED
				04-13-06	7:58	P	UPPER INCISOR(S) LONG, TRIMMED
				04-13-06	7:58	P	LOWER INCISOR(S) LONG, TRIMMED
				04-17-06	8:55	P	UPPER INCISOR(S) MALALIGNED
				04-17-06	8:55	P	LOWER INCISOR(S) LONG, TRIMMED
				04-24-06	10:38	P	UPPER INCISOR(S) BROKEN
				04-24-06	10:38	P	UPPER INCISOR(S) MALALIGNED
				04-24-06	10:39	P	LOWER INCISOR(S) LONG, TRIMMED
				05-01-06	10:30	P	UPPER INCISOR(S) BROKEN
				05-01-06	10:30	P	UPPER INCISOR(S) MALALIGNED
				05-01-06	10:31	P	LOWER INCISOR(S) LONG, TRIMMED
				05-08-06	9:40	P	UPPER INCISOR(S) MALALIGNED
				05-08-06	9:40	P	LOWER INCISOR(S) LONG, TRIMMED
				05-15-06	8:53	P	UPPER INCISOR(S) MALALIGNED
				05-15-06	8:53	P	LOWER INCISOR(S) LONG, TRIMMED
				05-22-06	7:51	P	UPPER INCISOR(S) MALALIGNED
				05-22-06	7:51	P	LOWER INCISOR(S) LONG, TRIMMED
				05-29-06	10:42	P	UPPER INCISOR(S) MISSING
				05-29-06	10:42	P	LOWER INCISOR(S) LONG, TRIMMED
				06-02-06	8:04	P	LOWER INCISOR(S) LONG, TRIMMED
				06-05-06	7:46	P	UPPER INCISOR(S) BROKEN
				06-05-06	7:46	P	UPPER INCISOR(S) MALALIGNED
19625	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19625	M	1000 MG/KG/DAY	NORMAL	04-03-06	7:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19625	M	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19625	M	1000 MG/KG/DAY	ORAL/DENTAL	05-22-06	7:52	P	UPPER INCISOR(S) MALALIGNED
				05-22-06	7:52	P	LOWER INCISOR(S) LONG, TRIMMED
				05-29-06	10:43	P	UPPER INCISOR(S) LONG, TRIMMED
				05-29-06	10:43	P	UPPER INCISOR(S) MALALIGNED
				05-29-06	10:43	P	LOWER INCISOR(S) LONG, TRIMMED
				06-02-06	8:04	P	UPPER INCISOR(S) LONG, TRIMMED
				06-02-06	8:04	P	LOWER INCISOR(S) LONG, TRIMMED
				06-06-06	6:54	P	UPPER INCISOR(S) MALALIGNED
				06-06-06	6:54	P	LOWER INCISOR(S) LONG, TRIMMED
19633	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19633	M	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19633	M	1000 MG/KG/DAY	BODY/INTEGUMENT	05-01-06	10:32	P	HAIR LOSS FORELIMB(S)
				05-08-06	9:42	P	HAIR LOSS FORELIMB(S)
				05-15-06	8:55	P	HAIR LOSS FORELIMB(S)

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19633	M	1000 MG/KG/DAY	BODY/INTEGUMENT	05-22-06	7:53	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:45	P	HAIR LOSS FORELIMB(S)
				06-06-06	6:55	P	HAIR LOSS FORELIMB(S)
19633	M	1000 MG/KG/DAY	BODY/INTEG II	05-08-06	9:42	P	SCABBING FORELIMB(S)
				05-22-06	7:53	P	SCABBING FORELIMB(S)
				05-29-06	10:45	P	SCABBING FORELIMB(S)
19641	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19641	M	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19641	M	1000 MG/KG/DAY	BODY INTEG III	05-08-06	9:43	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-08-06	9:44	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-15-06	8:56	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-29-06	10:46	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
				06-05-06	7:47	P	DRIED BROWN MATERIAL ANOGENITAL AREA
19643	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19643	M	1000 MG/KG/DAY	NORMAL	04-24-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19643	M	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19649	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19649	M	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:58	P	PRIMARY NECROPSY (WEEK 13)
19653	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19653	M	1000 MG/KG/DAY	NORMAL	04-17-06	9:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19653	M	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19653	M	1000 MG/KG/DAY	BODY/INTEGUMENT	06-05-06	7:47	P	HAIR LOSS FORELIMB(S)
19662	M	1000 MG/KG/DAY	NORMAL	03-06-06	10:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19662	M	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19662	M	1000 MG/KG/DAY	BODY/INTEGUMENT	04-03-06	7:31	P	HAIR LOSS FORELIMB(S)
				04-10-06	10:06	P	HAIR LOSS FORELIMB(S)
				04-17-06	9:02	P	HAIR LOSS FORELIMB(S)
				04-24-06	10:44	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:35	P	HAIR LOSS FORELIMB(S)
				05-08-06	9:48	P	HAIR LOSS FORELIMB(S)
19662	M	1000 MG/KG/DAY	EYES/EARS/NOSE	03-20-06	7:52	P	DRIED RED MATERIAL AROUND LEFT EYE
				03-20-06	7:52	P	DRIED RED MATERIAL AROUND RIGHT EYE
19662	M	1000 MG/KG/DAY	BODY/INTEG II	04-10-06	10:06	P	SCABBING FORELIMB(S)
19662	M	1000 MG/KG/DAY	ORAL/DENTAL	03-20-06	7:52	P	UPPER INCISOR(S) MALALIGNED
				04-03-06	7:31	P	UPPER INCISOR(S) MALALIGNED
				04-10-06	10:06	P	UPPER INCISOR(S) MALALIGNED
				04-10-06	10:07	P	LOWER INCISOR(S) LONG, TRIMMED
				04-17-06	9:03	P	UPPER INCISOR(S) MALALIGNED
				04-17-06	9:03	P	UPPER INCISOR(S) BROKEN
				04-17-06	9:03	P	LOWER INCISOR(S) LONG, TRIMMED

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19662	M	1000 MG/KG/DAY	ORAL/DENTAL	04-24-06	10:44	P	UPPER INCISOR(S) BROKEN
				04-24-06	10:45	P	UPPER INCISOR(S) MALALIGNED
				04-24-06	10:45	P	LOWER INCISOR(S) LONG, TRIMMED
				05-01-06	10:36	P	UPPER INCISOR(S) BROKEN
				05-01-06	10:36	P	UPPER INCISOR(S) MALALIGNED
				05-01-06	10:36	P	LOWER INCISOR(S) LONG, TRIMMED
				05-08-06	9:47	P	LOWER INCISOR(S) LONG, TRIMMED
				05-08-06	9:47	P	UPPER INCISOR(S) BROKEN
				05-15-06	9:01	P	UPPER INCISOR(S) MALALIGNED
				05-15-06	9:01	P	LOWER INCISOR(S) LONG, TRIMMED
				05-22-06	7:58	P	LOWER INCISOR(S) LONG, TRIMMED
				05-29-06	10:48	P	UPPER INCISOR(S) BROKEN
				05-29-06	10:48	P	UPPER INCISOR(S) MALALIGNED
				05-29-06	10:48	P	LOWER INCISOR(S) LONG, TRIMMED
				06-06-06	6:56	P	UPPER INCISOR(S) MALALIGNED
				06-06-06	6:56	P	LOWER INCISOR(S) LONG, TRIMMED
19668	F	0 MG/KG/DAY	NORMAL	03-06-06	9:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	7:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	7:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19668	F	0 MG/KG/DAY	NORMAL	06-05-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19668	F	0 MG/KG/DAY	DISPOSITION	06-05-06	8:55	P	PRIMARY NECROPSY (WEEK 13)
19670	F	0 MG/KG/DAY	NORMAL	03-06-06	9:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19670	F	0 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19670	F	0 MG/KG/DAY	BODY/INTEGUMENT	03-27-06	10:49	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:11	P	HAIR LOSS FORELIMB(S)
				06-05-06	7:21	P	HAIR LOSS FORELIMB(S)
19670	F	0 MG/KG/DAY	EYES/EARS/NOSE	05-22-06	7:01	P	DRIED RED MATERIAL AROUND NOSE
19675	F	0 MG/KG/DAY	NORMAL	03-06-06	9:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19675	F	0 MG/KG/DAY	NORMAL	05-29-06	10:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19675	F	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19683	F	0 MG/KG/DAY	NORMAL	03-06-06	9:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19683	F	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19683	F	0 MG/KG/DAY	BODY/INTEGUMENT	05-01-06	9:46	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:12	P	HAIR LOSS FORELIMB(S)
				06-06-06	6:40	P	HAIR LOSS FORELIMB(S)
19687	F	0 MG/KG/DAY	NORMAL	03-06-06	9:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	8:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19687	F	0 MG/KG/DAY	NORMAL	05-22-06	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19687	F	0 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19692	F	0 MG/KG/DAY	NORMAL	03-06-06	9:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19692	F	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19696	F	0 MG/KG/DAY	NORMAL	03-06-06	9:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19696	F	0 MG/KG/DAY	NORMAL	05-15-06	8:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19696	F	0 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19698	F	0 MG/KG/DAY	NORMAL	03-06-06	9:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19698	F	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19698	F	0 MG/KG/DAY	BODY/INTEGUMENT	03-20-06	7:05	P	HAIR LOSS FORELIMB(S)
				04-24-06	9:56	P	HAIR LOSS FORELIMB(S)
19703	F	0 MG/KG/DAY	NORMAL	03-06-06	9:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19703	F	0 MG/KG/DAY	NORMAL	05-08-06	9:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19703	F	0 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19709	F	0 MG/KG/DAY	NORMAL	03-06-06	9:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	10:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	9:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19709	F	0 MG/KG/DAY	DISPOSITION	06-06-06	9:28	P	PRIMARY NECROPSY (WEEK 13)
19709	F	0 MG/KG/DAY	SPECIAL	05-15-06	8:07	P	SWOLLEN LEFT EAR
				05-15-06	8:07	P	SWOLLEN RIGHT EAR
				05-22-06	7:08	P	SWOLLEN LEFT EAR
				05-22-06	7:08	P	SWOLLEN RIGHT EAR
				05-29-06	10:15	P	SWOLLEN LEFT EAR
				05-29-06	10:15	P	REDDENED LEFT EAR
				06-06-06	6:45	P	SWOLLEN LEFT EAR
				06-06-06	6:45	P	REDDENED LEFT EAR
19664	F	160 MG/KG/DAY	NORMAL	03-06-06	9:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19664	F	160 MG/KG/DAY	NORMAL	04-03-06	7:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19664	F	160 MG/KG/DAY	DISPOSITION	06-05-06	8:55	P	PRIMARY NECROPSY (WEEK 13)
19669	F	160 MG/KG/DAY	NORMAL	03-06-06	9:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19669	F	160 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19669	F	160 MG/KG/DAY	BODY/INTEGUMENT	03-27-06	11:12	P	HAIR LOSS FORELIMB(S)
				04-17-06	8:21	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:04	P	HAIR LOSS FORELIMB(S)
19669	F	160 MG/KG/DAY	ORAL/DENTAL	06-05-06	7:27	P	UPPER INCISOR(S) BROKEN
19672	F	160 MG/KG/DAY	NORMAL	03-06-06	9:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

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TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19672	F	160 MG/KG/DAY	NORMAL	03-27-06	11:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19672	F	160 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19672	F	160 MG/KG/DAY	BODY/INTEGUMENT	05-29-06	10:24	P	HAIR LOSS FORELIMB(S)
				06-06-06	6:48	P	HAIR LOSS FORELIMB(S)
19674	F	160 MG/KG/DAY	NORMAL	03-06-06	9:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19674	F	160 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19674	F	160 MG/KG/DAY	EYES/EARS/NOSE	04-17-06	8:23	P	DRIED RED MATERIAL AROUND NOSE
19676	F	160 MG/KG/DAY	NORMAL	03-06-06	10:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19676	F	160 MG/KG/DAY	NORMAL	03-20-06	7:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19676	F	160 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19690	F	160 MG/KG/DAY	NORMAL	03-06-06	10:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19690	F	160 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19690	F	160 MG/KG/DAY	BODY/INTEGUMENT	04-17-06	8:25	P	HAIR LOSS FORELIMB(S)
				04-24-06	10:14	P	HAIR LOSS FORELIMB(S)
				05-08-06	9:17	P	HAIR LOSS VENTRAL NECK
				05-15-06	8:26	P	HAIR LOSS VENTRAL NECK
				05-22-06	7:25	P	HAIR LOSS VENTRAL NECK
				05-22-06	7:25	P	HAIR LOSS FORELIMB(S)
				05-22-06	7:26	P	HAIR LOSS BASE OF TAIL

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19690	F	160 MG/KG/DAY	BODY/INTEGUMENT	05-29-06	10:26	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:26	P	HAIR LOSS VENTRAL NECK
				05-29-06	10:26	P	HAIR LOSS BASE OF TAIL
19694	F	160 MG/KG/DAY	NORMAL	03-06-06	10:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19694	F	160 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19699	F	160 MG/KG/DAY	NORMAL	03-06-06	10:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19699	F	160 MG/KG/DAY	NORMAL	05-22-06	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19699	F	160 MG/KG/DAY	DISPOSITION	06-06-06	9:29	P	PRIMARY NECROPSY (WEEK 13)
19706	F	160 MG/KG/DAY	NORMAL	03-06-06	10:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19706	F	160 MG/KG/DAY	DISPOSITION	06-05-06	8:58	P	PRIMARY NECROPSY (WEEK 13)
19707	F	160 MG/KG/DAY	NORMAL	03-06-06	10:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	8:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19707	F	160 MG/KG/DAY	NORMAL	05-15-06	8:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19707	F	160 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19665	F	400 MG/KG/DAY	NORMAL	03-06-06	10:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:02	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:28	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19665	F	400 MG/KG/DAY	DISPOSITION	06-05-06	8:55	P	PRIMARY NECROPSY (WEEK 13)
19666	F	400 MG/KG/DAY	NORMAL	03-06-06	10:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19666	F	400 MG/KG/DAY	NORMAL	05-08-06	9:29	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19666	F	400 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19667	F	400 MG/KG/DAY	NORMAL	03-06-06	10:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19667	F	400 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19673	F	400 MG/KG/DAY	NORMAL	03-06-06	10:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19673	F	400 MG/KG/DAY	NORMAL	05-01-06	10:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:30	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19673	F	400 MG/KG/DAY	DISPOSITION	05-10-06	7:27	P	FOUND DEAD
19677	F	400 MG/KG/DAY	NORMAL	03-06-06	10:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19677	F	400 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19685	F	400 MG/KG/DAY	NORMAL	03-06-06	10:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:36	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

187054 AD

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19685	F	400 MG/KG/DAY	NORMAL	05-22-06	7:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19685	F	400 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19686	F	400 MG/KG/DAY	NORMAL	03-06-06	10:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:44	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19686	F	400 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)
19689	F	400 MG/KG/DAY	NORMAL	03-06-06	10:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19689	F	400 MG/KG/DAY	NORMAL	05-15-06	8:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:45	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19689	F	400 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19693	F	400 MG/KG/DAY	NORMAL	03-06-06	10:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	9:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	8:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19693	F	400 MG/KG/DAY	DISPOSITION	06-05-06	8:58	P	PRIMARY NECROPSY (WEEK 13)
19693	F	400 MG/KG/DAY	EXCRETA	03-20-06	7:41	P	SOFT FECES
19705	F	400 MG/KG/DAY	NORMAL	03-13-06	9:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:27	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	8:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19705	F	400 MG/KG/DAY	DISPOSITION	06-06-06	9:30	P	PRIMARY NECROPSY (WEEK 13)

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19705	F	400 MG/KG/DAY	BODY/INTEGUMENT	03-06-06	10:25	P	HAIR LOSS FORELIMB(S)
				03-27-06	11:39	P	HAIR LOSS FORELIMB(S)
				04-10-06	9:57	P	HAIR LOSS FORELIMB(S)
				04-17-06	8:52	P	HAIR LOSS FORELIMB(S)
				04-24-06	10:35	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:28	P	HAIR LOSS FORELIMB(S)
19705	F	400 MG/KG/DAY	ORAL/DENTAL	04-17-06	8:52	P	LOWER INCISOR(S) LONG, TRIMMED
19671	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:31	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:46	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19671	F	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19678	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:19	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

187054 AD

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19678	F	1000 MG/KG/DAY	NORMAL	04-24-06	10:47	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	7:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19678	F	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:56	P	PRIMARY NECROPSY (WEEK 13)
19679	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:37	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:20	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:32	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	8:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19679	F	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:57	P	PRIMARY NECROPSY (WEEK 13)
19680	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:38	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:21	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19680	F	1000 MG/KG/DAY	NORMAL	04-17-06	9:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:06	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	8:00	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19680	F	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19681	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:39	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:33	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:07	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	8:01	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-05-06	7:48	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19681	F	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:58	P	PRIMARY NECROPSY (WEEK 13)
19681	F	1000 MG/KG/DAY	BODY/INTEGUMENT	03-13-06	9:22	P	HAIR LOSS FORELIMB(S)
				03-27-06	11:51	P	HAIR LOSS FORELIMB(S)
				04-17-06	9:07	P	HAIR LOSS FORELIMB(S)
				04-24-06	10:49	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:39	P	HAIR LOSS FORELIMB(S)
19688	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:22	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:56	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19688	F	1000 MG/KG/DAY	NORMAL	04-10-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:50	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:08	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19688	F	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19688	F	1000 MG/KG/DAY	BODY/INTEGUMENT	05-22-06	8:02	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:52	P	HAIR LOSS FORELIMB(S)
19688	F	1000 MG/KG/DAY	EYES/EARS/NOSE	06-06-06	6:57	P	DRIED RED MATERIAL AROUND RIGHT EYE
19688	F	1000 MG/KG/DAY	ORAL/DENTAL	05-29-06	10:52	P	UPPER INCISOR(S) MALALIGNED
				05-29-06	10:52	P	LOWER INCISOR(S) LONG, TRIMMED
				05-29-06	10:52	P	UPPER INCISOR(S) LONG, TRIMMED
				06-02-06	8:04	P	UPPER INCISOR(S) LONG, TRIMMED
				06-02-06	8:04	P	LOWER INCISOR(S) LONG, TRIMMED
				06-06-06	6:57	P	UPPER INCISOR(S) MALALIGNED
19691	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:40	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:23	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:51	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-08-06	9:52	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	8:03	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 44

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19691	F	1000 MG/KG/DAY	NORMAL	06-05-06	7:49	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19691	F	1000 MG/KG/DAY	DISPOSITION	06-05-06	8:59	P	PRIMARY NECROPSY (WEEK 13)
19695	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:41	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:24	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:34	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19695	F	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19695	F	1000 MG/KG/DAY	BODY/INTEGUMENT	04-17-06	9:10	P	HAIR LOSS FORELIMB(S)
				05-01-06	10:41	P	HAIR LOSS FORELIMB(S)
				05-08-06	9:53	P	HAIR LOSS FORELIMB(S)
				05-22-06	8:03	P	HAIR LOSS FORELIMB(S)
				05-29-06	10:54	P	HAIR LOSS FORELIMB(S)
19695	F	1000 MG/KG/DAY	EYES/EARS/NOSE	05-01-06	10:41	P	DRIED RED MATERIAL AROUND RIGHT EYE
19695	F	1000 MG/KG/DAY	BODY/INTEG II	04-17-06	9:10	P	SCABBING FORELIMB(S)
19695	F	1000 MG/KG/DAY	ORAL/DENTAL	04-24-06	10:52	P	DRIED RED MATERIAL AROUND MOUTH
19695	F	1000 MG/KG/DAY	BODY INTEG III	04-24-06	10:52	P	DRIED RED MATERIAL FORELIMB(S)
19700	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:25	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:53	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-06-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19700	F	1000 MG/KG/DAY	NORMAL	05-08-06	9:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	8:04	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:57	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19700	F	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19701	F	1000 MG/KG/DAY	NORMAL	03-06-06	10:42	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-13-06	9:26	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-20-06	7:59	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				03-27-06	11:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-03-06	7:35	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-10-06	10:15	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-17-06	9:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				04-24-06	10:54	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-01-06	10:43	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-15-06	9:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-22-06	8:05	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				05-29-06	10:55	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
				06-06-06	6:58	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
19701	F	1000 MG/KG/DAY	DISPOSITION	06-06-06	9:31	P	PRIMARY NECROPSY (WEEK 13)
19701	F	1000 MG/KG/DAY	EYES/EARS/NOSE	05-08-06	9:54	P	DRIED RED MATERIAL AROUND RIGHT EYE

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
07/25/2006

Audited Draft

Modified: 8/30/2006

AT TIME OF DOSING

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 1

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19639	M	0 MG/KG/DAY	BEHAVIOR/CNS	05-13-06	7:26	P	UNKEMPT APPEARANCE
19639	M	0 MG/KG/DAY	BODY/INTEGUMENT	05-13-06	7:24	P	THIN
19639	M	0 MG/KG/DAY	CARDIO-PULMONARY	05-12-06	11:08	P	RESPIRATION LABORED
				05-14-06	6:46	P	RALES
19639	M	0 MG/KG/DAY	EYES/EARS/NOSE	05-12-06	11:07	P	DRIED RED MATERIAL AROUND LEFT EYE
				05-12-06	11:07	P	DRIED RED MATERIAL AROUND RIGHT EYE
				05-12-06	11:07	P	DRIED RED MATERIAL AROUND NOSE
				05-13-06	7:25	P	DRIED RED MATERIAL AROUND NOSE
19639	M	0 MG/KG/DAY	EXCRETA	05-13-06	7:24	P	DEFECATION DECREASED
				05-14-06	6:46	P	DEFECATION DECREASED
				05-14-06	6:46	P	SOFT FECES
19639	M	0 MG/KG/DAY	ORAL/DENTAL	05-12-06	11:07	P	DRIED RED MATERIAL AROUND MOUTH
				05-13-06	7:25	P	DRIED RED MATERIAL AROUND MOUTH
19639	M	0 MG/KG/DAY	BODY INTEG III	05-12-06	11:06	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-12-06	11:06	P	DRIED RED MATERIAL FORELIMB(S)
				05-13-06	7:25	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-14-06	6:47	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-14-06	6:47	P	DRIED YELLOW MATERIAL VENTRAL TRUNK
				05-14-06	6:47	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
19644	M	0 MG/KG/DAY	EYES/EARS/NOSE	06-01-06	9:12	P	DRIED RED MATERIAL AROUND NOSE
19652	M	0 MG/KG/DAY	BODY INTEG III	05-25-06	12:47	P	WET YELLOW MATERIAL ANOGENITAL AREA
19655	M	0 MG/KG/DAY	EYES/EARS/NOSE	05-28-06	9:42	P	DRIED RED MATERIAL AROUND NOSE
19655	M	0 MG/KG/DAY	SPECIAL	05-31-06	9:58	P	SWOLLEN LEFT EAR
				05-31-06	9:59	P	SWOLLEN RIGHT EAR
				05-31-06	9:59	P	REDDENED LEFT EAR
				05-31-06	9:59	P	REDDENED RIGHT EAR
				06-01-06	9:13	P	SWOLLEN LEFT EAR
				06-01-06	9:13	P	SWOLLEN RIGHT EAR
				06-01-06	9:13	P	REDDENED LEFT EAR

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19655	M	0 MG/KG/DAY	SPECIAL	06-01-06	9:13	P	REDDENED RIGHT EAR
				06-03-06	11:21	P	SWOLLEN LEFT EAR
				06-03-06	11:21	P	SWOLLEN RIGHT EAR
				06-03-06	11:21	P	REDDENED LEFT EAR
				06-03-06	11:21	P	REDDENED RIGHT EAR
				06-04-06	11:05	P	SWOLLEN LEFT EAR
19657	M	0 MG/KG/DAY	EXCRETA	04-16-06	10:23	P	URINE CONTAINING WHITE MATERIAL
19660	M	0 MG/KG/DAY	EXCRETA	04-15-06	7:28	P	URINE CONTAINING WHITE MATERIAL
				04-16-06	10:24	P	URINE CONTAINING WHITE MATERIAL
19619	M	160 MG/KG/DAY	EYES/EARS/NOSE	03-21-06	12:14	P	DRIED RED MATERIAL AROUND NOSE
19650	M	160 MG/KG/DAY	BODY/INTEGUMENT	04-05-06	10:08	P	HAIR LOSS FORELIMB(S)
19663	M	160 MG/KG/DAY	EXCRETA	04-15-06	7:39	P	URINE CONTAINING WHITE MATERIAL
				04-16-06	10:33	P	URINE CONTAINING WHITE MATERIAL
19621	M	400 MG/KG/DAY	EXCRETA	04-16-06	10:39	P	URINE CONTAINING WHITE MATERIAL
19631	M	400 MG/KG/DAY	ORAL/DENTAL	04-05-06	10:18	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	7:46	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	10:40	P	WET CLEAR MATERIAL AROUND MOUTH
				04-26-06	11:46	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	11:22	P	WET CLEAR MATERIAL AROUND MOUTH
19635	M	400 MG/KG/DAY	EYES/EARS/NOSE	04-14-06	10:34	P	DRIED RED MATERIAL AROUND RIGHT EYE
				04-15-06	7:47	P	DRIED RED MATERIAL AROUND RIGHT EYE
				04-16-06	10:42	P	RED DISCHARGE RIGHT EYE
				04-16-06	10:42	P	DRIED RED MATERIAL AROUND RIGHT EYE
				04-18-06	7:23	P	DRIED RED MATERIAL AROUND RIGHT EYE
19661	M	400 MG/KG/DAY	EYES/EARS/NOSE	05-27-06	9:57	P	DRIED RED MATERIAL AROUND NOSE
19661	M	400 MG/KG/DAY	EXCRETA	04-15-06	7:49	P	URINE CONTAINING WHITE MATERIAL
19618	M	1000 MG/KG/DAY	ORAL/DENTAL	03-30-06	10:27	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	10:30	P	WET CLEAR MATERIAL AROUND MOUTH
				04-07-06	11:02	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

AT TIME OF DOSING

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-012

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19618	M	1000 MG/KG/DAY	ORAL/DENTAL	04-11-06	9:48	P	WET CLEAR MATERIAL AROUND MOUTH
19618	M	1000 MG/KG/DAY	BODY INTEG III	05-24-06	10:32	P	WET YELLOW MATERIAL UROGENITAL AREA
19624	M	1000 MG/KG/DAY	BODY INTEG III	05-03-06	13:05	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-23-06	11:22	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-28-06	10:06	P	DRIED BROWN MATERIAL ANOGENITAL AREA
19625	M	1000 MG/KG/DAY	EXCRETA	04-16-06	10:50	P	URINE CONTAINING WHITE MATERIAL
19641	M	1000 MG/KG/DAY	EYES/EARS/NOSE	05-20-06	11:36	P	DRIED RED MATERIAL AROUND NOSE
19641	M	1000 MG/KG/DAY	ORAL/DENTAL	05-14-06	7:13	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-23-06	11:23	P	DRIED RED MATERIAL AROUND MOUTH
				05-25-06	13:13	P	DRIED CLEAR MATERIAL AROUND MOUTH
19641	M	1000 MG/KG/DAY	BODY INTEG III	05-07-06	10:37	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-07-06	10:37	P	WET YELLOW MATERIAL VENTRAL TRUNK
				05-07-06	10:37	P	WET YELLOW MATERIAL ANOGENITAL AREA
				05-18-06	11:18	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-18-06	11:18	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
				05-21-06	13:09	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-23-06	11:23	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-24-06	10:35	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-28-06	10:08	P	DRIED BROWN MATERIAL ANOGENITAL AREA
19649	M	1000 MG/KG/DAY	ORAL/DENTAL	04-05-06	10:34	P	WET CLEAR MATERIAL AROUND MOUTH
19653	M	1000 MG/KG/DAY	EXCRETA	04-16-06	10:52	P	URINE CONTAINING WHITE MATERIAL
19675	F	0 MG/KG/DAY	EXCRETA	04-15-06	7:30	P	URINE CONTAINING WHITE MATERIAL
				04-16-06	10:26	P	URINE CONTAINING WHITE MATERIAL
19683	F	0 MG/KG/DAY	EXCRETA	04-15-06	7:31	P	URINE CONTAINING WHITE MATERIAL
19698	F	0 MG/KG/DAY	EXCRETA	04-16-06	10:27	P	URINE CONTAINING WHITE MATERIAL
19709	F	0 MG/KG/DAY	SPECIAL	05-20-06	11:11	P	SWOLLEN LEFT EAR
				05-20-06	11:11	P	SWOLLEN RIGHT EAR
				05-20-06	11:11	P	REDDENED LEFT EAR
				05-20-06	11:11	P	REDDENED RIGHT EAR

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19709	F	0 MG/KG/DAY	SPECIAL	05-25-06	12:52	P	SWOLLEN LEFT EAR
				05-31-06	10:03	P	SWOLLEN LEFT EAR
				05-31-06	10:03	P	SWOLLEN RIGHT EAR
				06-01-06	9:17	P	SWOLLEN LEFT EAR
				06-01-06	9:17	P	SWOLLEN RIGHT EAR
				06-01-06	9:17	P	REDDENED LEFT EAR
				06-01-06	9:17	P	REDDENED RIGHT EAR
				06-04-06	11:08	P	SWOLLEN LEFT EAR
				06-04-06	11:09	P	SWOLLEN RIGHT EAR
				06-04-06	11:09	P	REDDENED LEFT EAR
				06-04-06	11:09	P	REDDENED RIGHT EAR
19669	F	160 MG/KG/DAY	EYES/EARS/NOSE	04-14-06	10:29	P	DRIED RED MATERIAL AROUND NOSE
				05-31-06	10:10	P	DRIED RED MATERIAL AROUND NOSE
19672	F	160 MG/KG/DAY	ORAL/DENTAL	03-09-06	8:22	P	WET RED MATERIAL AROUND MOUTH
19674	F	160 MG/KG/DAY	ORAL/DENTAL	03-12-06	9:08	P	DRIED RED MATERIAL AROUND MOUTH
19694	F	160 MG/KG/DAY	EXCRETA	04-15-06	7:42	P	URINE CONTAINING WHITE MATERIAL
				04-16-06	10:35	P	URINE CONTAINING WHITE MATERIAL
19707	F	160 MG/KG/DAY	EXCRETA	04-16-06	10:37	P	URINE CONTAINING WHITE MATERIAL
19665	F	400 MG/KG/DAY	EYES/EARS/NOSE	05-20-06	11:28	P	DRIED RED MATERIAL AROUND NOSE
				05-21-06	13:03	P	DRIED RED MATERIAL AROUND NOSE
19666	F	400 MG/KG/DAY	ORAL/DENTAL	05-11-06	8:58	P	WET CLEAR MATERIAL AROUND MOUTH
19685	F	400 MG/KG/DAY	EXCRETA	04-16-06	10:46	P	URINE CONTAINING WHITE MATERIAL
19693	F	400 MG/KG/DAY	EXCRETA	03-18-06	7:41	P	SOFT FECES
19671	F	1000 MG/KG/DAY	ORAL/DENTAL	04-05-06	10:36	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	9:53	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	10:54	P	WET RED MATERIAL AROUND MOUTH
				04-26-06	12:04	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	11:44	P	WET CLEAR MATERIAL AROUND MOUTH
				05-31-06	10:28	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

AT TIME OF DOSING

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19678	F	1000 MG/KG/DAY	ORAL/DENTAL	05-27-06	10:07	P	DRIED RED MATERIAL AROUND MOUTH
19679	F	1000 MG/KG/DAY	ORAL/DENTAL	04-15-06	8:02	P	WET CLEAR MATERIAL AROUND MOUTH
19688	F	1000 MG/KG/DAY	EXCRETA	05-26-06	8:40	P	RED MATERIAL ON CAGE FLOOR
19695	F	1000 MG/KG/DAY	EYES/EARS/NOSE	05-23-06	11:30	P	DRIED RED MATERIAL AROUND RIGHT EYE
19695	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	8:43	P	WET CLEAR MATERIAL AROUND MOUTH
19700	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	8:43	P	WET CLEAR MATERIAL AROUND MOUTH
				04-06-06	11:27	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	9:57	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	8:04	P	WET CLEAR MATERIAL AROUND MOUTH
				05-03-06	13:12	P	WET CLEAR MATERIAL AROUND MOUTH
19700	F	1000 MG/KG/DAY	BODY INTEG III	04-15-06	8:04	P	WET YELLOW MATERIAL ANOGENITAL AREA
19701	F	1000 MG/KG/DAY	ORAL/DENTAL	04-05-06	10:40	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
07/25/2006

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19636	M	0 MG/KG/DAY	EYES/EARS/NOSE	05-25-06	14:19	P	DRIED RED MATERIAL AROUND NOSE
19639	M	0 MG/KG/DAY	CARDIO-PULMONARY	05-14-06	8:27	P	RALES
19639	M	0 MG/KG/DAY	EYES/EARS/NOSE	05-13-06	9:09	P	DRIED RED MATERIAL AROUND NOSE
19639	M	0 MG/KG/DAY	EXCRETA	05-12-06	12:44	P	SOFT FECES
19639	M	0 MG/KG/DAY	ORAL/DENTAL	05-11-06	10:27	P	WET CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:09	P	DRIED RED MATERIAL AROUND MOUTH
19639	M	0 MG/KG/DAY	BODY INTEG III	05-12-06	12:44	P	WET BROWN MATERIAL ANOGENITAL AREA
				05-12-06	12:45	P	DRIED RED MATERIAL FORELIMB(S)
				05-12-06	12:45	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-13-06	9:09	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-14-06	8:27	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-14-06	8:27	P	DRIED YELLOW MATERIAL VENTRAL TRUNK
				05-14-06	8:27	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
19644	M	0 MG/KG/DAY	EYES/EARS/NOSE	06-01-06	10:52	P	DRIED RED MATERIAL AROUND NOSE
19644	M	0 MG/KG/DAY	ORAL/DENTAL	05-26-06	9:05	P	WET CLEAR MATERIAL AROUND MOUTH
19652	M	0 MG/KG/DAY	BODY INTEG III	05-25-06	14:20	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
19655	M	0 MG/KG/DAY	EXCRETA	04-16-06	11:58	P	URINE CONTAINING WHITE MATERIAL
19655	M	0 MG/KG/DAY	SPECIAL	05-31-06	11:22	P	SWOLLEN LEFT EAR
				05-31-06	11:22	P	SWOLLEN RIGHT EAR
				05-31-06	11:22	P	REDDENED LEFT EAR
				05-31-06	11:22	P	REDDENED RIGHT EAR
				06-01-06	10:51	P	SWOLLEN LEFT EAR
				06-01-06	10:51	P	SWOLLEN RIGHT EAR
				06-03-06	13:11	P	SWOLLEN LEFT EAR
				06-03-06	13:11	P	SWOLLEN RIGHT EAR
				06-03-06	13:11	P	REDDENED LEFT EAR
				06-03-06	13:11	P	REDDENED RIGHT EAR
				06-04-06	12:41	P	SWOLLEN LEFT EAR
				06-04-06	12:41	P	SWOLLEN RIGHT EAR

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19655	M	0 MG/KG/DAY	SPECIAL	06-04-06	12:41	P	REDDENED LEFT EAR
				06-04-06	12:41	P	REDDENED RIGHT EAR
19619	M	160 MG/KG/DAY	EYES/EARS/NOSE	05-19-06	13:18	P	DRIED RED MATERIAL AROUND NOSE
19619	M	160 MG/KG/DAY	ORAL/DENTAL	05-19-06	13:18	P	DRIED RED MATERIAL AROUND MOUTH
19628	M	160 MG/KG/DAY	EYES/EARS/NOSE	05-16-06	12:37	P	RED NASAL DISCHARGE
19628	M	160 MG/KG/DAY	ORAL/DENTAL	04-15-06	8:59	P	DRIED YELLOW MATERIAL AROUND MOUTH
				05-09-06	14:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:37	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:38	P	WET RED MATERIAL AROUND MOUTH
				05-29-06	12:57	P	DRIED RED MATERIAL AROUND MOUTH
19640	M	160 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:00	P	DRIED YELLOW MATERIAL AROUND MOUTH
				04-16-06	12:01	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:01	P	WET CLEAR MATERIAL VENTRAL NECK
				04-16-06	12:01	P	WET CLEAR MATERIAL FORELIMB(S)
				05-16-06	12:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:38	P	WET CLEAR MATERIAL VENTRAL NECK
19646	M	160 MG/KG/DAY	EXCRETA	04-03-06	9:17	P	RED PENILE DISCHARGE
19646	M	160 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:00	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:39	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:39	P	WET CLEAR MATERIAL VENTRAL NECK
19647	M	160 MG/KG/DAY	ORAL/DENTAL	04-27-06	13:51	P	WET CLEAR MATERIAL VENTRAL NECK
19648	M	160 MG/KG/DAY	ORAL/DENTAL	04-27-06	13:49	P	WET CLEAR MATERIAL VENTRAL NECK
				05-31-06	11:25	P	DRIED RED MATERIAL AROUND MOUTH
19654	M	160 MG/KG/DAY	ORAL/DENTAL	04-27-06	13:50	P	WET CLEAR MATERIAL VENTRAL NECK
19621	M	400 MG/KG/DAY	ORAL/DENTAL	05-09-06	14:39	P	WET CLEAR MATERIAL VENTRAL NECK
19621	M	400 MG/KG/DAY	BODY INTEG III	04-10-06	12:32	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-21-06	14:08	P	WET YELLOW MATERIAL UROGENITAL AREA
19622	M	400 MG/KG/DAY	EYES/EARS/NOSE	04-15-06	9:02	P	WET RED MATERIAL AROUND NOSE
				05-04-06	13:35	P	WET CLEAR MATERIAL AROUND NOSE

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

1 HOUR POST-DOSING

PROJECT NO.:WIL-187054 A 90-DAY REPEATED DOSE ORAL STUDY OF [redacted] IN RATS PAGE 3

SPONSOR:[redacted]

SPONSOR NO.:06-012

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19622	M	400 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:02	P	WET RED MATERIAL AROUND MOUTH
				04-27-06	13:53	P	WET CLEAR MATERIAL AROUND MOUTH
				05-04-06	13:35	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:49	P	WET CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:12	P	WET CLEAR MATERIAL AROUND MOUTH
				05-29-06	12:59	P	WET CLEAR MATERIAL AROUND MOUTH
19631	M	400 MG/KG/DAY	EYES/EARS/NOSE	04-16-06	12:08	P	DRIED RED MATERIAL AROUND NOSE
19631	M	400 MG/KG/DAY	ORAL/DENTAL	04-11-06	10:59	P	DRIED CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:03	P	DRIED RED MATERIAL AROUND MOUTH
				04-16-06	12:08	P	DRIED RED MATERIAL AROUND MOUTH
				04-19-06	13:01	P	DRIED CLEAR MATERIAL AROUND MOUTH
				04-27-06	13:53	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:55	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:39	P	WET CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:13	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:42	P	WET CLEAR MATERIAL AROUND MOUTH
				05-17-06	13:32	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:20	P	WET CLEAR MATERIAL AROUND MOUTH
				05-21-06	14:09	P	DRIED RED MATERIAL AROUND MOUTH
				05-28-06	11:18	P	DRIED RED MATERIAL AROUND MOUTH
				06-05-06	12:04	P	DRIED CLEAR MATERIAL AROUND MOUTH
19632	M	400 MG/KG/DAY	ORAL/DENTAL	04-11-06	10:59	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	10:59	P	WET CLEAR MATERIAL VENTRAL NECK
				04-11-06	10:59	P	WET CLEAR MATERIAL FORELIMB(S)
				04-16-06	12:08	P	WET CLEAR MATERIAL AROUND MOUTH
				04-19-06	13:01	P	WET CLEAR MATERIAL AROUND MOUTH
				04-27-06	13:53	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:35	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:35	P	WET CLEAR MATERIAL VENTRAL NECK

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19632	M	400 MG/KG/DAY	ORAL/DENTAL	05-05-06	12:51	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:40	P	WET CLEAR MATERIAL VENTRAL NECK
				05-16-06	12:43	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:43	P	WET CLEAR MATERIAL VENTRAL NECK
				05-16-06	12:43	P	WET CLEAR MATERIAL FORELIMB(S)
				05-24-06	11:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-28-06	11:18	P	DRIED RED MATERIAL AROUND MOUTH
19632	M	400 MG/KG/DAY	BODY INTEG III	05-05-06	12:51	P	WET YELLOW MATERIAL UROGENITAL AREA
19634	M	400 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:03	P	DRIED YELLOW MATERIAL AROUND MOUTH
				04-25-06	11:30	P	WET CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:14	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:43	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:43	P	WET CLEAR MATERIAL VENTRAL NECK
				05-16-06	12:43	P	WET CLEAR MATERIAL FORELIMB(S)
				05-19-06	13:21	P	WET CLEAR MATERIAL AROUND MOUTH
19634	M	400 MG/KG/DAY	BODY INTEG III	05-17-06	13:33	P	WET YELLOW MATERIAL UROGENITAL AREA
19635	M	400 MG/KG/DAY	EYES/EARS/NOSE	03-28-06	10:46	P	DRIED RED MATERIAL AROUND NOSE
				04-14-06	12:04	P	DRIED RED MATERIAL AROUND RIGHT EYE
				04-15-06	9:05	P	DRIED RED MATERIAL AROUND RIGHT EYE
				04-15-06	9:05	P	RED DISCHARGE RIGHT EYE
				04-15-06	9:07	P	WET CLEAR MATERIAL AROUND NOSE
				04-16-06	12:09	P	DRIED RED MATERIAL AROUND RIGHT EYE
				04-18-06	8:55	P	DRIED RED MATERIAL AROUND RIGHT EYE
				05-19-06	13:20	P	DRIED RED MATERIAL AROUND NOSE
19635	M	400 MG/KG/DAY	ORAL/DENTAL	03-24-06	10:14	P	DRIED RED MATERIAL AROUND MOUTH
				04-05-06	11:30	P	DRIED RED MATERIAL AROUND MOUTH
				04-06-06	12:37	P	WET CLEAR MATERIAL AROUND MOUTH
				04-09-06	14:47	P	DRIED RED MATERIAL AROUND MOUTH
				04-15-06	9:05	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

187054 AD

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Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19635	M	400 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:05	P	WET RED MATERIAL AROUND MOUTH
				04-15-06	9:05	P	WET CLEAR MATERIAL FORELIMB(S)
				04-25-06	11:29	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:20	P	DRIED RED MATERIAL AROUND MOUTH
19645	M	400 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:07	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:07	P	WET CLEAR MATERIAL VENTRAL NECK
				04-15-06	9:07	P	WET CLEAR MATERIAL FORELIMB(S)
				04-15-06	9:09	P	WET CLEAR MATERIAL FACIAL AREA
19645	M	400 MG/KG/DAY	BODY INTEG III	03-29-06	11:35	P	DRIED YELLOW MATERIAL UROGENITAL AREA
19656	M	400 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:09	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:09	P	WET CLEAR MATERIAL VENTRAL NECK
				04-16-06	12:09	P	WET CLEAR MATERIAL FORELIMB(S)
				04-16-06	12:09	P	DRIED RED MATERIAL AROUND MOUTH
				04-29-06	14:35	P	WET CLEAR MATERIAL AROUND MOUTH
				05-23-06	12:32	P	WET CLEAR MATERIAL AROUND MOUTH
				05-28-06	11:19	P	WET CLEAR MATERIAL AROUND MOUTH
19658	M	400 MG/KG/DAY	ORAL/DENTAL	04-27-06	13:53	P	WET CLEAR MATERIAL VENTRAL NECK
				05-05-06	12:51	P	WET CLEAR MATERIAL AROUND MOUTH
19658	M	400 MG/KG/DAY	BODY INTEG III	06-02-06	9:14	P	WET RED MATERIAL UROGENITAL AREA
19661	M	400 MG/KG/DAY	BODY INTEG III	06-02-06	9:15	P	WET RED MATERIAL UROGENITAL AREA
19618	M	1000 MG/KG/DAY	EYES/EARS/NOSE	04-05-06	11:34	P	WET RED MATERIAL AROUND NOSE
19618	M	1000 MG/KG/DAY	ORAL/DENTAL	03-22-06	12:39	P	WET CLEAR MATERIAL AROUND MOUTH
				03-24-06	10:16	P	WET CLEAR MATERIAL AROUND MOUTH
				03-25-06	8:38	P	WET YELLOW MATERIAL AROUND MOUTH
				03-29-06	11:37	P	DRIED CLEAR MATERIAL AROUND MOUTH
				03-30-06	11:51	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	10:42	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	10:42	P	WET CLEAR MATERIAL VENTRAL TRUNK
				04-02-06	11:55	P	WET CLEAR MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19618	M	1000 MG/KG/DAY	ORAL/DENTAL	04-04-06	11:16	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:34	P	WET CLEAR MATERIAL AROUND MOUTH
				04-07-06	12:14	P	WET CLEAR MATERIAL AROUND MOUTH
				04-08-06	8:52	P	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	12:35	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	11:01	P	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	9:19	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:13	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:12	P	DRIED YELLOW MATERIAL AROUND MOUTH
				05-06-06	12:46	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:52	P	WET CLEAR MATERIAL AROUND MOUTH
				05-17-06	13:34	P	WET CLEAR MATERIAL AROUND MOUTH
19618	M	1000 MG/KG/DAY	BODY INTEG III	03-25-06	8:38	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-16-06	12:52	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-24-06	11:41	P	DRIED YELLOW MATERIAL UROGENITAL AREA
19620	M	1000 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:14	P	WET CLEAR MATERIAL AROUND MOUTH
				05-06-06	12:47	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:42	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:42	P	WET CLEAR MATERIAL VENTRAL NECK
				05-16-06	12:53	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:53	P	WET CLEAR MATERIAL VENTRAL NECK
				05-17-06	13:34	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:23	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:23	P	WET CLEAR MATERIAL VENTRAL NECK
				05-21-06	14:13	P	DRIED RED MATERIAL AROUND MOUTH
19624	M	1000 MG/KG/DAY	ORAL/DENTAL	03-20-06	11:38	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	10:43	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:14	P	DRIED YELLOW MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19624	M	1000 MG/KG/DAY	ORAL/DENTAL	04-27-06	13:55	P	WET CLEAR MATERIAL AROUND MOUTH
				05-29-06	13:01	P	WET CLEAR MATERIAL AROUND MOUTH
19624	M	1000 MG/KG/DAY	BODY INTEG III	05-08-06	12:09	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-10-06	13:52	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-15-06	13:03	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-20-06	12:59	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-23-06	12:35	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-27-06	11:19	P	WET BROWN MATERIAL ANOGENITAL AREA
				05-28-06	11:21	P	DRIED BROWN MATERIAL ANOGENITAL AREA
19625	M	1000 MG/KG/DAY	ORAL/DENTAL	03-24-06	10:16	P	WET CLEAR MATERIAL AROUND MOUTH
				03-28-06	10:49	P	WET CLEAR MATERIAL AROUND MOUTH
				04-07-06	12:14	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:14	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:13	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:55	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:57	P	WET CLEAR MATERIAL AROUND MOUTH
				05-15-06	13:03	P	DRIED CLEAR MATERIAL AROUND MOUTH
19633	M	1000 MG/KG/DAY	ORAL/DENTAL	03-22-06	12:40	P	WET CLEAR MATERIAL AROUND MOUTH
				03-26-06	8:38	P	WET YELLOW MATERIAL AROUND MOUTH
				03-31-06	10:45	P	WET YELLOW MATERIAL AROUND MOUTH
				04-05-06	11:35	P	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	9:18	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:15	P	DRIED YELLOW MATERIAL AROUND MOUTH
				04-16-06	12:13	P	WET CLEAR MATERIAL AROUND MOUTH
				04-24-06	13:10	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:54	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:54	P	WET CLEAR MATERIAL FORELIMB(S)
19641	M	1000 MG/KG/DAY	ORAL/DENTAL	03-28-06	10:47	P	WET CLEAR MATERIAL AROUND MOUTH
				04-07-06	12:15	P	WET CLEAR MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19641	M	1000 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:15	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-06-06	12:47	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:54	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:54	P	WET CLEAR MATERIAL VENTRAL NECK
				05-16-06	12:54	P	WET CLEAR MATERIAL FORELIMB(S)
19641	M	1000 MG/KG/DAY	BODY INTEG III	05-03-06	14:15	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-07-06	11:57	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-07-06	11:57	P	WET YELLOW MATERIAL VENTRAL TRUNK
				05-07-06	11:57	P	WET YELLOW MATERIAL ANOGENITAL AREA
				05-08-06	12:08	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-08-06	12:08	P	WET YELLOW MATERIAL VENTRAL TRUNK
				05-08-06	12:08	P	WET YELLOW MATERIAL ANOGENITAL AREA
				05-13-06	9:16	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-13-06	9:16	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
				05-18-06	12:21	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-18-06	12:21	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
				05-20-06	13:00	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				05-20-06	13:00	P	DRIED YELLOW MATERIAL ANOGENITAL AREA
				05-21-06	14:13	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-23-06	12:35	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-24-06	11:44	P	DRIED BROWN MATERIAL ANOGENITAL AREA
				05-28-06	11:22	P	DRIED BROWN MATERIAL ANOGENITAL AREA
19643	M	1000 MG/KG/DAY	ORAL/DENTAL	03-20-06	11:39	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:16	P	DRIED RED MATERIAL AROUND MOUTH
				05-05-06	12:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-06-06	12:47	P	WET CLEAR MATERIAL AROUND MOUTH
				05-11-06	10:36	P	WET CLEAR MATERIAL AROUND MOUTH
19649	M	1000 MG/KG/DAY	ORAL/DENTAL	03-26-06	8:38	P	WET CLEAR MATERIAL AROUND MOUTH

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ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19649	M	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	10:45	P	WET RED MATERIAL AROUND MOUTH
				04-05-06	11:36	P	DRIED CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:16	P	DRIED CLEAR MATERIAL AROUND MOUTH
				04-26-06	13:04	P	WET CLEAR MATERIAL AROUND MOUTH
				05-06-06	12:47	P	WET CLEAR MATERIAL AROUND MOUTH
				05-11-06	10:36	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:55	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:55	P	WET CLEAR MATERIAL VENTRAL NECK
				05-17-06	13:35	P	WET CLEAR MATERIAL AROUND MOUTH
				05-17-06	13:35	P	WET CLEAR MATERIAL VENTRAL NECK
				05-21-06	14:13	P	DRIED RED MATERIAL AROUND MOUTH
				05-24-06	11:43	P	DRIED RED MATERIAL AROUND MOUTH
				05-25-06	14:28	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-29-06	13:01	P	WET CLEAR MATERIAL AROUND MOUTH
				05-31-06	11:35	P	WET RED MATERIAL AROUND MOUTH
19649	M	1000 MG/KG/DAY	BODY INTEG III	05-07-06	11:57	P	WET YELLOW MATERIAL UROGENITAL AREA
19653	M	1000 MG/KG/DAY	EYES/EARS/NOSE	04-22-06	11:34	P	DRIED RED MATERIAL AROUND NOSE
19653	M	1000 MG/KG/DAY	ORAL/DENTAL	03-15-06	9:56	P	DRIED CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:37	P	WET CLEAR MATERIAL AROUND MOUTH
				04-09-06	14:50	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:16	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:16	P	WET CLEAR MATERIAL AROUND MOUTH
				04-19-06	13:05	P	WET CLEAR MATERIAL AROUND MOUTH
				04-25-06	11:33	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:37	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:58	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:42	P	WET CLEAR MATERIAL VENTRAL NECK
				05-15-06	13:05	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:55	P	WET CLEAR MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19653	M	1000 MG/KG/DAY	ORAL/DENTAL	05-17-06	13:36	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:23	P	WET CLEAR MATERIAL AROUND MOUTH
				05-21-06	14:12	P	DRIED RED MATERIAL AROUND MOUTH
				05-23-06	12:36	P	DRIED RED MATERIAL AROUND MOUTH
				05-28-06	11:22	P	WET CLEAR MATERIAL AROUND MOUTH
				05-29-06	13:02	P	WET CLEAR MATERIAL AROUND MOUTH
19653	M	1000 MG/KG/DAY	BODY INTEG III	04-05-06	11:37	P	WET YELLOW MATERIAL UROGENITAL AREA
19662	M	1000 MG/KG/DAY	EYES/EARS/NOSE	05-03-06	14:15	P	WET CLEAR MATERIAL AROUND NOSE
				05-19-06	13:22	P	WET CLEAR MATERIAL AROUND NOSE
19662	M	1000 MG/KG/DAY	ORAL/DENTAL	03-22-06	12:41	P	WET CLEAR MATERIAL AROUND MOUTH
				03-23-06	11:00	P	WET CLEAR MATERIAL AROUND MOUTH
				03-26-06	8:38	P	WET CLEAR MATERIAL AROUND MOUTH
				03-29-06	11:38	P	WET CLEAR MATERIAL AROUND MOUTH
				03-30-06	11:50	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	10:46	P	WET CLEAR MATERIAL AROUND MOUTH
				04-01-06	8:08	P	WET CLEAR MATERIAL AROUND MOUTH
				04-02-06	11:54	P	WET CLEAR MATERIAL AROUND MOUTH
				04-04-06	11:17	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:37	P	WET CLEAR MATERIAL AROUND MOUTH
				04-06-06	12:40	P	WET CLEAR MATERIAL AROUND MOUTH
				04-08-06	8:51	P	WET CLEAR MATERIAL AROUND MOUTH
				04-09-06	14:49	P	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	12:36	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	11:02	P	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	9:18	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:17	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:17	P	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	11:42	P	WET CLEAR MATERIAL AROUND MOUTH
				04-18-06	8:59	P	WET CLEAR MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19662	M	1000 MG/KG/DAY	ORAL/DENTAL	04-19-06	13:05	P	WET YELLOW MATERIAL AROUND MOUTH
				04-21-06	12:36	P	WET CLEAR MATERIAL AROUND MOUTH
				04-22-06	11:34	P	WET CLEAR MATERIAL AROUND MOUTH
				04-24-06	13:11	P	WET CLEAR MATERIAL AROUND MOUTH
				04-25-06	11:33	P	WET CLEAR MATERIAL AROUND MOUTH
				04-28-06	10:51	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:37	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-01-06	13:09	P	WET CLEAR MATERIAL AROUND MOUTH
				05-02-06	12:54	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-03-06	14:15	P	WET CLEAR MATERIAL AROUND MOUTH
				05-04-06	13:39	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:58	P	WET CLEAR MATERIAL AROUND MOUTH
				05-08-06	12:10	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:41	P	WET CLEAR MATERIAL AROUND MOUTH
				05-10-06	13:53	P	WET CLEAR MATERIAL AROUND MOUTH
				05-10-06	13:53	P	WET CLEAR MATERIAL VENTRAL NECK
				05-11-06	10:36	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:56	P	WET CLEAR MATERIAL VENTRAL NECK
				05-17-06	13:36	P	WET CLEAR MATERIAL AROUND MOUTH
				05-18-06	12:22	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:22	P	WET CLEAR MATERIAL AROUND MOUTH
				05-21-06	14:11	P	WET CLEAR MATERIAL AROUND MOUTH
				05-23-06	12:36	P	WET CLEAR MATERIAL AROUND MOUTH
				05-24-06	11:42	P	WET CLEAR MATERIAL AROUND MOUTH
				05-27-06	11:19	P	WET CLEAR MATERIAL AROUND MOUTH
				05-28-06	11:22	P	WET CLEAR MATERIAL AROUND MOUTH
				05-29-06	13:02	P	WET CLEAR MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19662	M	1000 MG/KG/DAY	ORAL/DENTAL	05-30-06	13:50	P	WET CLEAR MATERIAL AROUND MOUTH
				05-31-06	11:35	P	WET CLEAR MATERIAL AROUND MOUTH
				06-03-06	13:16	P	WET CLEAR MATERIAL AROUND MOUTH
				06-04-06	12:45	P	WET CLEAR MATERIAL AROUND MOUTH
				06-05-06	12:07	P	WET CLEAR MATERIAL AROUND MOUTH
19662	M	1000 MG/KG/DAY	BODY INTEG III	06-04-06	12:45	P	WET YELLOW MATERIAL UROGENITAL AREA
19670	F	0 MG/KG/DAY	ORAL/DENTAL	04-15-06	8:31	P	WET CLEAR MATERIAL AROUND MOUTH
19683	F	0 MG/KG/DAY	EXCRETA	04-16-06	11:58	P	URINE CONTAINING WHITE MATERIAL
19692	F	0 MG/KG/DAY	EXCRETA	05-25-06	14:23	P	MUCOID FECES
19709	F	0 MG/KG/DAY	SPECIAL	05-15-06	12:53	P	SWOLLEN LEFT EAR
				05-15-06	12:53	P	SWOLLEN RIGHT EAR
				05-18-06	8:45	P	SWOLLEN RIGHT EAR
				05-20-06	12:53	P	SWOLLEN LEFT EAR
				05-20-06	12:53	P	SWOLLEN RIGHT EAR
				05-20-06	12:53	P	REDDENED LEFT EAR
				05-20-06	12:53	P	REDDENED RIGHT EAR
				05-21-06	14:02	P	SWOLLEN LEFT EAR
				05-21-06	14:03	P	SWOLLEN RIGHT EAR
				05-21-06	14:03	P	REDDENED LEFT EAR
				05-21-06	14:03	P	REDDENED RIGHT EAR
				05-25-06	14:21	P	SWOLLEN LEFT EAR
				05-31-06	11:32	P	SWOLLEN LEFT EAR
				05-31-06	11:32	P	SWOLLEN RIGHT EAR
				05-31-06	11:32	P	REDDENED LEFT EAR
				05-31-06	11:32	P	REDDENED RIGHT EAR
				06-01-06	10:53	P	SWOLLEN LEFT EAR
				06-01-06	10:53	P	SWOLLEN RIGHT EAR
				06-01-06	10:53	P	REDDENED LEFT EAR
				06-01-06	10:53	P	REDDENED RIGHT EAR

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19709	F	0 MG/KG/DAY	SPECIAL	06-03-06	13:12	P	SWOLLEN LEFT EAR
				06-03-06	13:12	P	SWOLLEN RIGHT EAR
				06-03-06	13:12	P	REDDENED LEFT EAR
				06-03-06	13:12	P	REDDENED RIGHT EAR
				06-04-06	12:42	P	SWOLLEN LEFT EAR
				06-04-06	12:42	P	SWOLLEN RIGHT EAR
				06-04-06	12:42	P	REDDENED LEFT EAR
				06-04-06	12:42	P	REDDENED RIGHT EAR
19672	F	160 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:03	P	WET CLEAR MATERIAL VENTRAL NECK
				04-16-06	12:03	P	WET CLEAR MATERIAL FORELIMB(S)
				04-16-06	12:03	P	WET CLEAR MATERIAL VENTRAL TRUNK
				04-16-06	12:05	P	WET CLEAR MATERIAL HINDLIMB(S)
19674	F	160 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:06	P	WET CLEAR MATERIAL VENTRAL TRUNK
19690	F	160 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:06	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:06	P	WET CLEAR MATERIAL VENTRAL NECK
				04-16-06	12:06	P	WET CLEAR MATERIAL FORELIMB(S)
19665	F	400 MG/KG/DAY	EYES/EARS/NOSE	04-15-06	9:10	P	RED DISCHARGE RIGHT EYE
				04-15-06	9:10	P	CLEAR DISCHARGE LEFT EYE
				05-19-06	13:21	P	WET CLEAR MATERIAL AROUND NOSE
19665	F	400 MG/KG/DAY	ORAL/DENTAL	03-28-06	10:46	P	WET CLEAR MATERIAL VENTRAL NECK
				04-15-06	9:10	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:11	P	WET CLEAR MATERIAL VENTRAL NECK
				04-15-06	9:11	P	WET CLEAR MATERIAL FORELIMB(S)
				05-05-06	12:52	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:21	P	WET CLEAR MATERIAL AROUND MOUTH
19666	F	400 MG/KG/DAY	EYES/EARS/NOSE	04-15-06	9:11	P	CLEAR DISCHARGE LEFT EYE
				04-15-06	9:11	P	CLEAR DISCHARGE RIGHT EYE
				04-15-06	9:12	P	WET RED MATERIAL AROUND NOSE
19666	F	400 MG/KG/DAY	ORAL/DENTAL	03-22-06	12:37	P	WET CLEAR MATERIAL AROUND MOUTH

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TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19666	F	400 MG/KG/DAY	ORAL/DENTAL	03-22-06	12:37	P	WET CLEAR MATERIAL VENTRAL NECK
				03-26-06	8:34	P	WET CLEAR MATERIAL AROUND MOUTH
				03-28-06	10:47	P	WET CLEAR MATERIAL AROUND MOUTH
				03-30-06	11:49	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	10:40	P	WET CLEAR MATERIAL AROUND MOUTH
				04-01-06	8:05	P	WET CLEAR MATERIAL AROUND MOUTH
				04-01-06	8:05	P	WET CLEAR MATERIAL VENTRAL NECK
				04-02-06	11:53	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:32	P	WET CLEAR MATERIAL AROUND MOUTH
				04-06-06	12:38	P	WET CLEAR MATERIAL AROUND MOUTH
				04-06-06	12:38	P	WET CLEAR MATERIAL VENTRAL NECK
				04-09-06	14:48	P	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	12:34	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	11:00	P	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	9:17	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:11	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:11	P	WET CLEAR MATERIAL VENTRAL NECK
				04-15-06	9:11	P	WET CLEAR MATERIAL FORELIMB(S)
				04-15-06	9:12	P	WET CLEAR MATERIAL FACIAL AREA
				04-19-06	13:02	P	WET CLEAR MATERIAL AROUND MOUTH
				04-20-06	10:33	P	WET CLEAR MATERIAL AROUND MOUTH
				04-21-06	12:33	P	WET CLEAR MATERIAL AROUND MOUTH
				04-24-06	13:08	P	WET CLEAR MATERIAL AROUND MOUTH
				04-25-06	11:31	P	WET CLEAR MATERIAL AROUND MOUTH
				04-28-06	10:49	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:37	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:37	P	WET CLEAR MATERIAL FACIAL AREA
				05-04-06	13:37	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:52	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19666	F	400 MG/KG/DAY	ORAL/DENTAL	05-05-06	12:52	P	WET CLEAR MATERIAL FORELIMB(S)
				05-07-06	11:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:40	P	WET CLEAR MATERIAL VENTRAL NECK
				05-10-06	13:50	P	WET CLEAR MATERIAL AROUND MOUTH
				05-10-06	13:50	P	WET CLEAR MATERIAL VENTRAL NECK
				05-11-06	10:34	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:14	P	WET CLEAR MATERIAL AROUND MOUTH
				05-15-06	13:00	P	WET CLEAR MATERIAL AROUND MOUTH
				05-19-06	13:22	P	WET CLEAR MATERIAL AROUND MOUTH
				05-20-06	12:58	P	WET CLEAR MATERIAL AROUND MOUTH
				05-23-06	12:33	P	WET CLEAR MATERIAL AROUND MOUTH
				05-24-06	11:39	P	WET CLEAR MATERIAL AROUND MOUTH
				05-26-06	9:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-27-06	11:18	P	WET CLEAR MATERIAL AROUND MOUTH
				05-28-06	11:19	P	WET CLEAR MATERIAL AROUND MOUTH
				05-29-06	13:00	P	WET CLEAR MATERIAL AROUND MOUTH
				05-31-06	11:32	P	WET CLEAR MATERIAL AROUND MOUTH
				06-05-06	12:05	P	DRIED CLEAR MATERIAL AROUND MOUTH
19667	F	400 MG/KG/DAY	EYES/EARS/NOSE	06-04-06	12:44	P	DRIED RED MATERIAL AROUND NOSE
19667	F	400 MG/KG/DAY	EXCRETA	04-16-06	12:14	P	URINE CONTAINING WHITE MATERIAL
19667	F	400 MG/KG/DAY	ORAL/DENTAL	06-04-06	12:44	P	DRIED RED MATERIAL AROUND MOUTH
19673	F	400 MG/KG/DAY	EXCRETA	04-16-06	12:15	P	URINE CONTAINING WHITE MATERIAL
19673	F	400 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:11	P	DRIED RED MATERIAL AROUND MOUTH
				04-26-06	12:57	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:36	P	WET CLEAR MATERIAL AROUND MOUTH
				05-04-06	13:37	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:53	P	WET CLEAR MATERIAL AROUND MOUTH
				05-08-06	12:08	P	DRIED RED MATERIAL AROUND MOUTH
				05-09-06	14:41	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

187054 AD

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19689	F	400 MG/KG/DAY	ORAL/DENTAL	04-09-06	14:48	P	DRIED RED MATERIAL AROUND MOUTH
				04-15-06	9:13	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:53	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:56	P	WET CLEAR MATERIAL AROUND MOUTH
				06-02-06	9:16	P	WET CLEAR MATERIAL AROUND MOUTH
19705	F	400 MG/KG/DAY	EYES/EARS/NOSE	04-16-06	12:12	P	DRIED RED MATERIAL AROUND NOSE
19671	F	1000 MG/KG/DAY	EYES/EARS/NOSE	05-02-06	12:55	P	DRIED RED MATERIAL AROUND NOSE
19671	F	1000 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:17	P	WET CLEAR MATERIAL AROUND MOUTH
				04-26-06	13:07	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:59	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:59	P	WET CLEAR MATERIAL VENTRAL NECK
				05-05-06	12:59	P	WET CLEAR MATERIAL FORELIMB(S)
				05-06-06	12:48	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:57	P	WET CLEAR MATERIAL AROUND MOUTH
				05-21-06	14:14	P	DRIED RED MATERIAL AROUND MOUTH
				05-31-06	11:36	P	DRIED RED MATERIAL AROUND MOUTH
19678	F	1000 MG/KG/DAY	ORAL/DENTAL	04-15-06	9:17	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:18	P	DRIED YELLOW MATERIAL AROUND MOUTH
				04-16-06	12:17	P	WET YELLOW MATERIAL AROUND MOUTH
				04-29-06	14:38	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:38	P	WET CLEAR MATERIAL VENTRAL NECK
				05-16-06	12:57	P	WET CLEAR MATERIAL AROUND MOUTH
				05-29-06	13:03	P	DRIED RED MATERIAL AROUND MOUTH
19679	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	10:48	P	WET YELLOW MATERIAL AROUND MOUTH
				04-03-06	9:19	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:38	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	11:04	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:18	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:18	P	DRIED RED MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19679	F	1000 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:18	P	WET RED MATERIAL AROUND MOUTH
				05-16-06	12:58	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:58	P	WET CLEAR MATERIAL VENTRAL NECK
				05-29-06	13:03	P	DRIED RED MATERIAL AROUND MOUTH
19679	F	1000 MG/KG/DAY	BODY INTEG III	04-03-06	9:19	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-14-06	8:32	P	WET YELLOW MATERIAL UROGENITAL AREA
19680	F	1000 MG/KG/DAY	ORAL/DENTAL	04-11-06	11:04	P	WET CLEAR MATERIAL AROUND MOUTH
				04-27-06	13:56	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	12:59	P	WET CLEAR MATERIAL AROUND MOUTH
				05-23-06	12:37	P	WET CLEAR MATERIAL AROUND MOUTH
19680	F	1000 MG/KG/DAY	BODY INTEG III	05-21-06	14:14	P	WET YELLOW MATERIAL UROGENITAL AREA
19681	F	1000 MG/KG/DAY	ORAL/DENTAL	03-26-06	8:39	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:19	P	DRIED YELLOW MATERIAL AROUND MOUTH
				04-16-06	12:18	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:41	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:58	P	WET CLEAR MATERIAL AROUND MOUTH
				05-21-06	14:15	P	WET CLEAR MATERIAL AROUND MOUTH
				06-03-06	13:18	P	WET CLEAR MATERIAL AROUND MOUTH
19688	F	1000 MG/KG/DAY	EYES/EARS/NOSE	04-25-06	11:35	P	DRIED RED MATERIAL AROUND NOSE
				05-02-06	12:57	P	DRIED RED MATERIAL AROUND NOSE
19688	F	1000 MG/KG/DAY	ORAL/DENTAL	04-11-06	11:04	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:19	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:19	P	DRIED RED MATERIAL AROUND MOUTH
				04-16-06	12:19	P	DRIED RED MATERIAL AROUND MOUTH
				05-08-06	12:10	P	WET CLEAR MATERIAL AROUND MOUTH
				05-11-06	10:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:16	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	12:59	P	WET CLEAR MATERIAL AROUND MOUTH
19688	F	1000 MG/KG/DAY	BODY INTEG III	03-26-06	8:40	P	WET YELLOW MATERIAL UROGENITAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19688	F	1000 MG/KG/DAY	BODY INTEG III	05-02-06	12:57	P	DRIED RED MATERIAL FORELIMB(S)
				05-13-06	9:16	P	WET YELLOW MATERIAL UROGENITAL AREA
				05-21-06	14:15	P	WET YELLOW MATERIAL UROGENITAL AREA
				06-03-06	13:17	P	WET YELLOW MATERIAL UROGENITAL AREA
				06-04-06	12:46	P	DRIED YELLOW MATERIAL UROGENITAL AREA
				06-04-06	12:46	P	DRIED YELLOW MATERIAL VENTRAL TRUNK
19691	F	1000 MG/KG/DAY	ORAL/DENTAL	04-05-06	11:39	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:19	P	WET CLEAR MATERIAL AROUND MOUTH
				04-27-06	13:55	P	WET CLEAR MATERIAL VENTRAL NECK
				04-30-06	11:40	P	DRIED RED MATERIAL AROUND MOUTH
				05-16-06	12:59	P	WET CLEAR MATERIAL AROUND MOUTH
19695	F	1000 MG/KG/DAY	EYES/EARS/NOSE	04-25-06	11:36	P	CLEAR DISCHARGE RIGHT EYE
				05-23-06	12:38	P	DRIED RED MATERIAL AROUND RIGHT EYE
19695	F	1000 MG/KG/DAY	ORAL/DENTAL	03-29-06	11:40	P	WET CLEAR MATERIAL AROUND MOUTH
				03-31-06	10:49	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:39	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:20	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:19	P	WET CLEAR MATERIAL AROUND MOUTH
				04-25-06	11:36	P	WET CLEAR MATERIAL AROUND MOUTH
				04-27-06	13:56	P	WET CLEAR MATERIAL AROUND MOUTH
				04-28-06	10:54	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:40	P	WET CLEAR MATERIAL AROUND MOUTH
				05-10-06	13:54	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	13:00	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	13:00	P	WET CLEAR MATERIAL VENTRAL NECK
19700	F	1000 MG/KG/DAY	EYES/EARS/NOSE	05-11-06	10:38	P	RED NASAL DISCHARGE
				05-19-06	13:25	P	DRIED RED MATERIAL AROUND NOSE
19700	F	1000 MG/KG/DAY	ORAL/DENTAL	03-22-06	12:42	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:40	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19700	F	1000 MG/KG/DAY	ORAL/DENTAL	04-07-06	12:16	P	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	12:20	P	DRIED CLEAR MATERIAL AROUND MOUTH
				04-17-06	11:43	P	WET CLEAR MATERIAL AROUND MOUTH
				04-26-06	13:08	P	WET CLEAR MATERIAL AROUND MOUTH
				04-27-06	13:56	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:40	P	WET CLEAR MATERIAL AROUND MOUTH
				05-05-06	13:00	P	WET CLEAR MATERIAL AROUND MOUTH
				05-07-06	11:59	P	WET CLEAR MATERIAL AROUND MOUTH
				05-09-06	14:43	P	WET CLEAR MATERIAL AROUND MOUTH
				05-11-06	10:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-15-06	13:07	P	WET CLEAR MATERIAL AROUND MOUTH
				05-15-06	13:08	P	DRIED CLEAR MATERIAL AROUND MOUTH
				05-16-06	13:00	P	WET CLEAR MATERIAL AROUND MOUTH
				05-27-06	11:20	P	DRIED RED MATERIAL AROUND MOUTH
				06-03-06	13:18	P	WET CLEAR MATERIAL AROUND MOUTH
				06-03-06	13:18	P	WET CLEAR MATERIAL VENTRAL NECK
				06-05-06	12:08	P	DRIED RED MATERIAL AROUND MOUTH
19700	F	1000 MG/KG/DAY	BODY INTEG III	05-13-06	9:17	P	WET YELLOW MATERIAL UROGENITAL AREA
19701	F	1000 MG/KG/DAY	EYES/EARS/NOSE	03-20-06	11:41	P	RED NASAL DISCHARGE
				04-16-06	12:20	P	CLEAR DISCHARGE LEFT EYE
				04-16-06	12:20	P	CLEAR DISCHARGE RIGHT EYE
19701	F	1000 MG/KG/DAY	ORAL/DENTAL	03-31-06	10:50	P	WET CLEAR MATERIAL AROUND MOUTH
				04-02-06	11:55	P	WET CLEAR MATERIAL AROUND MOUTH
				04-05-06	11:40	P	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	11:05	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:20	P	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	9:20	P	WET CLEAR MATERIAL VENTRAL NECK
				04-15-06	9:21	P	WET CLEAR MATERIAL FORELIMB(S)
				04-16-06	12:21	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Audited Draft

Modified: 8/30/2006

TABLE RANGE: 03-06-06 TO 06-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
19701	F	1000 MG/KG/DAY	ORAL/DENTAL	04-16-06	12:21	P	WET YELLOW MATERIAL AROUND MOUTH
				04-16-06	12:21	P	WET CLEAR MATERIAL VENTRAL NECK
				04-16-06	12:21	P	WET YELLOW MATERIAL VENTRAL NECK
				04-17-06	11:44	P	WET CLEAR MATERIAL AROUND MOUTH
				04-18-06	9:01	P	WET CLEAR MATERIAL AROUND MOUTH
				04-24-06	13:12	P	WET CLEAR MATERIAL AROUND MOUTH
				04-28-06	10:54	P	WET CLEAR MATERIAL AROUND MOUTH
				04-29-06	14:39	P	WET CLEAR MATERIAL AROUND MOUTH
				04-30-06	11:41	P	WET CLEAR MATERIAL AROUND MOUTH
				05-11-06	10:38	P	WET CLEAR MATERIAL AROUND MOUTH
				05-13-06	9:18	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	13:01	P	WET CLEAR MATERIAL AROUND MOUTH
				05-16-06	13:01	P	WET CLEAR MATERIAL VENTRAL NECK
				05-19-06	13:25	P	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

APPENDIX J

Study Protocol

Audited Draft

Study Number: WIL-187054

PROTOCOL AMENDMENT I

Sponsor: [redacted]

A. Title of Study:

A 90-Day Repeated-Dose Oral (Gavage) Toxicity Study of [redacted] in Rats

B. Protocol Modification:

1) **7.5.1 Test Article Preparation:**

In accordance with the study director notification dated March 2, 2006, dosing formulations will be stored at room temperature.

2) **7.5.2 Homogeneity and Stability of the Test Material Preparations:**

In accordance with the study director notification dated March 2, 2006, bulk homogeneity will be determined for all dose levels.

8.7.1 Macroscopic Examination:

3) In accordance with the study director notification dated June 1, 2006, the tissue "Jejunum" is changed to "Jejunum with Peyer's patches."

4) In accordance with the study director notification dated June 1, 2006, the tissue "Popliteal lymph nodes" is added to the list of tissues to be collected at necropsy. The separate identity of the popliteal lymph nodes will be maintained through collection, processing and examination.

5) In accordance with the study director notification dated June 3, 2006, animals will be euthanized by carbon dioxide inhalation and exsanguinated.

6) **8.7.2 Organ Weights:**

In accordance with the study director notification dated June 1, 2006, the tissue "Popliteal lymph nodes" is added to the list of organs to be weighed.

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7) **8.7.3 Microscopic Examination:**

In accordance with the study director notification dated June 1, 2006, the Peyer's patches (collected with the tissue "Jejunum") and Popliteal lymph nodes will be examined microscopically in the protocol-specified groups.

C. Reason for Protocol Modification:

1) Addition of storage conditions for dosing formulations.

2) Clarification of instructions for homogeneity determinations.

3) Modification of tissue to be collected at necropsy.

4) Addition of tissue to be collected at necropsy.

5) Clarification of method of euthanasia.

6) Addition of organ to be weighed.

7) Addition of tissues for microscopic examination.

Approved By:

[redacted]

08 June 2006
Date

Sponsor Representative

Prepared By:
WIL Research Laboratories, LLC

[redacted]

7 June 2006
Date

Study Director

[redacted]

7 June 2006
Date

Audited Draft

PROTOCOL

A 90-DAY REPEATED DOSE ORAL (GAVAGE) TOXICITY STUDY OF [redacted] IN RATS

(OECD Guideline 408)

Sponsor Number: 06-012

Submitted To:

[redacted]

Audited Draft

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

Audited Draft

1 OBJECTIVE:

The objective of this study is to evaluate the possible toxic effects of the test article when administered orally to rats for at least 90 days.

This protocol has been designed and the study will be conducted in general accordance with the OECD (Organisation for Economic Cooperation and Development) Guidelines for Testing of Chemicals, Health Effects Test Guidelines, Section 408, September 1998.

The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF), Law No. 82, 1948, Good Laboratory Practice (GLP) Standards. The study will be performed according to the protocol and WIL Standard Operating Procedures and European Union (EU) Directives 2004/9/EC and 2004/10/EC.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]
Toxicologist
[redacted]

2.2 WIL Study Director:

[redacted]

2.3 WIL Deputy Director:

[redacted]

2.4 WIL Departmental Responsibilities:

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3 STUDY SCHEDULE:

Proposed Experimental Starting Date (Animal Receipt):	February 21, 2006
Proposed Experimental Start Date:	March 6, 2006
Proposed Necropsy Dates:	June 5-6, 2006
Proposed Experimental Termination (Completion) Date:	To be amended.
Proposed Audited Draft Report Date:	To be determined.

4 TEST ARTICLE:

4.1 Identification:

[redacted]

4.2 Lot Number:

[redacted]

4.3 Purity:

100%

4.4 Stability:

The test article is considered stable under the storage conditions provided by the Sponsor.

4.5 Physical Description:

Dark brown viscous liquid.

4.6 Storage Conditions:

Store at ambient conditions.

4.7 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures.

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4.8 Personnel Safety:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A Material Safety Data Sheet (MSDS) will accompany the test article upon arrival at the laboratory.

4.9 Vehicle:

Corn oil.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Crl:CD(SD)

5.3 Source:

Charles River Laboratories
Raleigh, NC

5.4 Number of Study:

Forty-six animals of each sex will be ordered. Forty males and 40 females will be placed on study. This study is designed to use the smallest number of animals possible consistent with the objective(s) of the study. Animals not utilized on study will be deemed as part of the stock colony or euthanized by CO_2 inhalation and discarded.

5.5 Approximate Age and Weight:

Animals will be 4 to 6 weeks of age when received, and 6 to 8 weeks of age at initiation of dosing. The males will weigh approximately 160-260 g and the females approximately 110-180 g at initiation of dosing.

5.6 Identification System:

Animals will be uniquely identified by a metal eartag displaying the animal number. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex.

5.7 Justification for Selection:

This species and strain of animal is recognized to be appropriate for subchronic toxicity studies. The Sprague-Dawley rat will be used because it is a widely used strain for which significant control data are available. The number of animals is the minimum required to yield scientifically meaningful and statistically significant data.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

Weanling animals (less than approximately 35 days of age) will be housed three per cage by sex in an environmentally controlled room in clean suspended wire-mesh cages for approximately three days following receipt. If the number of animals received does not allow for all animals to be housed three per cage by sex, than some animals will be pair-housed by sex. Thereafter, the animals will be housed individually. The cages will be elevated above cage-board or other suitable material which will be changed at least three times each week.

The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71° ± 5°F (22 ± 3°C) and an average daily relative humidity of approximately 50 ± 20%. Fluorescent lighting will provide illumination for 12 hours per day. The light/dark period may be interrupted, however, to allow for protocol-specified activities. Temperature and relative humidity will be monitored continually and scheduled for automatic hourly data capturing. Ventilation rate will be set at 10 to 15 room changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-treated tap water will be available *ad libitum*. Filters servicing the automatic watering system will be changed regularly according to standard operating procedures. The municipal water supplying the laboratory will be analyzed for contaminants according to standard operating procedures to ascertain that none are present at concentrations that would be expected to affect the outcome of the study.

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6.4 Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 (meal) will be offered *ad libitum* during the study except during fasting prior to clinical pathology blood collection. Each lot utilized will be identified and recorded. Standard operating procedures provide specifications for acceptable levels of heavy metals and pesticides that are reasonably expected to be present in the diet without interfering with the purpose or conduct of the study. Each lot of feed has been analyzed by the manufacturer to assure specifications are met. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Acclimation:

Each animal will be inspected by a qualified technician upon receipt. Animals judged to be in good health will be placed immediately in acclimation for at least 10 days. All animals will be weighed and assigned a permanent animal number. During the acclimation period, each animal will be observed twice daily for changes in general appearance or behavior. The animals will be allowed a pretreatment week (as part of the acclimation period) during which body weights and food consumption will be recorded and general health will be monitored, but they will not receive the test material. All animals will receive a detailed physical examination approximately one week prior to initiation of dosing and at the time of animal selection for randomization.

7.2 Randomization:

Animals judged to be suitable for testing will be assigned to groups at random based on body weight stratification into a block design using a computer program. A printout containing the animal numbers and individual group assignments will be generated. Animals will then be arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean for each sex. If, after randomization, significant differences between groups exist, new randomizations will be generated until group mean body weights are not statistically different between groups by sex.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral by gavage since this is an acceptable and standard method for administering test article per OECD Guideline 408. Appropriate-sized flexible, Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage.

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7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of a 28-day study (WIL-187051) and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Treatment	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals	
					Males	Females
1	Vehicle	0	0	5	10	10
2	[redacted]	160	32	5	10	10
3	[redacted]	400	80	5	10	10
4	[redacted]	1000	200	5	10	10

7.4.2 Vehicle:

Corn oil will be used as the vehicle.

7.4.3 Treatment Regimen:

The test article and vehicle will be administered once daily for a minimum of 90 consecutive days (until the day prior to necropsy). Day 0 is the first day of dosing, and Day 91 is the first day of necropsy. The first week of dosing is week 0.

7.4.4 Adjustment of Dosages:

Individual doses will be adjusted weekly for the duration of the study, based on the most recent body weights.

7.5 Preparation and Analysis of Test Article Preparations:

7.5.1 Test Article Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

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7.5.2 Homogeneity and Stability of the Test Material Preparations:

Information regarding the stability of the test article in the dosing formulations will be provided by the Sponsor. Dosing mixture homogeneity in bulk preparations will be collected from high and low dose formulations prepared for the first week of dosing. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted], for analysis of homogeneity over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and stratum will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first day of formulations prepared for study weeks 0, 4, 8 and 12. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The methods employed will be one or more of the following:

[redacted] SOP #ME-125

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Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

8 PARAMETERS TO BE EVALUATED:

8.1 Viability Observations:

All animals will be observed for mortality/moribundity twice daily, once in the morning and once in the afternoon. Moribund animals will be euthanized to ensure that tissues will not be lost due to autolysis.

8.2 Clinical Observations:

8.2.1 Daily Observations:

A clinical examination will be performed daily for all animals at the time of dosing and approximately 1-2 hours after dosing. The clinical observations prior to dosing need not be recorded on the days of detailed physical examinations, provided the detailed physicals are performed prior to dosing. Observations will include, but are not limited to, changes in the skin, fur, eyes and mucous membranes; respiratory, circulatory, autonomic and central nervous systems functions; somatomotor activity and behavior patterns. Findings noted at the clinical examination will be recorded for individual animals; the condition of animals without signs will be documented in a general comment.

8.2.2 Detailed Physical Examinations:

A detailed physical examination will be conducted at least once during the pretreatment period, once weekly during the treatment period and on the day(s) of necropsy. The animals will be removed from their home cages and placed in a standard arena for observations. Observations will be detailed and carefully recorded. Where appropriate, explicitly defined scoring systems will be used if, in the opinion of the Study Director, doing so increases the utility of the data. Signs noted shall include, but are not limited to, changes in skin, fur, eyes, mucous membranes; occurrence of secretions and excretions and autonomic activity (e.g. lacrimation, piloerection, pupil size, unusual respiratory pattern). Changes in gait, posture and response to handling, as well as the presence of clonic or tonic movements, stereotypies (e.g. excessive grooming, repetitive circling) or bizarre behavior (e.g. self-mutilation, walking backwards) will be recorded. Animals without signs will be noted individually.

8.2.3 Unscheduled Observations:

A separate computer protocol will be used to collect any findings outside the above-specified observations. Only the presence of findings

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will be recorded; the absence of findings will thus not be recorded. Unscheduled observations will be included in the final report as individual animal data only.

8.3 Individual Body Weights:

Individual body weights will be recorded approximately weekly, beginning at least one week prior to test article administration, at least weekly during treatment, the day prior to the first day of scheduled necropsy (non-fasted) and on the days of necropsy (fasted).

8.4 Individual Food Consumption:

Individual food consumption will be recorded approximately weekly, beginning at least one week prior to test material administration.

8.5 Ophthalmic Examinations:

Ophthalmic examinations will be conducted by a board-certified veterinary ophthalmologist using an indirect ophthalmoscope and slit lamp biomicroscope. Prior to examination, animals will be treated with 0.5% mydriacyl. All animals will be examined prior to randomization and near the end of the dosing period.

8.6 Clinical Pathology:

The following clinical pathology parameters will be evaluated on all surviving rats just prior to their scheduled necropsy. The animals will be fasted overnight before taking blood samples. Blood for hematology and serum chemistry evaluations will be collected prior to necropsy from the retro-orbital sinus of animals anesthetized by inhalation of isoflurane. Blood for coagulation parameters will be collected from the vena cava at the time of necropsy.

Anticoagulants used will be potassium EDTA for the hematology and sodium citrate for the coagulation tests. Samples for serum chemistry will be collected without anticoagulants.

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8.6.1 Hematology:

Activated partial thromboplastin time	MCHC
Differential leukocyte count[a]	MCV
Erythrocyte count	Platelet count
Hematocrit	Prothrombin time
Hemoglobin	Reticulocyte count
MCH	Total leukocyte count

a = If performed manually, results will include platelet estimates and RBC morphology.

8.6.2 Serum Chemistry:

A/G ratio	Glucose
Alanine aminotransferase	Phosphorus
Albumin	Potassium
Alkaline phosphatase	Sodium
Aspartate aminotransferase	Total bilirubin
Calcium	Total cholesterol
Chloride	Total protein
Creatinine	Triglycerides
Globulin	Urea nitrogen

8.7 Anatomic Pathology:

8.7.1 Macroscopic Examination:

A complete necropsy will be conducted on all animals dying spontaneously, euthanized *in extremis* or at the scheduled necropsy. Animals euthanized *in extremis* or at the scheduled necropsy will be anesthetized via carbon dioxide and exsanguinated. Necropsy will include examination of the external surface, all orifices and the cranial, thoracic, abdominal and pelvic cavities (including viscera). At the time of necropsy, the following tissues and organs will be collected and placed in 10% neutral-buffered formalin (except as noted):

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Adrenals (2)
Aorta
Bone with marrow
  Sternum
Bone marrow smear (from femur[a])
Brain
  Cerebrum Level 1
  Cerebrum Level 2
  Cerebellum with medulla/pons
Epididymides (2)[c]
Exorbital lacrimal glands (2)
Eyes with optic nerve (2)[b]
Gastrointestinal tract
  Esophagus
  Stomach
  Duodenum
  Jejunum
  Ileum
  Cecum
  Colon
  Rectum
Harderian glands (2)
Heart
Kidneys (2)
Larynx
Liver (sections of two lobes)
Lungs (including bronchi, fixed by inflation with fixative)
Lymph node
  Mesenteric
  Mandibular
Mammary gland (females only)
Nasal tissues[d]
Ovaries (2) with oviducts[e]
Pancreas
Peripheral nerve (sciatic)
Pharynx
Pituitary
Prostate
Salivary glands [mandibular (2)]
Seminal vesicles (2)
Skeletal muscle (rectus femoris)
Skin
Spinal cord
  Cervical
  Thoracic
  Lumbar
Spleen
Testes (2)[c]
Thymus
Thyroids (with parathyroids[e])
Trachea
Urinary bladder
Uterus
Cervix
Vagina
All gross lesions (when possible)

a - Not taken from animals found dead, not placed in formalin; to be examined only if scientifically warranted.
b - To be placed in Davidson's solution.
c - To be placed in Bouin's solution.
d - Levels I and III according to the method of Young (Young 1981) will be examined.
e - Organ will be examined microscopically if in the plane of section, or if gross lesions are present.

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8.7.2 Organ Weights:

The following organs will be weighed from all animals at the scheduled necropsy:

Adrenals	Prostate
Brain	Seminal vesicles/coagulating gland
Epididymides	Spleen
Heart	Testes
Kidneys	Thymus
Liver	Thyroids with parathyroids*
Ovaries (with oviducts)	Uterus

* - Fixed in 10% neutral-buffered formalin prior to weighing.

Paired organs will be weighed together. Organ-to-body-weight and organ-to-brain-weight ratios will be calculated from animals euthanized at the scheduled necropsies.

8.7.3 Microscopic Examination:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the tissues listed in Section 8.7.1 from all animals in the control and high dose groups, and from all animals that die or are euthanized *in extremis*. Gross lesions will be examined from animals in Groups 2, and 3. Microscopic examination may be extended by amendment (additional cost) to include other animals if a potential target organ is noted based on histopathological examination of tissues from the high dose group or other parameters (organ weights, clinical pathology, etc.). Special stains may be used at the discretion of the pathologist to further characterize lesions and changes. Any special stains used will be documented in the individual animal data and interpretation of results will be included in the final report.

9 STATISTICAL METHODS:

All analyses will be two-tailed for significance levels of 5% and 1%. All means will be presented with standard deviations. All statistical tests will be performed using appropriate computing devices or programs. Body weights, body weight changes, food consumption, as well as clinical pathology values and absolute and relative organ weights will be analyzed by a one-way analysis of variance (ANOVA) (Snedecor, 1980). If significant differences are indicated by the ANOVA, Dunnett's test (Dunnett, 1964) will be used to compare the control and treated groups.

10 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the U.S EPA, OECD and MAFF Good Laboratory Practice regulations, and EU Directives 2004/9/ED and 2004/10/ED, adherence to the protocol and to WIL Standard Operating Procedures. The raw data and draft report will be audited by the WIL Quality Assurance Unit to assure that the final report accurately describes the conduct and the findings of the study.

This study is a regulated study and will be included on the WIL master list of regulated studies.

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11 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 12 in the Archives at WIL Research Laboratories, LLC.

12 WORK PRODUCT:

Sponsor will have title to all documentation records, raw data, slides, specimens, or other work product generated during the performance of the study. All work product including raw paper data, pertinent electronic storage media and specimens will be retained at no charge for a period of 6 months following issuance of the final report in the Archives at WIL Research Laboratories, LLC. All work product, including raw paper data, pertinent electronic storage media and specimens, will be returned to the Sponsor after a period of six months or following issuance of the final report. Any remaining formulation or clinical pathology samples will not be sent to Archives and will be discarded following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

13 REPORTS:

The final report will contain a summary, test material data, methods and procedures, appropriate individual animal and summary data tables, a copy of the protocol and amendments (if any) and an interpretation and discussion of the study results. The report will contain all information necessary to conform with current U.S. EPA, OECD, MAFF and EU specifications. The report will be comprehensive and shall

attempt to define toxicity and the no-observed-effect level(s) under the conditions of this investigation.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional electronic or paper copies of the final report may result in additional charges.

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14 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

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15 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the verbal or written permission of the Sponsor. In the event that the Sponsor verbally requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of a protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

16 REFERENCES:

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods,* 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

Young, J.T. Histopathological examination of the rat nasal cavity. *Fundamental and Applied Toxicology* **1981,** *1,* 309-312.

17 PROTOCOL APPROVAL:

Sponsor approval received via e-mail on February 20, 2006.

[redacted]

[redacted]

Feb 21, 2006
Date

WIL Research Laboratories, LLC

[redacted]

2/20/2006
Date

[redacted]

20 Feb 2006
Date

307491

COMPANY SANITIZED

ABBREVIATED REVISED DRAFT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [ ] AND [ ]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187055

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

1 March 2006

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

06-010

SPONSOR

[ ]

COMPLIANCE STATEMENT

This study, designated WIL-187055, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) Good Laboratory Practice Standards (11 Nousan No. 6283), 1 October 1999; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor. **A Certificate of Analysis was provided by the sponsor (presented in Appendix A); the characterization analyses were conducted according to Good Laboratory Practices (GLP)/unknown standards [sponsor-supplied documentation required].**

_____ _____

[ ] Date

Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] or [ ], in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to 3 groups each of 15 Crl:CD(SD) immature female rats. Dosage levels for each test article were 60, 250 and 1000 mg/kg/day, and the dosage volume was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director.

Dosing procedures were performed from 14 March 2006 through 4 April 2006, when the animals were 22 to 41 days of age; the start of dose administration was staggered, based on age. At the initiation of dose administration, body weights ranged from 42.2 g to 63.8 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[ ]	60	12	5	15
3	[ ]	250	50	5	15
4	[ ]	1000	200	5	15
5	[ ]	60	12	5	15
6	[ ]	250	50	5	15
7	[ ]	1000	200	5	15

Due to spacing constraints, the dosage group names are presented on the tables and figures as corn oil, [ ]/60, [ ]/250 and [ ]/1000 for the vehicle control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively, and [ ]/60, [

]/250 and [ ]/1000 for the 60, 250 and 1000 mg/kg/day [ ] groups, respectively.

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (100% pure corn oil, exp. dates: 1 and 23 February 2007) was placed into a storage container and stirred throughout use. The [ ] and [ ] dosing formulations were prepared as follows. The appropriate amount of test article for each group was weighed into a tared, calibrated glass container. A stir bar and approximately 80% of the vehicle were added to each container, and the mixtures were stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The [ ] and [ ] dosing formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature. Three samples from the middle stratum of the control group formulation and 3 sets of samples from the top, middle and bottom strata of the test article formulations were collected prior to the initiation of dose administration. Additional samples (3 sets) were collected for resuspension homogeneity from the same formulations following 10 days of room temperature storage. Two sets of samples for concentration verification were collected on each day of preparation and 2 sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and 6 sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC, for possible future analysis.

Thirteen dams with 10 female pups each (130 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on 28 February 2006. The pups were 6 to 8 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam for 14 to 16 days) during the acclimation period until randomization of the pups on postnatal day (PND) 21.

Following randomization, the female pups were weaned, identified by metal eartag and housed 3 per cage in plastic maternity cages. Environmental controls were set to maintain an average daily temperature of 71°F ± 5°F and an average daily relative humidity of 50% ± 20%. Actual mean daily temperatures ranged from 70.2°F to 70.8°F (21.2°C to 21.5°C) and mean daily relative humidity ranged from 38.3% to 56.1%. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse osmosis-purified water were offered ad libitum.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on postnatal day (PND) 25 (Adams et al., 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (i.e., the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia). Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A complete gross necropsy was performed only on the animal that was found dead; however, all surviving animals (euthanized on PND 42 by carbon dioxide) were examined for gross lesions (i.e., masses) at the scheduled euthanasia. In addition, at the scheduled euthanasia on PND 42, blood was collected via

the vena cava for evaluation of serum thyroxine (T_4), thyroid stimulating hormone (TSH), estradiol (E_2) and lutenizing hormone (LH) levels. Serum not utilized for these analyses was stored frozen for possible future analysis. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, adrenal glands, pituitary gland, spleen, thymus gland and thyroid glands (with parathyroid glands, following fixation) were weighed. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The ovaries, uterus (horns and body), cervix, vagina, pituitary gland, thyroid glands (with parathyroids), spleen, thymus, axillary lymph nodes and gross lesions were retained from all surviving females. Gross lesions were also retained for the single animal that was found dead.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. In addition, percent difference from control was presented for body weights, clinical pathology parameters and organ weights. Mean body weights, body weight changes, days of acquisition of vaginal patency, estrous cycle lengths, ages at the first occurrence of estrus, serum hormone levels, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
28 February 2006	Experimental starting date (animal receipt)
14 March 2006	Experimental start date (first day of dose administration)
14 March - 4 April 2006	Test article administration
5 April 2006	Last euthanasia
20 April 2006	Experimental termination/completion date (last serum hormone analysis)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS - [ ]

All females in the [ ]-treated groups survived to the scheduled euthanasia; there were no gross lesions at necropsy. Salivation and/or clear material around the mouth were noted infrequently for the 1000 mg/kg/day [ ] group females 1 hour following dose administration. These findings were attributed to the test article, but were not considered adverse.

No test article-related effects on mean body weights or body weight gains were noted in the 60, 250 and 1000 mg/kg/day [ ] groups. The only statistically significant ($p<0.05$) difference from the control group was a higher mean body weight gain in the 60 mg/kg/day [ ] group during PND 35-36.

Vaginal patency in the 1000 mg/kg/day [ ] group was attained earlier than in the control group; the difference was statistically significant ($p<0.01$). Mean ages of attainment were 32.1, 32.7, 31.7 and 28.1 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. The value in the 1000 mg/kg/day [ ] group was below the minimum mean value in the WIL historical control data for female pubertal assays (31.8 days). The value in the 250 mg/kg/day group was also slightly lower than the minimum mean value in the WIL historical control data for female pubertal assays; however, this was not considered toxicologically relevant because the value was similar to the concurrent control group. Because the females in the 1000 mg/kg/day group were younger on the day vaginal patency was observed, the mean body weight at the age of attainment of vaginal patency was statistically significantly lower ($p<0.01$) than the control group value and was lower than the minimum mean value in the WIL historical control data for female pubertal assays. The changes in these parameters in the 1000 mg/kg/day group were consistent with an interpretation of estrogenic effects resulting from the test article.

Corresponding to the earlier attainment of vaginal patency, the mean age at the first occurrence of estrus was earlier (not statistically significant) in the 1000 mg/kg/day [

] group (31.6 days) than in the concurrent control group (34.3 days). In the WIL historical control data for female pubertal assays, the mean age at the first occurrence of estrus ranged from 34.1-38.0 days. The mean age at first estrus in the 60 and 250 mg/kg/day groups (33.9 and 33.3 days, respectively) was also lower relative to the WIL historical control data. However, the values in these groups were similar to the value in the concurrent control group (34.3 days); therefore, no relationship to the test article was evident.

No differences in mean estrous cycle length were observed when the [ ]-treated groups were compared to the control group. Estrous cycle length could not be determined for 2 females each in the control, 250 and 1000 mg/kg/day [ ] groups, and for 4 females in the 60 mg/kg/day [ ] group, due to incomplete estrous cycles; estrous cycle lengths in females of this age are highly variable.

There were no test article-related effects on mean T_4, TSH, E_2 or LH values in the 60, 250 or 1000 mg/kg/day [ ] groups; none of the differences from the control group were statistically significant.

In the 1000 mg/kg/day group, the mean absolute wet uterus and luminal fluid weights were 33.7% and 65.9% lower than the concurrent control group values, respectively. The differences from the concurrent control group were not statistically significant; however, the mean absolute and relative (to final body weight) blotted uterus weights were statistically significantly lower than the concurrent control group. Based on the magnitudes of the changes and the effects on other endpoints (earlier occurrences of vaginal patency and first estrus), the lower values for luminal fluid and uterus weights were considered test article-related.

In the 60 and 250 mg/k/day groups, mean absolute wet uterus weight values were 18.4% and 14.4% lower than the control group, respectively, and mean luminal fluid weights were 53.7% and 38.9% lower than the control group value, respectively. However, the differences did not occur in a dose-related manner and were not statistically significant;

there was also no effect on the mean blotted uterus weights in these groups. In addition, there were no other indications of estrogenic effects at these dosage levels and the concurrent control group values for mean luminal fluid and absolute and relative (to final body weight) uterus weights exceeded the mean or maximum mean values in the WIL historical control data for female pubertal studies. Therefore, the apparent lower mean weights in the 60 and 250 mg/kg/day groups compared to the concurrent control group were not considered test article-related.

There were no other test article-related effects on absolute or relative (to final body weight) organ weights; differences from the control group were slight, did not occur in a dose-related manner and/or were not statistically significant. Based on the vaginal lavages performed immediately prior to euthanasia, females in estrus or proestrus numbered 8/15, 9/15, 3/15 and 2/15 in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively.

1.6. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats at a dosage level of 1000 mg/kg/day resulted lower mean luminal fluid weights and absolute and relative (to final body weight) wet and blotted uterus weights. In addition, an acceleration in the age of attainment of vaginal patency in the 1000 mg/kg/day group was accompanied by an age-related lower body weight at the age of attainment. Because of the earlier attainment of vaginal patency in this group, the mean age at the first occurrence of estrus was lower. However, there were no test article-related effects on mean estrous cycle length at any dosage level evaluated. Mean luminal fluid and uterus weights were unaffected at 60 and 250 mg/kg/day, as were attainment of vaginal patency and initiation of estrus. There were no test article-related effects on survival, body weights or serum hormone levels at any dosage level; there were no gross lesions (i.e., masses) at necropsy.

1.7. RESULTS - [ ]

A single 1000 mg/kg/day [ ] group female was found dead on PND 25 within 1 hour of dose administration. There were no clinical signs or effects on body weight prior to death; macroscopic findings consisted of red areas on the lungs and red fluid in the thoracic cavity. The death was considered a probable intubation error.

There were no test article-related clinical findings at the daily examinations or 1 hour following dose administration at any dosage level.

No test article-related effects on mean body weights or body weight gains were noted in the 60, 250 and 1000 mg/kg/day [ ] groups. The only statistically significant ($p<0.05$) difference from the control group was a slightly lower mean body weight gain in the 1000 mg/kg/day [ ] group during PND 30-31.

Vaginal patency in the 1000 mg/kg/day [ ] group was attained slightly earlier than in the control group; the difference was not statistically significant. Mean ages of attainment were 32.1, 32.5, 32.5 and 31.1 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. The value in the 1000 mg/kg/day [ ] group was below the minimum mean value in the WIL historical control data for female pubertal assays (31.8 days). Because the females were younger on the day vaginal patency was observed, the mean body weight at the age of attainment of vaginal patency in the 1000 mg/kg/day [ ] group was slightly lower (not statistically significant) than the control group value. The changes in these parameters were consistent with an interpretation of estrogenic effects resulting from the test article.

Corresponding to the earlier attainment of vaginal patency, the mean age at the first occurrence of estrus was earlier (not statistically significant) in the 1000 mg/kg/day [ ] group than in the concurrent control group. The ages of the first occurrence of estrus in the concurrent control, 60, 250 and 1000 mg/kg/day groups were 34.3, 34.5, 34.0 and 32.6 days, respectively. In the WIL historical control data for female pubertal assays, the mean ages at the first occurrence of estrus ranged from 34.1-38.0 days. While the age at

first occurrence of estrus in the 250 mg/kg/day group was also slightly lower than the minimum mean value in the WIL historical control data, no relationship to the test article was evident because the value was similar to the concurrent control group value.

No differences in mean estrous cycle length were observed when the [ ]-treated groups were compared to the control group. Estrous cycle length could not be determined for 2, 4, 2 and 3 surviving females in the control, 60, 250 and 1000 mg/kg/day [ ] groups, due to incomplete estrous cycles; estrous cycle lengths in females of this age are highly variable.

There were no test article-related effects on mean T_4, TSH, E_2 or LH values in the 60, 250 or 1000 mg/kg/day [ ] groups; none of the differences from the control group were statistically significant.

There were no test article-related gross lesions in the [ ]-treated females. Single animals were noted with an ovarian cyst (60 mg/kg/day) or a depressed area on the kidney (1000 mg/kg/day).

There were no test article-related effects on organ weights at any dosage level. In the 250 and 1000 mg/kg/day [ ] groups, apparent reductions in luminal fluid weight (61.7% and 35.0% lower than the control group, respectively), mean absolute wet uterus weights (23.3% and 14.7% lower than the control group, respectively) and relative (to final body weight) uterus weights compared to the concurrent control group did not show a clear relationship to dosage level and were not statistically significant. These apparent reductions were likely the result of a higher number of concurrent control group females in estrus or proestrus at euthanasia, which resulted in mean luminal fluid and uterus weights for the concurrent control group that were higher than the mean or maximum mean values in the WIL historical control data for female pubertal assays. Based on the vaginal lavages performed immediately prior to euthanasia, females in estrus or proestrus numbered 8/15, 7/14, 3/15 and 4/14 in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. There were no effects on absolute or relative (to final body weight)

organ weights, including wet or blotted uterus weights or luminal fluid weights, at 60 mg/kg/day [ ].

1.8. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in a slight acceleration in the age of attainment of vaginal patency in the 1000 mg/kg/day group accompanied by an age-related lower body weight at the age of attainment. Because of the earlier attainment of vaginal patency in this group, the mean age at the first occurrence of estrus was slightly lower. However, there were no test article-related effects on mean estrous cycle length at any dosage level evaluated. There were no test article-related effects on mean uterus weights or luminal fluid weights, or on survival, body weights or serum hormone levels at any dosage level.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____
[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____
[ ] Date
Senior Study Analyst

Report Reviewed By:

_____ _____
[ ] Date
Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

[ ]	Manager, Clinical Pathology
[ ]	Senior Operations Manager, Vivarium
[ ]	Manager, Gross Pathology and Developmental Toxicology Laboratory
[ ]	Group Manager, Formulations Laboratory
[ ]	Director, Metabolism and Analytical Chemistry
[ ]	Operations Manager, Developmental, Reproductive and Neurotoxicology
[ ]	Manager, Reporting and Regulatory Technical Services

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
17-Mar-2006	Vaginal Perforation	17-Mar-2006	24-Apr-2006	[ ]
17-May-2006, 18-May-2006, 19-May-2006	Study Records (I-1)	19-May-2006	26-Jun-2006	[ ]
18-May-2006, 19-May-2006	Study Records (I-2)	19-May-2006	26-Jun-2006	[ ]
06-Jun-2006	Study Records (N-1)	06-Jun-2006	25-Jul-2006	[ ]
06-Jun-2006	Study Records (C-1)	07-Jun-2006	25-Jul-2006	[ ]
08-Jun-2006, 09-Jun-2006	Draft Report	09-Jun-2006	25-Jul-2006	[ ]
07-Jun-2006, 12-Jun-2006	Study Records (C-2)	12-Jun-2006	25-Jul-2006	[ ]
12-Jun-2006	Study Records (Rx-1)	12-Jun-2006	25-Jul-2006	[ ]

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Part 792), the OECD Principles of Good Laboratory Practice, the Japanese MAFF Good Laboratory Practice Standards, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendment with the following exceptions. The data located in Appendices A (Certificates of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____
[ ] Date
Compliance Specialist

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 5.5** states that the body weight range at randomization would be 30 g to 50 g for immature females. The actual body weight range was 40.6 g to 58.2 g.
- **Protocol Section 5.7** states that the pups would be identified by tail tattoo prior to randomization and by an ear tag following randomization. In addition, the protocol states that individual cage cards would be affixed to each cage and would display the animal number, group number, study number, dosage level and sex of the animal. On PND 31, animals were placed into clean caging. At that time, new cage cards with the incorrect ear tag numbers were placed on the cages for 3 females in the 250 mg/kg/day [ ] group. The new cage cards had ear tag numbers recorded on them that did not match the original cage cards.
- **Protocol Section 7.4.4** states that individual doses would be calculated based on each daily body weight to provide the proper dosage. On PND 31, the following females in the 250 mg/kg/day [ ] group were dosed incorrectly. Female no. 20610-03 was dosed based on the body weight of female no. 20610-10 and received 256.4 mg/kg for that day. Female no. 20611-06 was dosed based on the body weight of female no. 20610-03 and received 213.8 mg/kg for that day. Female no. 20610-10 was dosed based on the body weight of female no. 20611-06 and received 288.4 mg/kg for that day.
- **Protocol Section 7.5.3** states that samples of the dosing mixtures would be collected on the first and last day of each weekly preparation and that for each time point, two 5-mL aliquots would be taken from each dosage level (including the control group formulation) for concentration analysis. On 20 March 2006, the last day of the first week of dose administration, three 5-mL samples were collected.
- **Protocol Section 7.6.4** states that daily vaginal lavages would be performed to determine the stage of estrus beginning on the day vaginal perforation was observed and continuing through the day of necropsy. Vaginal lavages were performed 1 day prior to complete vaginal opening for female no. 20604-01 in the 1000 mg/kg/day [ ] group (lavaged on PND 30, vaginal opening documented on PND 31) and female no. 20611-09 in the 1000 mg/kg/day [ ] group (lavaged on PND 35, vaginal opening documented on PND 36).

- **Protocol Section 7.6.4** states that daily vaginal lavages would be performed to determine the stage of estrus beginning on the day vaginal perforation was observed and continuing through the day of necropsy. On the day of euthanasia, the samples taken from female no. 20603-04 in the 1000 mg/kg/day [ ] group and female no. 20607-06 in the 60 mg/kg/day [ ] group were placed on the same slide. Therefore, the stage of estrus could not be determined for either female.

- **Protocol Section 7.7** states that the time of euthanasia would be recorded for each animal. The time of euthanasia was not recorded for female no. 20603-09 in the 250 mg/kg/day [ ] group, but was between 1015 hours (the time of euthanasia for the preceding animal) and 1029 hours (the time of euthanasia of the following animal).

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1-8

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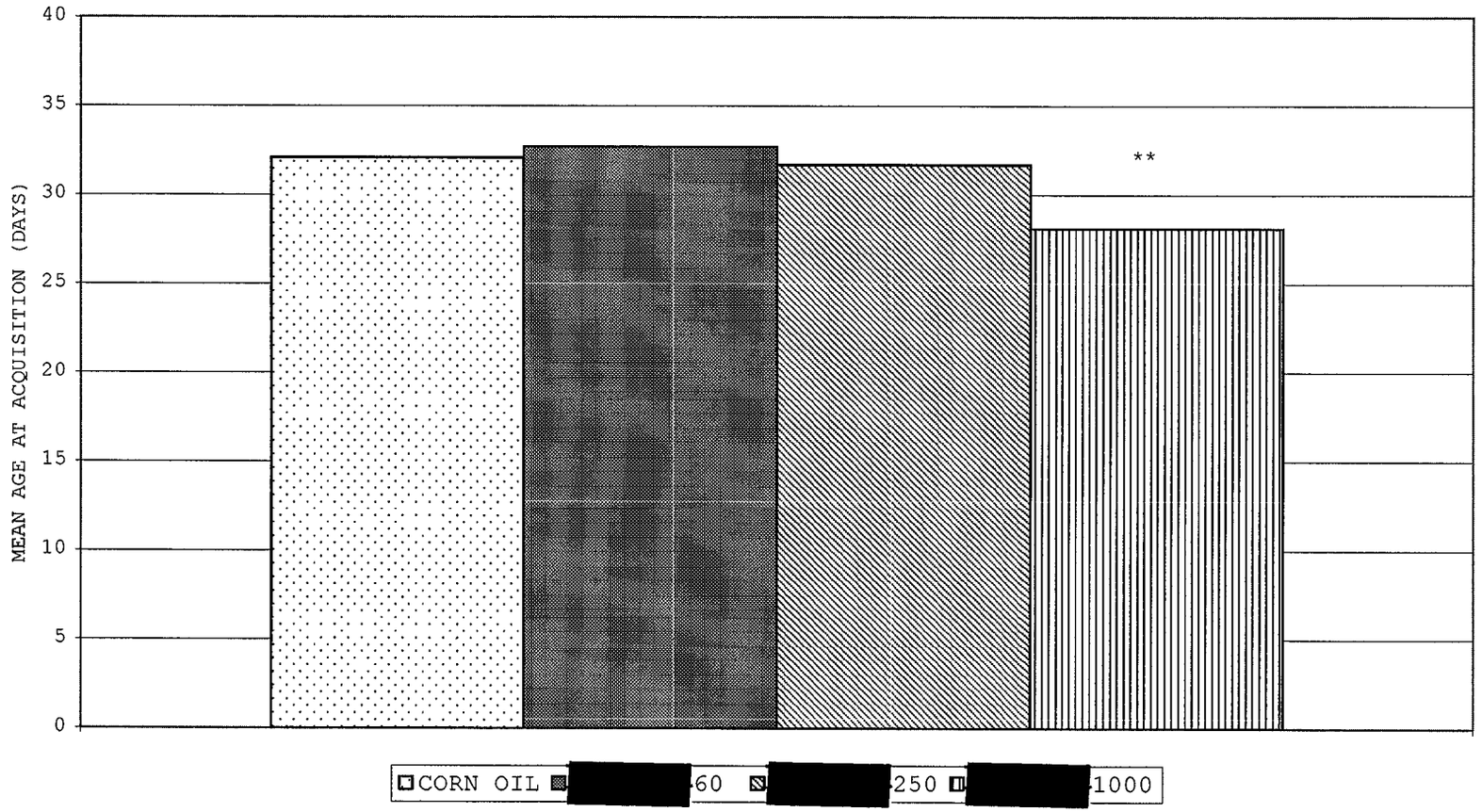
Revised Draft

PROJECT [redacted]-187055
SPONSOR [redacted]
SPONSOR [redacted]010

FIGURE 1 ([redacted])
MEAN AGE (DAYS) AT ACQUISI [redacted] VAGINAL PATENCY

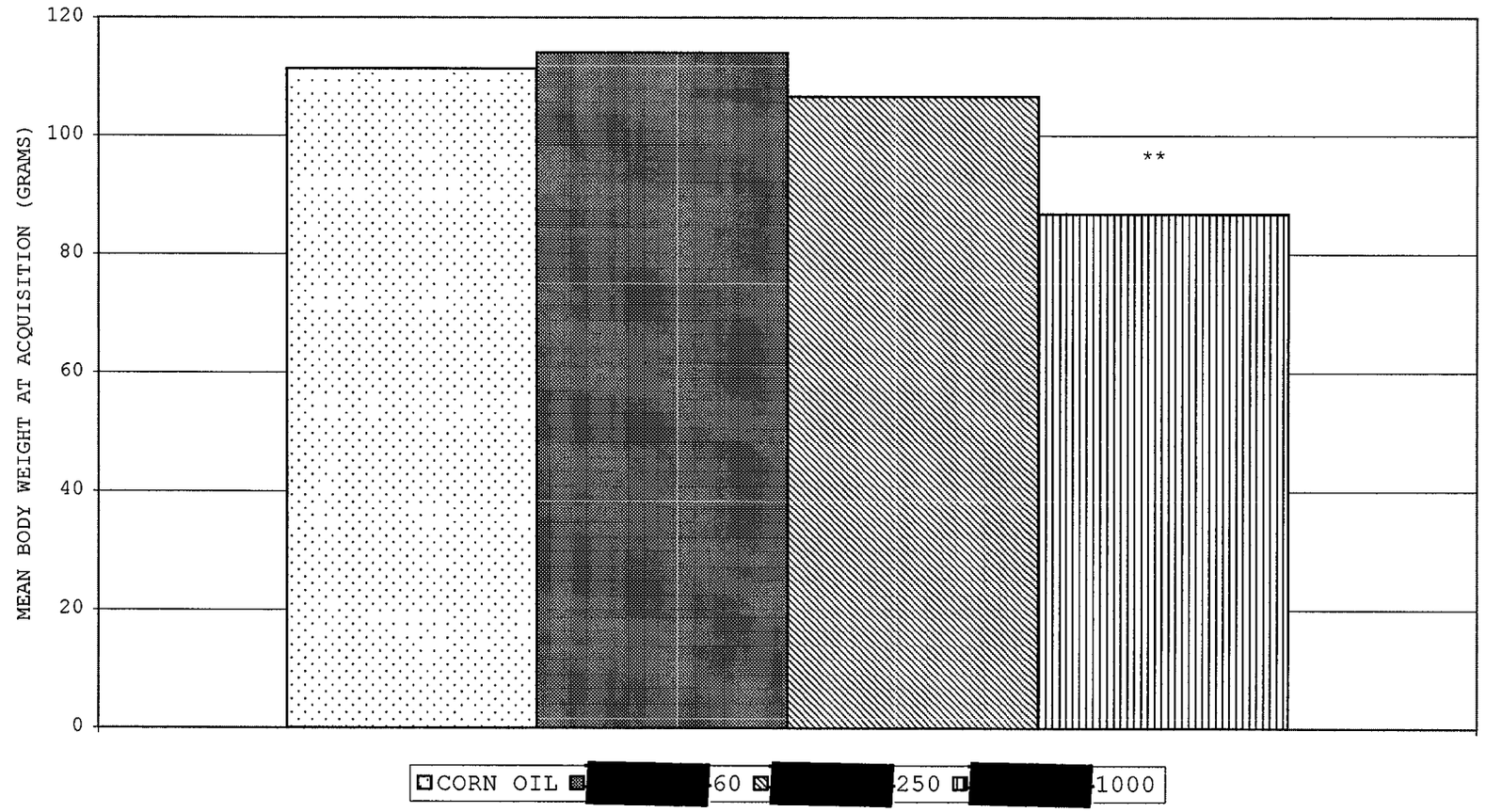


** = Significantly different from the control group at 0.01 using Dunnett's test

Revised Draft

PROJECT [redacted]-187055
SPONSOR [redacted]
SPONSOR [redacted]010

FIGURE 2 ([redacted])
MEAN WEIGHT (GRAMS) AT ACQUI[redacted]OF VAGINAL PATENCY



** = Significantly different from the control group at 0.01 using Dunnett's test

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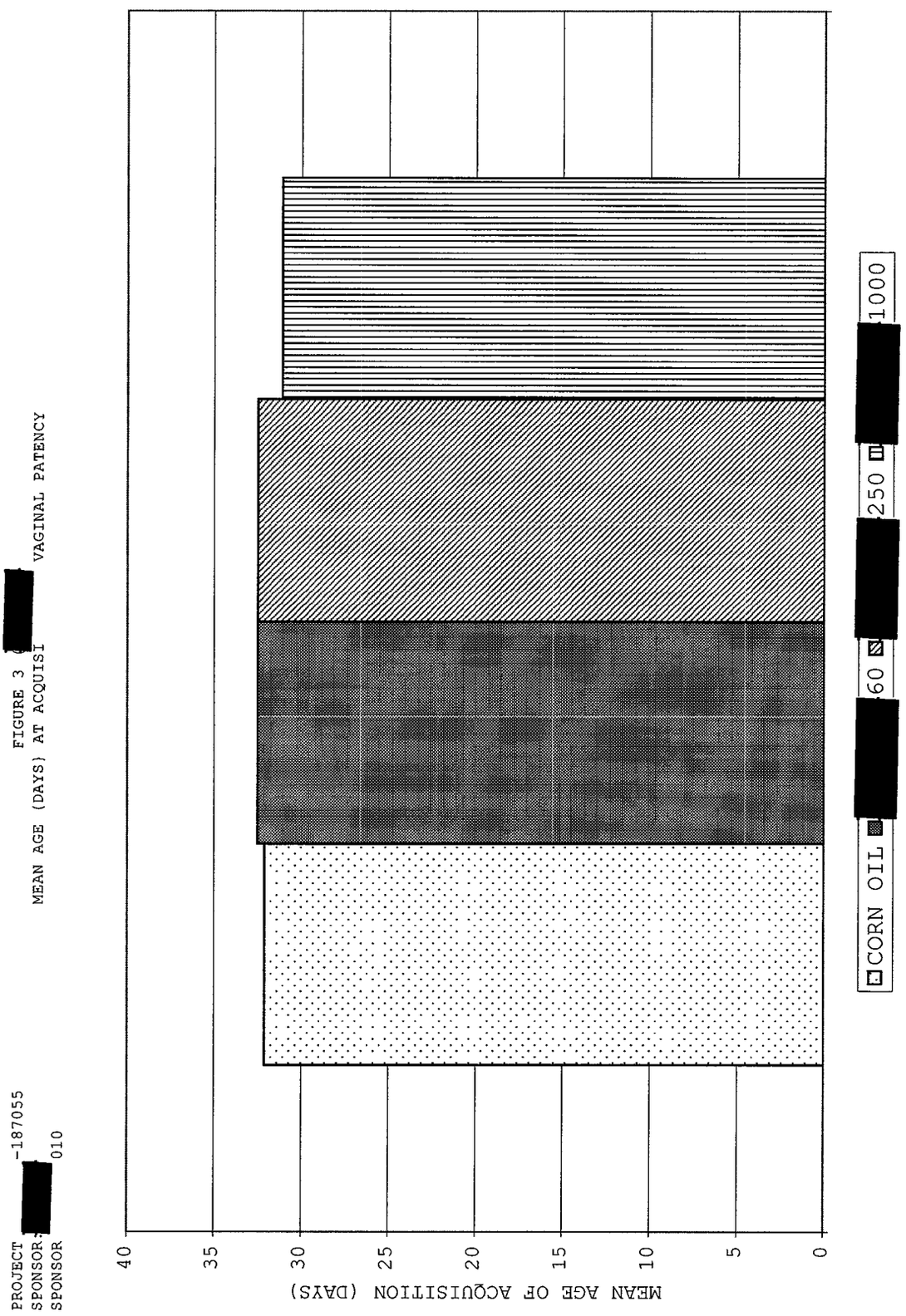

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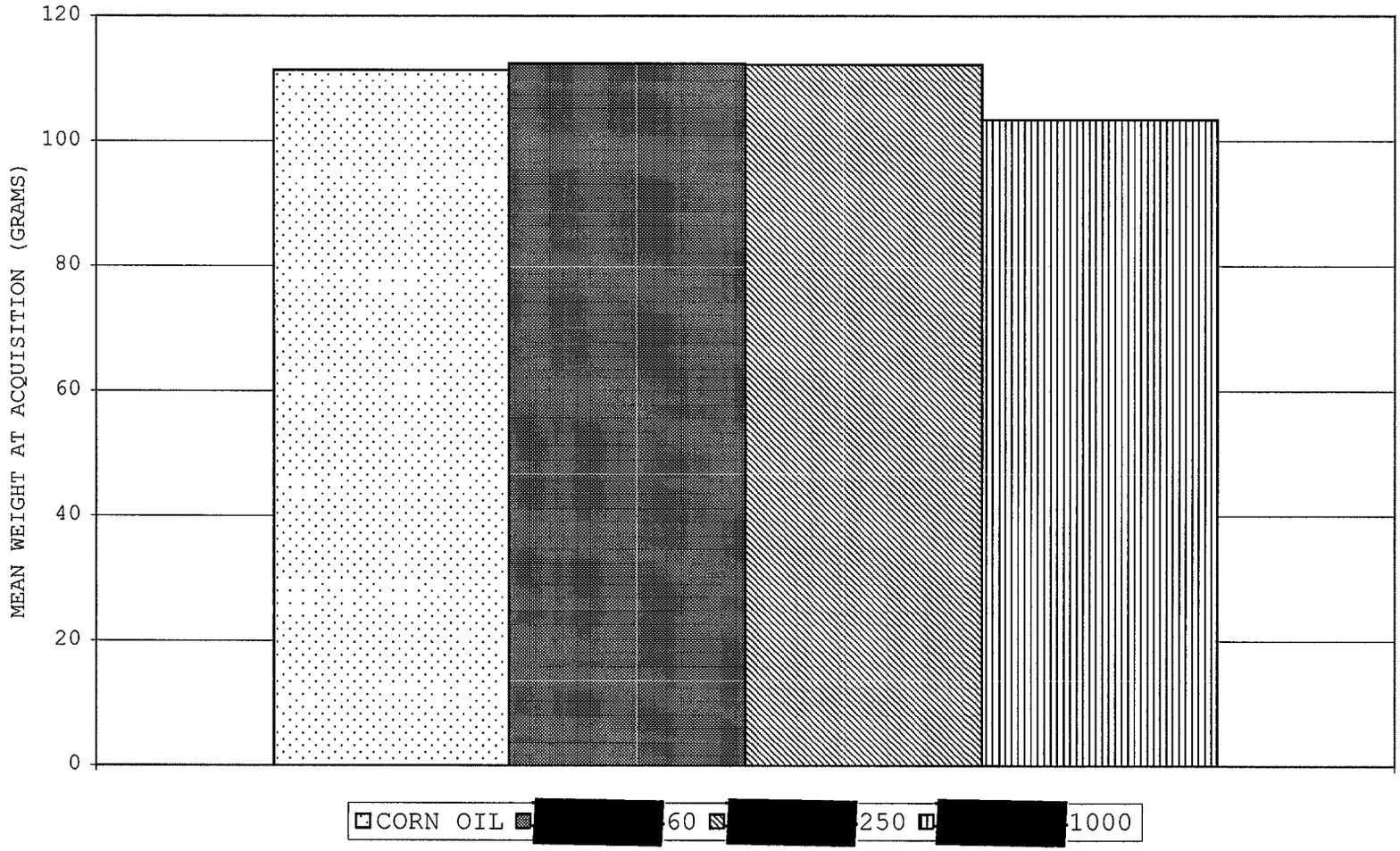
PROJECT [redacted]-187055
SPONSOR: [redacted]
SPONSOR [redacted]010

FIGURE 4 ([redacted])
MEAN WEIGHT (GRAMS) AT ACQUI[redacted]OF VAGINAL PATENCY



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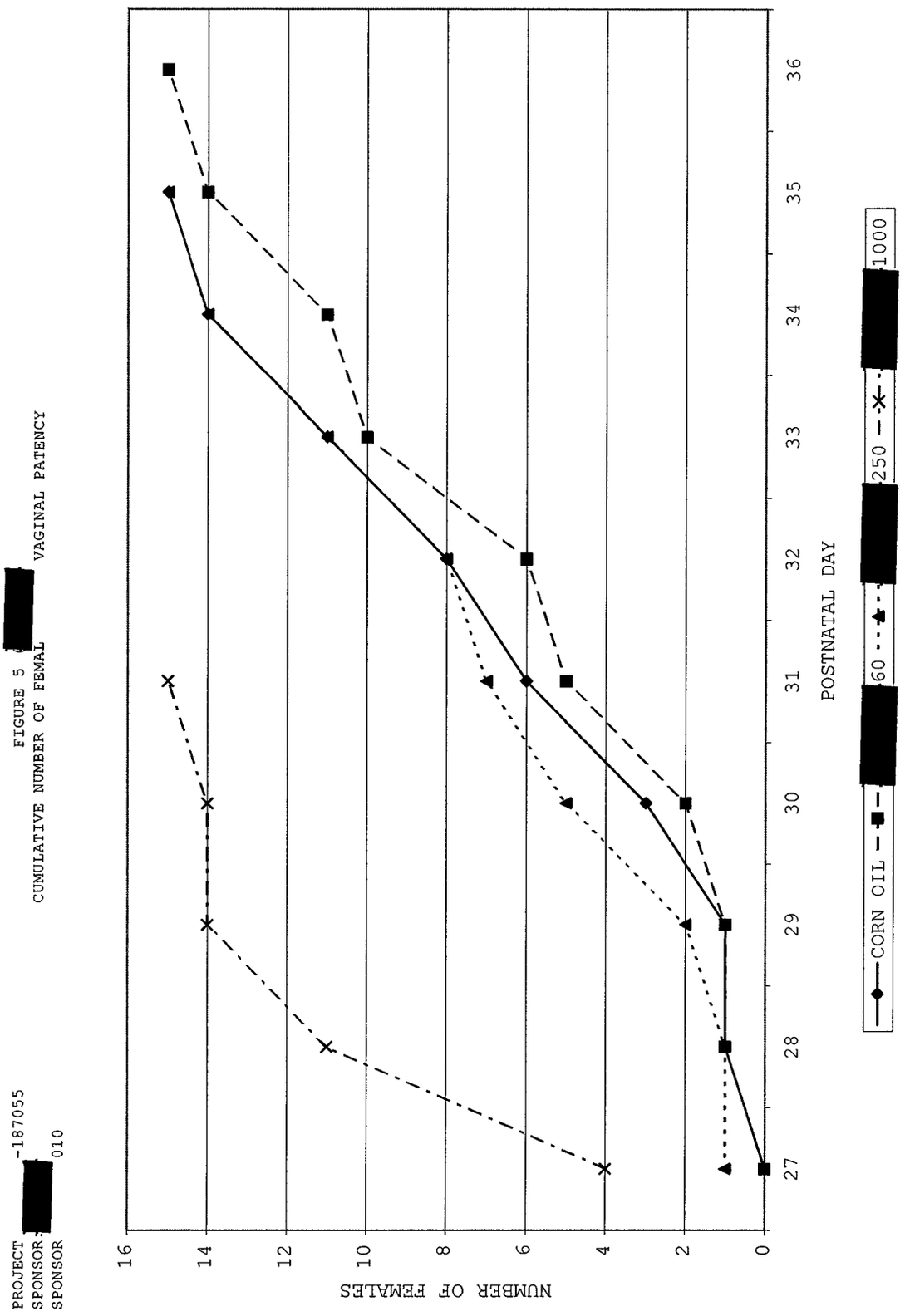

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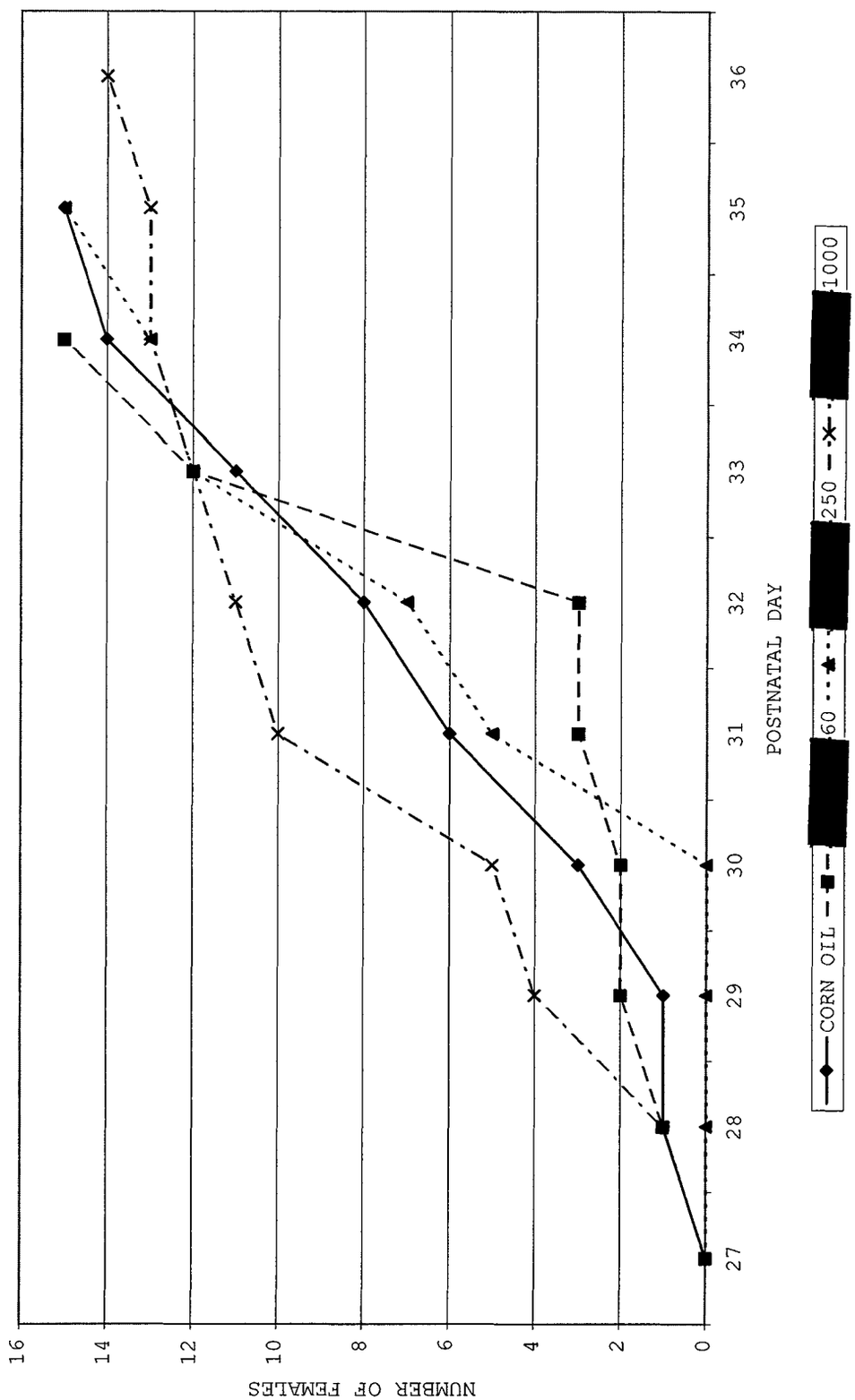
FIGURE 6 [redacted] VAGINAL PATENCY
CUMULATIVE NUMBER OF FEMAL

PROJECT [redacted]-187055
SPONSOR: [redacted]
SPONSOR 010



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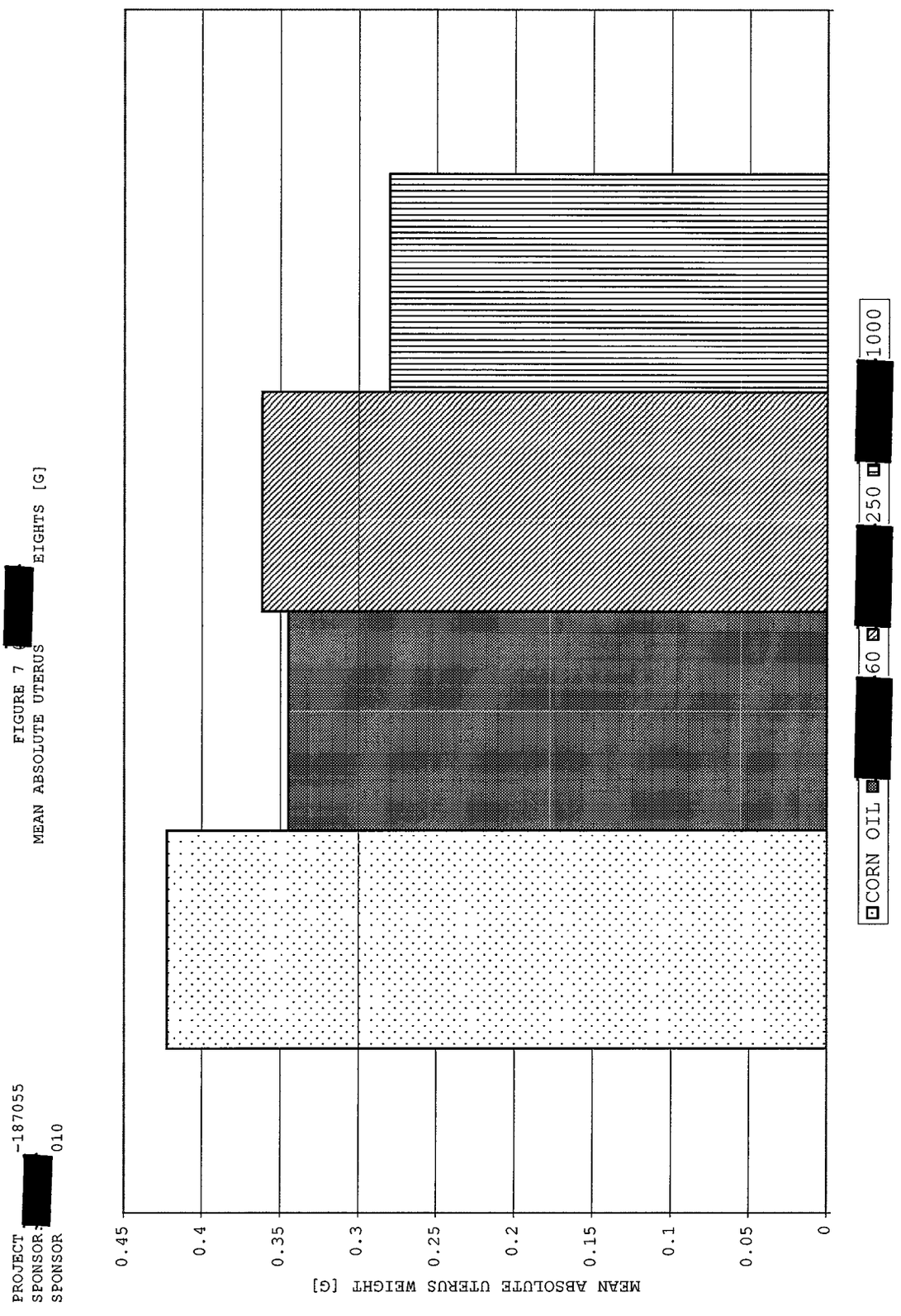

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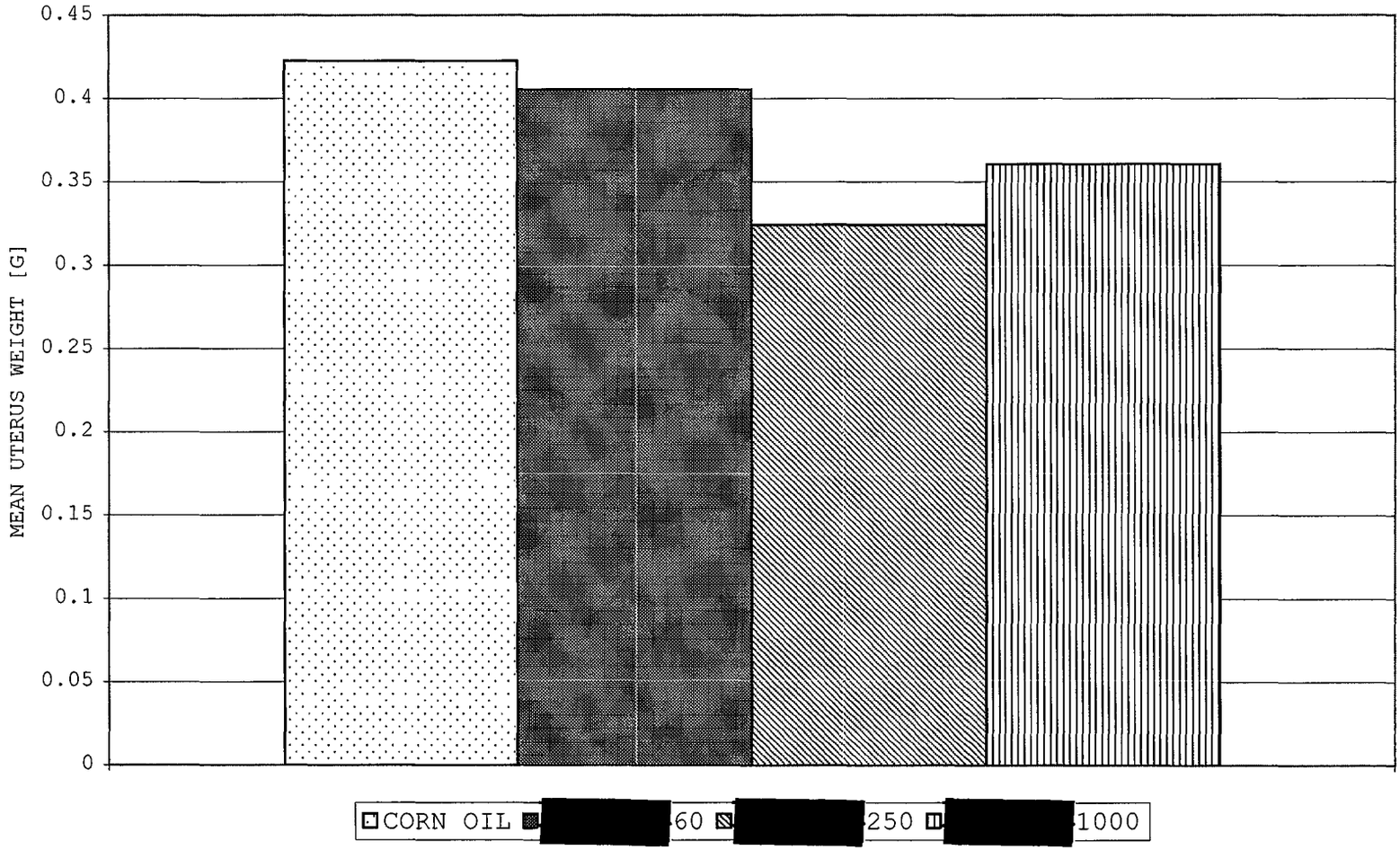
PROJECT [redacted] 187055
SPONSOR: [redacted]
SPONSOR [redacted] 010

FIGURE 8 ([redacted])
MEAN ABSOLUTE UTERUS [redacted] EIGHTS [G]



TABLES 1-22

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Modified: 6/13/2006

TABLE 1 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:06-010

----- F E M A L E -----

TABLE RANGE:	03-14-06 TO 04-05-06						
GROUP:	1	2	3	4	5	6	7
NORMAL							
-NO SIGNIFICANT CLINICAL OBSERVATIONS	315/15	315/15	308/15	314/15	315/15	314/15	297/15
DISPOSITION							
-FOUND DEAD	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-SCHEDULED EUTHANASIA	15/15	15/15	15/15	15/15	15/15	15/15	14/14
EYES/EARS/NOSE							
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	7/ 1	1/ 1	0/ 0	1/ 1	1/ 1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
06/13/2006

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TABLE 2 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	03-14-06 TO 04-04-06						
GROUP:	1	2	3	4	5	6	7
ORAL/DENTAL							
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
-SALIVATION	0/ 0	0/ 0	0/ 0	2/ 1	0/ 0	0/ 0	0/ 0
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	5/ 3	0/ 0	0/ 0	1/ 1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
05/17/2006
R:05/17/2006

Revised Draft

Modified: 6/13/2006

TABLE 3

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-010

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22								
	MEAN	53.2	53.4	53.2	53.5	53.6	53.2	53.9
	% CHANGE		0.4	0.0	0.6	0.8	0.0	1.3
	S.D.	4.02	4.86	5.21	4.19	4.70	4.08	3.37
	N	15	15	15	15	15	15	15
PND 23								
	MEAN	57.4	58.2	58.1	57.8	58.2	57.6	58.6
	% CHANGE		1.4	1.2	0.7	1.4	0.3	2.1
	S.D.	3.73	4.56	5.51	4.09	4.54	3.57	2.86
	N	15	15	15	15	15	15	15
PND 24								
	MEAN	63.4	63.5	63.7	63.9	63.8	63.4	64.3
	% CHANGE		0.2	0.5	0.8	0.6	0.0	1.4
	S.D.	4.43	4.32	5.69	4.80	4.41	3.80	3.05
	N	15	15	15	15	15	15	15
PND 25								
	MEAN	69.0	69.1	69.1	69.3	69.1	68.6	69.4
	% CHANGE		0.1	0.1	0.4	0.1	-0.6	0.6
	S.D.	4.46	4.58	5.34	4.87	4.83	3.67	3.14
	N	15	15	15	15	15	15	15
PND 26								
	MEAN	74.1	74.5	74.3	74.9	74.2	73.8	75.3
	% CHANGE		0.5	0.3	1.1	0.1	-0.4	1.6
	S.D.	4.67	4.72	5.19	5.32	5.09	3.95	3.32
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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TABLE 3

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 27								
	MEAN	79.5	79.8	80.0	80.4	79.6	79.1	80.4
	% CHANGE		0.4	0.6	1.1	0.1	-0.5	1.1
	S.D.	5.29	5.37	5.50	6.18	5.42	4.06	4.03
	N	15	15	15	15	15	15	14
PND 28								
	MEAN	85.8	85.9	85.7	86.2	85.4	85.1	85.9
	% CHANGE		0.1	-0.1	0.5	-0.5	-0.8	0.1
	S.D.	6.06	5.36	5.85	6.86	5.87	4.41	4.40
	N	15	15	15	15	15	15	14
PND 29								
	MEAN	91.6	91.3	91.4	91.7	89.9	90.4	91.6
	% CHANGE		-0.3	-0.2	0.1	-1.9	-1.3	0.0
	S.D.	6.86	6.11	6.57	8.00	5.25	4.68	4.75
	N	15	15	15	15	15	15	14
PND 30								
	MEAN	97.8	97.7	97.0	97.4	97.6	96.1	97.3
	% CHANGE		-0.1	-0.8	-0.4	-0.2	-1.7	-0.5
	S.D.	8.22	6.79	6.65	8.06	6.62	4.89	5.65
	N	15	15	15	15	15	15	14
PND 31								
	MEAN	104.6	103.1	103.9	103.9	103.5	103.4	102.7
	% CHANGE		-1.4	-0.7	-0.7	-1.1	-1.1	-1.8
	S.D.	7.53	6.90	7.15	8.55	6.79	5.47	5.99
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

Revised Draft

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TABLE 3

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR: [redacted]
SPONSOR NO.:06-010
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 32								
	MEAN	110.7	109.8	110.1	109.7	109.6	108.8	109.6
	% CHANGE		-0.8	-0.5	-0.9	-1.0	-1.7	-1.0
	S.D.	9.08	6.91	8.28	9.98	7.66	6.36	6.46
	N	15	15	15	15	15	15	14
PND 33								
	MEAN	117.2	116.0	116.3	116.2	116.5	116.0	116.3
	% CHANGE		-1.0	-0.8	-0.9	-0.6	-1.0	-0.8
	S.D.	9.41	8.36	8.50	10.59	7.94	7.03	7.12
	N	15	15	15	15	15	15	14
PND 34								
	MEAN	122.8	121.7	120.6	121.1	121.8	120.9	122.3
	% CHANGE		-0.9	-1.8	-1.4	-0.8	-1.5	-0.4
	S.D.	9.81	8.46	7.63	10.79	8.38	6.90	7.44
	N	15	15	15	15	15	15	14
PND 35								
	MEAN	128.7	125.9	124.8	125.9	126.9	124.8	126.9
	% CHANGE		-2.2	-3.0	-2.2	-1.4	-3.0	-1.4
	S.D.	10.87	8.45	9.95	12.14	9.70	7.52	8.70
	N	15	15	15	15	15	15	14
PND 36								
	MEAN	133.1	132.6	130.4	131.2	131.8	129.9	132.1
	% CHANGE		-0.4	-2.0	-1.4	-1.0	-2.4	-0.8
	S.D.	11.84	9.23	10.82	12.20	9.81	8.94	10.01
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

Revised Draft

Modified: 6/13/2006

TABLE 3

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-010

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 37								
	MEAN	139.0	136.8	134.6	136.2	136.5	135.2	137.0
	% CHANGE		-1.6	-3.2	-2.0	-1.8	-2.7	-1.4
	S.D.	12.68	9.55	11.13	13.94	10.46	9.57	11.89
	N	15	15	15	15	15	15	14
PND 38								
	MEAN	143.2	141.4	140.6	141.6	142.0	138.7	141.6
	% CHANGE		-1.3	-1.8	-1.1	-0.8	-3.1	-1.1
	S.D.	13.76	10.26	12.47	13.80	11.85	9.12	12.92
	N	15	15	15	15	15	15	14
PND 39								
	MEAN	148.1	145.7	143.8	145.5	146.3	143.0	146.0
	% CHANGE		-1.6	-2.9	-1.8	-1.2	-3.4	-1.4
	S.D.	13.42	11.57	13.14	13.83	12.29	9.35	13.65
	N	15	15	15	15	15	15	14
PND 40								
	MEAN	153.3	151.8	148.5	150.0	151.9	148.4	151.7
	% CHANGE		-1.0	-3.1	-2.2	-0.9	-3.2	-1.0
	S.D.	14.79	12.75	14.18	14.77	13.11	10.97	15.02
	N	15	15	15	15	15	15	14
PND 41								
	MEAN	158.3	156.1	152.2	153.7	156.8	152.3	155.7
	% CHANGE		-1.4	-3.9	-2.9	-0.9	-3.8	-1.6
	S.D.	15.03	13.60	14.45	13.63	13.85	12.21	15.54
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

Revised Draft

Modified: 6/13/2006

TABLE 3

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-010

	FEMALES						
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 42							
MEAN	160.8	157.5	156.1	157.9	158.4	157.4	160.9
% CHANGE		-2.1	-2.9	-1.8	-1.5	-2.1	0.1
S.D.	14.75	13.40	15.39	14.92	13.74	12.05	16.96
N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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TABLE 4

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-010

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22- 23	MEAN	4.2	4.8	4.9	4.3	4.6	4.3	4.7
	S.D.	1.18	0.86	1.25	0.81	0.74	1.23	1.48
	N	15	15	15	15	15	15	15
PND 23- 24	MEAN	5.9	5.2	5.6	6.1	5.6	5.9	5.7
	S.D.	1.04	1.12	1.15	1.33	1.26	0.84	0.68
	N	15	15	15	15	15	15	15
PND 24- 25	MEAN	5.7	5.6	5.4	5.4	5.2	5.1	5.1
	S.D.	1.08	0.99	0.91	0.89	1.19	0.57	1.05
	N	15	15	15	15	15	15	15
PND 25- 26	MEAN	5.1	5.4	5.2	5.6	5.2	5.2	5.8
	S.D.	1.10	0.99	1.04	0.68	0.71	1.19	1.10
	N	15	15	15	15	15	15	14
PND 26- 27	MEAN	5.4	5.3	5.7	5.5	5.3	5.3	5.1
	S.D.	1.05	1.15	1.23	1.08	1.31	1.03	1.20
	N	15	15	15	15	15	15	14
PND 27- 28	MEAN	6.3	6.1	5.7	5.8	5.8	6.1	5.5
	S.D.	1.62	1.21	0.98	1.00	1.30	1.26	1.02
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

Revised Draft

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TABLE 4

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28- 29								
	MEAN	5.9	5.4	5.7	5.5	4.6	5.2	5.7
	S.D.	2.75	1.15	1.12	1.49	2.16	1.21	1.07
	N	15	15	15	15	15	15	14
PND 29- 30								
	MEAN	6.2	6.4	5.6	5.7	7.6	5.7	5.7
	S.D.	3.54	1.33	1.42	1.40	2.25	1.44	1.66
	N	15	15	15	15	15	15	14
PND 30- 31								
	MEAN	6.8	5.4	6.8	6.5	6.0	7.4	5.3c
	S.D.	2.00	1.47	1.69	1.45	1.87	1.31	1.27
	N	15	15	15	15	15	15	14
PND 31- 32								
	MEAN	6.0	6.7	6.2	5.8	6.1	5.4	6.9
	S.D.	2.05	2.50	2.06	2.28	2.43	2.52	2.00
	N	15	15	15	15	15	15	14
PND 32- 33								
	MEAN	6.5	6.1	6.2	6.5	6.8	7.2	6.7
	S.D.	2.59	3.07	2.42	1.64	1.69	2.84	1.91
	N	15	15	15	15	15	15	14
PND 33- 34								
	MEAN	5.7	5.7	4.3	4.9	5.3	5.0	6.0
	S.D.	1.94	2.37	2.41	1.89	2.92	2.06	2.15
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
c = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 4

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34- 35								
	MEAN	5.9	4.2	4.3	4.8	5.1	3.9	4.6
	S.D.	2.47	1.61	3.49	2.06	3.29	1.99	1.87
	N	15	15	15	15	15	15	14
PND 35- 36								
	MEAN	4.4	6.7a	5.5	5.3	5.0	5.1	5.3
	S.D.	2.40	2.04	2.18	2.01	2.69	2.85	2.31
	N	15	15	15	15	15	15	14
PND 36- 37								
	MEAN	5.9	4.2	4.2	5.0	4.7	5.3	4.8
	S.D.	1.77	1.62	3.12	3.02	2.19	3.07	2.84
	N	15	15	15	15	15	15	14
PND 37- 38								
	MEAN	4.3	4.6	6.0	5.4	5.4	3.5	4.7
	S.D.	2.43	2.34	2.45	1.58	3.18	2.75	2.25
	N	15	15	15	15	15	15	14
PND 38- 39								
	MEAN	4.8	4.3	3.2	3.9	4.3	4.2	4.4
	S.D.	2.16	2.69	3.35	2.83	2.50	2.37	3.23
	N	15	15	15	15	15	15	14
PND 39- 40								
	MEAN	5.2	6.1	4.8	4.4	5.6	5.4	5.7
	S.D.	2.84	4.64	3.16	4.35	3.34	3.00	3.40
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 4

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-010

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40- 41								
	MEAN	5.0	4.2	3.6	3.7	5.0	4.0	4.0
	S.D.	2.07	3.45	4.23	3.54	2.79	4.48	4.51
	N	15	15	15	15	15	15	14
PND 41- 42								
	MEAN	2.5	1.4	4.0	4.2	1.5	5.0	5.2
	S.D.	2.47	3.37	3.28	2.98	3.79	3.25	4.96
	N	15	15	15	15	15	15	14
PND 22- 42								
	MEAN	107.6	104.0	103.0	104.4	104.8	104.1	106.7
	S.D.	12.06	11.20	15.78	12.12	11.87	12.68	15.36
	N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.13
06/13/2006

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TABLE 5

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
VAGINAL PATENCY (PND)							
MEAN	32.1	32.7	31.7	28.1b	32.5	32.5	31.1
S.D.	1.91	2.19	2.25	1.06	1.77	1.41	2.16
N	15	15	15	15	15	15	14
BODY WEIGHT (GRAMS)							
MEAN	111.4	114.0	106.6	86.8b	112.4	112.2	103.4
S.D.	7.55	12.45	11.50	7.08	11.66	10.00	15.00
N	15	15	15	15	15	15	14

PND= POSTNATAL DAY
MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test

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TABLE 6

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ESTROUS CYCLE DATA
SPONSOR NO.:06-010

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ESTROUS CYCLE LENGTH (DAYS)							
MEAN	5.1	4.9	5.0	5.3	4.9	4.9	5.0
S.D.	0.84	0.83	0.52	0.63	0.70	0.51	0.45
N	13	11	13	13	11	13	11
MEAN AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)							
MEAN	34.3	33.9	33.3	31.5	34.5	34.0	32.6
S.D.	2.91	3.22	3.06	2.47	2.90	1.77	2.95
N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PCYCv5.23
05/17/2006
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TABLE 7

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF SERUM HORMONE VALUES

		FEMALES						
ANALYSIS	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
TOTAL T4 (uG/dL)								
DAY 42	MEAN	5.00	5.29	4.74	5.32	5.37	5.01	4.82
	% CHANGE		5.8	-5.2	6.4	7.4	0.2	-3.6
	S.D.	1.927	0.940	0.794	1.043	0.887	1.051	0.851
	N	15	15	15	15	15	15	14
TSH (ng/mL)								
DAY 42	MEAN	7.3	7.9	7.3	7.3	7.1	6.8	7.9
	% CHANGE		8.2	0.0	0.0	-2.7	-6.8	8.2
	S.D.	1.95	2.91	2.70	2.03	1.31	1.17	2.11
	N	15	14	15	15	15	15	14
ESTRADIOL (pg/mL)								
DAY 42	MEAN	121.	125.	135.	116.	121.	127.	135.
	% CHANGE		3.3	11.6	-4.1	0.0	5.0	11.6
	S.D.	19.7	26.7	31.0	16.0	30.2	39.7	37.5
	N	14	15	15	15	15	15	14
LUTEIN' HORMONE (ng/mL)								
DAY 42	MEAN	3.7	3.4	4.1	3.3	3.6	2.9	3.0
	% CHANGE		-8.1	10.8	-10.8	-2.7	-21.6	-18.9
	S.D.	1.31	1.05	4.81	2.45	2.56	1.10	1.22
	N	15	15	15	15	15	14	14

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

PCPSv5.21
06/13/2006
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TABLE 8 (UNSCHEDULED DEATH)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF MACROSCOPIC FINDINGS

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	0	0	0	0	0	0	1
LUNGS							
-AREA(S), DARK RED	0	0	0	0	0	0	1
THORACIC CAVITY							
-CONTENTS, DARK RED FLUID	0	0	0	0	0	0	1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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06/13/2006
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TABLE 9 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

SCHEDULED NECROPSY

	----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	15	15	15	15	15	15	14
KIDNEYS							
-AREA(S), DEPRESSED	0	0	0	0	0	0	1
OVARIES							
-CYST(S)	0	0	0	0	1	0	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	15	15	15	15	14	15	13

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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TABLE 10

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS
SPONSOR NO.:06-010

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
ADRENAL GLANDS (G)							
MEAN	0.0379	0.0393	0.0393	0.0415	0.0404	0.0407	0.0403
% CHANGE		3.7	3.7	9.5	6.6	7.4	6.3
S.D.	0.00555	0.00717	0.00529	0.00744	0.00593	0.00424	0.00363
N	15	15	15	15	15	15	14
KIDNEYS (G)							
MEAN	1.6573	1.7240	1.7413	1.7447	1.7022	1.6380	1.6828
% CHANGE		4.0	5.1	5.3	2.7	-1.2	1.5
S.D.	0.14439	0.15541	0.16985	0.22438	0.15410	0.17054	0.19829
N	15	15	15	15	15	15	14
LIVER (G)							
MEAN	8.9920	8.5399	8.7728	9.3325	8.5741	8.3687	8.8392
% CHANGE		-5.0	-2.4	3.8	-4.6	-6.9	-1.7
S.D.	1.19827	1.05655	1.31211	1.20602	1.21540	1.14120	1.55063
N	15	15	15	15	15	15	14
OVARIES/OVIDUCTS (G)							
MEAN	0.0829	0.0829	0.0812	0.0784	0.0902	0.0834	0.0799
% CHANGE		0.0	-2.1	-5.4	8.8	0.6	-3.6
S.D.	0.01344	0.01556	0.01235	0.01953	0.01636	0.00952	0.01142
N	15	15	15	15	15	15	14
PITUITARY (G)							
MEAN	0.0091	0.0091	0.0086	0.0082	0.0090	0.0091	0.0092
% CHANGE		0.0	-5.5	-9.9	-1.1	0.0	1.1
S.D.	0.00166	0.00180	0.00125	0.00165	0.00185	0.00176	0.00120
N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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Modified: 6/13/2006

TABLE 10

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
SPLEEN (G)							
MEAN	0.4342	0.4297	0.4480	0.4436	0.4460	0.4598	0.4445
% CHANGE		-1.0	3.2	2.2	2.7	5.9	2.4
S.D.	0.08548	0.08924	0.07420	0.08752	0.07776	0.09763	0.07982
N	15	15	15	15	15	15	14
THYMUS (G)							
MEAN	0.5892	0.5556	0.5519	0.5791	0.5681	0.5524	0.5299
% CHANGE		-5.7	-6.3	-1.7	-3.6	-6.2	-10.1
S.D.	0.12260	0.12554	0.09922	0.11217	0.09585	0.10929	0.09960
N	15	15	15	15	15	15	14
THYROIDS/PARA (G)							
MEAN	0.0135	0.0130	0.0134	0.0142	0.0138	0.0133	0.0124
% CHANGE		-3.7	-0.7	5.2	2.2	-1.5	-8.1
S.D.	0.00359	0.00200	0.00230	0.00247	0.00261	0.00235	0.00205
N	15	15	15	15	15	15	14
UTERUS- BLOTTED (G)							
MEAN	0.3226	0.2986	0.3007	0.2462a	0.3106	0.2949	0.2956
% CHANGE		-7.4	-6.8	-23.7	-3.7	-8.6	-8.4
S.D.	0.09543	0.06989	0.07226	0.05437	0.07371	0.07678	0.07515
N	15	15	15	15	15	15	14
UTERUS- LUMINAL FLUID (G)							
MEAN	0.1001	0.0463	0.0612	0.0341	0.0948	0.0383	0.0651
% CHANGE		-53.7	-38.9	-65.9	-5.3	-61.7	-35.0
S.D.	0.10640	0.07066	0.08299	0.05551	0.13289	0.04198	0.11926
N	15	15	15	15	15	14	14
UTERUS- WET (G)							
MEAN	0.4227	0.3450	0.3619	0.2803	0.4055	0.3243	0.3607
% CHANGE		-18.4	-14.4	-33.7	-4.1	-23.3	-14.7
S.D.	0.18524	0.12998	0.12442	0.09662	0.19390	0.10213	0.17906
N	15	15	15	15	15	14	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test

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TABLE 11

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-010

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
FINAL BODY WT (G)							
MEAN	161.	157.	156.	158.	158.	157.	161.
S.D.	14.6	13.4	15.4	14.8	13.8	12.1	16.9
N	15	15	15	15	15	15	14
ADRENAL GLANDS (G/100 G FINAL BODY WEIGHT)							
MEAN	0.023	0.025	0.025	0.026	0.026	0.026	0.025
S.D.	0.0030	0.0042	0.0033	0.0034	0.0030	0.0024	0.0030
N	15	15	15	15	15	15	14
KIDNEYS (G/100 G FINAL BODY WEIGHT)							
MEAN	1.034	1.096	1.117a	1.103a	1.076	1.041	1.046
S.D.	0.0892	0.0703	0.0478	0.0854	0.0612	0.0850	0.0593
N	15	15	15	15	15	15	14
LIVER (G/100 G FINAL BODY WEIGHT)							
MEAN	5.573	5.422	5.601	5.887	5.395	5.303	5.457
S.D.	0.3356	0.4324	0.3639	0.3405	0.4134	0.4608	0.4478
N	15	15	15	15	15	15	14
OVARIES/OVIDUCTS (G/100 G FINAL BODY WEIGHT)							
MEAN	0.051	0.053	0.052	0.049	0.057	0.053	0.050
S.D.	0.0062	0.0086	0.0080	0.0101	0.0083	0.0072	0.0083
N	15	15	15	15	15	15	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test

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Modified: 6/13/2006

TABLE 11

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-010

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PITUITARY (G/100 G FINAL BODY WEIGHT)							
MEAN	0.006	0.006	0.006	0.005	0.006	0.006	0.006
S.D.	0.0010	0.0011	0.0008	0.0007	0.0013	0.0010	0.0005
N	15	15	15	15	15	15	14
SPLEEN (G/100 G FINAL BODY WEIGHT)							
MEAN	0.269	0.271	0.287	0.281	0.281	0.291	0.275
S.D.	0.0401	0.0382	0.0354	0.0513	0.0373	0.0487	0.0312
N	15	15	15	15	15	15	14
THYMUS (G/100 G FINAL BODY WEIGHT)							
MEAN	0.368	0.354	0.354	0.366	0.361	0.349	0.331
S.D.	0.0781	0.0786	0.0512	0.0624	0.0659	0.0513	0.0680
N	15	15	15	15	15	15	14
THYROIDS/PARA (G/100 G FINAL BODY WEIGHT)							
MEAN	0.009	0.008	0.009	0.009	0.009	0.009	0.008
S.D.	0.0019	0.0015	0.0019	0.0019	0.0013	0.0016	0.0017
N	15	15	15	15	15	15	14
UTERUS- BLOTTED (G/100 G FINAL BODY WEIGHT)							
MEAN	0.200	0.189	0.193	0.155a	0.198	0.187	0.184
S.D.	0.0547	0.0374	0.0434	0.0307	0.0547	0.0476	0.0428
N	15	15	15	15	15	15	14

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For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test

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TABLE 11

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
UTERUS- WET (G/100 G FINAL BODY WEIGHT)							
MEAN	0.261	0.217	0.234	0.177	0.261	0.207	0.223
S.D.	0.1135	0.0707	0.0849	0.0620	0.1407	0.0699	0.1042
N	15	15	15	15	15	14	14

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group

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05/17/2006

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TABLE 12 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 03-14-06 TO 04-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
20605-10	F	CORN OIL	DISPOSITION	04-03-06	8:38	P	SCHEDULED EUTHANASIA
20603-03	F	CORN OIL	DISPOSITION	04-03-06	8:38	P	SCHEDULED EUTHANASIA
20607-08	F	CORN OIL	DISPOSITION	04-03-06	8:38	P	SCHEDULED EUTHANASIA
20606-09	F	CORN OIL	DISPOSITION	04-03-06	8:38	P	SCHEDULED EUTHANASIA
20604-03	F	CORN OIL	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20603-01	F	CORN OIL	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20605-08	F	CORN OIL	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20608-02	F	CORN OIL	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20609-08	F	CORN OIL	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20611-01	F	CORN OIL	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20610-04	F	CORN OIL	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20609-04	F	CORN OIL	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20613-03	F	CORN OIL	DISPOSITION	04-05-06	7:27	P	SCHEDULED EUTHANASIA
20615-03	F	CORN OIL	DISPOSITION	04-05-06	7:28	P	SCHEDULED EUTHANASIA
20612-03	F	CORN OIL	DISPOSITION	04-05-06	7:28	P	SCHEDULED EUTHANASIA
20607-09	F	[redacted]60	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20605-05	F	[redacted]60	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20606-02	F	[redacted]60	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20604-08	F	[redacted]60	DISPOSITION	04-03-06	8:39	P	SCHEDULED EUTHANASIA
20603-10	F	[redacted]60	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20604-09	F	[redacted]60	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20607-03	F	[redacted]60	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20609-05	F	[redacted]60	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20608-07	F	[redacted]60	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20610-05	F	[redacted]60	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20611-07	F	[redacted]60	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20610-07	F	[redacted]60	DISPOSITION	04-04-06	7:24	P	SCHEDULED EUTHANASIA
20613-06	F	[redacted]60	DISPOSITION	04-05-06	7:28	P	SCHEDULED EUTHANASIA
20612-07	F	[redacted]60	DISPOSITION	04-05-06	7:29	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 6/13/2006

TABLE 12 (DAILY OBSERVATIONS)

SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-010

TABLE RANGE: 03-14-06 TO 04-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
20615-07	F	[redacted]60	DISPOSITION	04-05-06	7:29	P	SCHEDULED EUTHANASIA
20606-07	F	[redacted]250	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20603-09	F	[redacted]250	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20607-01	F	[redacted]250	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20604-02	F	[redacted]250	DISPOSITION	04-03-06	8:40	P	SCHEDULED EUTHANASIA
20604-02	F	[redacted]250	EYES/EARS/NOSE	03-14-06	9:55	1	DRIED RED MATERIAL AROUND NOSE
				03-19-06	10:52	1	DRIED RED MATERIAL AROUND NOSE
				03-20-06	10:38	1	DRIED RED MATERIAL AROUND NOSE
				03-21-06	10:16	1	DRIED RED MATERIAL AROUND NOSE
				03-25-06	6:46	1	DRIED RED MATERIAL AROUND NOSE
				03-26-06	6:31	1	DRIED RED MATERIAL AROUND NOSE
				04-01-06	11:21	1	DRIED RED MATERIAL AROUND NOSE
20605-01	F	[redacted]250	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20605-04	F	[redacted]250	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20606-05	F	[redacted]250	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20608-08	F	[redacted]250	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20609-09	F	[redacted]250	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20610-02	F	[redacted]250	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20611-02	F	[redacted]250	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20611-05	F	[redacted]250	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20608-10	F	[redacted]250	DISPOSITION	04-04-06	7:43	P	SCHEDULED EUTHANASIA
20613-08	F	[redacted]250	DISPOSITION	04-05-06	7:29	P	SCHEDULED EUTHANASIA
20614-01	F	[redacted]250	DISPOSITION	04-05-06	7:29	P	SCHEDULED EUTHANASIA
20606-10	F	[redacted]1000	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20605-07	F	[redacted]1000	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20604-04	F	[redacted]1000	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20603-04	F	[redacted]1000	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20607-05	F	[redacted]1000	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA
20604-01	F	[redacted]1000	DISPOSITION	04-03-06	8:41	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 12 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-010

TABLE RANGE: 03-14-06 TO 04-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
20606-01	F	1000	DISPOSITION	04-03-06	8:42	P	SCHEDULED EUTHANASIA
20608-03	F	1000	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20609-01	F	1000	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20611-03	F	1000	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20610-06	F	1000	DISPOSITION	04-04-06	7:25	P	SCHEDULED EUTHANASIA
20610-06	F	1000	EYES/EARS/NOSE	04-04-06	7:05	1	DRIED RED MATERIAL AROUND NOSE
20610-08	F	1000	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20608-01	F	1000	DISPOSITION	04-04-06	7:44	P	SCHEDULED EUTHANASIA
20612-05	F	1000	DISPOSITION	04-05-06	7:30	P	SCHEDULED EUTHANASIA
20613-01	F	1000	DISPOSITION	04-05-06	7:30	P	SCHEDULED EUTHANASIA
20606-08	F	60	DISPOSITION	04-03-06	8:42	P	SCHEDULED EUTHANASIA
20605-02	F	60	DISPOSITION	04-03-06	8:42	P	SCHEDULED EUTHANASIA
20607-06	F	60	DISPOSITION	04-03-06	8:42	P	SCHEDULED EUTHANASIA
20603-06	F	60	DISPOSITION	04-03-06	8:42	P	SCHEDULED EUTHANASIA
20604-06	F	60	DISPOSITION	04-03-06	8:42	P	SCHEDULED EUTHANASIA
20606-03	F	60	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20607-02	F	60	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20608-05	F	60	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20609-07	F	60	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20610-01	F	60	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20611-04	F	60	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20609-03	F	60	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20611-10	F	60	DISPOSITION	04-04-06	12:29	P	SCHEDULED EUTHANASIA
20613-10	F	60	DISPOSITION	04-05-06	7:31	P	SCHEDULED EUTHANASIA
20612-01	F	60	DISPOSITION	04-05-06	7:31	P	SCHEDULED EUTHANASIA
20604-05	F	250	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20606-06	F	250	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20605-06	F	250	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20603-02	F	250	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 12 (DAILY OBSERVATIONS)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-010

TABLE RANGE: 03-14-06 TO 04-05-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
20607-10	F	[redacted] 250	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20603-07	F	250	DISPOSITION	04-03-06	8:43	P	SCHEDULED EUTHANASIA
20603-07	F	250	EYES/EARS/NOSE	03-26-06	6:49	1	DRIED RED MATERIAL AROUND NOSE
20607-04	F	250	DISPOSITION	04-03-06	8:44	P	SCHEDULED EUTHANASIA
20608-09	F	250	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20609-10	F	250	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20610-10	F	250	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20611-06	F	250	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20610-03	F	250	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20614-03	F	250	DISPOSITION	04-05-06	7:31	P	SCHEDULED EUTHANASIA
20613-04	F	250	DISPOSITION	04-05-06	7:31	P	SCHEDULED EUTHANASIA
20615-01	F	250	DISPOSITION	04-05-06	7:32	P	SCHEDULED EUTHANASIA
20604-10	F	1000	DISPOSITION	04-03-06	8:44	P	SCHEDULED EUTHANASIA
20603-08	F	1000	DISPOSITION	04-03-06	8:44	P	SCHEDULED EUTHANASIA
20607-07	F	1000	DISPOSITION	04-03-06	8:44	P	SCHEDULED EUTHANASIA
20605-03	F	1000	DISPOSITION	04-03-06	8:44	P	SCHEDULED EUTHANASIA
20606-04	F	1000	DISPOSITION	04-03-06	8:45	P	SCHEDULED EUTHANASIA
20604-07	F	1000	DISPOSITION	04-03-06	8:45	P	SCHEDULED EUTHANASIA
20604-07	F	1000	EYES/EARS/NOSE	04-01-06	11:41	1	DRIED RED MATERIAL AROUND NOSE
20605-09	F	1000	DISPOSITION	04-03-06	8:45	P	SCHEDULED EUTHANASIA
20608-06	F	1000	DISPOSITION	03-18-06	13:39	P	FOUND DEAD
20609-06	F	1000	DISPOSITION	04-04-06	7:27	P	SCHEDULED EUTHANASIA
20611-08	F	1000	DISPOSITION	04-04-06	7:26	P	SCHEDULED EUTHANASIA
20610-09	F	1000	DISPOSITION	04-04-06	7:27	P	SCHEDULED EUTHANASIA
20611-09	F	1000	DISPOSITION	04-04-06	7:27	P	SCHEDULED EUTHANASIA
20614-04	F	1000	DISPOSITION	04-05-06	7:32	P	SCHEDULED EUTHANASIA
20613-07	F	1000	DISPOSITION	04-05-06	7:32	P	SCHEDULED EUTHANASIA
20612-09	F	1000	DISPOSITION	04-05-06	7:32	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
06/13/2006

Revised Draft

Modified: 6/13/2006

TABLE 13 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-14-06 TO 04-04-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
20604-04	F	[redacted]1000	ORAL/DENTAL	03-23-06	13:36	1	DRIED RED MATERIAL AROUND MOUTH
				03-25-06	13:55	2	SALIVATION
				03-25-06	13:56	1	WET CLEAR MATERIAL AROUND MOUTH
				03-26-06	14:02	1	WET CLEAR MATERIAL AROUND MOUTH
				04-01-06	13:53	1	WET CLEAR MATERIAL AROUND MOUTH
				04-01-06	13:53	1	SALIVATION
20603-04	F	[redacted]1000	ORAL/DENTAL	03-30-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
20608-03	F	[redacted]1000	ORAL/DENTAL	04-02-06	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
20611-09	F	[redacted]1000	ORAL/DENTAL	03-25-06	13:58	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
05/17/2006

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: CORN OIL												
20605-10	57.7	63.6	71.5	76.1	80.9	88.2	92.9	100.3	108.4	113.1	121.0	127.0
20603-03	54.4	57.8	63.0	67.4	71.6	76.5	81.4	85.7	90.8	98.6	102.4	110.2
20607-08	52.8	57.1	63.4	69.8	73.5	80.1	85.8	94.1	100.7	106.1	111.9	125.1
20606-09	51.4	54.6	61.2	65.6	71.3	75.0	78.7	84.1	88.8	95.9	98.5	104.1
20604-03	47.4	51.3	57.1	62.1	67.8	72.4	79.0	82.7	85.8	95.7	99.6	105.5
20603-01	52.4	56.3	61.3	67.8	73.1	76.9	83.8	87.6	94.0	101.9	105.7	112.4
20605-08	58.3	62.1	70.0	75.2	83.0	88.5	95.5	102.3	110.7	117.4	125.3	131.1
20608-02	44.7	50.8	55.3	60.7	66.0	70.5	75.4	87.7	84.3	90.8	95.1	100.3
20609-08	50.6	56.3	61.5	67.3	71.5	77.0	80.6	80.5	92.8	100.3	105.5	112.3
20611-01	55.6	58.4	64.9	70.0	75.9	81.1	88.7	92.3	102.1	105.2	112.4	120.6
20610-04	58.9	62.5	68.0	73.3	78.3	83.3	90.9	97.2	105.7	109.9	117.1	119.6
20609-04	52.5	58.5	65.3	70.5	76.8	82.1	88.9	94.7	102.2	108.4	116.3	125.4
20613-03	57.5	60.2	65.9	73.9	77.4	84.1	92.4	99.7	104.1	114.3	120.4	127.3
20615-03	52.1	56.9	62.0	69.6	74.6	81.1	90.0	96.6	101.7	107.9	115.1	120.4
20612-03	51.5	54.9	60.0	66.1	70.5	75.8	82.9	89.2	95.0	103.9	113.7	116.2
MEAN	53.2	57.4	63.4	69.0	74.1	79.5	85.8	91.6	97.8	104.6	110.7	117.2
S.D.	4.02	3.73	4.43	4.46	4.67	5.29	6.06	6.86	8.22	7.53	9.08	9.41
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: CORN OIL									
20605-10	135.2	138.4	141.1	148.4	153.1	154.5	164.2	169.6	171.3
20603-03	114.7	119.1	126.5	131.3	132.7	139.3	145.5	148.7	150.7
20607-08	131.7	135.8	143.3	148.5	155.4	156.7	164.9	169.8	171.4
20606-09	112.1	112.7	116.6	119.1	120.8	128.5	131.2	134.8	138.9
20604-03	113.8	116.2	118.6	122.6	126.1	131.4	130.2	138.5	141.6
20603-01	116.4	122.4	127.2	134.7	138.2	141.5	146.2	153.6	159.6
20605-08	139.2	147.6	154.0	160.6	168.3	171.6	177.4	185.7	185.4
20608-02	103.9	111.1	110.6	116.6	120.8	123.9	128.3	133.8	136.1
20609-08	116.7	122.6	129.3	133.2	139.6	142.7	150.8	153.0	151.5
20611-01	123.9	132.4	136.4	141.2	149.6	154.3	160.3	163.1	166.9
20610-04	126.6	133.4	136.0	144.4	146.2	151.8	155.7	160.7	160.8
20609-04	128.0	135.0	142.5	147.0	153.5	159.4	160.5	167.1	167.1
20613-03	132.6	141.0	145.6	153.2	155.1	162.9	170.6	175.1	178.6
20615-03	125.9	134.7	136.3	144.2	148.3	155.6	160.9	166.1	173.9
20612-03	121.7	128.6	132.4	139.5	140.7	146.9	152.9	154.5	158.3
MEAN	122.8	128.7	133.1	139.0	143.2	148.1	153.3	158.3	160.8
S.D.	9.81	10.87	11.84	12.68	13.76	13.42	14.79	15.03	14.75
N	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: [redacted]60												
20607-09	59.1	63.0	68.7	73.9	81.5	86.9	92.6	99.9	106.0	110.6	115.6	121.8
20605-05	52.9	57.6	64.9	68.7	74.8	81.2	87.7	91.0	99.2	108.0	113.2	122.7
20606-02	52.4	56.2	60.7	66.7	72.6	78.6	85.3	91.7	97.0	104.1	103.8	114.4
20604-08	52.1	57.3	62.8	69.6	74.9	80.1	86.4	92.8	99.3	105.9	112.3	118.5
20603-10	47.2	51.3	56.0	61.2	67.3	71.8	75.8	80.3	85.9	91.2	100.5	104.4
20604-09	49.5	55.1	62.3	66.3	71.6	77.8	83.6	88.1	93.0	100.0	109.1	116.0
20607-03	54.5	58.8	65.3	72.4	76.3	84.3	89.5	96.8	104.7	110.3	116.0	121.8
20609-05	42.2	48.8	54.5	59.1	64.5	67.6	74.9	79.1	85.1	89.0	95.8	101.9
20608-07	51.1	57.1	61.5	68.1	71.9	75.8	83.5	88.5	94.4	99.0	107.4	112.2
20610-05	57.2	61.8	65.5	71.2	75.5	80.3	84.9	90.2	97.6	102.2	107.2	115.3
20611-07	58.8	64.5	69.3	75.6	81.9	87.1	93.5	99.8	108.6	111.6	120.9	131.5
20610-07	60.5	64.8	68.7	73.7	79.2	85.1	89.6	95.4	100.7	105.5	113.7	115.5
20613-06	56.9	62.1	66.2	71.9	77.1	82.6	90.0	95.5	103.7	109.5	118.1	126.5
20612-07	54.9	59.0	64.5	70.9	75.5	80.5	88.4	93.3	98.2	102.9	110.6	113.7
20615-07	52.2	56.2	61.3	67.3	72.6	77.1	82.5	87.2	92.5	96.9	103.5	103.6
MEAN	53.4	58.2	63.5	69.1	74.5	79.8	85.9	91.3	97.7	103.1	109.8	116.0
S.D.	4.86	4.56	4.32	4.58	4.72	5.37	5.36	6.11	6.79	6.90	6.91	8.36
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: [redacted]60									
20607-09	128.2	130.9	136.1	140.5	144.2	148.6	152.7	161.1	162.0
20605-05	129.7	134.0	137.8	142.3	149.5	153.7	161.8	165.8	169.2
20606-02	122.0	127.5	130.6	132.8	139.9	145.0	147.9	150.0	153.7
20604-08	121.7	127.7	134.6	137.8	143.4	148.0	149.5	150.8	155.4
20603-10	112.2	114.3	119.7	124.3	129.0	131.0	132.4	142.1	145.2
20604-09	121.0	126.9	136.3	140.5	150.1	154.0	157.0	164.0	166.5
20607-03	129.1	129.9	135.7	137.0	142.3	146.0	150.2	151.0	155.2
20609-05	105.1	109.9	115.8	121.4	124.2	130.0	134.3	131.1	130.5
20608-07	117.9	120.9	127.4	133.6	134.9	143.8	148.3	154.5	156.6
20610-05	116.7	120.5	125.9	130.0	133.6	138.0	144.0	150.8	147.4
20611-07	135.2	138.0	146.9	150.9	153.2	159.1	167.0	171.7	177.0
20610-07	119.6	125.1	133.8	136.9	143.3	145.6	149.9	153.9	158.5
20613-06	135.0	141.2	151.1	158.4	162.9	170.8	184.6	190.4	185.0
20612-07	118.8	123.7	132.2	138.0	141.5	146.2	153.7	154.0	152.2
20615-07	113.7	118.5	125.3	127.6	128.8	125.9	144.4	150.2	147.4
MEAN	121.7	125.9	132.6	136.8	141.4	145.7	151.8	156.1	157.5
S.D.	8.46	8.45	9.23	9.55	10.26	11.57	12.75	13.60	13.40
N	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-010

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: [redacted]250												
20606-07	55.8	60.4	66.0	70.9	75.0	80.4	86.1	90.4	96.8	102.4	110.1	112.0
20603-09	51.5	54.1	61.0	66.1	70.9	75.7	81.7	86.7	93.3	99.4	104.9	111.1
20607-01	53.6	56.9	63.7	68.1	73.6	77.7	84.0	88.5	94.3	101.0	106.1	112.4
20604-02	48.8	52.7	59.3	65.7	70.7	76.9	82.1	86.7	90.1	100.7	103.8	108.2
20605-01	44.8	49.5	54.6	60.6	65.2	71.7	77.0	82.1	90.1	94.8	101.1	110.1
20605-04	51.1	55.6	61.9	67.6	71.3	76.5	83.1	89.0	95.3	101.1	107.5	114.4
20606-05	57.1	62.5	68.9	73.7	78.7	84.6	90.5	96.2	101.7	108.6	112.7	120.2
20608-08	44.9	50.1	54.2	60.9	68.4	74.1	79.6	86.0	92.0	96.4	102.8	110.3
20609-09	51.5	59.3	64.0	70.5	77.6	83.7	88.2	94.4	100.7	107.9	112.9	121.4
20610-02	55.9	60.1	63.0	67.0	72.6	76.0	80.4	85.7	89.5	95.1	100.1	107.5
20611-02	56.7	61.9	67.6	72.5	78.3	82.5	86.5	92.0	94.4	102.5	106.6	113.0
20611-05	58.1	63.4	70.3	74.4	80.2	87.9	93.4	100.9	106.8	113.1	124.6	131.4
20608-10	48.0	54.2	59.8	66.3	71.5	79.2	85.2	92.5	99.2	108.8	116.5	123.9
20613-08	63.8	70.0	75.6	81.6	85.8	92.4	100.1	107.9	113.6	121.2	128.9	135.7
20614-01	55.7	60.4	65.1	70.4	75.0	80.4	87.3	92.0	97.6	105.1	112.4	112.3
MEAN	53.2	58.1	63.7	69.1	74.3	80.0	85.7	91.4	97.0	103.9	110.1	116.3
S.D.	5.21	5.51	5.69	5.34	5.19	5.50	5.85	6.57	6.65	7.15	8.28	8.50
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: [redacted]250									
20606-07	114.8	119.8	126.0	128.6	134.2	134.0	137.7	147.5	149.1
20603-09	117.8	118.8	123.8	129.6	131.7	135.2	140.4	143.9	145.3
20607-01	118.2	118.1	121.2	122.7	131.0	129.6	134.7	133.0	131.2
20604-02	114.8	117.5	121.6	124.1	126.4	130.1	132.8	138.1	140.2
20605-01	115.7	117.2	120.6	129.1	133.1	138.3	138.2	149.9	150.0
20605-04	123.4	123.9	128.7	133.0	135.6	140.0	145.6	149.9	152.2
20606-05	122.4	125.6	135.1	137.4	143.8	140.9	151.4	151.6	161.1
20608-08	117.5	122.7	128.7	137.6	145.1	154.4	160.3	168.6	172.8
20609-09	124.4	133.1	136.6	140.8	148.8	154.7	156.2	161.2	167.8
20610-02	108.8	110.7	117.1	120.3	126.8	130.1	131.7	136.4	144.1
20611-02	116.5	120.7	125.3	127.9	133.5	138.2	143.1	139.2	147.3
20611-05	132.2	145.3	149.2	156.8	163.7	165.0	176.5	179.3	181.1
20608-10	128.4	132.5	141.4	150.3	156.8	164.9	169.3	171.8	178.0
20613-08	137.9	144.6	154.0	152.2	163.3	164.1	166.5	169.0	175.2
20614-01	115.7	122.2	126.4	128.6	134.9	136.9	143.7	143.0	146.5
MEAN	120.6	124.8	130.4	134.6	140.6	143.8	148.5	152.2	156.1
S.D.	7.63	9.95	10.82	11.13	12.47	13.14	14.18	14.45	15.39
N	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: [redacted]1000												
20606-10	56.6	61.8	68.3	74.0	79.0	83.8	90.6	94.5	100.0	104.8	110.8	116.9
20605-07	52.7	56.1	63.2	68.0	73.8	79.2	85.3	91.1	97.1	103.5	110.0	115.3
20604-04	52.7	57.7	64.0	71.5	78.0	82.8	89.4	95.4	102.5	110.6	117.1	125.5
20603-04	51.5	55.8	62.3	67.7	73.6	79.2	84.3	88.9	93.4	101.4	102.7	109.7
20607-05	50.5	55.6	62.4	66.1	71.6	75.6	80.4	84.9	88.2	93.8	97.1	101.6
20604-01	50.5	55.3	61.8	67.2	72.3	77.8	82.0	87.0	91.8	99.2	101.0	106.2
20606-01	54.5	59.7	63.9	69.5	75.2	80.2	86.5	91.6	97.1	102.7	107.0	113.9
20608-03	43.8	47.7	51.6	56.5	60.4	63.7	67.6	70.2	76.2	82.1	86.7	91.7
20609-01	51.7	55.9	61.5	67.6	73.1	78.9	85.4	89.4	98.3	104.3	112.1	120.5
20611-03	55.1	59.7	66.3	70.7	76.8	82.9	88.2	95.2	101.3	107.3	114.4	122.6
20610-06	60.0	64.7	70.8	76.5	81.9	89.7	95.2	102.5	106.9	114.7	121.1	130.5
20610-08	59.1	62.3	68.1	72.9	78.5	84.2	89.8	96.0	103.5	107.7	116.6	122.0
20608-01	50.0	54.8	58.4	64.7	70.2	75.3	81.1	87.6	93.4	98.4	105.0	112.9
20612-05	58.1	60.6	68.8	74.1	80.6	87.2	94.2	102.5	106.9	114.0	121.4	126.3
20613-01	55.6	59.4	67.3	72.2	78.8	85.3	92.5	98.7	104.2	113.7	122.1	126.8
MEAN	53.5	57.8	63.9	69.3	74.9	80.4	86.2	91.7	97.4	103.9	109.7	116.2
S.D.	4.19	4.09	4.80	4.87	5.32	6.18	6.86	8.00	8.06	8.55	9.98	10.59
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: [redacted]1000									
20606-10	119.9	121.6	128.4	130.5	135.1	135.7	138.5	142.7	143.7
20605-07	123.2	126.4	128.9	131.9	139.2	145.6	144.4	149.5	157.3
20604-04	131.0	135.5	140.9	143.3	146.5	151.0	158.9	161.9	171.6
20603-04	116.3	119.2	128.5	127.8	136.6	138.6	142.0	145.5	149.5
20607-05	107.9	114.1	115.3	119.2	124.1	130.5	134.7	137.9	139.6
20604-01	114.4	119.8	125.4	128.8	133.0	136.7	145.6	148.5	150.7
20606-01	117.8	121.7	128.4	132.7	137.2	141.9	147.0	152.8	157.3
20608-03	93.8	94.6	100.9	105.3	110.6	113.4	118.6	122.8	124.6
20609-01	123.5	129.9	134.4	140.3	148.0	150.6	153.0	163.1	164.5
20611-03	127.6	133.4	139.4	148.3	153.9	152.2	165.1	162.0	170.5
20610-06	136.3	145.3	149.0	160.2	163.8	165.1	177.2	173.5	175.2
20610-08	124.4	130.2	135.5	141.4	148.0	151.7	152.1	160.6	166.0
20608-01	116.9	122.2	125.7	131.5	136.1	143.0	142.5	146.9	150.5
20612-05	130.6	136.7	142.8	148.4	152.9	162.5	165.6	168.4	170.6
20613-01	132.5	137.6	144.6	153.5	159.6	164.7	164.7	169.1	177.3
MEAN	121.1	125.9	131.2	136.2	141.6	145.5	150.0	153.7	157.9
S.D.	10.79	12.14	12.20	13.94	13.80	13.83	14.77	13.63	14.92
N	15	15	15	15	15	15	15	15	15

Revised Draft

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: [redacted]60												
20606-08	59.8	64.2	67.6	74.6	80.6	86.8	91.7	97.1	103.5	110.2	111.4	120.3
20605-02	52.9	57.5	63.9	70.1	74.4	81.1	89.1	91.9	99.0	107.0	113.9	123.0
20607-06	53.1	58.4	63.6	68.1	73.6	80.6	85.8	89.7	101.2	104.8	114.0	120.5
20603-06	53.3	57.1	63.1	68.9	74.2	78.8	85.1	90.7	97.4	102.7	106.7	114.8
20604-06	45.4	50.6	55.5	60.4	65.0	68.9	75.4	78.1	82.9	86.3	91.0	97.9
20606-03	49.1	52.8	59.6	64.5	69.0	74.8	80.8	85.6	92.4	98.7	104.4	109.9
20607-02	53.5	57.3	63.0	70.7	76.9	83.8	89.1	93.4	100.2	107.4	116.2	120.0
20608-05	46.6	51.4	56.8	61.7	67.5	73.8	79.2	85.1	92.4	101.6	110.6	120.4
20609-07	50.6	56.2	64.9	68.5	73.7	79.4	83.6	89.1	99.0	101.2	108.3	115.5
20610-01	55.1	59.0	65.0	69.0	74.3	76.5	83.2	88.0	94.2	100.9	106.5	111.9
20611-04	58.7	63.8	69.3	74.7	79.3	83.9	90.0	96.7	104.0	108.5	116.2	124.2
20609-03	54.4	60.0	64.1	68.9	72.8	77.5	81.5	87.0	93.0	99.8	101.4	106.4
20611-10	53.8	58.9	64.2	67.7	73.4	79.1	83.7	87.5	93.9	100.9	107.3	114.0
20613-10	63.4	66.9	73.2	79.4	85.5	91.0	99.6	98.3	111.6	117.2	124.4	130.6
20612-01	53.9	59.2	63.5	68.7	73.5	77.7	82.8	91.0	98.7	105.5	112.3	117.9
MEAN	53.6	58.2	63.8	69.1	74.2	79.6	85.4	89.9	97.6	103.5	109.6	116.5
S.D.	4.70	4.54	4.41	4.83	5.09	5.42	5.87	5.25	6.62	6.79	7.66	7.94
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: [redacted]60									
20606-08	120.9	129.1	133.5	137.0	138.6	141.0	149.5	152.5	157.3
20605-02	131.1	131.4	139.4	144.6	153.8	156.0	160.8	168.8	174.7
20607-06	128.6	142.0	142.6	148.1	160.1	162.5	165.3	173.8	171.4
20603-06	115.3	118.3	127.5	128.5	130.0	137.0	137.8	145.5	145.7
20604-06	104.9	108.4	110.2	114.8	116.9	122.5	124.0	126.6	127.1
20606-03	117.2	120.4	124.5	129.4	134.4	137.8	144.6	151.1	150.2
20607-02	127.5	131.4	135.9	141.4	144.2	149.8	151.6	158.8	161.9
20608-05	121.6	129.4	135.5	136.9	144.8	152.1	162.2	166.0	161.5
20609-07	119.5	125.8	125.8	134.5	139.6	146.6	156.8	165.0	158.9
20610-01	120.1	124.0	129.5	133.3	141.2	145.9	152.4	160.4	166.3
20611-04	126.8	130.5	136.1	138.1	146.1	151.2	153.4	155.9	161.9
20609-03	110.7	111.2	119.5	123.9	127.5	125.6	134.8	135.4	139.6
20611-10	119.4	126.1	130.9	136.9	143.3	145.7	150.1	152.8	155.8
20613-10	139.1	144.0	151.3	159.4	161.4	168.0	177.5	179.2	181.5
20612-01	124.4	130.9	135.0	141.1	147.5	152.1	157.0	160.9	161.5
MEAN	121.8	126.9	131.8	136.5	142.0	146.3	151.9	156.8	158.4
S.D.	8.38	9.70	9.81	10.46	11.85	12.29	13.11	13.85	13.74
N	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 6: [redacted]250												
20604-05	55.0	59.6	64.1	69.3	76.0	81.1	88.6	92.8	99.2	104.3	108.2	121.4
20606-06	51.9	56.0	60.9	65.1	71.2	76.2	81.6	85.7	91.8	97.7	100.6	108.1
20605-06	53.7	59.1	64.1	68.9	74.6	80.4	85.7	89.1	94.2	102.1	104.1	115.3
20603-02	50.7	56.3	62.9	67.9	73.0	79.9	86.2	90.5	97.0	105.0	112.1	118.5
20607-10	49.1	52.8	58.9	63.8	68.0	72.9	77.2	81.5	87.3	94.3	99.0	103.3
20603-07	45.1	50.5	56.6	62.2	67.5	72.7	79.4	85.5	91.5	99.6	107.0	114.1
20607-04	59.1	62.0	67.4	72.8	76.3	83.6	86.9	94.5	100.3	106.3	110.5	117.4
20608-09	49.8	56.1	61.2	67.1	73.8	80.4	87.3	93.4	100.2	107.4	118.9	127.8
20609-10	50.4	56.3	62.3	67.4	72.7	77.9	85.2	91.8	98.1	106.1	113.3	120.2
20610-10	57.1	59.3	65.6	70.6	74.8	80.4	85.5	89.9	96.4	105.3	106.5	117.2
20611-06	56.8	61.2	66.8	72.7	77.8	82.0	88.3	93.3	100.5	107.6	113.0	119.7
20610-03	50.9	53.5	58.8	64.5	69.0	72.7	77.9	84.2	86.3	91.9	98.2	102.2
20614-03	58.1	61.6	68.9	72.8	79.7	84.6	91.0	97.4	100.9	110.0	116.4	119.4
20613-04	58.4	62.3	69.6	74.5	80.5	84.4	91.9	97.3	101.3	110.8	115.7	122.4
20615-01	52.4	56.9	63.3	68.7	71.6	77.1	84.5	88.8	96.0	103.1	108.3	112.6
MEAN	53.2	57.6	63.4	68.6	73.8	79.1	85.1	90.4	96.1	103.4	108.8	116.0
S.D.	4.08	3.57	3.80	3.67	3.95	4.06	4.41	4.68	4.89	5.47	6.36	7.03
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 6: [redacted]250									
20604-05	126.5	127.6	130.5	129.8	137.3	142.5	148.6	151.2	149.8
20606-06	111.5	113.7	118.9	124.1	125.3	128.7	129.9	135.7	138.3
20605-06	121.7	124.2	126.4	128.9	135.9	137.5	141.9	139.4	146.0
20603-02	124.9	130.9	135.4	137.2	142.3	148.9	151.2	159.9	165.9
20607-10	107.6	113.3	111.4	116.6	119.4	124.3	126.2	132.5	137.0
20603-07	120.8	125.9	130.0	137.2	139.8	149.0	159.0	156.4	162.0
20607-04	123.4	126.7	132.0	137.3	143.7	144.0	145.8	155.2	156.9
20608-09	129.9	135.9	143.5	150.5	152.0	158.2	161.8	172.3	177.0
20609-10	124.6	132.1	135.7	146.4	143.2	148.4	158.5	165.9	167.2
20610-10	120.4	125.7	132.1	133.6	137.7	140.7	148.9	149.4	155.5
20611-06	124.0	125.6	132.0	140.4	146.0	149.9	156.7	155.7	163.1
20610-03	107.3	109.6	116.2	124.7	127.7	133.3	137.9	137.1	149.5
20614-03	120.7	122.8	128.1	134.2	136.7	138.1	143.1	146.6	151.2
20613-04	128.4	133.3	143.3	150.3	152.0	153.8	159.6	167.9	172.9
20615-01	122.2	124.7	133.2	137.1	141.9	147.3	156.5	159.8	168.0
MEAN	120.9	124.8	129.9	135.2	138.7	143.0	148.4	152.3	157.4
S.D.	6.90	7.52	8.94	9.57	9.12	9.35	10.97	12.21	12.05
N	15	15	15	15	15	15	15	15	15

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 7: [redacted]1000												
20604-10	58.7	63.2	70.0	76.7	82.7	90.8	97.6	104.4	110.6	117.4	124.9	132.0
20603-08	54.2	57.8	64.0	68.0	74.5	79.0	83.5	88.5	93.8	99.7	104.2	111.1
20607-07	54.4	56.9	63.3	68.2	73.4	77.9	83.3	86.8	92.1	97.1	100.3	105.7
20605-03	52.3	56.0	62.2	67.0	72.7	77.8	83.1	89.8	94.0	99.0	108.5	115.4
20606-04	52.2	56.0	61.7	65.3	70.7	76.5	81.3	87.5	91.1	94.5	101.6	109.5
20604-07	50.8	54.7	60.4	66.3	71.8	76.0	82.0	86.8	93.6	99.2	106.3	112.4
20605-09	57.6	61.1	67.2	71.7	78.4	83.0	91.0	96.0	103.2	110.1	115.9	123.3
20608-06	49.1	56.4	61.1	67.3								
20609-06	48.0	54.8	60.6	67.3	73.8	78.5	84.6	89.1	95.6	102.3	106.6	115.5
20611-08	52.3	59.3	64.5	69.2	76.4	80.2	85.3	91.1	95.0	100.7	108.6	114.4
20610-09	59.1	62.6	68.2	73.3	79.6	85.6	89.5	95.9	104.7	109.3	117.6	128.2
20611-09	52.6	58.4	63.1	66.8	73.9	78.0	83.8	90.6	96.4	101.7	108.6	116.1
20614-04	57.4	62.6	68.9	72.8	78.1	82.9	88.5	93.2	101.2	104.7	110.7	116.5
20613-07	56.1	60.4	64.9	70.5	73.9	78.6	83.4	89.6	92.8	99.7	109.9	112.3
20612-09	53.2	58.9	64.3	70.2	74.2	81.2	86.2	93.1	98.6	102.0	110.5	115.6
MEAN	53.9	58.6	64.3	69.4	75.3	80.4	85.9	91.6	97.3	102.7	109.6	116.3
S.D.	3.37	2.86	3.05	3.14	3.32	4.03	4.40	4.75	5.65	5.99	6.46	7.12
N	15	15	15	15	14	14	14	14	14	14	14	14

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TABLE 14

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 7: [redacted]1000									
20604-10	138.5	143.0	150.8	155.8	165.0	166.2	171.6	172.2	184.2
20603-08	118.5	123.1	130.9	131.9	134.5	137.6	146.9	154.9	153.5
20607-07	109.5	109.4	113.9	115.5	119.1	119.9	123.0	127.6	133.5
20605-03	122.9	128.1	130.4	138.1	142.7	143.7	152.3	156.9	161.6
20606-04	115.9	119.3	123.3	126.6	128.1	135.1	138.6	140.2	144.5
20604-07	116.0	121.2	124.1	130.4	135.2	134.4	143.1	147.7	152.2
20605-09	128.0	133.2	137.1	141.8	149.1	152.2	153.1	165.3	166.5
20609-06	120.2	126.3	130.2	133.4	136.7	143.2	148.8	152.2	150.0
20611-08	120.7	125.4	132.2	137.6	140.8	147.8	152.8	155.4	162.1
20610-09	133.5	140.5	150.3	162.1	166.2	175.4	187.2	196.0	201.9
20611-09	126.7	134.0	139.0	144.3	151.0	153.0	157.3	155.2	168.5
20614-04	118.9	121.3	124.1	125.9	133.8	140.0	141.4	150.5	149.0
20613-07	120.9	125.3	133.1	136.6	139.3	147.7	157.5	153.1	164.4
20612-09	122.1	125.9	130.4	137.3	141.4	147.9	150.4	152.5	160.2
MEAN	122.3	126.9	132.1	137.0	141.6	146.0	151.7	155.7	160.9
S.D.	7.44	8.70	10.01	11.89	12.92	13.65	15.02	15.54	16.96
N	14	14	14	14	14	14	14	14	14

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TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: CORN OIL												
20605-10	5.9	7.9	4.6	4.8	7.3	4.7	7.4	8.1	4.7	7.9	6.0	8.2
20603-03	3.4	5.2	4.4	4.2	4.9	4.9	4.3	5.1	7.8	3.8	7.8	4.5
20607-08	4.3	6.3	6.4	3.7	6.6	5.7	8.3	6.6	5.4	5.8	13.2	6.6
20606-09	3.2	6.6	4.4	5.7	3.7	3.7	5.4	4.7	7.1	2.6	5.6	8.0
20604-03	3.9	5.8	5.0	5.7	4.6	6.6	3.7	3.1	9.9	3.9	5.9	8.3
20603-01	3.9	5.0	6.5	5.3	3.8	6.9	3.8	6.4	7.9	3.8	6.7	4.0
20605-08	3.8	7.9	5.2	7.8	5.5	7.0	6.8	8.4	6.7	7.9	5.8	8.1
20608-02	6.1	4.5	5.4	5.3	4.5	4.9	12.3	-3.4	6.5	4.3	5.2	3.6
20609-08	5.7	5.2	5.8	4.2	5.5	3.6	-0.1	12.3	7.5	5.2	6.8	4.4
20611-01	2.8	6.5	5.1	5.9	5.2	7.6	3.6	9.8	3.1	7.2	8.2	3.3
20610-04	3.6	5.5	5.3	5.0	5.0	7.6	6.3	8.5	4.2	7.2	2.5	7.0
20609-04	6.0	6.8	5.2	6.3	5.3	6.8	5.8	7.5	6.2	7.9	9.1	2.6
20613-03	2.7	5.7	8.0	3.5	6.7	8.3	7.3	4.4	10.2	6.1	6.9	5.3
20615-03	4.8	5.1	7.6	5.0	6.5	8.9	6.6	5.1	6.2	7.2	5.3	5.5
20612-03	3.4	5.1	6.1	4.4	5.3	7.1	6.3	5.8	8.9	9.8	2.5	5.5
MEAN	4.2	5.9	5.7	5.1	5.4	6.3	5.9	6.2	6.8	6.0	6.5	5.7
S.D.	1.18	1.04	1.08	1.10	1.05	1.62	2.75	3.54	2.00	2.05	2.59	1.94
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: CORN OIL									
20605-10	3.2	2.7	7.3	4.7	1.4	9.7	5.4	1.7	113.6
20603-03	4.4	7.4	4.8	1.4	6.6	6.2	3.2	2.0	96.3
20607-08	4.1	7.5	5.2	6.9	1.3	8.2	4.9	1.6	118.6
20606-09	0.6	3.9	2.5	1.7	7.7	2.7	3.6	4.1	87.5
20604-03	2.4	2.4	4.0	3.5	5.3	-1.2	8.3	3.1	94.2
20603-01	6.0	4.8	7.5	3.5	3.3	4.7	7.4	6.0	107.2
20605-08	8.4	6.4	6.6	7.7	3.3	5.8	8.3	-0.3	127.1
20608-02	7.2	-0.5	6.0	4.2	3.1	4.4	5.5	2.3	91.4
20609-08	5.9	6.7	3.9	6.4	3.1	8.1	2.2	-1.5	100.9
20611-01	8.5	4.0	4.8	8.4	4.7	6.0	2.8	3.8	111.3
20610-04	6.8	2.6	8.4	1.8	5.6	3.9	5.0	0.1	101.9
20609-04	7.0	7.5	4.5	6.5	5.9	1.1	6.6	0.0	114.6
20613-03	8.4	4.6	7.6	1.9	7.8	7.7	4.5	3.5	121.1
20615-03	8.8	1.6	7.9	4.1	7.3	5.3	5.2	7.8	121.8
20612-03	6.9	3.8	7.1	1.2	6.2	6.0	1.6	3.8	106.8
MEAN	5.9	4.4	5.9	4.3	4.8	5.2	5.0	2.5	107.6
S.D.	2.47	2.40	1.77	2.43	2.16	2.84	2.07	2.47	12.06
N	15	15	15	15	15	15	15	15	15

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Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: [redacted]60												
20607-09	3.9	5.7	5.2	7.6	5.4	5.7	7.3	6.1	4.6	5.0	6.2	6.4
20605-05	4.7	7.3	3.8	6.1	6.4	6.5	3.3	8.2	8.8	5.2	9.5	7.0
20606-02	3.8	4.5	6.0	5.9	6.0	6.7	6.4	5.3	7.1	-0.3	10.6	7.6
20604-08	5.2	5.5	6.8	5.3	5.2	6.3	6.4	6.5	6.6	6.4	6.2	3.2
20603-10	4.1	4.7	5.2	6.1	4.5	4.0	4.5	5.6	5.3	9.3	3.9	7.8
20604-09	5.6	7.2	4.0	5.3	6.2	5.8	4.5	4.9	7.0	9.1	6.9	5.0
20607-03	4.3	6.5	7.1	3.9	8.0	5.2	7.3	7.9	5.6	5.7	5.8	7.3
20609-05	6.6	5.7	4.6	5.4	3.1	7.3	4.2	6.0	3.9	6.8	6.1	3.2
20608-07	6.0	4.4	6.6	3.8	3.9	7.7	5.0	5.9	4.6	8.4	4.8	5.7
20610-05	4.6	3.7	5.7	4.3	4.8	4.6	5.3	7.4	4.6	5.0	8.1	1.4
20611-07	5.7	4.8	6.3	6.3	5.2	6.4	6.3	8.8	3.0	9.3	10.6	3.7
20610-07	4.3	3.9	5.0	5.5	5.9	4.5	5.8	5.3	4.8	8.2	1.8	4.1
20613-06	5.2	4.1	5.7	5.2	5.5	7.4	5.5	8.2	5.8	8.6	8.4	8.5
20612-07	4.1	5.5	6.4	4.6	5.0	7.9	4.9	4.9	4.7	7.7	3.1	5.1
20615-07	4.0	5.1	6.0	5.3	4.5	5.4	4.7	5.3	4.4	6.6	0.1	10.1
MEAN	4.8	5.2	5.6	5.4	5.3	6.1	5.4	6.4	5.4	6.7	6.1	5.7
S.D.	0.86	1.12	0.99	0.99	1.15	1.21	1.15	1.33	1.47	2.50	3.07	2.37
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: [redacted]60									
20607-09	2.7	5.2	4.4	3.7	4.4	4.1	8.4	0.9	102.9
20605-05	4.3	3.8	4.5	7.2	4.2	8.1	4.0	3.4	116.3
20606-02	5.5	3.1	2.2	7.1	5.1	2.9	2.1	3.7	101.3
20604-08	6.0	6.9	3.2	5.6	4.6	1.5	1.3	4.6	103.3
20603-10	2.1	5.4	4.6	4.7	2.0	1.4	9.7	3.1	98.0
20604-09	5.9	9.4	4.2	9.6	3.9	3.0	7.0	2.5	117.0
20607-03	0.8	5.8	1.3	5.3	3.7	4.2	0.8	4.2	100.7
20609-05	4.8	5.9	5.6	2.8	5.8	4.3	-3.2	-0.6	88.3
20608-07	3.0	6.5	6.2	1.3	8.9	4.5	6.2	2.1	105.5
20610-05	3.8	5.4	4.1	3.6	4.4	6.0	6.8	-3.4	90.2
20611-07	2.8	8.9	4.0	2.3	5.9	7.9	4.7	5.3	118.2
20610-07	5.5	8.7	3.1	6.4	2.3	4.3	4.0	4.6	98.0
20613-06	6.2	9.9	7.3	4.5	7.9	13.8	5.8	-5.4	128.1
20612-07	4.9	8.5	5.8	3.5	4.7	7.5	0.3	-1.8	97.3
20615-07	4.8	6.8	2.3	1.2	-2.9	18.5	5.8	-2.8	95.2
MEAN	4.2	6.7	4.2	4.6	4.3	6.1	4.2	1.4	104.0
S.D.	1.61	2.04	1.62	2.34	2.69	4.64	3.45	3.37	11.20
N	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: [redacted]250												
20606-07	4.6	5.6	4.9	4.1	5.4	5.7	4.3	6.4	5.6	7.7	1.9	2.8
20603-09	2.6	6.9	5.1	4.8	4.8	6.0	5.0	6.6	6.1	5.5	6.2	6.7
20607-01	3.3	6.8	4.4	5.5	4.1	6.3	4.5	5.8	6.7	5.1	6.3	5.8
20604-02	3.9	6.6	6.4	5.0	6.2	5.2	4.6	3.4	10.6	3.1	4.4	6.6
20605-01	4.7	5.1	6.0	4.6	6.5	5.3	5.1	8.0	4.7	6.3	9.0	5.6
20605-04	4.5	6.3	5.7	3.7	5.2	6.6	5.9	6.3	5.8	6.4	6.9	9.0
20606-05	5.4	6.4	4.8	5.0	5.9	5.9	5.7	5.5	6.9	4.1	7.5	2.2
20608-08	5.2	4.1	6.7	7.5	5.7	5.5	6.4	6.0	4.4	6.4	7.5	7.2
20609-09	7.8	4.7	6.5	7.1	6.1	4.5	6.2	6.3	7.2	5.0	8.5	3.0
20610-02	4.2	2.9	4.0	5.6	3.4	4.4	5.3	3.8	5.6	5.0	7.4	1.3
20611-02	5.2	5.7	4.9	5.8	4.2	4.0	5.5	2.4	8.1	4.1	6.4	3.5
20611-05	5.3	6.9	4.1	5.8	7.7	5.5	7.5	5.9	6.3	11.5	6.8	0.8
20608-10	6.2	5.6	6.5	5.2	7.7	6.0	7.3	6.7	9.6	7.7	7.4	4.5
20613-08	6.2	5.6	6.0	4.2	6.6	7.7	7.8	5.7	7.6	7.7	6.8	2.2
20614-01	4.7	4.7	5.3	4.6	5.4	6.9	4.7	5.6	7.5	7.3	-0.1	3.4
MEAN	4.9	5.6	5.4	5.2	5.7	5.7	5.7	5.6	6.8	6.2	6.2	4.3
S.D.	1.25	1.15	0.91	1.04	1.23	0.98	1.12	1.42	1.69	2.06	2.42	2.41
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: [redacted]250									
20606-07	5.0	6.2	2.6	5.6	-0.2	3.7	9.8	1.6	93.3
20603-09	1.0	5.0	5.8	2.1	3.5	5.2	3.5	1.4	93.8
20607-01	-0.1	3.1	1.5	8.3	-1.4	5.1	-1.7	-1.8	77.6
20604-02	2.7	4.1	2.5	2.3	3.7	2.7	5.3	2.1	91.4
20605-01	1.5	3.4	8.5	4.0	5.2	-0.1	11.7	0.1	105.2
20605-04	0.5	4.8	4.3	2.6	4.4	5.6	4.3	2.3	101.1
20606-05	3.2	9.5	2.3	6.4	-2.9	10.5	0.2	9.5	104.0
20608-08	5.2	6.0	8.9	7.5	9.3	5.9	8.3	4.2	127.9
20609-09	8.7	3.5	4.2	8.0	5.9	1.5	5.0	6.6	116.3
20610-02	1.9	6.4	3.2	6.5	3.3	1.6	4.7	7.7	88.2
20611-02	4.2	4.6	2.6	5.6	4.7	4.9	-3.9	8.1	90.6
20611-05	13.1	3.9	7.6	6.9	1.3	11.5	2.8	1.8	123.0
20608-10	4.1	8.9	8.9	6.5	8.1	4.4	2.5	6.2	130.0
20613-08	6.7	9.4	-1.8	11.1	0.8	2.4	2.5	6.2	111.4
20614-01	6.5	4.2	2.2	6.3	2.0	6.8	-0.7	3.5	90.8
MEAN	4.3	5.5	4.2	6.0	3.2	4.8	3.6	4.0	103.0
S.D.	3.49	2.18	3.12	2.45	3.35	3.16	4.23	3.28	15.78
N	15	15	15	15	15	15	15	15	15

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TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-010

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: [redacted]1000												
20606-10	5.2	6.5	5.7	5.0	4.8	6.8	3.9	5.5	4.8	6.0	6.1	3.0
20605-07	3.4	7.1	4.8	5.8	5.4	6.1	5.8	6.0	6.4	6.5	5.3	7.9
20604-04	5.0	6.3	7.5	6.5	4.8	6.6	6.0	7.1	8.1	6.5	8.4	5.5
20603-04	4.3	6.5	5.4	5.9	5.6	5.1	4.6	4.5	8.0	1.3	7.0	6.6
20607-05	5.1	6.8	3.7	5.5	4.0	4.8	4.5	3.3	5.6	3.3	4.5	6.3
20604-01	4.8	6.5	5.4	5.1	5.5	4.2	5.0	4.8	7.4	1.8	5.2	8.2
20606-01	5.2	4.2	5.6	5.7	5.0	6.3	5.1	5.5	5.6	4.3	6.9	3.9
20608-03	3.9	3.9	4.9	3.9	3.3	3.9	2.6	6.0	5.9	4.6	5.0	2.1
20609-01	4.2	5.6	6.1	5.5	5.8	6.5	4.0	8.9	6.0	7.8	8.4	3.0
20611-03	4.6	6.6	4.4	6.1	6.1	5.3	7.0	6.1	6.0	7.1	8.2	5.0
20610-06	4.7	6.1	5.7	5.4	7.8	5.5	7.3	4.4	7.8	6.4	9.4	5.8
20610-08	3.2	5.8	4.8	5.6	5.7	5.6	6.2	7.5	4.2	8.9	5.4	2.4
20608-01	4.8	3.6	6.3	5.5	5.1	5.8	6.5	5.8	5.0	6.6	7.9	4.0
20612-05	2.5	8.2	5.3	6.5	6.6	7.0	8.3	4.4	7.1	7.4	4.9	4.3
20613-01	3.8	7.9	4.9	6.6	6.5	7.2	6.2	5.5	9.5	8.4	4.7	5.7
MEAN	4.3	6.1	5.4	5.6	5.5	5.8	5.5	5.7	6.5	5.8	6.5	4.9
S.D.	0.81	1.33	0.89	0.68	1.08	1.00	1.49	1.40	1.45	2.28	1.64	1.89
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: [redacted]1000									
20606-10	1.7	6.8	2.1	4.6	0.6	2.8	4.2	1.0	87.1
20605-07	3.2	2.5	3.0	7.3	6.4	-1.2	5.1	7.8	104.6
20604-04	4.5	5.4	2.4	3.2	4.5	7.9	3.0	9.7	118.9
20603-04	2.9	9.3	-0.7	8.8	2.0	3.4	3.5	4.0	98.0
20607-05	6.2	1.2	3.9	4.9	6.4	4.2	3.2	1.7	89.1
20604-01	5.4	5.6	3.4	4.2	3.7	8.9	2.9	2.2	100.2
20606-01	3.9	6.7	4.3	4.5	4.7	5.1	5.8	4.5	102.8
20608-03	0.8	6.3	4.4	5.3	2.8	5.2	4.2	1.8	80.8
20609-01	6.4	4.5	5.9	7.7	2.6	2.4	10.1	1.4	112.8
20611-03	5.8	6.0	8.9	5.6	-1.7	12.9	-3.1	8.5	115.4
20610-06	9.0	3.7	11.2	3.6	1.3	12.1	-3.7	1.7	115.2
20610-08	5.8	5.3	5.9	6.6	3.7	0.4	8.5	5.4	106.9
20608-01	5.3	3.5	5.8	4.6	6.9	-0.5	4.4	3.6	100.5
20612-05	6.1	6.1	5.6	4.5	9.6	3.1	2.8	2.2	112.5
20613-01	5.1	7.0	8.9	6.1	5.1	0.0	4.4	8.2	121.7
MEAN	4.8	5.3	5.0	5.4	3.9	4.4	3.7	4.2	104.4
S.D.	2.06	2.01	3.02	1.58	2.83	4.35	3.54	2.98	12.12
N	15	15	15	15	15	15	15	15	15

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Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: [redacted]60												
20606-08	4.4	3.4	7.0	6.0	6.2	4.9	5.4	6.4	6.7	1.2	8.9	0.6
20605-02	4.6	6.4	6.2	4.3	6.7	8.0	2.8	7.1	8.0	6.9	9.1	8.1
20607-06	5.3	5.2	4.5	5.5	7.0	5.2	3.9	11.5	3.6	9.2	6.5	8.1
20603-06	3.8	6.0	5.8	5.3	4.6	6.3	5.6	6.7	5.3	4.0	8.1	0.5
20604-06	5.2	4.9	4.9	4.6	3.9	6.5	2.7	4.8	3.4	4.7	6.9	7.0
20606-03	3.7	6.8	4.9	4.5	5.8	6.0	4.8	6.8	6.3	5.7	5.5	7.3
20607-02	3.8	5.7	7.7	6.2	6.9	5.3	4.3	6.8	7.2	8.8	3.8	7.5
20608-05	4.8	5.4	4.9	5.8	6.3	5.4	5.9	7.3	9.2	9.0	9.8	1.2
20609-07	5.6	8.7	3.6	5.2	5.7	4.2	5.5	9.9	2.2	7.1	7.2	4.0
20610-01	3.9	6.0	4.0	5.3	2.2	6.7	4.8	6.2	6.7	5.6	5.4	8.2
20611-04	5.1	5.5	5.4	4.6	4.6	6.1	6.7	7.3	4.5	7.7	8.0	2.6
20609-03	5.6	4.1	4.8	3.9	4.7	4.0	5.5	6.0	6.8	1.6	5.0	4.3
20611-10	5.1	5.3	3.5	5.7	5.7	4.6	3.8	6.4	7.0	6.4	6.7	5.4
20613-10	3.5	6.3	6.2	6.1	5.5	8.6	-1.3	13.3	5.6	7.2	6.2	8.5
20612-01	5.3	4.3	5.2	4.8	4.2	5.1	8.2	7.7	6.8	6.8	5.6	6.5
MEAN	4.6	5.6	5.2	5.2	5.3	5.8	4.6	7.6	6.0	6.1	6.8	5.3
S.D.	0.74	1.26	1.19	0.71	1.31	1.30	2.16	2.25	1.87	2.43	1.69	2.92
N	15	15	15	15	15	15	15	15	15	15	15	15

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Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: [redacted]60									
20606-08	8.2	4.4	3.5	1.6	2.4	8.5	3.0	4.8	97.5
20605-02	0.3	8.0	5.2	9.2	2.2	4.8	8.0	5.9	121.8
20607-06	13.4	0.6	5.5	12.0	2.4	2.8	8.5	-2.4	118.3
20603-06	3.0	9.2	1.0	1.5	7.0	0.8	7.7	0.2	92.4
20604-06	3.5	1.8	4.6	2.1	5.6	1.5	2.6	0.5	81.7
20606-03	3.2	4.1	4.9	5.0	3.4	6.8	6.5	-0.9	101.1
20607-02	3.9	4.5	5.5	2.8	5.6	1.8	7.2	3.1	108.4
20608-05	7.8	6.1	1.4	7.9	7.3	10.1	3.8	-4.5	114.9
20609-07	6.3	0.0	8.7	5.1	7.0	10.2	8.2	-6.1	108.3
20610-01	3.9	5.5	3.8	7.9	4.7	6.5	8.0	5.9	111.2
20611-04	3.7	5.6	2.0	8.0	5.1	2.2	2.5	6.0	103.2
20609-03	0.5	8.3	4.4	3.6	-1.9	9.2	0.6	4.2	85.2
20611-10	6.7	4.8	6.0	6.4	2.4	4.4	2.7	3.0	102.0
20613-10	4.9	7.3	8.1	2.0	6.6	9.5	1.7	2.3	118.1
20612-01	6.5	4.1	6.1	6.4	4.6	4.9	3.9	0.6	107.6
MEAN	5.1	5.0	4.7	5.4	4.3	5.6	5.0	1.5	104.8
S.D.	3.29	2.69	2.19	3.18	2.50	3.34	2.79	3.79	11.87
N	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 6: [redacted]250												
20604-05	4.6	4.5	5.2	6.7	5.1	7.5	4.2	6.4	5.1	3.9	13.2	5.1
20606-06	4.1	4.9	4.2	6.1	5.0	5.4	4.1	6.1	5.9	2.9	7.5	3.4
20605-06	5.4	5.0	4.8	5.7	5.8	5.3	3.4	5.1	7.9	2.0	11.2	6.4
20603-02	5.6	6.6	5.0	5.1	6.9	6.3	4.3	6.5	8.0	7.1	6.4	6.4
20607-10	3.7	6.1	4.9	4.2	4.9	4.3	4.3	5.8	7.0	4.7	4.3	4.3
20603-07	5.4	6.1	5.6	5.3	5.2	6.7	6.1	6.0	8.1	7.4	7.1	6.7
20607-04	2.9	5.4	5.4	3.5	7.3	3.3	7.6	5.8	6.0	4.2	6.9	6.0
20608-09	6.3	5.1	5.9	6.7	6.6	6.9	6.1	6.8	7.2	11.5	8.9	2.1
20609-10	5.9	6.0	5.1	5.3	5.2	7.3	6.6	6.3	8.0	7.2	6.9	4.4
20610-10	2.2	6.3	5.0	4.2	5.6	5.1	4.4	6.5	8.9	1.2	10.7	3.2
20611-06	4.4	5.6	5.9	5.1	4.2	6.3	5.0	7.2	7.1	5.4	6.7	4.3
20610-03	2.6	5.3	5.7	4.5	3.7	5.2	6.3	2.1	5.6	6.3	4.0	5.1
20614-03	3.5	7.3	3.9	6.9	4.9	6.4	6.4	3.5	9.1	6.4	3.0	1.3
20613-04	3.9	7.3	4.9	6.0	3.9	7.5	5.4	4.0	9.5	4.9	6.7	6.0
20615-01	4.5	6.4	5.4	2.9	5.5	7.4	4.3	7.2	7.1	5.2	4.3	9.6
MEAN	4.3	5.9	5.1	5.2	5.3	6.1	5.2	5.7	7.4	5.4	7.2	5.0
S.D.	1.23	0.84	0.57	1.19	1.03	1.26	1.21	1.44	1.31	2.52	2.84	2.06
N	15	15	15	15	15	15	15	15	15	15	15	15

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Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 6: [redacted]250									
20604-05	1.1	2.9	-0.7	7.5	5.2	6.1	2.6	-1.4	94.8
20606-06	2.2	5.2	5.2	1.2	3.4	1.2	5.8	2.6	86.4
20605-06	2.5	2.2	2.5	7.0	1.6	4.4	-2.5	6.6	92.3
20603-02	6.0	4.5	1.8	5.1	6.6	2.3	8.7	6.0	115.2
20607-10	5.7	-1.9	5.2	2.8	4.9	1.9	6.3	4.5	87.9
20603-07	5.1	4.1	7.2	2.6	9.2	10.0	-2.6	5.6	116.9
20607-04	3.3	5.3	5.3	6.4	0.3	1.8	9.4	1.7	97.8
20608-09	6.0	7.6	7.0	1.5	6.2	3.6	10.5	4.7	127.2
20609-10	7.5	3.6	10.7	-3.2	5.2	10.1	7.4	1.3	116.8
20610-10	5.3	6.4	1.5	4.1	3.0	8.2	0.5	6.1	98.4
20611-06	1.6	6.4	8.4	5.6	3.9	6.8	-1.0	7.4	106.3
20610-03	2.3	6.6	8.5	3.0	5.6	4.6	-0.8	12.4	98.6
20614-03	2.1	5.3	6.1	2.5	1.4	5.0	3.5	4.6	93.1
20613-04	4.9	10.0	7.0	1.7	1.8	5.8	8.3	5.0	114.5
20615-01	2.5	8.5	3.9	4.8	5.4	9.2	3.3	8.2	115.6
MEAN	3.9	5.1	5.3	3.5	4.2	5.4	4.0	5.0	104.1
S.D.	1.99	2.85	3.07	2.75	2.37	3.00	4.48	3.25	12.68
N	15	15	15	15	15	15	15	15	15

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Modified: 6/13/2006

TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-010

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 7: [redacted]1000												
20604-10	4.5	6.8	6.7	6.0	8.1	6.8	6.8	6.2	6.8	7.5	7.1	6.5
20603-08	3.6	6.2	4.0	6.5	4.5	4.5	5.0	5.3	5.9	4.5	6.9	7.4
20607-07	2.5	6.4	4.9	5.2	4.5	5.4	3.5	5.3	5.0	3.2	5.4	3.8
20605-03	3.7	6.2	4.8	5.7	5.1	5.3	6.7	4.2	5.0	9.5	6.9	7.5
20606-04	3.8	5.7	3.6	5.4	5.8	4.8	6.2	3.6	3.4	7.1	7.9	6.4
20604-07	3.9	5.7	5.9	5.5	4.2	6.0	4.8	6.8	5.6	7.1	6.1	3.6
20605-09	3.5	6.1	4.5	6.7	4.6	8.0	5.0	7.2	6.9	5.8	7.4	4.7
20608-06	7.3	4.7	6.2									
20609-06	6.8	5.8	6.7	6.5	4.7	6.1	4.5	6.5	6.7	4.3	8.9	4.7
20611-08	7.0	5.2	4.7	7.2	3.8	5.1	5.8	3.9	5.7	7.9	5.8	6.3
20610-09	3.5	5.6	5.1	6.3	6.0	3.9	6.4	8.8	4.6	8.3	10.6	5.3
20611-09	5.8	4.7	3.7	7.1	4.1	5.8	6.8	5.8	5.3	6.9	7.5	10.6
20614-04	5.2	6.3	3.9	5.3	4.8	5.6	4.7	8.0	3.5	6.0	5.8	2.4
20613-07	4.3	4.5	5.6	3.4	4.7	4.8	6.2	3.2	6.9	10.2	2.4	8.6
20612-09	5.7	5.4	5.9	4.0	7.0	5.0	6.9	5.5	3.4	8.5	5.1	6.5
MEAN	4.7	5.7	5.1	5.8	5.1	5.5	5.7	5.7	5.3	6.9	6.7	6.0
S.D.	1.48	0.68	1.05	1.10	1.20	1.02	1.07	1.66	1.27	2.00	1.91	2.15
N	15	15	15	14	14	14	14	14	14	14	14	14

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TABLE 15

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-010

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 7: [redacted]1000									
20604-10	4.5	7.8	5.0	9.2	1.2	5.4	0.6	12.0	125.5
20603-08	4.6	7.8	1.0	2.6	3.1	9.3	8.0	-1.4	99.3
20607-07	-0.1	4.5	1.6	3.6	0.8	3.1	4.6	5.9	79.1
20605-03	5.2	2.3	7.7	4.6	1.0	8.6	4.6	4.7	109.3
20606-04	3.4	4.0	3.3	1.5	7.0	3.5	1.6	4.3	92.3
20604-07	5.2	2.9	6.3	4.8	-0.8	8.7	4.6	4.5	101.4
20605-09	5.2	3.9	4.7	7.3	3.1	0.9	12.2	1.2	108.9
20609-06	6.1	3.9	3.2	3.3	6.5	5.6	3.4	-2.2	102.0
20611-08	4.7	6.8	5.4	3.2	7.0	5.0	2.6	6.7	109.8
20610-09	7.0	9.8	11.8	4.1	9.2	11.8	8.8	5.9	142.8
20611-09	7.3	5.0	5.3	6.7	2.0	4.3	-2.1	13.3	115.9
20614-04	2.4	2.8	1.8	7.9	6.2	1.4	9.1	-1.5	91.6
20613-07	4.4	7.8	3.5	2.7	8.4	9.8	-4.4	11.3	108.3
20612-09	3.8	4.5	6.9	4.1	6.5	2.5	2.1	7.7	107.0
MEAN	4.6	5.3	4.8	4.7	4.4	5.7	4.0	5.2	106.7
S.D.	1.87	2.31	2.84	2.25	3.23	3.40	4.51	4.96	15.36
N	14	14	14	14	14	14	14	14	14

PJTBWv4.22
06/13/2006

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Modified: 6/13/2006

TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: CORN OIL SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20605-10	31	116.4	N	N	N	N	Y					
20603-03	33	108.6	N	N	N	N	N	N	Y			
20607-08	31	106.3	N	N	N	N	Y					
20606-09	34	111.0	N	N	N	N	N	N	N	Y		
20604-03	35	117.7	N	N	N	N	N	N	N	N	Y	
20603-01	34	117.6	N	N	N	N	N	N	N	Y		
20605-08	30	112.0	N	N	N	Y						
20608-02	34	107.2	N	N	N	N	N	N	N	Y		
20609-08	33	112.4	N	N	N	N	N	N	Y			
20611-01	28	90.0	N	Y								
20610-04	30	106.5	N	N	N	Y						
20609-04	32	115.8	N	N	N	N	N	Y				
20613-03	32	120.6	N	N	N	N	N	Y				
20615-03	31	110.3	N	N	N	N	Y					
20612-03	33	118.8	N	N	N	N	N	N	Y			
MEAN	32.1	111.4										
S.D.	1.91	7.55										
N	15	15										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Draft

Modified: 6/13/2006

TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20607-09	28	94.7	N	Y								
20605-05	33	121.4	N	N	N	N	N	N	Y			
20606-02	31	103.5	N	N	N	N	Y					
20604-08	35	129.1	N	N	N	N	N	N	N	N	Y	
20603-10	33	103.8	N	N	N	N	N	N	Y			
20604-09	36	135.1	N	N	N	N	N	N	N	N	N	Y
20607-03	31	112.3	N	N	N	N	Y					
20609-05	34	107.5	N	N	N	N	N	N	N	Y		
20608-07	35	124.3	N	N	N	N	N	N	N	N	Y	
20610-05	32	106.8	N	N	N	N	N	Y				
20611-07	31	112.7	N	N	N	N	Y					
20610-07	35	128.9	N	N	N	N	N	N	N	N	Y	
20613-06	33	124.7	N	N	N	N	N	N	Y			
20612-07	30	97.5	N	N	N	Y						
20615-07	33	107.6	N	N	N	N	N	N	Y			
MEAN	32.7	114.0										
S.D.	2.19	12.45										
N	15	15										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Draft

Modified: 6/13/2006

TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20606-07	33	110.5	N	N	N	N	N	N	Y			
20603-09	33	110.0	N	N	N	N	N	N	Y			
20607-01	30	95.2	N	N	N	Y						
20604-02	35	119.3	N	N	N	N	N	N	N	N	Y	
20605-01	34	114.6	N	N	N	N	N	N	N	Y		
20605-04	33	111.3	N	N	N	N	N	N	Y			
20606-05	30	101.7	N	N	N	Y						
20608-08	31	96.7	N	N	N	N	Y					
20609-09	34	125.5	N	N	N	N	N	N	N	Y		
20610-02	32	95.6	N	N	N	N	N	Y				
20611-02	34	115.9	N	N	N	N	N	N	N	Y		
20611-05	27	89.2	Y									
20608-10	30	100.0	N	N	N	Y						
20613-08	31	121.2	N	N	N	N	Y					
20614-01	29	92.4	N	N	Y							
MEAN	31.7	106.6										
S.D.	2.25	11.50										
N	15	15										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20606-10	29	95.3	N	N	Y							
20605-07	29	91.3	N	N	Y							
20604-04	28	89.7	N	Y								
20603-04	28	84.0	N	Y								
20607-05	29	84.4	N	N	Y							
20604-01	31	97.2	N	N	N	N	Y					
20606-01	28	85.6	N	Y								
20608-03	28	68.8	N	Y								
20609-01	28	85.8	N	Y								
20611-03	28	88.5	N	Y								
20610-06	27	88.8	Y									
20610-08	27	84.9	Y									
20608-01	27	77.0	Y									
20612-05	28	93.6	N	Y								
20613-01	27	87.1	Y									
MEAN	28.1	86.8										
S.D.	1.06	7.08										
N	15	15										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Draft

Modified: 6/13/2006

TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20606-08	29	98.5	N	N	Y							
20605-02	33	122.1	N	N	N	N	N	N	Y			
20607-06	28	85.0	N	Y								
20603-06	33	114.5	N	N	N	N	N	N	Y			
20604-06	33	96.9	N	N	N	N	N	N	Y			
20606-03	33	109.4	N	N	N	N	N	N	Y			
20607-02	33	118.3	N	N	N	N	N	N	Y			
20608-05	33	119.0	N	N	N	N	N	N	Y			
20609-07	33	118.4	N	N	N	N	N	N	Y			
20610-01	34	120.2	N	N	N	N	N	N	N	Y		
20611-04	33	121.5	N	N	N	N	N	N	Y			
20609-03	34	110.2	N	N	N	N	N	N	N	Y		
20611-10	34	119.6	N	N	N	N	N	N	N	Y		
20613-10	33	127.6	N	N	N	N	N	N	Y			
20612-01	31	104.3	N	N	N	N	Y					
MEAN	32.5	112.4										
S.D.	1.77	11.66										
N	15	15										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

187055 RD

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Modified: 6/13/2006

TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20604-05	31	104.3	N	N	N	N	Y					
20606-06	31	96.9	N	N	N	N	Y					
20605-06	31	101.9	N	N	N	N	Y					
20603-02	33	116.9	N	N	N	N	N	N	Y			
20607-10	32	98.0	N	N	N	N	N	Y				
20603-07	35	127.2	N	N	N	N	N	N	N	N	Y	
20607-04	33	115.5	N	N	N	N	N	N	Y			
20608-09	33	126.9	N	N	N	N	N	N	Y			
20609-10	34	123.8	N	N	N	N	N	N	N	Y		
20610-10	33	117.1	N	N	N	N	N	N	Y			
20611-06	31	106.4	N	N	N	N	Y					
20610-03	35	114.1	N	N	N	N	N	N	N	N	Y	
20614-03	31	107.6	N	N	N	N	Y					
20613-04	33	120.2	N	N	N	N	N	N	Y			
20615-01	32	105.9	N	N	N	N	N	Y				
MEAN	32.5	112.2										
S.D.	1.41	10.00										
N	15	15										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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Modified: 6/13/2006

TABLE 16

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-010

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36
20604-10	31	119.1	N	N	N	N	Y					
20603-08	33	109.8	N	N	N	N	N	N	Y			
20607-07	30	92.0	N	N	N	Y						
20605-03	31	102.5	N	N	N	N	Y					
20606-04	29	87.4	N	N	Y							
20604-07	34	117.0	N	N	N	N	N	N	N	Y		
20605-09	29	95.8	N	N	Y							
20608-06	RESPONSE NOT EXHIBITED BY DAY 25, DAY OF DEATH											
20609-06	32	106.1	N	N	N	N	N	Y				
20611-08	28	84.7	N	Y								
20610-09	29	90.1	N	N	Y							
20611-09	36	141.2	N	N	N	N	N	N	N	N	N	Y
20614-04	31	103.9	N	N	N	N	Y					
20613-07	31	97.0	N	N	N	N	Y					
20612-09	31	101.6	N	N	N	N	Y					
MEAN	31.1	103.4										
S.D.	2.16	15.00										
N	14	14										

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

PJTBBv1.14
05/17/2006
R:05/17/2006

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Modified: 6/13/2006

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-010

FEMALES FROM GROUP 1: CORN OIL

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9	1 0	1 1 2	1 3	1 4	1 5	1 6	1 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20605-10	N N N P E D D D P	E	M	D	D	P	E		5.0
20603-03	N N N N N E D D D	P	E	D	D	D	E		5.0
20607-08	N N N D D D P E D	D	P	E	D	D	P		4.0
20606-09	N N N N N N D D D	P	E	D	D	D	P		A
20604-03	N N N N N N N E D	D	D	D	E	D	D		5.0
20603-01	N N N N N N P D D	D	P	E	D	D	D		5.0
20605-08	N N D P E D D D D	D	P	E	D	D	D		7.0
20608-02	N N N N N N N D P	D	D	D	D	E	D	D	5.0
20609-08	N N N N N N D D D	D	E	D	D	D	P	E	A
20611-01	N D P D D D E D D	D	E	D	D	D	E	D	4.0
20610-04	N N N P E D D D P	E	D	D	P	E	D	D	4.5
20609-04	N N N N N E D D D	D	D	E	D	D	P	E	6.0
20613-03	N N N N N N E D D	D	D	E	E	D	D	D P	6.0
20615-03	N N N N N P E D D	D	E	E	D	D	D	E D	4.5
20612-03	N N N N N N N E D	D	D	D	E	D	D	D P	5.0
							MEAN		5.1
							S.D.		0.84
							N		13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED

Revised Draft

Modified: 6/13/2006

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-010

FEMALES FROM GROUP 2: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9	1 0	1 1 2	1 3	1 4	1 5	1 6	1 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20607-09	D D D E D D D E D	D	P	E	D	D	P		4.0
20605-05	N N N N N D D D P	E	D	D	D	E	E		A
20606-02	N N N D E D D D E	E	D	D	D	E	E		5.0
20604-08	N N N N N N N E D	D	D	D	E	E	D		6.0
20603-10	N N N N N E D D D	P	E	D	D	D	D		5.0
20604-09	N N N N N N N N D	P	D	D	D	P	E		A
20607-03	N N N E D D D P E	D	D	D	E	E	D		5.0
20609-05	N N N N N N N E D	D	D	D	E	D	D	D	5.0
20608-07	N N N N N N N N E	D	D	D	D	D	P	E	A
20610-05	N N N N N E D D D	D	E	E	D	D	D	E	6.0
20611-07	N N N N E D D D E	D	D	D	E	D	D	P	4.0
20610-07	N N N N N N N N E	D	E	I	P	E	D	D	4.0
20613-06	N N N N N N N M D	D	D	P	E	D	D	D E	A
20612-07	N N N N E D D D E	D	D	P	E	D	D	D E	4.0
20615-07	N N N N N N N E D	D	D	D	D	E	E	D D D	6.0

MEAN	4.9
S.D.	0.83
N	11

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED, I = INSUFFICIENT CELLS PRESENT

Revised Draft

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-010

FEMALES FROM GROUP 3: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20606-07	N N N N N D E D D D D E D D D	5.0
20603-09	N N N N N E D D D D E E D D D	6.0
20607-01	N N D D E D D D P E D D D E E	5.0
20604-02	N N N N N N N P D D D P E D D	5.0
20605-01	N N N N N N E D D D D E D D D	5.0
20605-04	N N N N N D P D D D P E D D D	5.0
20606-05	N N E D D D D E D D D E E D D	5.0
20608-08	N N N N E D D D D D D D D D D	A
20609-09	N N N N N N N E M D D P E M D D	5.0
20610-02	N N N N N E D D D D E E D D D E	6.0
20611-02	N N N N N N N D D E D D D D D E	A
20611-05	D P E D D D P E D D D P E D D D	5.0
20608-10	N N N D P E D D D E D D D P E D	4.5
20613-08	N N N N N E D D D P E D D D E E D	5.0
20614-01	N N N P D D D E D D D E D D P E D	4.0
	MEAN	5.0
	S.D.	0.52
	N	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED

Revised Draft

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-010

FEMALES FROM GROUP 4: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20606-10	N P E D D D D E D D D P E D D	5.0
20605-07	N D E E D D D D E M D D E E D	5.0
20604-04	D D D E E D D D D D E D D D D	6.0
20603-04	D D P D D E E D D D D E E D N	5.0
20607-05	N D D D D D D D E M D D D E E	A
20604-01	N N D D D D D D P E D D D D P	A
20606-01	D D P E D D D D D P E E D D D	7.0
20608-03	N D D D D E E D D D D D E D D D	6.0
20609-01	N D D D D D D D E D D D D E D D D	5.0
20611-03	N D E E M D D D P E D D D E E D	5.5
20610-06	D D E E D D D D P E D D D P E D D	5.0
20610-08	D D D E E D D D P E D D D P E D D	5.0
20608-01	D D D D D E D D D P E D D D P E D	5.0
20612-05	N N D D D D E D D D P E D D D D E E D	5.0
20613-01	N D D D D E D D D P E D D D D E D D	5.0
	MEAN	5.3
	S.D.	0.63
	N	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED

Revised Draft

Modified: 6/13/2006

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 5: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20606-08	N E D D D D E D D D E E D D P	5.0
20605-02	N N N N N E D D D D P E D D D	6.0
20607-06	D D D D D D D D D D D D E N	A
20603-06	N N N N N E D D D P E D D D P	5.0
20604-06	N N N N N E D D D P E D D D E	5.0
20606-03	N N N N N D D D P E D D D D E	A
20607-02	N N N N N D D D E E D D P E D	4.0
20608-05	N N N N N N D D D D E D D D P E	A
20609-07	N N N N N N D D P E D D D E D D	4.0
20610-01	N N N N N N N E D D D D E M D D	5.0
20611-04	N N N N N N E D D D E D D D E D	4.0
20609-03	N N N N N N N E D D D E E D D D	5.0
20611-10	N N N N N N N E D D D D E E D D	6.0
20613-10	N N N N N N N D D D D E E D D D E	A
20612-01	N N N N N E E D D D P E D D D E E	5.0
	MEAN	4.9
	S.D.	0.70
	N	11

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED

Revised Draft

Modified: 6/13/2006

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-010

FEMALES FROM GROUP 6: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20604-05	N N N D D D D D D E D D D D E	A
20606-06	N N N D D D D D E E D D D E D D	4.0
20605-06	N N N D E D D D E E D D P E D	4.5
20603-02	N N N N N E D D D P E D D D D	5.0
20607-10	N N N N D E D D D P E D D D E	5.0
20603-07	N N N N N N N E E D D D P E D	5.0
20607-04	N N N N N E D D D D E D D D E	5.0
20608-09	N N N N N N P E D D D E E D D D	5.0
20609-10	N N N N N N N E M D D E E D D D	5.0
20610-10	N N N N N N D D D D E E D D D E D	4.0
20611-06	N N N N E D D D P E D D D D P E D	5.0
20610-03	N N N N N N N N P E D D D P E D	5.0
20614-03	N N N N N D D D P E D D D E E D D	5.0
20613-04	N N N N N N N E D D D D P E D D D	6.0
20615-01	N N N N N N E D D D D D D D D D D	A
	MEAN	4.9
	S.D.	0.51
	N	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED

Revised Draft

Modified: 6/13/2006

TABLE 17

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-010

FEMALES FROM GROUP 7: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
20604-10	N N N P E D D D D D D D D D D	A
20603-08	N N N N N E D D D P E D D D E	5.0
20607-07	N N E D D D D E D D D E E D D	5.0
20605-03	N N N D E D D D P E D D D D D	5.0
20606-04	N D P E D D D D P E D D D P E	6.0
20604-07	N N N N N N E D D D P E D D D	5.0
20605-09	N D E E D D D P E D D D E E D	5.0
20608-06		F
20609-06	N N N N N P D D D D E D D D P E	5.0
20611-08	N D D E D D D E D D P E D D P E	4.0
20610-09	N N D D E D D D D D D D D D D D	A
20611-09	N N N N N N N N D D D D P E D D	A
20614-04	N N N N N D D D P E D D D E E D D	5.0
20613-07	N N N N N E D D D P E D D D P E D	5.0
20612-09	N N N N N E D D D E E D D D P E D	5.0
	MEAN	5.0
	S.D.	0.45
	N	11

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P].
N = NOT ENTERED
F = FEMALE DIED

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Modified: 6/13/2006

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP:	CORN OIL	FEMALES		
20605-10	4.30	7.1	115.	4.6
20603-03	6.50	5.7	124.	3.0
20607-08	4.50	8.1	106.	2.9
20606-09	8.00	5.6	130.	5.7
20604-03	4.20	5.3	93.	2.6
20603-01	4.00	7.0	135.	3.3
20605-08	6.20	7.3	140.	2.2
20608-02	1.60	9.4	UR	6.1
20609-08	7.60	6.8	117.	2.5
20611-01	1.30	7.6	99.	4.2
20610-04	4.00	4.7	85.	2.5
20609-04	6.90	5.5	135.	3.5
20613-03	5.30	12.3	125.	3.7
20615-03	5.20	9.0	131.	2.4
20612-03	5.40	7.9	156.	5.7
MEAN	5.00	7.3	121.	3.7
S.D.	1.927	1.95	19.7	1.31
N	15	15	14	15

UR = BELOW INSTRUMENT RANGE

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

Modified: 6/13/2006

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP: [redacted]60	FEMALES			
20607-09	4.50	8.0	106.	2.2
20605-05	6.10	5.0	112.	2.8
20606-02	5.60	5.8	97.	3.7
20604-08	4.90	6.1	103.	3.2
20603-10	4.20	6.3	84.	2.5
20604-09	6.40	RU	99.	3.7
20607-03	4.50	5.5	164.	2.3
20609-05	3.60	7.1	110.	4.9
20608-07	5.00	11.0	114.	3.3
20610-05	4.90	6.6	143.	3.6
20611-07	5.30	11.5	125.	5.7
20610-07	5.70	5.2	156.	2.0
20613-06	6.40	12.1	136.	4.6
20612-07	7.10	13.7	154.	3.6
20615-07	5.10	6.4	166.	2.8
MEAN	5.29	7.9	125.	3.4
S.D.	0.940	2.91	26.7	1.05
N	15	14	15	15

RU = RESULT UNOBTAINABLE

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

Modified: 6/13/2006

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP: [redacted]250	FEMALES			
20606-07	3.80	4.7	126.	1.8
20603-09	3.90	5.2	128.	2.1
20607-01	4.20	6.8	112.	1.9
20604-02	4.40	6.9	132.	2.5
20605-01	6.30	5.9	92.	2.9
20605-04	4.90	4.4	121.	2.9
20606-05	4.20	6.0	111.	4.3
20608-08	4.90	6.8	218.	2.0
20609-09	5.30	6.1	153.	2.8
20610-02	4.70	9.9	106.	4.9
20611-02	5.40	13.7	172.	21.2
20611-05	6.30	12.3	132.	2.3
20608-10	4.40	8.3	144.	3.0
20613-08	3.90	5.7	120.	3.3
20614-01	4.50	6.7	156.	3.8
MEAN	4.74	7.3	135.	4.1
S.D.	0.794	2.70	31.0	4.81
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

Modified: 6/13/2006

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP: [redacted]1000	FEMALES			
20606-10	5.00	5.5	139.	2.0
20605-07	4.10	10.6	91.	6.4
20604-04	7.70	5.9	98.	2.1
20603-04	4.60	6.8	122.	3.7
20607-05	5.90	5.0	115.	1.8
20604-01	7.00	5.5	114.	10.5
20606-01	5.20	6.4	110.	4.7
20608-03	4.70	6.4	127.	3.9
20609-01	5.00	7.7	93.	2.1
20611-03	4.00	6.8	139.	2.1
20610-06	5.20	9.5	134.	1.2
20610-08	5.10	6.1	122.	1.3
20608-01	4.30	7.8	107.	2.1
20612-05	6.10	7.9	126.	3.5
20613-01	5.90	12.2	99.	1.8
MEAN	5.32	7.3	116.	3.3
S.D.	1.043	2.03	16.0	2.45
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP: [redacted]60	FEMALES			
20606-08	5.40	6.0	133.	2.3
20605-02	5.40	5.7	150.	2.8
20607-06	6.20	7.1	106.	2.0
20603-06	5.10	9.2	107.	10.1
20604-06	6.80	8.0	180.	8.9
20606-03	5.00	7.0	85.	3.6
20607-02	4.10	7.3	111.	3.8
20608-05	5.10	7.2	154.	2.2
20609-07	3.90	5.5	115.	3.0
20610-01	4.70	5.8	98.	2.2
20611-04	5.20	8.1	135.	4.3
20609-03	7.00	6.7	125.	2.6
20611-10	5.40	5.3	138.	0.4
20613-10	6.30	9.7	120.	3.0
20612-01	4.90	7.3	55.	3.4
MEAN	5.37	7.1	121.	3.6
S.D.	0.887	1.31	30.2	2.56
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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Modified: 6/13/2006

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP: [redacted]250	FEMALES			
20604-05	6.40	6.9	110.	5.2
20606-06	4.60	7.7	186.	1.9
20605-06	5.30	5.3	107.	4.2
20603-02	5.40	5.8	96.	2.5
20607-10	6.70	8.2	105.	4.6
20603-07	4.50	4.6	112.	2.0
20607-04	5.40	7.6	101.	RU
20608-09	3.80	6.0	131.	2.1
20609-10	3.90	7.9	142.	3.5
20610-10	3.60	7.3	130.	2.7
20611-06	4.40	8.4	94.	3.6
20610-03	4.80	6.3	116.	2.4
20614-03	4.40	5.6	98.	2.4
20613-04	7.10	6.2	242.	1.7
20615-01	4.90	7.8	134.	2.2
MEAN	5.01	6.8	127.	2.9
S.D.	1.051	1.17	39.7	1.10
N	15	15	15	14

RU = RESULT UNOBTAINABLE

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

TABLE 18

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-010

ANIMAL	TOTAL T4	TSH	ESTRA-DIOL	LUTEIN' HORMONE
	uG/dL	ng/mL	pg/mL	ng/mL
GROUP: [redacted]1000	FEMALES			
20604-10	3.70	6.4	172.	1.7
20603-08	5.40	10.5	125.	2.9
20607-07	4.50	11.3	75.	2.2
20605-03	4.60	4.2	89.	4.6
20606-04	3.40	5.8	131.	3.5
20604-07	5.30	8.7	125.	2.5
20605-09	4.30	6.1	126.	2.3
20609-06	6.40	7.2	117.	4.3
20611-08	4.00	10.8	96.	5.2
20610-09	5.80	9.5	202.	1.9
20611-09	4.70	8.2	182.	2.4
20614-04	5.20	8.5	120.	1.0
20613-07	4.50	7.3	169.	3.8
20612-09	5.70	6.1	166.	3.9
MEAN	4.82	7.9	135.	3.0
S.D.	0.851	2.11	37.5	1.22
N	14	14	14	14

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

PCHEv4.03
06/13/2006
R:06/13/2006

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Modified: 6/13/2006

TABLE 19 (UNSCHEDULED DEATH)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-06 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 03/18/06 DATE OF DEATH: 03/18/06

		GRADE
LUNGS	GROSS: AREA(S), DARK RED ONE, IRREGULARLY SHAPED, RIGHT INTERMEDIATE AND RIGHT DIAPHRAGMATIC LOBES	P
THORACIC CAVITY	GROSS: CONTENTS, DARK RED FLUID	P

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	MAMMARY GLAND	OVIDUCTS	OVARIES
PANCREAS	PITUITARY	SPINAL CORD	SAL. GLAND MAND
SKIN	SPLEEN	STOMACH	LYMPH NODE, AXI
THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
UTERUS	CERVIX	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.54
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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-10 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4062	0.238		
UTERUS- BLOTTED	0.3826	0.224		
LIVER	9.3917	5.492		
KIDNEYS	1.7318	1.013		
SPLEEN	0.3223	0.188		
THYMUS	0.5856	0.342		
OVARIES/OVIDUCTS	0.1029	0.060		
ADRENAL GLANDS	0.0425	0.025		
PITUITARY	0.0112	0.007		
THYROIDS/PARA	0.0116	0.007		
FINAL BODY WT(G)	171.			

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20603-03 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3605	0.239		
UTERUS- BLOTTED	0.3344	0.221		
LIVER	8.2343	5.453		
KIDNEYS	1.5919	1.054		
SPLEEN	0.3553	0.235		
THYMUS	0.6204	0.411		
OVARIES/OVIDUCTS	0.0742	0.049		
ADRENAL GLANDS	0.0402	0.027		
PITUITARY	0.0107	0.007		
THYROIDS/PARA	0.0130	0.009		
FINAL BODY WT(G)	151.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20607-08 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6282	0.367
UTERUS- BLOTTED	0.4599	0.269
LIVER	9.7907	5.726
KIDNEYS	1.7257	1.009
SPLEEN	0.4103	0.240
THYMUS	0.8054	0.471
OVARIES/OVIDUCTS	0.0791	0.046
ADRENAL GLANDS	0.0397	0.023
PITUITARY	0.0104	0.006
THYROIDS/PARA	0.0204	0.012
FINAL BODY WT(G)	171.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-09 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6885	0.495
UTERUS- BLOTTED	0.4008	0.288
LIVER	6.7619	4.865
KIDNEYS	1.3922	1.002
SPLEEN	0.3322	0.239
THYMUS	0.7051	0.507
OVARIES/OVIDUCTS	0.0686	0.049
ADRENAL GLANDS	0.0228	0.016
PITUITARY	0.0061	0.004
THYROIDS/PARA	0.0137	0.010
FINAL BODY WT(G)	139.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-03 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1880	0.132
UTERUS- BLOTTED	0.1659	0.117
LIVER	8.0257	5.652
KIDNEYS	1.7689	1.246
SPLEEN	0.3696	0.260
THYMUS	0.4085	0.288
OVARIES/OVIDUCTS	0.0783	0.055
ADRENAL GLANDS	0.0360	0.025
PITUITARY	0.0090	0.006
THYROIDS/PARA	0.0115	0.008
FINAL BODY WT(G)	142.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20603-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4670	0.292		
UTERUS- BLOTTED	0.3378	0.211		
LIVER	8.6276	5.392		
KIDNEYS	1.4437	0.902		
SPLEEN	0.5196	0.325		
THYMUS	0.8206	0.513		
OVARIES/OVIDUCTS	0.0605	0.038		
ADRENAL GLANDS	0.0356	0.022		
PITUITARY	0.0077	0.005		
THYROIDS/PARA	0.0144	0.009		
FINAL BODY WT(G)	160.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-08 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.6477	0.350	GROSS:ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
UTERUS- BLOTTED	0.4538	0.245	OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
LIVER	11.1107	6.006	THYMUS	THYROID GLANDS	UTERUS	CERVIX	
KIDNEYS	1.7281	0.934	VAGINA				
SPLEEN	0.6084	0.329					
THYMUS	0.6709	0.363					
OVARIES/OVIDUCTS	0.1027	0.056					
ADRENAL GLANDS	0.0392	0.021					
PITUITARY	0.0110	0.006					
THYROIDS/PARA	0.0142	0.008					
FINAL BODY WT(G)	185.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-02 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.1761	0.129		
UTERUS- BLOTTED	0.1559	0.115		
LIVER	6.8659	5.048		
KIDNEYS	1.4513	1.067		
SPLEEN	0.3688	0.271		
THYMUS	0.5368	0.395		
OVARIES/OVIDUCTS	0.0601	0.044		
ADRENAL GLANDS	0.0312	0.023		
PITUITARY	0.0058	0.004		
THYROIDS/PARA	0.0103	0.008		
FINAL BODY WT(G)	136.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20609-08 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3317	0.218		
UTERUS- BLOTTED	0.3123	0.205		
LIVER	8.6852	5.714		
KIDNEYS	1.5980	1.051		
SPLEEN	0.4550	0.299		
THYMUS	0.5137	0.338		
OVARIES/OVIDUCTS	0.0890	0.059		
ADRENAL GLANDS	0.0443	0.029		
PITUITARY	0.0086	0.006		
THYROIDS/PARA	0.0118	0.008		
FINAL BODY WT(G)	152.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2359	0.141	GROSS:	
UTERUS- BLOTTED	0.2166	0.130		
LIVER	9.0362	5.411		
KIDNEYS	1.7152	1.027		
SPLEEN	0.4243	0.254		
THYMUS	0.4176	0.250		
OVARIES/OVIDUCTS	0.0778	0.047		
ADRENAL GLANDS	0.0369	0.022		
PITUITARY	0.0088	0.005		
THYROIDS/PARA	0.0097	0.006		
FINAL BODY WT(G)	167.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.3030	0.188		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2750	0.171		OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
LIVER	9.6722	6.008		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.9027	1.182		VAGINA			
SPLEEN	0.3817	0.237					
THYMUS	0.4724	0.293					
OVARIES/OVIDUCTS	0.0891	0.055					
ADRENAL GLANDS	0.0371	0.023					
PITUITARY	0.0100	0.006					
THYROIDS/PARA	0.0178	0.011					
FINAL BODY WT(G)	161.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20609-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3455	0.207		
UTERUS- BLOTTED	0.3286	0.197		
LIVER	8.9181	5.340		
KIDNEYS	1.6408	0.983		
SPLEEN	0.5258	0.315		
THYMUS	0.5769	0.345		
OVARIES/OVIDUCTS	0.0835	0.050		
ADRENAL GLANDS	0.0356	0.021		
PITUITARY	0.0086	0.005		
THYROIDS/PARA	0.0127	0.008		
FINAL BODY WT(G)	167.			

GRADE

GROSS: ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20613-03 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.6516	0.364	GROSS:	
UTERUS- BLOTTED	0.3854	0.215		
LIVER	10.1249	5.656		
KIDNEYS	1.6731	0.935		
SPLEEN	0.4808	0.269		
THYMUS	0.6112	0.341		
OVARIES/OVIDUCTS	0.0900	0.050		
ADRENAL GLANDS	0.0437	0.024		
PITUITARY	0.0083	0.005		
THYROIDS/PARA	0.0144	0.008		
FINAL BODY WT(G)	179.			

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20615-03 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2594	0.149	
UTERUS- BLOTTED	0.2398	0.138	
LIVER	10.3023	5.921	
KIDNEYS	1.8416	1.058	
SPLEEN	0.5449	0.313	
THYMUS	0.5620	0.323	
OVARIES/OVIDUCTS	0.0958	0.055	
ADRENAL GLANDS	0.0433	0.025	
PITUITARY	0.0099	0.006	
THYROIDS/PARA	0.0195	0.011	
FINAL BODY WT(G)	174.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20612-03 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.6515	0.412	
UTERUS- BLOTTED	0.3902	0.247	
LIVER	9.3332	5.907	
KIDNEYS	1.6546	1.047	
SPLEEN	0.4146	0.262	
THYMUS	0.5302	0.336	
OVARIES/OVIDUCTS	0.0918	0.058	
ADRENAL GLANDS	0.0407	0.026	
PITUITARY	0.0104	0.007	
THYROIDS/PARA	0.0072	0.005	
FINAL BODY WT(G)	158.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20607-09 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.5843	0.361
UTERUS- BLOTTED	0.3980	0.246
LIVER	7.9859	4.930
KIDNEYS	1.5924	0.983
SPLEEN	0.5157	0.318
THYMUS	0.5344	0.330
OVARIES/OVIDUCTS	0.0848	0.052
ADRENAL GLANDS	0.0383	0.024
PITUITARY	0.0105	0.006
THYROIDS/PARA	0.0140	0.009
FINAL BODY WT(G)	162.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-05 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3572	0.211	
UTERUS- BLOTTED	0.3338	0.198	
LIVER	8.3054	4.914	
KIDNEYS	1.7897	1.059	
SPLEEN	0.3866	0.229	
THYMUS	0.4321	0.256	
OVARIES/OVIDUCTS	0.1024	0.061	
ADRENAL GLANDS	0.0458	0.027	
PITUITARY	0.0100	0.006	
THYROIDS/PARA	0.0129	0.008	
FINAL BODY WT(G)	169.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-02 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3930	0.255
UTERUS- BLOTTED	0.3704	0.241
LIVER	7.8382	5.090
KIDNEYS	1.6468	1.069
SPLEEN	0.4450	0.289
THYMUS	0.7285	0.473
OVARIES/OVIDUCTS	0.0983	0.064
ADRENAL GLANDS	0.0502	0.033
PITUITARY	0.0102	0.007
THYROIDS/PARA	0.0175	0.011
FINAL BODY WT(G)	154.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-08 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2336	0.151		
UTERUS- BLOTTED	0.2161	0.139		
LIVER	7.7103	4.974		
KIDNEYS	1.5616	1.007		
SPLEEN	0.4063	0.262		
THYMUS	0.5472	0.353		
OVARIES/OVIDUCTS	0.0721	0.047		
ADRENAL GLANDS	0.0318	0.021		
PITUITARY	0.0078	0.005		
THYROIDS/PARA	0.0142	0.009		
FINAL BODY WT(G)	155.			

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20603-10 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2255	0.156
UTERUS- BLOTTED	0.2093	0.144
LIVER	8.0914	5.580
KIDNEYS	1.6752	1.155
SPLEEN	0.4248	0.293
THYMUS	0.7307	0.504
OVARIES/OVIDUCTS	0.0630	0.043
ADRENAL GLANDS	0.0353	0.024
PITUITARY	0.0091	0.006
THYROIDS/PARA	0.0101	0.007
FINAL BODY WT(G)	145.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 21

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-09 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2897	0.173	
UTERUS- BLOTTED	0.2709	0.162	
LIVER	9.1225	5.463	
KIDNEYS	1.7652	1.057	
SPLEEN	0.4450	0.266	
THYMUS	0.6655	0.399	
OVARIES/OVIDUCTS	0.0878	0.053	
ADRENAL GLANDS	0.0423	0.025	
PITUITARY	0.0118	0.007	
THYROIDS/PARA	0.0143	0.009	
FINAL BODY WT(G)	167.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20607-03 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2437	0.157		
UTERUS- BLOTTED	0.2261	0.146		
LIVER	8.4457	5.449		
KIDNEYS	1.7408	1.123		
SPLEEN	0.3463	0.223		
THYMUS	0.3877	0.250		
OVARIES/OVIDUCTS	0.0823	0.053		
ADRENAL GLANDS	0.0433	0.028		
PITUITARY	0.0086	0.006		
THYROIDS/PARA	0.0138	0.009		
FINAL BODY WT(G)	155.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20609-05 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2700	0.206
UTERUS- BLOTTED	0.2495	0.190
LIVER	7.3759	5.630
KIDNEYS	1.4654	1.119
SPLEEN	0.3398	0.259
THYMUS	0.4242	0.324
OVARIES/OVIDUCTS	0.0669	0.051
ADRENAL GLANDS	0.0252	0.019
PITUITARY	0.0057	0.004
THYROIDS/PARA	0.0123	0.009
FINAL BODY WT(G)	131.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-07 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2874	0.183
UTERUS- BLOTTED	0.2711	0.173
LIVER	8.6952	5.538
KIDNEYS	1.6544	1.054
SPLEEN	0.4098	0.261
THYMUS	0.6584	0.419
OVARIES/OVIDUCTS	0.0649	0.041
ADRENAL GLANDS	0.0314	0.020
PITUITARY	0.0064	0.004
THYROIDS/PARA	0.0098	0.006
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-05 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.2983	0.203		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2793	0.190		OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
LIVER	7.7385	5.264		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.8701	1.272		VAGINA			
SPLEEN	0.3761	0.256					
THYMUS	0.4433	0.302					
OVARIES/OVIDUCTS	0.0742	0.050					
ADRENAL GLANDS	0.0376	0.026					
PITUITARY	0.0095	0.006					
THYROIDS/PARA	0.0124	0.008					
FINAL BODY WT(G)	147.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 26

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-07 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6848	0.387
UTERUS- BLOTTED	0.4355	0.246
LIVER	9.5616	5.402
KIDNEYS	1.8942	1.070
SPLEEN	0.4823	0.272
THYMUS	0.5274	0.298
OVARIES/OVIDUCTS	0.0767	0.043
ADRENAL GLANDS	0.0355	0.020
PITUITARY	0.0087	0.005
THYROIDS/PARA	0.0127	0.007
FINAL BODY WT(G)	177.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-07 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2520	0.158	NO SIGNIFICANT
UTERUS- BLOTTED	0.2300	0.145	CHANGES OBSERVED
LIVER	7.8313	4.925	
KIDNEYS	1.8418	1.158	
SPLEEN	0.4038	0.254	
THYMUS	0.4682	0.294	
OVARIES/OVIDUCTS	0.0793	0.050	
ADRENAL GLANDS	0.0347	0.022	
PITUITARY	0.0077	0.005	
THYROIDS/PARA	0.0132	0.008	
FINAL BODY WT(G)	159.		

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR:[redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20613-06 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3814	0.206
UTERUS- BLOTTED	0.3589	0.194
LIVER	11.5235	6.229
KIDNEYS	2.0698	1.119
SPLEEN	0.7029	0.380
THYMUS	0.7404	0.400
OVARIES/OVIDUCTS	0.1072	0.058
ADRENAL GLANDS	0.0477	0.026
PITUITARY	0.0111	0.006
THYROIDS/PARA	0.0099	0.005
FINAL BODY WT(G)	185.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR:[redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20612-07 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3444	0.227
UTERUS- BLOTTED	0.3234	0.213
LIVER	9.5499	6.283
KIDNEYS	1.7238	1.134
SPLEEN	0.3770	0.248
THYMUS	0.4260	0.280
OVARIES/OVIDUCTS	0.1115	0.073
ADRENAL GLANDS	0.0485	0.032
PITUITARY	0.0115	0.008
THYROIDS/PARA	0.0138	0.009
FINAL BODY WT(G)	152.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20615-07 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3291	0.224	GROSS:ADRENAL GLANDS	KIDNEYS
UTERUS- BLOTTED	0.3069	0.209	OVARIES	PITUITARY
LIVER	8.3234	5.662	THYMUS	THYROID GLANDS
KIDNEYS	1.5681	1.067	VAGINA	
SPLEEN	0.3844	0.261		
THYMUS	0.6207	0.422		
OVARIES/OVIDUCTS	0.0721	0.049		
ADRENAL GLANDS	0.0417	0.028		
PITUITARY	0.0080	0.005		
THYROIDS/PARA	0.0140	0.010		
FINAL BODY WT(G)	147.			

LIVER	OVIDUCTS		
SPLEEN	LYMPH NODE, AXI		
UTERUS	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-07 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3355	0.225	GROSS:ADRENAL GLANDS	KIDNEYS
UTERUS- BLOTTED	0.3081	0.207	OVARIES	PITUITARY
LIVER	7.6916	5.162	THYMUS	THYROID GLANDS
KIDNEYS	1.7147	1.151	VAGINA	
SPLEEN	0.5334	0.358		
THYMUS	0.6177	0.415		
OVARIES/OVIDUCTS	0.1059	0.071		
ADRENAL GLANDS	0.0464	0.031		
PITUITARY	0.0107	0.007		
THYROIDS/PARA	0.0161	0.011		
FINAL BODY WT(G)	149.			

GRADE	
LIVER	OVIDUCTS
SPLEEN	LYMPH NODE, AXI
UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 32

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20603-09 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2158	0.149		
UTERUS- BLOTTED	0.1975	0.136		
LIVER	8.0484	5.551		
KIDNEYS	1.5299	1.055		
SPLEEN	0.3912	0.270		
THYMUS	0.5643	0.389		
OVARIES/OVIDUCTS	0.0732	0.050		
ADRENAL GLANDS	0.0353	0.024		
PITUITARY	0.0081	0.006		
THYROIDS/PARA	0.0131	0.009		
FINAL BODY WT(G)	145.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 33

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20607-01 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.2995	0.229		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2828	0.216		OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
LIVER	7.3062	5.577		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.5187	1.159		VAGINA			
SPLEEN	0.3515	0.268					
THYMUS	0.4508	0.344					
OVARIES/OVIDUCTS	0.0779	0.059					
ADRENAL GLANDS	0.0355	0.027					
PITUITARY	0.0090	0.007					
THYROIDS/PARA	0.0132	0.010					
FINAL BODY WT(G)	131.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-02 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2041	0.146
UTERUS- BLOTTED	0.1851	0.132
LIVER	6.9945	4.996
KIDNEYS	1.4931	1.067
SPLEEN	0.4336	0.310
THYMUS	0.5628	0.402
OVARIES/OVIDUCTS	0.0732	0.052
ADRENAL GLANDS	0.0349	0.025
PITUITARY	0.0069	0.005
THYROIDS/PARA	0.0163	0.012
FINAL BODY WT(G)	140.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-01 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4645	0.310
UTERUS- BLOTTED	0.3783	0.252
LIVER	8.5296	5.686
KIDNEYS	1.6938	1.129
SPLEEN	0.4185	0.279
THYMUS	0.4992	0.333
OVARIES/OVIDUCTS	0.0867	0.058
ADRENAL GLANDS	0.0343	0.023
PITUITARY	0.0097	0.006
THYROIDS/PARA	0.0129	0.009
FINAL BODY WT(G)	150.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-04 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3963	0.261	
UTERUS- BLOTTED	0.3696	0.243	
LIVER	8.5741	5.641	
KIDNEYS	1.8026	1.186	
SPLEEN	0.4346	0.286	
THYMUS	0.4652	0.306	
OVARIES/OVIDUCTS	0.0784	0.052	
ADRENAL GLANDS	0.0353	0.023	
PITUITARY	0.0072	0.005	
THYROIDS/PARA	0.0144	0.009	
FINAL BODY WT(G)	152.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-05 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3110	0.193	GROSS:ADRENAL GLANDS	KIDNEYS
UTERUS- BLOTTED	0.2888	0.179	OVARIES	PITUITARY
LIVER	8.4604	5.255	THYMUS	THYROID GLANDS
KIDNEYS	1.8134	1.126	VAGINA	
SPLEEN	0.4235	0.263		
THYMUS	0.6183	0.384		
OVARIES/OVIDUCTS	0.0936	0.058		
ADRENAL GLANDS	0.0390	0.024		
PITUITARY	0.0087	0.005		
THYROIDS/PARA	0.0191	0.012		
FINAL BODY WT(G)	161.			

GRADE			
LIVER	OVIDUCTS		
SPLEEN	LYMPH NODE, AXI		
UTERUS	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-08 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4424	0.256	
UTERUS- BLOTTED	0.4077	0.236	
LIVER	10.3219	5.966	
KIDNEYS	1.9559	1.131	
SPLEEN	0.5624	0.325	
THYMUS	0.6968	0.403	
OVARIES/OVIDUCTS	0.0651	0.038	
ADRENAL GLANDS	0.0406	0.023	
PITUITARY	0.0082	0.005	
THYROIDS/PARA	0.0121	0.007	
FINAL BODY WT(G)	173.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20609-09 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3590	0.214		
UTERUS- BLOTTED	0.3067	0.183		
LIVER	9.5516	5.685		
KIDNEYS	1.8500	1.101		
SPLEEN	0.5881	0.350		
THYMUS	0.5461	0.325		
OVARIES/OVIDUCTS	0.0871	0.052		
ADRENAL GLANDS	0.0421	0.025		
PITUITARY	0.0092	0.005		
THYROIDS/PARA	0.0133	0.008		
FINAL BODY WT(G)	168.			

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-02 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.5238	0.364
UTERUS- BLOTTED	0.3109	0.216
LIVER	7.5797	5.264
KIDNEYS	1.7136	1.190
SPLEEN	0.3805	0.264
THYMUS	0.4646	0.323
OVARIES/OVIDUCTS	0.0632	0.044
ADRENAL GLANDS	0.0364	0.025
PITUITARY	0.0075	0.005
THYROIDS/PARA	0.0107	0.007
FINAL BODY WT(G)	144.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20611-02 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.6446	0.439	
UTERUS- BLOTTED	0.3442	0.234	
LIVER	8.1235	5.526	
KIDNEYS	1.6156	1.099	
SPLEEN	0.4108	0.279	
THYMUS	0.5302	0.361	
OVARIES/OVIDUCTS	0.0673	0.046	
ADRENAL GLANDS	0.0377	0.026	
PITUITARY	0.0065	0.004	
THYROIDS/PARA	0.0122	0.008	
FINAL BODY WT(G)	147.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-05 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4463	0.247
UTERUS- BLOTTED	0.4089	0.226
LIVER	11.7738	6.505
KIDNEYS	2.0903	1.155
SPLEEN	0.5260	0.291
THYMUS	0.5168	0.286
OVARIES/OVIDUCTS	0.0850	0.047
ADRENAL GLANDS	0.0345	0.019
PITUITARY	0.0095	0.005
THYROIDS/PARA	0.0127	0.007
FINAL BODY WT(G)	181.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-10 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2857	0.161	
UTERUS- BLOTTED	0.2630	0.148	
LIVER	10.1190	5.685	
KIDNEYS	1.8274	1.027	
SPLEEN	0.4947	0.278	
THYMUS	0.8036	0.451	
OVARIES/OVIDUCTS	0.0807	0.045	
ADRENAL GLANDS	0.0399	0.022	
PITUITARY	0.0102	0.006	
THYROIDS/PARA	0.0130	0.007	
FINAL BODY WT(G)	178.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20613-08 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2739	0.157
UTERUS- BLOTTED	0.2527	0.144
LIVER	9.8743	5.642
KIDNEYS	1.8770	1.073
SPLEEN	0.4027	0.230
THYMUS	0.4989	0.285
OVARIES/OVIDUCTS	0.1004	0.057
ADRENAL GLANDS	0.0528	0.030
PITUITARY	0.0097	0.006
THYROIDS/PARA	0.0105	0.006
FINAL BODY WT(G)	175.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20614-01 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2267	0.154
UTERUS- BLOTTED	0.2064	0.140
LIVER	8.6437	5.880
KIDNEYS	1.6228	1.104
SPLEEN	0.3679	0.250
THYMUS	0.4434	0.302
OVARIES/OVIDUCTS	0.0804	0.055
ADRENAL GLANDS	0.0442	0.030
PITUITARY	0.0082	0.006
THYROIDS/PARA	0.0112	0.008
FINAL BODY WT(G)	147.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-10 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2267	0.157	NO SIGNIFICANT
UTERUS- BLOTTED	0.2088	0.145	CHANGES OBSERVED
LIVER	7.6774	5.332	
KIDNEYS	1.5054	1.045	
SPLEEN	0.3370	0.234	
THYMUS	0.5755	0.400	
OVARIES/OVIDUCTS	0.0578	0.040	
ADRENAL GLANDS	0.0325	0.023	
PITUITARY	0.0054	0.004	
THYROIDS/PARA	0.0195	0.014	
FINAL BODY WT(G)	144.		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR:[redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-07 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2417	0.154
UTERUS- BLOTTED	0.2248	0.143
LIVER	9.5556	6.086
KIDNEYS	1.7912	1.141
SPLEEN	0.3738	0.238
THYMUS	0.3736	0.238
OVARIES/OVIDUCTS	0.0961	0.061
ADRENAL GLANDS	0.0396	0.025
PITUITARY	0.0097	0.006
THYROIDS/PARA	0.0139	0.009
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

PROJECT NO.:WIL-187055
SPONSOR:[redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-04 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2915	0.169
UTERUS- BLOTTED	0.2645	0.154
LIVER	9.6291	5.598
KIDNEYS	1.7761	1.033
SPLEEN	0.4635	0.269
THYMUS	0.6673	0.388
OVARIES/OVIDUCTS	0.0828	0.048
ADRENAL GLANDS	0.0441	0.026
PITUITARY	0.0092	0.005
THYROIDS/PARA	0.0173	0.010
FINAL BODY WT(G)	172.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20603-04 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1905	0.127
UTERUS- BLOTTED	0.1747	0.116
LIVER	8.0719	5.381
KIDNEYS	1.8449	1.230
SPLEEN	0.4183	0.279
THYMUS	0.6243	0.416
OVARIES/OVIDUCTS	0.0668	0.045
ADRENAL GLANDS	0.0348	0.023
PITUITARY	0.0062	0.004
THYROIDS/PARA	0.0118	0.008
FINAL BODY WT(G)	150.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20607-05 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.2375	0.170		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2223	0.159		OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
LIVER	7.7243	5.517		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.4120	1.009		VAGINA			
SPLEEN	0.4990	0.356					
THYMUS	0.4721	0.337					
OVARIES/OVIDUCTS	0.0683	0.049					
ADRENAL GLANDS	0.0355	0.025					
PITUITARY	0.0067	0.005					
THYROIDS/PARA	0.0168	0.012					
FINAL BODY WT(G)	140.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5813	0.385	NO SIGNIFICANT
UTERUS- BLOTTED	0.3473	0.230	CHANGES OBSERVED
LIVER	9.0190	5.973	
KIDNEYS	1.6824	1.114	
SPLEEN	0.3660	0.242	
THYMUS	0.6673	0.442	
OVARIES/OVIDUCTS	0.0707	0.047	
ADRENAL GLANDS	0.0463	0.031	
PITUITARY	0.0078	0.005	
THYROIDS/PARA	0.0150	0.010	
FINAL BODY WT(G)	151.		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1713	0.109
UTERUS- BLOTTED	0.1498	0.095
LIVER	9.3227	5.938
KIDNEYS	1.5543	0.990
SPLEEN	0.4125	0.263
THYMUS	0.7079	0.451
OVARIES/OVIDUCTS	0.0513	0.033
ADRENAL GLANDS	0.0356	0.023
PITUITARY	0.0067	0.004
THYROIDS/PARA	0.0128	0.008
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-03 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.1836	0.147	
UTERUS- BLOTTED	0.1682	0.135	
LIVER	6.9588	5.567	
KIDNEYS	1.4050	1.124	
SPLEEN	0.3695	0.296	
THYMUS	0.4429	0.354	
OVARIES/OVIDUCTS	0.0520	0.042	
ADRENAL GLANDS	0.0308	0.025	
PITUITARY	0.0062	0.005	
THYROIDS/PARA	0.0108	0.009	
FINAL BODY WT(G)	125.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20609-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3057	0.185	GROSS:	
UTERUS- BLOTTED	0.2755	0.167		
LIVER	10.1742	6.166		
KIDNEYS	1.8274	1.108		
SPLEEN	0.7003	0.424		
THYMUS	0.4842	0.293		
OVARIES/OVIDUCTS	0.0655	0.040		
ADRENAL GLANDS	0.0430	0.026		
PITUITARY	0.0083	0.005		
THYROIDS/PARA	0.0100	0.006		
FINAL BODY WT(G)	165.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-03 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2841	0.166
UTERUS- BLOTTED	0.2673	0.156
LIVER	10.5529	6.171
KIDNEYS	2.1962	1.284
SPLEEN	0.4699	0.275
THYMUS	0.7224	0.422
OVARIES/OVIDUCTS	0.1152	0.067
ADRENAL GLANDS	0.0539	0.032
PITUITARY	0.0111	0.006
THYROIDS/PARA	0.0139	0.008
FINAL BODY WT(G)	171.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 56

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-06 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3018	0.172
UTERUS- BLOTTED	0.2840	0.162
LIVER	10.0170	5.724
KIDNEYS	1.7676	1.010
SPLEEN	0.5201	0.297
THYMUS	0.7454	0.426
OVARIES/OVIDUCTS	0.0778	0.044
ADRENAL GLANDS	0.0434	0.025
PITUITARY	0.0095	0.005
THYROIDS/PARA	0.0137	0.008
FINAL BODY WT(G)	175.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

PROJECT NO.:WIL-187055
SPONSOR: [redacted]
SPONSOR NO.:06-010

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-08 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3361	0.202
UTERUS- BLOTTED	0.3089	0.186
LIVER	10.5833	6.375
KIDNEYS	1.9461	1.172
SPLEEN	0.4282	0.258
THYMUS	0.5261	0.317
OVARIES/OVIDUCTS	0.1028	0.062
ADRENAL GLANDS	0.0560	0.034
PITUITARY	0.0086	0.005
THYROIDS/PARA	0.0139	0.008
FINAL BODY WT(G)	166.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2844	0.188	
UTERUS- BLOTTED	0.2684	0.178	
LIVER	9.5291	6.311	
KIDNEYS	1.6169	1.071	
SPLEEN	0.4493	0.298	
THYMUS	0.5504	0.365	
OVARIES/OVIDUCTS	0.0913	0.060	
ADRENAL GLANDS	0.0360	0.024	
PITUITARY	0.0090	0.006	
THYROIDS/PARA	0.0132	0.009	
FINAL BODY WT(G)	151.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20612-05 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2945	0.172		
UTERUS- BLOTTED	0.2714	0.159		
LIVER	10.2985	6.023		
KIDNEYS	1.7870	1.045		
SPLEEN	0.4443	0.260		
THYMUS	0.4988	0.292		
OVARIES/OVIDUCTS	0.1022	0.060		
ADRENAL GLANDS	0.0453	0.026		
PITUITARY	0.0094	0.005		
THYROIDS/PARA	0.0155	0.009		
FINAL BODY WT(G)	171.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20613-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2744	0.155
UTERUS- BLOTTED	0.2574	0.145
LIVER	10.8735	6.143
KIDNEYS	2.0582	1.163
SPLEEN	0.4024	0.227
THYMUS	0.6286	0.355
OVARIES/OVIDUCTS	0.0756	0.043
ADRENAL GLANDS	0.0454	0.026
PITUITARY	0.0097	0.005
THYROIDS/PARA	0.0142	0.008
FINAL BODY WT(G)	177.	

		GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	
	ADRENAL GLANDS	
	KIDNEYS	
	LIVER	
	OVIDUCTS	
	OVARIES	
	PITUITARY	
	SPLEEN	
	LYMPH NODE, AXI	
	THYMUS	
	THYROID GLANDS	
	UTERUS	
	CERVIX	
	VAGINA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-08 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5982	0.381	NO SIGNIFICANT
UTERUS- BLOTTED	0.4183	0.266	CHANGES OBSERVED
LIVER	7.9368	5.055	
KIDNEYS	1.6783	1.069	
SPLEEN	0.5123	0.326	
THYMUS	0.5439	0.346	
OVARIES/OVIDUCTS	0.1045	0.067	
ADRENAL GLANDS	0.0494	0.031	
PITUITARY	0.0089	0.006	
THYROIDS/PARA	0.0138	0.009	
FINAL BODY WT(G)	157.		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-02 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3813	0.218
UTERUS- BLOTTED	0.3485	0.199
LIVER	9.0518	5.172
KIDNEYS	1.9331	1.105
SPLEEN	0.4303	0.246
THYMUS	0.4644	0.265
OVARIES/OVIDUCTS	0.0973	0.056
ADRENAL GLANDS	0.0423	0.024
PITUITARY	0.0099	0.006
THYROIDS/PARA	0.0157	0.009
FINAL BODY WT(G)	175.	

		GRADE
OVARIES	GROSS: CYST(S)	
	ONE, 7 MM IN DIAMETER, RIGHT	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS; PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS; THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20607-06 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2893	0.169	
UTERUS- BLOTTED	0.2681	0.157	
LIVER	9.5454	5.582	
KIDNEYS	1.8837	1.102	
SPLEEN	0.5963	0.349	
THYMUS	0.6378	0.373	
OVARIES/OVIDUCTS	0.1138	0.067	
ADRENAL GLANDS	0.0334	0.020	
PITUITARY	0.0075	0.004	
THYROIDS/PARA	0.0143	0.008	
FINAL BODY WT(G)	171.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20603-06 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.6062	0.415		
UTERUS- BLOTTED	0.3673	0.252		
LIVER	7.4734	5.119		
KIDNEYS	1.7359	1.189		
SPLEEN	0.3750	0.257		
THYMUS	0.6927	0.474		
OVARIES/OVIDUCTS	0.0661	0.045		
ADRENAL GLANDS	0.0385	0.026		
PITUITARY	0.0087	0.006		
THYROIDS/PARA	0.0132	0.009		
FINAL BODY WT(G)	146.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-06 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.8049	0.634
UTERUS- BLOTTED	0.4074	0.321
LIVER	6.4141	5.050
KIDNEYS	1.3892	1.094
SPLEEN	0.3475	0.274
THYMUS	0.4689	0.369
OVARIES/OVIDUCTS	0.0706	0.056
ADRENAL GLANDS	0.0324	0.026
PITUITARY	0.0087	0.007
THYROIDS/PARA	0.0131	0.010
FINAL BODY WT(G)	127.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20606-03 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2628	0.175
UTERUS- BLOTTED	0.2463	0.164
LIVER	8.3139	5.543
KIDNEYS	1.6003	1.067
SPLEEN	0.3249	0.217
THYMUS	0.6972	0.465
OVARIES/OVIDUCTS	0.0827	0.055
ADRENAL GLANDS	0.0415	0.028
PITUITARY	0.0073	0.005
THYROIDS/PARA	0.0114	0.008
FINAL BODY WT(G)	150.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20607-02 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2112	0.130
UTERUS- BLOTTED	0.1983	0.122
LIVER	8.3684	5.166
KIDNEYS	1.7677	1.091
SPLEEN	0.4750	0.293
THYMUS	0.4546	0.281
OVARIES/OVIDUCTS	0.0999	0.062
ADRENAL GLANDS	0.0461	0.028
PITUITARY	0.0102	0.006
THYROIDS/PARA	0.0138	0.009
FINAL BODY WT(G)	162.	

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
		OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
		THYMUS	THYROID GLANDS	UTERUS	CERVIX
		VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-05 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3481	0.215
UTERUS- BLOTTED	0.3273	0.202
LIVER	8.4932	5.243
KIDNEYS	1.6628	1.026
SPLEEN	0.4260	0.263
THYMUS	0.7580	0.468
OVARIES/OVIDUCTS	0.1129	0.070
ADRENAL GLANDS	0.0427	0.026
PITUITARY	0.0105	0.006
THYROIDS/PARA	0.0112	0.007
FINAL BODY WT(G)	162.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20609-07 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2744	0.173	GROSS:ADRENAL GLANDS	KIDNEYS
UTERUS- BLOTTED	0.2472	0.155	OVARIES	PITUITARY
LIVER	8.5805	5.397	THYMUS	THYROID GLANDS
KIDNEYS	1.7423	1.096	VAGINA	
SPLEEN	0.3770	0.237		
THYMUS	0.4807	0.302		
OVARIES/OVIDUCTS	0.0910	0.057		
ADRENAL GLANDS	0.0426	0.027		
PITUITARY	0.0087	0.005		
THYROIDS/PARA	0.0160	0.010		
FINAL BODY WT(G)	159.			

LIVER	OVIDUCTS
SPLEEN	LYMPH NODE, AXI
UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-01 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3422	0.206
UTERUS- BLOTTED	0.3135	0.189
LIVER	9.9107	5.970
KIDNEYS	1.5556	0.937
SPLEEN	0.4540	0.273
THYMUS	0.6313	0.380
OVARIES/OVIDUCTS	0.0816	0.049
ADRENAL GLANDS	0.0326	0.020
PITUITARY	0.0090	0.005
THYROIDS/PARA	0.0143	0.009
FINAL BODY WT(G)	166.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-04 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2225	0.137		
UTERUS- BLOTTED	0.2077	0.128		
LIVER	8.0278	4.955		
KIDNEYS	1.5724	0.971		
SPLEEN	0.4047	0.250		
THYMUS	0.4995	0.308		
OVARIES/OVIDUCTS	0.0866	0.053		
ADRENAL GLANDS	0.0366	0.023		
PITUITARY	0.0067	0.004		
THYROIDS/PARA	0.0105	0.006		
FINAL BODY WT(G)	162.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 72

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20609-03 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3432	0.245
UTERUS- BLOTTED	0.3112	0.222
LIVER	7.2423	5.173
KIDNEYS	1.5399	1.100
SPLEEN	0.4409	0.315
THYMUS	0.5025	0.359
OVARIES/OVIDUCTS	0.0709	0.051
ADRENAL GLANDS	0.0324	0.023
PITUITARY	0.0061	0.004
THYROIDS/PARA	0.0106	0.008
FINAL BODY WT(G)	140.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-10 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2578	0.165		
UTERUS- BLOTTED	0.2371	0.152		
LIVER	7.9983	5.127		
KIDNEYS	1.7689	1.134		
SPLEEN	0.4803	0.308		
THYMUS	0.5768	0.370		
OVARIES/OVIDUCTS	0.0711	0.046		
ADRENAL GLANDS	0.0419	0.027		
PITUITARY	0.0084	0.005		
THYROIDS/PARA	0.0155	0.010		
FINAL BODY WT(G)	156.			

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20613-10 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.7693	0.423
UTERUS- BLOTTED	0.4106	0.226
LIVER	11.1196	6.110
KIDNEYS	1.9378	1.065
SPLEEN	0.5829	0.320
THYMUS	0.5710	0.314
OVARIES/OVIDUCTS	0.0923	0.051
ADRENAL GLANDS	0.0505	0.028
PITUITARY	0.0100	0.005
THYROIDS/PARA	0.0208	0.011
FINAL BODY WT(G)	182.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20612-01 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3705	0.229	
UTERUS- BLOTTED	0.3505	0.216	
LIVER	10.1360	6.257	
KIDNEYS	1.7657	1.090	
SPLEEN	0.4634	0.286	
THYMUS	0.5415	0.334	
OVARIES/OVIDUCTS	0.1120	0.069	
ADRENAL GLANDS	0.0425	0.026	
PITUITARY	0.0138	0.009	
THYROIDS/PARA	0.0135	0.008	
FINAL BODY WT(G)	162.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20604-05 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3515	0.234
UTERUS- BLOTTED	0.3320	0.221
LIVER	7.9139	5.276
KIDNEYS	1.5373	1.025
SPLEEN	0.4445	0.296
THYMUS	0.5688	0.379
OVARIES/OVIDUCTS	0.0959	0.064
ADRENAL GLANDS	0.0372	0.025
PITUITARY	0.0061	0.004
THYROIDS/PARA	0.0173	0.012
FINAL BODY WT(G)	150.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE			
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-06 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2258	0.164
UTERUS- BLOTTED	0.2079	0.151
LIVER	6.9729	5.053
KIDNEYS	1.3372	0.969
SPLEEN	0.4159	0.301
THYMUS	0.4256	0.308
OVARIES/OVIDUCTS	0.0790	0.057
ADRENAL GLANDS	0.0292	0.021
PITUITARY	0.0067	0.005
THYROIDS/PARA	0.0125	0.009
FINAL BODY WT(G)	138.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20605-06 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2805	0.192
UTERUS- BLOTTED	0.2614	0.179
LIVER	7.7014	5.275
KIDNEYS	1.5832	1.084
SPLEEN	0.4099	0.281
THYMUS	0.5451	0.373
OVARIES/OVIDUCTS	0.0930	0.064
ADRENAL GLANDS	0.0459	0.031
PITUITARY	0.0077	0.005
THYROIDS/PARA	0.0125	0.009
FINAL BODY WT(G)	146.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20603-02 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3487	0.210		
UTERUS- BLOTTED	0.3215	0.194		
LIVER	9.1694	5.524		
KIDNEYS	1.6554	0.997		
SPLEEN	0.4034	0.243		
THYMUS	0.7228	0.435		
OVARIES/OVIDUCTS	0.0741	0.045		
ADRENAL GLANDS	0.0403	0.024		
PITUITARY	0.0098	0.006		
THYROIDS/PARA	0.0121	0.007		
FINAL BODY WT(G)	166.			

GRADE			
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20607-10 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.5610	0.409
UTERUS- BLOTTED	0.3867	0.282
LIVER	6.0375	4.407
KIDNEYS	1.3334	0.973
SPLEEN	0.3281	0.239
THYMUS	0.4800	0.350
OVARIES/OVIDUCTS	0.0711	0.052
ADRENAL GLANDS	0.0381	0.028
PITUITARY	0.0070	0.005
THYROIDS/PARA	0.0127	0.009
FINAL BODY WT(G)	137.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20603-07 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2546	0.157
UTERUS- BLOTTED	0.2341	0.145
LIVER	9.2814	5.729
KIDNEYS	1.7345	1.071
SPLEEN	0.4519	0.279
THYMUS	0.6314	0.390
OVARIES/OVIDUCTS	0.0906	0.056
ADRENAL GLANDS	0.0419	0.026
PITUITARY	0.0106	0.007
THYROIDS/PARA	0.0149	0.009
FINAL BODY WT(G)	162.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20607-04 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- BLOTTED	0.4179	0.266
LIVER	7.3403	4.675
KIDNEYS	1.5502	0.987
SPLEEN	0.4456	0.284
THYMUS	0.4976	0.317
OVARIES/OVIDUCTS	0.0960	0.061
ADRENAL GLANDS	0.0432	0.028
PITUITARY	0.0119	0.008
THYROIDS/PARA	0.0102	0.006
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20608-09 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4406	0.249		
UTERUS- BLOTTED	0.3845	0.217		
LIVER	9.9310	5.611		
KIDNEYS	1.7935	1.013		
SPLEEN	0.5709	0.323		
THYMUS	0.7464	0.422		
OVARIES/OVIDUCTS	0.0912	0.052		
ADRENAL GLANDS	0.0431	0.024		
PITUITARY	0.0108	0.006		
THYROIDS/PARA	0.0122	0.007		
FINAL BODY WT(G)	177.			

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20609-10 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4078	0.244	GROSS:ADRENAL GLANDS	KIDNEYS
UTERUS- BLOTTED	0.3408	0.204	OVARIES	PITUITARY
LIVER	9.4426	5.654	THYMUS	THYROID GLANDS
KIDNEYS	1.6857	1.009	VAGINA	
SPLEEN	0.5019	0.301		
THYMUS	0.5318	0.318		
OVARIES/OVIDUCTS	0.0670	0.040		
ADRENAL GLANDS	0.0402	0.024		
PITUITARY	0.0080	0.005		
THYROIDS/PARA	0.0126	0.008		
FINAL BODY WT(G)	167.			

LIVER	OVIDUCTS
SPLEEN	LYMPH NODE, AXI
UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-10 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2187	0.140
UTERUS- BLOTTED	0.2006	0.129
LIVER	8.8787	5.691
KIDNEYS	1.9117	1.225
SPLEEN	0.3615	0.232
THYMUS	0.4374	0.280
OVARIES/OVIDUCTS	0.0920	0.059
ADRENAL GLANDS	0.0392	0.025
PITUITARY	0.0106	0.007
THYROIDS/PARA	0.0143	0.009
FINAL BODY WT(G)	156.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20611-06 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2556	0.157	
UTERUS- BLOTTED	0.2375	0.146	
LIVER	9.3567	5.740	
KIDNEYS	1.8313	1.123	
SPLEEN	0.4585	0.281	
THYMUS	0.5222	0.320	
OVARIES/OVIDUCTS	0.0816	0.050	
ADRENAL GLANDS	0.0459	0.028	
PITUITARY	0.0104	0.006	
THYROIDS/PARA	0.0109	0.007	
FINAL BODY WT(G)	163.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20610-03 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2156	0.144
UTERUS- BLOTTED	0.1980	0.132
LIVER	8.0284	5.352
KIDNEYS	1.7151	1.143
SPLEEN	0.3930	0.262
THYMUS	0.4690	0.313
OVARIES/OVIDUCTS	0.0801	0.053
ADRENAL GLANDS	0.0389	0.026
PITUITARY	0.0077	0.005
THYROIDS/PARA	0.0118	0.008
FINAL BODY WT(G)	150.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20614-03 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2604	0.172
UTERUS- BLOTTED	0.2328	0.154
LIVER	7.8185	5.178
KIDNEYS	1.5883	1.052
SPLEEN	0.4665	0.309
THYMUS	0.4211	0.279
OVARIES/OVIDUCTS	0.0837	0.055
ADRENAL GLANDS	0.0390	0.026
PITUITARY	0.0095	0.006
THYROIDS/PARA	0.0130	0.009
FINAL BODY WT(G)	151.	

GRADE

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20613-04 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4189	0.242	
UTERUS- BLOTTED	0.3881	0.224	
LIVER	7.8302	4.526	
KIDNEYS	1.5057	0.870	
SPLEEN	0.5074	0.293	
THYMUS	0.7281	0.421	
OVARIES/OVIDUCTS	0.0844	0.049	
ADRENAL GLANDS	0.0429	0.025	
PITUITARY	0.0104	0.006	
THYROIDS/PARA	0.0192	0.011	
FINAL BODY WT(G)	173.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20615-01 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3011	0.179	
UTERUS- BLOTTED	0.2794	0.166	
LIVER	9.8272	5.850	
KIDNEYS	1.8077	1.076	
SPLEEN	0.7381	0.439	
THYMUS	0.5593	0.333	
OVARIES/OVIDUCTS	0.0718	0.043	
ADRENAL GLANDS	0.0451	0.027	
PITUITARY	0.0089	0.005	
THYROIDS/PARA	0.0140	0.008	
FINAL BODY WT(G)	168.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20604-10 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2666	0.145
UTERUS- BLOTTED	0.2481	0.135
LIVER	11.8192	6.423
KIDNEYS	2.0905	1.136
SPLEEN	0.6256	0.340
THYMUS	0.6206	0.337
OVARIES/OVIDUCTS	0.0856	0.047
ADRENAL GLANDS	0.0466	0.025
PITUITARY	0.0103	0.006
THYROIDS/PARA	0.0119	0.006
FINAL BODY WT(G)	184.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 92

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20603-08 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.8037	0.522
UTERUS- BLOTTED	0.3905	0.254
LIVER	7.7424	5.028
KIDNEYS	1.6156	1.049
SPLEEN	0.4175	0.271
THYMUS	0.5156	0.335
OVARIES/OVIDUCTS	0.0825	0.054
ADRENAL GLANDS	0.0437	0.028
PITUITARY	0.0092	0.006
THYROIDS/PARA	0.0158	0.010
FINAL BODY WT(G)	154.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20607-07 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2679	0.200		
UTERUS- BLOTTED	0.2503	0.187		
LIVER	6.1281	4.573		
KIDNEYS	1.5319	1.143		
SPLEEN	0.3802	0.284		
THYMUS	0.3642	0.272		
OVARIES/OVIDUCTS	0.0757	0.056		
ADRENAL GLANDS	0.0381	0.028		
PITUITARY	0.0067	0.005		
THYROIDS/PARA	0.0160	0.012		
FINAL BODY WT(G)	134.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20605-03 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2842	0.175	
UTERUS- BLOTTED	0.2693	0.166	
LIVER	8.9410	5.519	
KIDNEYS	1.6279	1.005	
SPLEEN	0.4408	0.272	
THYMUS	0.4781	0.295	
OVARIES/OVIDUCTS	0.0622	0.038	
ADRENAL GLANDS	0.0373	0.023	
PITUITARY	0.0092	0.006	
THYROIDS/PARA	0.0144	0.009	
FINAL BODY WT(G)	162.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20606-04 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2894	0.200	
UTERUS- BLOTTED	0.2685	0.185	
LIVER	7.3597	5.076	
KIDNEYS	1.4434	0.995	
SPLEEN	0.3095	0.213	
THYMUS	0.7559	0.521	
OVARIES/OVIDUCTS	0.0712	0.049	
ADRENAL GLANDS	0.0393	0.027	
PITUITARY	0.0087	0.006	
THYROIDS/PARA	0.0101	0.007	
FINAL BODY WT(G)	145.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20604-07 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4081	0.268	GROSS:ADRENAL GLANDS	KIDNEYS
UTERUS- BLOTTED	0.3701	0.243	OVARIES	PITUITARY
LIVER	7.8343	5.154	THYMUS	THYROID GLANDS
KIDNEYS	1.6730	1.101	VAGINA	
SPLEEN	0.4530	0.298		
THYMUS	0.5237	0.345		
OVARIES/OVIDUCTS	0.0654	0.043		
ADRENAL GLANDS	0.0347	0.023		
PITUITARY	0.0077	0.005		
THYROIDS/PARA	0.0107	0.007		
FINAL BODY WT(G)	152.			

LIVER	OVIDUCTS		
SPLEEN	LYMPH NODE, AXI		
UTERUS	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20605-09 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/03/06 DATE OF DEATH: 04/03/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2506	0.150	GROSS:	
UTERUS- BLOTTED	0.2318	0.139		
LIVER	9.5991	5.748		
KIDNEYS	1.6244	0.973		
SPLEEN	0.4590	0.275		
THYMUS	0.5708	0.342		
OVARIES/OVIDUCTS	0.0755	0.045		
ADRENAL GLANDS	0.0358	0.021		
PITUITARY	0.0088	0.005		
THYROIDS/PARA	0.0115	0.007		
FINAL BODY WT(G)	167.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20609-06 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3123	0.208		
UTERUS- BLOTTED	0.2964	0.198		
LIVER	7.9173	5.278		
KIDNEYS	1.4413	0.961		
SPLEEN	0.3576	0.238		
THYMUS	0.4058	0.271		
OVARIES/OVIDUCTS	0.0785	0.052		
ADRENAL GLANDS	0.0407	0.027		
PITUITARY	0.0079	0.005		
THYROIDS/PARA	0.0130	0.009		
FINAL BODY WT(G)	150.			

GRADE

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20611-08 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4058	0.250	GROSS:	
UTERUS- BLOTTED	0.3880	0.240		
LIVER	8.7891	5.425		
KIDNEYS	1.6522	1.020		
SPLEEN	0.4780	0.295		
THYMUS	0.5572	0.344		
OVARIES/OVIDUCTS	0.0856	0.053		
ADRENAL GLANDS	0.0443	0.027		
PITUITARY	0.0094	0.006		
THYROIDS/PARA	0.0115	0.007		
FINAL BODY WT(G)	162.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20610-09 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.7237	0.358	NO SIGNIFICANT CHANGES OBSERVED
UTERUS- BLOTTED	0.4621	0.229	
LIVER	11.5983	5.742	
KIDNEYS	2.1187	1.049	
SPLEEN	0.5536	0.274	
THYMUS	0.5837	0.289	
OVARIES/OVIDUCTS	0.0809	0.040	
ADRENAL GLANDS	0.0394	0.020	
PITUITARY	0.0115	0.006	
THYROIDS/PARA	0.0146	0.007	
FINAL BODY WT(G)	202.		

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN LYMPH NODE, AXI
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

PROJECT NO.:WIL-187055
SPONSOR:[redacted]
SPONSOR NO.:06-010

ANIMAL NO.20611-09 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/04/06 DATE OF DEATH: 04/04/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2413	0.143	
UTERUS- BLOTTED	0.2181	0.129	
LIVER	9.1968	5.442	
KIDNEYS	1.7082	1.011	
SPLEEN	0.4019	0.238	
THYMUS	0.4689	0.277	
OVARIES/OVIDUCTS	0.0703	0.042	
ADRENAL GLANDS	0.0372	0.022	
PITUITARY	0.0099	0.006	
THYROIDS/PARA	0.0116	0.007	
FINAL BODY WT(G)	169.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20614-04 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.2713	0.182		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2525	0.169		OVARIES	PITUITARY	SPLEEN	LYMPH NODE, AXI
LIVER	7.9798	5.356		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.6511	1.108		VAGINA			
SPLEEN	0.3957	0.266					
THYMUS	0.6171	0.414					
OVARIES/OVIDUCTS	0.0939	0.063					
ADRENAL GLANDS	0.0452	0.030					
PITUITARY	0.0094	0.006					
THYROIDS/PARA	0.0120	0.008					
FINAL BODY WT(G)	149.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.20613-07 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2646	0.161	
UTERUS- BLOTTED	0.2486	0.152	
LIVER	9.5392	5.817	
KIDNEYS	1.6536	1.008	
SPLEEN	0.4749	0.290	
THYMUS	0.4474	0.273	
OVARIES/OVIDUCTS	0.0858	0.052	
ADRENAL GLANDS	0.0419	0.026	
PITUITARY	0.0092	0.006	
THYROIDS/PARA	0.0116	0.007	
FINAL BODY WT(G)	164.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, LYMPH NODE, AXI, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/13/2006

TABLE 20 (GROSS LESIONS - SCHEDULED EUTHANASIA)

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-010

ANIMAL NO.20612-09 GROUP 7: [redacted]1000 FEMALE SCHEDULED EUTH 04/05/06 DATE OF DEATH: 04/05/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2599	0.162
UTERUS- BLOTTED	0.2434	0.152
LIVER	9.3044	5.815
KIDNEYS	1.7278	1.080
SPLEEN	0.4752	0.297
THYMUS	0.5089	0.318
OVARIES/OVIDUCTS	0.1056	0.066
ADRENAL GLANDS	0.0394	0.025
PITUITARY	0.0102	0.006
THYROIDS/PARA	0.0093	0.006
FINAL BODY WT(G)	160.	

		GRADE
KIDNEYS	GROSS: AREA(S), DEPRESSED ONE, 5 X 4 X 2 MM, IN CORTEX, RIGHT	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	LIVER	OVIDUCTS	OVARIES
PITUITARY	SPLEEN	LYMPH NODE, AXI	THYMUS
THYROID GLANDS	UTERUS	CERVIX	VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.53
05/17/2006

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TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-010

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS- WET	UTERUS- BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20605-10	171.	0.4062	0.3826	0.0236	9.3917	1.7318	0.3223	0.5856	0.1029	0.0425	0.0112	0.0116
20603-03	151.	0.3605	0.3344	0.0261	8.2343	1.5919	0.3553	0.6204	0.0742	0.0402	0.0107	0.0130
20607-08	171.	0.6282	0.4599	0.1683	9.7907	1.7257	0.4103	0.8054	0.0791	0.0397	0.0104	0.0204
20606-09	139.	0.6885	0.4008	0.2877	6.7619	1.3922	0.3322	0.7051	0.0686	0.0228	0.0061	0.0137
20604-03	142.	0.1880	0.1659	0.0221	8.0257	1.7689	0.3696	0.4085	0.0783	0.0360	0.0090	0.0115
20603-01	160.	0.4670	0.3378	0.1292	8.6276	1.4437	0.5196	0.8206	0.0605	0.0356	0.0077	0.0144
20605-08	185.	0.6477	0.4538	0.1939	11.1107	1.7281	0.6084	0.6709	0.1027	0.0392	0.0110	0.0142
20608-02	136.	0.1761	0.1559	0.0202	6.8659	1.4513	0.3688	0.5368	0.0601	0.0312	0.0058	0.0103
20609-08	152.	0.3317	0.3123	0.0194	8.6852	1.5980	0.4550	0.5137	0.0890	0.0443	0.0086	0.0118
20611-01	167.	0.2359	0.2166	0.0193	9.0362	1.7152	0.4243	0.4176	0.0778	0.0369	0.0088	0.0097
20610-04	161.	0.3030	0.2750	0.0280	9.6722	1.9027	0.3817	0.4724	0.0891	0.0371	0.0100	0.0178
20609-04	167.	0.3455	0.3286	0.0169	8.9181	1.6408	0.5258	0.5769	0.0835	0.0356	0.0086	0.0127
20613-03	179.	0.6516	0.3854	0.2662	10.1249	1.6731	0.4808	0.6112	0.0900	0.0437	0.0083	0.0144
20615-03	174.	0.2594	0.2398	0.0196	10.3023	1.8416	0.5449	0.5620	0.0958	0.0433	0.0099	0.0195
20612-03	158.	0.6515	0.3902	0.2613	9.3332	1.6546	0.4146	0.5302	0.0918	0.0407	0.0104	0.0072
MEAN	161.	0.4227	0.3226	0.1001	8.9920	1.6573	0.4342	0.5892	0.0829	0.0379	0.0091	0.0135
S.D.	14.6	0.18524	0.09543	0.10640	1.19827	0.14439	0.08548	0.12260	0.01344	0.00555	0.00166	0.00359
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-010

INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20607-09	162.	0.5843	0.3980	0.1863	7.9859	1.5924	0.5157	0.5344	0.0848	0.0383	0.0105	0.0140
20605-05	169.	0.3572	0.3338	0.0234	8.3054	1.7897	0.3866	0.4321	0.1024	0.0458	0.0100	0.0129
20606-02	154.	0.3930	0.3704	0.0226	7.8382	1.6468	0.4450	0.7285	0.0983	0.0502	0.0102	0.0175
20604-08	155.	0.2336	0.2161	0.0175	7.7103	1.5616	0.4063	0.5472	0.0721	0.0318	0.0078	0.0142
20603-10	145.	0.2255	0.2093	0.0162	8.0914	1.6752	0.4248	0.7307	0.0630	0.0353	0.0091	0.0101
20604-09	167.	0.2897	0.2709	0.0188	9.1225	1.7652	0.4450	0.6655	0.0878	0.0423	0.0118	0.0143
20607-03	155.	0.2437	0.2261	0.0176	8.4457	1.7408	0.3463	0.3877	0.0823	0.0433	0.0086	0.0138
20609-05	131.	0.2700	0.2495	0.0205	7.3759	1.4654	0.3398	0.4242	0.0669	0.0252	0.0057	0.0123
20608-07	157.	0.2874	0.2711	0.0163	8.6952	1.6544	0.4098	0.6584	0.0649	0.0314	0.0064	0.0098
20610-05	147.	0.2983	0.2793	0.0190	7.7385	1.8701	0.3761	0.4433	0.0742	0.0376	0.0095	0.0124
20611-07	177.	0.6848	0.4355	0.2493	9.5616	1.8942	0.4823	0.5274	0.0767	0.0355	0.0087	0.0127
20610-07	159.	0.2520	0.2300	0.0220	7.8313	1.8418	0.4038	0.4682	0.0793	0.0347	0.0077	0.0132
20613-06	185.	0.3814	0.3589	0.0225	11.5235	2.0698	0.7029	0.7404	0.1072	0.0477	0.0111	0.0099
20612-07	152.	0.3444	0.3234	0.0210	9.5499	1.7238	0.3770	0.4260	0.1115	0.0485	0.0115	0.0138
20615-07	147.	0.3291	0.3069	0.0222	8.3234	1.5681	0.3844	0.6207	0.0721	0.0417	0.0080	0.0140
MEAN	157.	0.3450	0.2986	0.0463	8.5399	1.7240	0.4297	0.5556	0.0829	0.0393	0.0091	0.0130
S.D.	13.4	0.12998	0.06989	0.07066	1.05655	0.15541	0.08924	0.12554	0.01556	0.00717	0.00180	0.00200
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-010

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20606-07	149.	0.3355	0.3081	0.0274	7.6916	1.7147	0.5334	0.6177	0.1059	0.0464	0.0107	0.0161
20603-09	145.	0.2158	0.1975	0.0183	8.0484	1.5299	0.3912	0.5643	0.0732	0.0353	0.0081	0.0131
20607-01	131.	0.2995	0.2828	0.0167	7.3062	1.5187	0.3515	0.4508	0.0779	0.0355	0.0090	0.0132
20604-02	140.	0.2041	0.1851	0.0190	6.9945	1.4931	0.4336	0.5628	0.0732	0.0349	0.0069	0.0163
20605-01	150.	0.4645	0.3783	0.0862	8.5296	1.6938	0.4185	0.4992	0.0867	0.0343	0.0097	0.0129
20605-04	152.	0.3963	0.3696	0.0267	8.5741	1.8026	0.4346	0.4652	0.0784	0.0353	0.0072	0.0144
20606-05	161.	0.3110	0.2888	0.0222	8.4604	1.8134	0.4235	0.6183	0.0936	0.0390	0.0087	0.0191
20608-08	173.	0.4424	0.4077	0.0347	10.3219	1.9559	0.5624	0.6968	0.0651	0.0406	0.0082	0.0121
20609-09	168.	0.3590	0.3067	0.0523	9.5516	1.8500	0.5881	0.5461	0.0871	0.0421	0.0092	0.0133
20610-02	144.	0.5238	0.3109	0.2129	7.5797	1.7136	0.3805	0.4646	0.0632	0.0364	0.0075	0.0107
20611-02	147.	0.6446	0.3442	0.3004	8.1235	1.6156	0.4108	0.5302	0.0673	0.0377	0.0065	0.0122
20611-05	181.	0.4463	0.4089	0.0374	11.7738	2.0903	0.5260	0.5168	0.0850	0.0345	0.0095	0.0127
20608-10	178.	0.2857	0.2630	0.0227	10.1190	1.8274	0.4947	0.8036	0.0807	0.0399	0.0102	0.0130
20613-08	175.	0.2739	0.2527	0.0212	9.8743	1.8770	0.4027	0.4989	0.1004	0.0528	0.0097	0.0105
20614-01	147.	0.2267	0.2064	0.0203	8.6437	1.6228	0.3679	0.4434	0.0804	0.0442	0.0082	0.0112
MEAN	156.	0.3619	0.3007	0.0612	8.7728	1.7413	0.4480	0.5519	0.0812	0.0393	0.0086	0.0134
S.D.	15.4	0.12442	0.07226	0.08299	1.31211	0.16985	0.07420	0.09922	0.01235	0.00529	0.00125	0.00230
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-010

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20606-10	144.	0.2267	0.2088	0.0179	7.6774	1.5054	0.3370	0.5755	0.0578	0.0325	0.0054	0.0195
20605-07	157.	0.2417	0.2248	0.0169	9.5556	1.7912	0.3738	0.3736	0.0961	0.0396	0.0097	0.0139
20604-04	172.	0.2915	0.2645	0.0270	9.6291	1.7761	0.4635	0.6673	0.0828	0.0441	0.0092	0.0173
20603-04	150.	0.1905	0.1747	0.0158	8.0719	1.8449	0.4183	0.6243	0.0668	0.0348	0.0062	0.0118
20607-05	140.	0.2375	0.2223	0.0152	7.7243	1.4120	0.4990	0.4721	0.0683	0.0355	0.0067	0.0168
20604-01	151.	0.5813	0.3473	0.2340	9.0190	1.6824	0.3660	0.6673	0.0707	0.0463	0.0078	0.0150
20606-01	157.	0.1713	0.1498	0.0215	9.3227	1.5543	0.4125	0.7079	0.0513	0.0356	0.0067	0.0128
20608-03	125.	0.1836	0.1682	0.0154	6.9588	1.4050	0.3695	0.4429	0.0520	0.0308	0.0062	0.0108
20609-01	165.	0.3057	0.2755	0.0302	10.1742	1.8274	0.7003	0.4842	0.0655	0.0430	0.0083	0.0100
20611-03	171.	0.2841	0.2673	0.0168	10.5529	2.1962	0.4699	0.7224	0.1152	0.0539	0.0111	0.0139
20610-06	175.	0.3018	0.2840	0.0178	10.0170	1.7676	0.5201	0.7454	0.0778	0.0434	0.0095	0.0137
20610-08	166.	0.3361	0.3089	0.0272	10.5833	1.9461	0.4282	0.5261	0.1028	0.0560	0.0086	0.0139
20608-01	151.	0.2844	0.2684	0.0160	9.5291	1.6169	0.4493	0.5504	0.0913	0.0360	0.0090	0.0132
20612-05	171.	0.2945	0.2714	0.0231	10.2985	1.7870	0.4443	0.4988	0.1022	0.0453	0.0094	0.0155
20613-01	177.	0.2744	0.2574	0.0170	10.8735	2.0582	0.4024	0.6286	0.0756	0.0454	0.0097	0.0142
MEAN	158.	0.2803	0.2462	0.0341	9.3325	1.7447	0.4436	0.5791	0.0784	0.0415	0.0082	0.0142
S.D.	14.8	0.09662	0.05437	0.05551	1.20602	0.22438	0.08752	0.11217	0.01953	0.00744	0.00165	0.00247
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-010

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20606-08	157.	0.5982	0.4183	0.1799	7.9368	1.6783	0.5123	0.5439	0.1045	0.0494	0.0089	0.0138
20605-02	175.	0.3813	0.3485	0.0328	9.0518	1.9331	0.4303	0.4644	0.0973	0.0423	0.0099	0.0157
20607-06	171.	0.2893	0.2681	0.0212	9.5454	1.8837	0.5963	0.6378	0.1138	0.0334	0.0075	0.0143
20603-06	146.	0.6062	0.3673	0.2389	7.4734	1.7359	0.3750	0.6927	0.0661	0.0385	0.0087	0.0132
20604-06	127.	0.8049	0.4074	0.3975	6.4141	1.3892	0.3475	0.4689	0.0706	0.0324	0.0087	0.0131
20606-03	150.	0.2628	0.2463	0.0165	8.3139	1.6003	0.3249	0.6972	0.0827	0.0415	0.0073	0.0114
20607-02	162.	0.2112	0.1983	0.0129	8.3684	1.7677	0.4750	0.4546	0.0999	0.0461	0.0102	0.0138
20608-05	162.	0.3481	0.3273	0.0208	8.4932	1.6628	0.4260	0.7580	0.1129	0.0427	0.0105	0.0112
20609-07	159.	0.2744	0.2472	0.0272	8.5805	1.7423	0.3770	0.4807	0.0910	0.0426	0.0087	0.0160
20610-01	166.	0.3422	0.3135	0.0287	9.9107	1.5556	0.4540	0.6313	0.0816	0.0326	0.0090	0.0143
20611-04	162.	0.2225	0.2077	0.0148	8.0278	1.5724	0.4047	0.4995	0.0866	0.0366	0.0067	0.0105
20609-03	140.	0.3432	0.3112	0.0320	7.2423	1.5399	0.4409	0.5025	0.0709	0.0324	0.0061	0.0106
20611-10	156.	0.2578	0.2371	0.0207	7.9983	1.7689	0.4803	0.5768	0.0711	0.0419	0.0084	0.0155
20613-10	182.	0.7693	0.4106	0.3587	11.1196	1.9378	0.5829	0.5710	0.0923	0.0505	0.0100	0.0208
20612-01	162.	0.3705	0.3505	0.0200	10.1360	1.7657	0.4634	0.5415	0.1120	0.0425	0.0138	0.0135
MEAN	158.	0.4055	0.3106	0.0948	8.5741	1.7022	0.4460	0.5681	0.0902	0.0404	0.0090	0.0138
S.D.	13.8	0.19390	0.07371	0.13289	1.21540	0.15410	0.07776	0.09585	0.01636	0.00593	0.00185	0.00261
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-010

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20604-05	150.	0.3515	0.3320	0.0195	7.9139	1.5373	0.4445	0.5688	0.0959	0.0372	0.0061	0.0173
20606-06	138.	0.2258	0.2079	0.0179	6.9729	1.3372	0.4159	0.4256	0.0790	0.0292	0.0067	0.0125
20605-06	146.	0.2805	0.2614	0.0191	7.7014	1.5832	0.4099	0.5451	0.0930	0.0459	0.0077	0.0125
20603-02	166.	0.3487	0.3215	0.0272	9.1694	1.6554	0.4034	0.7228	0.0741	0.0403	0.0098	0.0121
20607-10	137.	0.5610	0.3867	0.1743	6.0375	1.3334	0.3281	0.4800	0.0711	0.0381	0.0070	0.0127
20603-07	162.	0.2546	0.2341	0.0205	9.2814	1.7345	0.4519	0.6314	0.0906	0.0419	0.0106	0.0149
20607-04	157.	NA	0.4179	NA	7.3403	1.5502	0.4456	0.4976	0.0960	0.0432	0.0119	0.0102
20608-09	177.	0.4406	0.3845	0.0561	9.9310	1.7935	0.5709	0.7464	0.0912	0.0431	0.0108	0.0122
20609-10	167.	0.4078	0.3408	0.0670	9.4426	1.6857	0.5019	0.5318	0.0670	0.0402	0.0080	0.0126
20610-10	156.	0.2187	0.2006	0.0181	8.8787	1.9117	0.3615	0.4374	0.0920	0.0392	0.0106	0.0143
20611-06	163.	0.2556	0.2375	0.0181	9.3567	1.8313	0.4585	0.5222	0.0816	0.0459	0.0104	0.0109
20610-03	150.	0.2156	0.1980	0.0176	8.0284	1.7151	0.3930	0.4690	0.0801	0.0389	0.0077	0.0118
20614-03	151.	0.2604	0.2328	0.0276	7.8185	1.5883	0.4665	0.4211	0.0837	0.0390	0.0095	0.0130
20613-04	173.	0.4189	0.3881	0.0308	7.8302	1.5057	0.5074	0.7281	0.0844	0.0429	0.0104	0.0192
20615-01	168.	0.3011	0.2794	0.0217	9.8272	1.8077	0.7381	0.5593	0.0718	0.0451	0.0089	0.0140
MEAN	157.	0.3243	0.2949	0.0383	8.3687	1.6380	0.4598	0.5524	0.0834	0.0407	0.0091	0.0133
S.D.	12.1	0.10213	0.07678	0.11926	1.14120	0.17054	0.09763	0.10929	0.00952	0.00424	0.00176	0.00235
N	15	14	15	14	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

NA = NOT APPLICABLE

Revised Draft

Modified: 6/13/2006

TABLE 21

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID WEIGHTS AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20604-10	184.	0.2666	0.2481	0.0185	11.8192	2.0905	0.6256	0.6206	0.0856	0.0466	0.0103	0.0119
20603-08	154.	0.8037	0.3905	0.4132	7.7424	1.6156	0.4175	0.5156	0.0825	0.0437	0.0092	0.0158
20607-07	134.	0.2679	0.2503	0.0176	6.1281	1.5319	0.3802	0.3642	0.0757	0.0381	0.0067	0.0160
20605-03	162.	0.2842	0.2693	0.0149	8.9410	1.6279	0.4408	0.4781	0.0622	0.0373	0.0092	0.0144
20606-04	145.	0.2894	0.2685	0.0209	7.3597	1.4434	0.3095	0.7559	0.0712	0.0393	0.0087	0.0101
20604-07	152.	0.4081	0.3701	0.0380	7.8343	1.6730	0.4530	0.5237	0.0654	0.0347	0.0077	0.0107
20605-09	167.	0.2506	0.2318	0.0188	9.5991	1.6244	0.4590	0.5708	0.0755	0.0358	0.0088	0.0115
20609-06	150.	0.3123	0.2964	0.0159	7.9173	1.4413	0.3576	0.4058	0.0785	0.0407	0.0079	0.0130
20611-08	162.	0.4058	0.3880	0.0178	8.7891	1.6522	0.4780	0.5572	0.0856	0.0443	0.0094	0.0115
20610-09	202.	0.7237	0.4621	0.2616	11.5983	2.1187	0.5536	0.5837	0.0809	0.0394	0.0115	0.0146
20611-09	169.	0.2413	0.2181	0.0232	9.1968	1.7082	0.4019	0.4689	0.0703	0.0372	0.0099	0.0116
20614-04	149.	0.2713	0.2525	0.0188	7.9798	1.6511	0.3957	0.6171	0.0939	0.0452	0.0094	0.0120
20613-07	164.	0.2646	0.2486	0.0160	9.5392	1.6536	0.4749	0.4474	0.0858	0.0419	0.0092	0.0116
20612-09	160.	0.2599	0.2434	0.0165	9.3044	1.7278	0.4752	0.5089	0.1056	0.0394	0.0102	0.0093
MEAN	161.	0.3607	0.2956	0.0651	8.8392	1.6828	0.4445	0.5299	0.0799	0.0403	0.0092	0.0124
S.D.	16.9	0.17906	0.07515	0.11926	1.55063	0.19829	0.07982	0.09960	0.01142	0.00363	0.00120	0.00205
N	14	14	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

POFBWv4.14
05/17/2006
R:05/17/2006

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20605-10	171.	0.238	0.224	5.492	1.013	0.188	0.342	0.060	0.025	0.007	0.007
20603-03	151.	0.239	0.221	5.453	1.054	0.235	0.411	0.049	0.027	0.007	0.009
20607-08	171.	0.367	0.269	5.726	1.009	0.240	0.471	0.046	0.023	0.006	0.012
20606-09	139.	0.495	0.288	4.865	1.002	0.239	0.507	0.049	0.016	0.004	0.010
20604-03	142.	0.132	0.117	5.652	1.246	0.260	0.288	0.055	0.025	0.006	0.008
20603-01	160.	0.292	0.211	5.392	0.902	0.325	0.513	0.038	0.022	0.005	0.009
20605-08	185.	0.350	0.245	6.006	0.934	0.329	0.363	0.056	0.021	0.006	0.008
20608-02	136.	0.129	0.115	5.048	1.067	0.271	0.395	0.044	0.023	0.004	0.008
20609-08	152.	0.218	0.205	5.714	1.051	0.299	0.338	0.059	0.029	0.006	0.008
20611-01	167.	0.141	0.130	5.411	1.027	0.254	0.250	0.047	0.022	0.005	0.006
20610-04	161.	0.188	0.171	6.008	1.182	0.237	0.293	0.055	0.023	0.006	0.011
20609-04	167.	0.207	0.197	5.340	0.983	0.315	0.345	0.050	0.021	0.005	0.008
20613-03	179.	0.364	0.215	5.656	0.935	0.269	0.341	0.050	0.024	0.005	0.008
20615-03	174.	0.149	0.138	5.921	1.058	0.313	0.323	0.055	0.025	0.006	0.011
20612-03	158.	0.412	0.247	5.907	1.047	0.262	0.336	0.058	0.026	0.007	0.005
MEAN	161.	0.261	0.200	5.573	1.034	0.269	0.368	0.051	0.023	0.006	0.009
S.D.	14.6	0.1135	0.0547	0.3356	0.0892	0.0401	0.0781	0.0062	0.0030	0.0010	0.0019
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20607-09	162.	0.361	0.246	4.930	0.983	0.318	0.330	0.052	0.024	0.006	0.009
20605-05	169.	0.211	0.198	4.914	1.059	0.229	0.256	0.061	0.027	0.006	0.008
20606-02	154.	0.255	0.241	5.090	1.069	0.289	0.473	0.064	0.033	0.007	0.011
20604-08	155.	0.151	0.139	4.974	1.007	0.262	0.353	0.047	0.021	0.005	0.009
20603-10	145.	0.156	0.144	5.580	1.155	0.293	0.504	0.043	0.024	0.006	0.007
20604-09	167.	0.173	0.162	5.463	1.057	0.266	0.399	0.053	0.025	0.007	0.009
20607-03	155.	0.157	0.146	5.449	1.123	0.223	0.250	0.053	0.028	0.006	0.009
20609-05	131.	0.206	0.190	5.630	1.119	0.259	0.324	0.051	0.019	0.004	0.009
20608-07	157.	0.183	0.173	5.538	1.054	0.261	0.419	0.041	0.020	0.004	0.006
20610-05	147.	0.203	0.190	5.264	1.272	0.256	0.302	0.050	0.026	0.006	0.008
20611-07	177.	0.387	0.246	5.402	1.070	0.272	0.298	0.043	0.020	0.005	0.007
20610-07	159.	0.158	0.145	4.925	1.158	0.254	0.294	0.050	0.022	0.005	0.008
20613-06	185.	0.206	0.194	6.229	1.119	0.380	0.400	0.058	0.026	0.006	0.005
20612-07	152.	0.227	0.213	6.283	1.134	0.248	0.280	0.073	0.032	0.008	0.009
20615-07	147.	0.224	0.209	5.662	1.067	0.261	0.422	0.049	0.028	0.005	0.010
MEAN	157.	0.217	0.189	5.422	1.096	0.271	0.354	0.053	0.025	0.006	0.008
S.D.	13.4	0.0707	0.0374	0.4324	0.0703	0.0382	0.0786	0.0086	0.0042	0.0011	0.0015
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20606-07	149.	0.225	0.207	5.162	1.151	0.358	0.415	0.071	0.031	0.007	0.011
20603-09	145.	0.149	0.136	5.551	1.055	0.270	0.389	0.050	0.024	0.006	0.009
20607-01	131.	0.229	0.216	5.577	1.159	0.268	0.344	0.059	0.027	0.007	0.010
20604-02	140.	0.146	0.132	4.996	1.067	0.310	0.402	0.052	0.025	0.005	0.012
20605-01	150.	0.310	0.252	5.686	1.129	0.279	0.333	0.058	0.023	0.006	0.009
20605-04	152.	0.261	0.243	5.641	1.186	0.286	0.306	0.052	0.023	0.005	0.009
20606-05	161.	0.193	0.179	5.255	1.126	0.263	0.384	0.058	0.024	0.005	0.012
20608-08	173.	0.256	0.236	5.966	1.131	0.325	0.403	0.038	0.023	0.005	0.007
20609-09	168.	0.214	0.183	5.685	1.101	0.350	0.325	0.052	0.025	0.005	0.008
20610-02	144.	0.364	0.216	5.264	1.190	0.264	0.323	0.044	0.025	0.005	0.007
20611-02	147.	0.439	0.234	5.526	1.099	0.279	0.361	0.046	0.026	0.004	0.008
20611-05	181.	0.247	0.226	6.505	1.155	0.291	0.286	0.047	0.019	0.005	0.007
20608-10	178.	0.161	0.148	5.685	1.027	0.278	0.451	0.045	0.022	0.006	0.007
20613-08	175.	0.157	0.144	5.642	1.073	0.230	0.285	0.057	0.030	0.006	0.006
20614-01	147.	0.154	0.140	5.880	1.104	0.250	0.302	0.055	0.030	0.006	0.008
MEAN	156.	0.234	0.193	5.601	1.117	0.287	0.354	0.052	0.025	0.006	0.009
S.D.	15.4	0.0849	0.0434	0.3639	0.0478	0.0354	0.0512	0.0080	0.0033	0.0008	0.0019
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20606-10	144.	0.157	0.145	5.332	1.045	0.234	0.400	0.040	0.023	0.004	0.014
20605-07	157.	0.154	0.143	6.086	1.141	0.238	0.238	0.061	0.025	0.006	0.009
20604-04	172.	0.169	0.154	5.598	1.033	0.269	0.388	0.048	0.026	0.005	0.010
20603-04	150.	0.127	0.116	5.381	1.230	0.279	0.416	0.045	0.023	0.004	0.008
20607-05	140.	0.170	0.159	5.517	1.009	0.356	0.337	0.049	0.025	0.005	0.012
20604-01	151.	0.385	0.230	5.973	1.114	0.242	0.442	0.047	0.031	0.005	0.010
20606-01	157.	0.109	0.095	5.938	0.990	0.263	0.451	0.033	0.023	0.004	0.008
20608-03	125.	0.147	0.135	5.567	1.124	0.296	0.354	0.042	0.025	0.005	0.009
20609-01	165.	0.185	0.167	6.166	1.108	0.424	0.293	0.040	0.026	0.005	0.006
20611-03	171.	0.166	0.156	6.171	1.284	0.275	0.422	0.067	0.032	0.006	0.008
20610-06	175.	0.172	0.162	5.724	1.010	0.297	0.426	0.044	0.025	0.005	0.008
20610-08	166.	0.202	0.186	6.375	1.172	0.258	0.317	0.062	0.034	0.005	0.008
20608-01	151.	0.188	0.178	6.311	1.071	0.298	0.365	0.060	0.024	0.006	0.009
20612-05	171.	0.172	0.159	6.023	1.045	0.260	0.292	0.060	0.026	0.005	0.009
20613-01	177.	0.155	0.145	6.143	1.163	0.227	0.355	0.043	0.026	0.005	0.008
MEAN	158.	0.177	0.155	5.887	1.103	0.281	0.366	0.049	0.026	0.005	0.009
S.D.	14.8	0.0620	0.0307	0.3405	0.0854	0.0513	0.0624	0.0101	0.0034	0.0007	0.0019
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20606-08	157.	0.381	0.266	5.055	1.069	0.326	0.346	0.067	0.031	0.006	0.009
20605-02	175.	0.218	0.199	5.172	1.105	0.246	0.265	0.056	0.024	0.006	0.009
20607-06	171.	0.169	0.157	5.582	1.102	0.349	0.373	0.067	0.020	0.004	0.008
20603-06	146.	0.415	0.252	5.119	1.189	0.257	0.474	0.045	0.026	0.006	0.009
20604-06	127.	0.634	0.321	5.050	1.094	0.274	0.369	0.056	0.026	0.007	0.010
20606-03	150.	0.175	0.164	5.543	1.067	0.217	0.465	0.055	0.028	0.005	0.008
20607-02	162.	0.130	0.122	5.166	1.091	0.293	0.281	0.062	0.028	0.006	0.009
20608-05	162.	0.215	0.202	5.243	1.026	0.263	0.468	0.070	0.026	0.006	0.007
20609-07	159.	0.173	0.155	5.397	1.096	0.237	0.302	0.057	0.027	0.005	0.010
20610-01	166.	0.206	0.189	5.970	0.937	0.273	0.380	0.049	0.020	0.005	0.009
20611-04	162.	0.137	0.128	4.955	0.971	0.250	0.308	0.053	0.023	0.004	0.006
20609-03	140.	0.245	0.222	5.173	1.100	0.315	0.359	0.051	0.023	0.004	0.008
20611-10	156.	0.165	0.152	5.127	1.134	0.308	0.370	0.046	0.027	0.005	0.010
20613-10	182.	0.423	0.226	6.110	1.065	0.320	0.314	0.051	0.028	0.005	0.011
20612-01	162.	0.229	0.216	6.257	1.090	0.286	0.334	0.069	0.026	0.009	0.008
MEAN	158.	0.261	0.198	5.395	1.076	0.281	0.361	0.057	0.026	0.006	0.009
S.D.	13.8	0.1407	0.0547	0.4134	0.0612	0.0373	0.0659	0.0083	0.0030	0.0013	0.0013
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20604-05	150.	0.234	0.221	5.276	1.025	0.296	0.379	0.064	0.025	0.004	0.012
20606-06	138.	0.164	0.151	5.053	0.969	0.301	0.308	0.057	0.021	0.005	0.009
20605-06	146.	0.192	0.179	5.275	1.084	0.281	0.373	0.064	0.031	0.005	0.009
20603-02	166.	0.210	0.194	5.524	0.997	0.243	0.435	0.045	0.024	0.006	0.007
20607-10	137.	0.409	0.282	4.407	0.973	0.239	0.350	0.052	0.028	0.005	0.009
20603-07	162.	0.157	0.145	5.729	1.071	0.279	0.390	0.056	0.026	0.007	0.009
20607-04	157.	NA	0.266	4.675	0.987	0.284	0.317	0.061	0.028	0.008	0.006
20608-09	177.	0.249	0.217	5.611	1.013	0.323	0.422	0.052	0.024	0.006	0.007
20609-10	167.	0.244	0.204	5.654	1.009	0.301	0.318	0.040	0.024	0.005	0.008
20610-10	156.	0.140	0.129	5.691	1.225	0.232	0.280	0.059	0.025	0.007	0.009
20611-06	163.	0.157	0.146	5.740	1.123	0.281	0.320	0.050	0.028	0.006	0.007
20610-03	150.	0.144	0.132	5.352	1.143	0.262	0.313	0.053	0.026	0.005	0.008
20614-03	151.	0.172	0.154	5.178	1.052	0.309	0.279	0.055	0.026	0.006	0.009
20613-04	173.	0.242	0.224	4.526	0.870	0.293	0.421	0.049	0.025	0.006	0.011
20615-01	168.	0.179	0.166	5.850	1.076	0.439	0.333	0.043	0.027	0.005	0.008
MEAN	157.	0.207	0.187	5.303	1.041	0.291	0.349	0.053	0.026	0.006	0.009
S.D.	12.1	0.0699	0.0476	0.4608	0.0850	0.0487	0.0513	0.0072	0.0024	0.0010	0.0016
N	15	14	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

NA = NOT APPLICABLE

Revised Draft

Modified: 6/13/2006

TABLE 22

PROJECT NO.:WIL-187055 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-010
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS- WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/ OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
20604-10	184.	0.145	0.135	6.423	1.136	0.340	0.337	0.047	0.025	0.006	0.006
20603-08	154.	0.522	0.254	5.028	1.049	0.271	0.335	0.054	0.028	0.006	0.010
20607-07	134.	0.200	0.187	4.573	1.143	0.284	0.272	0.056	0.028	0.005	0.012
20605-03	162.	0.175	0.166	5.519	1.005	0.272	0.295	0.038	0.023	0.006	0.009
20606-04	145.	0.200	0.185	5.076	0.995	0.213	0.521	0.049	0.027	0.006	0.007
20604-07	152.	0.268	0.243	5.154	1.101	0.298	0.345	0.043	0.023	0.005	0.007
20605-09	167.	0.150	0.139	5.748	0.973	0.275	0.342	0.045	0.021	0.005	0.007
20609-06	150.	0.208	0.198	5.278	0.961	0.238	0.271	0.052	0.027	0.005	0.009
20611-08	162.	0.250	0.240	5.425	1.020	0.295	0.344	0.053	0.027	0.006	0.007
20610-09	202.	0.358	0.229	5.742	1.049	0.274	0.289	0.040	0.020	0.006	0.007
20611-09	169.	0.143	0.129	5.442	1.011	0.238	0.277	0.042	0.022	0.006	0.007
20614-04	149.	0.182	0.169	5.356	1.108	0.266	0.414	0.063	0.030	0.006	0.008
20613-07	164.	0.161	0.152	5.817	1.008	0.290	0.273	0.052	0.026	0.006	0.007
20612-09	160.	0.162	0.152	5.815	1.080	0.297	0.318	0.066	0.025	0.006	0.006
MEAN	161.	0.223	0.184	5.457	1.046	0.275	0.331	0.050	0.025	0.006	0.008
S.D.	16.9	0.1042	0.0428	0.4478	0.0593	0.0312	0.0680	0.0083	0.0030	0.0005	0.0017
N	14	14	14	14	14	14	14	14	14	14	14

FBW = FINAL BODY WEIGHT

POFBWv4.14
05/17/2006
R:05/24/2006

APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

Revised Draft

[redacted]

Revised Draft

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark amber viscous liquid

Storage Conditions
Ambient

Expiration Date
1 February 2007

Additional Comments
None

[redacted]

27 February 2006
Date

[redacted]

Revised Draft

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown very viscous liquid

Storage Conditions
Ambient

Expiration Date
1 August 2006

Additional Comments
None

[redacted]

27 February 2006
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

Revised Draft

APPENDIX C

Animal Room Environmental Conditions

Revised Draft

Revised Draft

Modified: 5/17/2006

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO [redacted] 187055 TEMPERATURE ITY Y SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187055

DATE IN: 02/28/06 TIME IN: 11:00
DATE OUT: 04/05/06 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
28-Feb-06	70.5	21.4	40.1
01-Mar-06	70.5	21.4	41.0
02-Mar-06	70.6	21.4	39.4
03-Mar-06	70.4	21.4	41.0
04-Mar-06	70.5	21.4	40.2
05-Mar-06	70.5	21.4	39.5
06-Mar-06	70.5	21.4	38.7
07-Mar-06	70.6	21.4	39.2
08-Mar-06	70.5	21.4	39.5
09-Mar-06	70.5	21.4	45.1
10-Mar-06	70.4	21.3	43.9
11-Mar-06	70.5	21.4	42.2
12-Mar-06	70.7	21.5	56.1
13-Mar-06	70.8	21.5	54.1
14-Mar-06	70.5	21.4	40.1
15-Mar-06	70.5	21.4	40.0
16-Mar-06	70.5	21.4	39.2
17-Mar-06	70.5	21.4	40.6
18-Mar-06	70.5	21.4	40.0
19-Mar-06	70.4	21.3	40.4
20-Mar-06	70.2	21.2	41.0
21-Mar-06	70.5	21.4	40.3
22-Mar-06	70.5	21.4	40.5

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
5/17/2006 10:01

187055 RD

Revised Draft

Modified: 5/17/2006

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO [redacted] 187055 TEMPERATURE [redacted]ITY [redacted]Y SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187055

DATE IN: 02/28/06 TIME IN: 11:00
DATE OUT: 04/05/06 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
23-Mar-06	70.5	21.4	40.3
24-Mar-06	70.5	21.4	40.5
25-Mar-06	70.4	21.3	41.8
26-Mar-06	70.5	21.4	40.0
27-Mar-06	70.5	21.4	41.2
28-Mar-06	70.5	21.4	39.5
29-Mar-06	70.5	21.4	40.8
30-Mar-06	70.5	21.4	40.0
31-Mar-06	70.5	21.4	46.8
01-Apr-06	70.6	21.4	41.5
02-Apr-06	70.5	21.4	39.8
03-Apr-06	70.5	21.4	45.4
04-Apr-06	70.6	21.4	39.7
05-Apr-06	70.5	21.4	38.3

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.2	70.8
TEMPERATURE °C	21.4	21.2	21.5
HUMIDITY (%RH)	41.6	38.3	56.1
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
5/17/2006 10:01

187055 RD

Revised Draft

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
PROJECT NO [redacted] 187055 TEMPERATUR [redacted] ITY OF STUDY SUMMARY REPORT 10:10 17-May-06 PAGE 1
SPONSOR: [redacted]

ROOM SPECIFICATIONS:	B ROOM 73		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	02/28/06
HIGH TEMPERATURE:	76.0	TIME IN:	11:00
LOW HUMIDITY:	30.0	DATE OUT:	04/05/06
HIGH HUMIDITY:	70.0	TIME OUT:	8:00

ROOM B ROOM 73 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	41.5
MIN	68.6	28.5
MAX	72.8	73.8
SD	0.36	4.78
N SAMPLES	854	854
FIRST DAY	02/28/06	
LAST DAY	04/05/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

REPORT 5
VERSION 1.10
5/17/2006 10:10

Revised Draft

STUDY 187055 SUMMARY

MEAN	70.5	41.5
MIN	68.6	28.5
MAX	72.8	73.8
SD	0.36	4.78
N SAMPLES	854	854
FIRST DAY	02/28/06	
LAST DAY	04/05/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

Modified: 5/17/2006

187055 RD

APPENDIX D

Clinical Pathology Methods, Procedures And References

Revised Draft

CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Immunoassay- DPC Immulite®

Estradiol (estradiol-17β) - Competitive Immunoassay for the quantitative measurement of estradiol in serum. Default unit: pg/mL.

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

Revised Draft

Immunoassay-GAMMA-C12 Gamma Counter

Rat Luteinizing Hormone (rLH) - ^{125}I radioimmunoassay system for the quantitative determination of (rLH) DPC GAMMA C-12 gamma counter. Default unit: mIU/mL. Biotrak™ rat luteinizing hormone [^{125}I] assay system©. Amersham Life Science Ltd. Package Insert.

Rat Thyroid Stimulating Hormone (rTSH) - ^{125}I assay system with magnetic separation for the quantitative measurement of (rTSH). DPC GAMMA C-12 gamma counter. Biotrak™ rat thyroid stimulating hormone ^{125}I assay system. Amersham Pharmacia Biotech. Package insert.

References:

Immulite®. Diagnostics Products Corporation. Package Insert.

APPENDIX E

WIL Female Pubertal Assay Historical Control Data Version 1.0 [Crl:CD(SD) Rats]

Revised Draft

Revised Draft

WIL Research Laboratories, LLC Historical Control

FEMALE PUBERTAL ASSAYS - Crl:CD(SD) RATS

	Grand Mean	SD	N	Min	Max	25th Quartile	75th Quartile
Vaginal Patency (PND)	34.0	1.3	9	31.8	36.5	33.5	34.5
Body Weight At Patency (g)	111.0	4.9	9	102.1	116.4	107.2	114.3
Estrous Cycle Length (days)	5.1	0.4	8	4.8	6.1	4.875	5.25
Age At First Estrus (PND)	35.8	1.4	9	34.1	38.0	35.1	37.1
T4 (µg/dL)	4.4	0.5	5	3.89	5.23	4.06	4.53
TSH (ng/mL)	9.3	1.9	5	7.7	11.4	7.8	11.3
Uterus - Wet (g)	0.3413	0.0492	9	0.2932	0.44	0.3132	0.3424
Uterus - Blotted (g)	0.2884	0.0307	9	0.2621	0.361	0.2763	0.283
Luminal Fluid (g)	0.0537	0.0227	9	0.0306	0.0924	0.038	0.061
Liver (g)	7.4265	0.4693	9	6.69	7.978	7.16	7.9285
Kidney (g)	1.6066	0.0369	5	1.5682	1.6541	1.5704	1.6237
Ovaries/Oviducts (g)	0.0841	0.0051	8	0.0769	0.094	0.0821	0.0859
Adrenal Glands (g)	0.0381	0.0039	9	0.0321	0.0428	0.0352	0.0415
Pituitary (g)	0.0085	0.0009	9	0.0074	0.0101	0.0079	0.0092
Thyroid Glands (g)	0.0171	0.0031	5	0.0129	0.0213	0.0158	0.0179

Version 1.0 - 23 January 2006

APPENDIX F

WIL Reproductive Historical Control Data Version 2.3 [Crl:CD(SD) Rats]

Revised Draft

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Reproductive Performance

Sex: M/F | Species: Rats | Number of Studies/Control Groups: 60 / 90
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Total	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Number of Males in Control Group	1600						
Male Mating Index (%)		96.8	3.69	61	89.42 / 100.0	85.73 / 100.0	86.7 / 100.0
Male Fertility Index (%)		89.8	6.89	61	76.02 / 100.0	69.13 / 100.0	72.0 / 100.0
Male Copulation Index (%)		92.7	6.08	61	80.54 / 100.0	74.46 / 100.0	75.0 / 100.0
Number of Females in Control Group	2223						
Female Mating Index (%)		97.8	3.27	72	91.26 / 100.0	87.99 / 100.0	86.7 / 100.0
Female Fertility Index (%)		91.3	7.20	81	76.90 / 100.0	69.70 / 100.0	72.0 / 100.0
Female Conception Index (%)		92.8	5.85	72	81.10 / 100.0	75.25 / 100.0	75.0 / 100.0
Number of Females Selected to Deliver	1301						
Number that Delivered	1151						
Number that did not Deliver	145						
Number with Total Litter Loss	11						
Number with Dystocia	3						

Version 2.3
24-Apr-06

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Reproductive Performance

Sex: Female | Species: Rats | Number of Studies/Control Groups: 62 / 88

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Mean Estrous Cycle Length (days)	4.5	0.41	62	3.68 / 5.32	3.27 / 5.73	4.0 / 5.8
Mean Pre-Coital Interval (days)	3.0	0.53	73	1.94 / 4.06	1.41 / 4.59	1.8 / 4.7
Mean Gestation Length (days)	21.9	0.20	46	21.50 / 22.30	21.30 / 22.50	21.5 / 22.3
Mean Number of Pups Born	14.3	0.91	46	12.48 / 16.12	11.57 / 17.03	12.2 / 16.0
Mean Viable Litter Size (PND 0)	14.1	0.94	46	12.22 / 15.98	11.28 / 16.92	12.0 / 16.0
Mean % Males/ Litter	50.1	2.78	58	44.54 / 55.66	41.76 / 58.44	42.7 / 58.5
Mean % Females/ Litter	49.9	2.78	58	44.34 / 55.46	41.56 / 58.24	41.5 / 57.3
Mean No. of Former Implantation Sites at Weaning	15.2	0.87	44	13.46 / 16.94	12.59 / 17.81	13.2 / 17.1
Mean No. of Sites Unaccounted for at Weaning	0.9	0.24	44	0.42 / 1.38	0.18 / 1.62	0.4 / 1.4
Mean Viable Embryos/Dam (GD 15)	14.8	0.77	24	13.26 / 16.34	12.49 / 17.11	13.5 / 16.3
Mean Viable Embryos (%/Litter)	95.0	1.86	24	91.28 / 98.72	89.42 / 100.58	90.0 / 97.1
Mean Viable Fetuses/Dam (GD 20)	14.4	0.87	17	12.66 / 16.14	11.79 / 17.01	13.0 / 16.0
Mean Viable Fetuses (%/Litter)	94.7	1.36	17	91.98 / 97.42	90.62 / 98.78	91.9 / 96.8
Mean Post-Implantation Loss/Dam	0.8	0.24	41	0.32 / 1.28	0.08 / 1.52	0.4 / 1.5
Mean Post-Implantation Loss (%/Litter)	5.1	1.65	41	1.80 / 8.40	0.15 / 10.05	2.9 / 10.0
Mean No. of Corpora Lutea/Dam	16.7	0.88	41	14.94 / 18.46	14.06 / 19.34	15.3 / 18.8
Mean No. of Implantation Sites/Dam	15.3	0.81	41	13.68 / 16.92	12.87 / 17.73	13.9 / 16.8
Mean Pre-Implantation Loss/Dam	1.4	0.41	41	0.58 / 2.22	0.17 / 2.63	0.5 / 2.1
Mean Pre-Implantation Loss (%/Litter)	8.2	1.65	41	4.90 / 11.50	3.25 / 13.15	2.7 / 13.8
Mean Fetal Body Weight (GD 20) (g)	3.6	0.17	17	3.26 / 3.94	3.09 / 4.11	3.3 / 3.8
Mean Primordial Follical Count of 10 Sections/Dam	115.2	31.74	11	51.72 / 178.68	19.98 / 210.42	50.4 / 148.8

Version 2.3

24-Apr-06

Revised Draft

Modified: 5/18/2006

-247-

187055 RD

WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Pup Body Weights (g)

Sex: M/F | Study Type: All | Number of Studies/Data Sets: 29 / 46

Species: Rats | Age Range: 1 - 28 Days | Range of Study Dates: 08/00 - 09/05

Strain: Crl:CD(SD)

Males (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	7.1	0.25	46	6.60 / 7.60	6.35 / 7.85	6.7 / 7.6
PND 4	10.0	0.58	45	8.84 / 11.16	8.26 / 11.74	9.0 / 11.4
PND 7	15.3	1.22	44	12.86 / 17.74	11.64 / 18.96	11.9 / 17 5
PND 14	30.4	3.70	36	23.00 / 37.80	19.30 / 41.50	20.2 / 35.3
PND 21	47.5	5.18	41	37.14 / 57.86	31.96 / 63.04	32.8 / 56.7
PND 28 (weaned PND 28)	82.0	6.86	15	68.28 / 95.72	61.42 / 102.58	69.8 / 94

Females (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	6.7	0.25	46	6.20 / 7.20	5.95 / 7.45	6.3 / 7.3
PND 4	9.5	0.56	45	8.38 / 10.62	7.82 / 11.18	8.6 / 10.9
PND 7	14.5	1.17	44	12.16 / 16.84	10.99 / 18.01	11.3 / 16.7
PND 14	29.2	3.46	36	22.28 / 36.12	18.82 / 39.58	20.3 / 33.9
PND 21	45.6	4.76	41	36.08 / 55.12	31.32 / 59.88	32.8 / 53.5
PND 28 (weaned PND 28)	75.8	6.11	15	63.58 / 88.02	57.47 / 94.13	66.7 / 86.2

Version 2.3

24-Apr-06

Revised Draft

Modified: 5/18/2006

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Survival Indices (%)

Sex: M/F
Species: Rats
Strain: Crl:CD(SD)

Study Type: All
Age Range: 0 - 21 Days

Number of Studies/Data Sets: 29 / 46
Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Number of Pups Born	14.3	0.91	46	12.48 / 16.12	11.57 / 17.03	12.2 / 16.0
Survival (%)						
PND 0 (Relative to No. Born)	98.0	1.53	46	94.94 / 100.00	93.41 / 100.00	93.3 / 100.0
PND 0 to PND 1	99.1	0.89	46	97.32 / 100.00	96.43 / 100.00	95.8 / 100.0
PND 1 to PND 4 (Before Selection)	98.6	1.33	45	95.94 / 100.00	94.61 / 100.00	94.1 / 100.0
PND 4 (After Selection) to PND 7	98.9	1.76	44	95.38 / 100.00	93.62 / 100.00	91.7 / 100.0
PND 7 to PND 14	99.3	1.46	41	96.38 / 100.00	94.92 / 100.00	93.5 / 100.0
PND 14 to PND 21	99.5	1.11	41	97.28 / 100.00	96.17 / 100.00	94.7 / 100.0
Birth to PND 4 (Before Selection)	95.8	2.26	43	91.28 / 100.00	89.02 / 100.00	86.6 / 98.7
PND 4 (After Selection) to PND 21	97.8	2.50	40	92.80 / 100.00	90.30 / 100.00	91.1 / 100.0

Version 2.3
24-Apr-06

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Developmental Landmarks

Sex: M/F | Species: Rats | Number of Studies/Control Groups: 28 / 36

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Male Anogenital Distance (PND1) (mm)	4.02	0.724	8	2.572 / 5.468	1.848 / 6.192	2.45 / 4.66
Mean Female Anogenital Distance (PND1) (mm)	2.18	0.420	8	1.340 / 3.020	0.920 / 3.440	1.34 / 2.57
Mean Day of Balanopreputial Separation	44.8	1.30	31	42.20 / 47.40	40.90 / 48.70	42.0 / 49.0
Mean Body Weight at Aquisition (g)	225.85	9.723	31	206.404 / 245.296	196.681 / 255.019	203.7 / 246.8
Mean Day of Vaginal Patency	33.6	1.05	31	31.50 / 35.70	30.45 / 36.75	31.7 / 37.0
Mean Body Weight at Aquisition (g)	111.85	6.419	31	99.012 / 124.688	92.593 / 131.107	99.5 / 127.4
Mean Day of Surface Righting Response						
Males	5.0	0.06	3	4.88 / 5.12	4.82 / 5.18	5.0 / 5.1
Females	5.2	0.10	3	5.00 / 5.40	4.90 / 5.50	5.1 / 5.3
Mean Day of Pinnal Detachment						
Males	4.1	0.15	4	3.80 / 4.40	3.65 / 4.55	4.0 / 4.3
Females	4.1	0.10	4	3.90 / 4.30	3.80 / 4.40	4.0 / 4.2
Mean Day of Eye Opening						
Males	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Females	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Mean Day of Air Drop Righting Reflex						
Males	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Females	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Mean Day of Hair Growth						
Males	13.5	1.43	4	10.64 / 16.36	9.21 / 17.79	11.7 / 15.0
Females	13.6	1.51	4	10.58 / 16.62	9.07 / 18.13	11.8 / 15.2
Mean Day of Incisor Eruption						
Males	9.9	0.41	5	9.08 / 10.72	8.67 / 11.13	9.3 / 10.4
Females	9.9	0.34	5	9.22 / 10.58	8.88 / 10.92	9.3 / 10.2

Version 2.3

24-Apr-06

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Organ Weights (PND 21)

Sex: M/F
Species: Rats
Strain: Crl:CD(SD)

Study Type: All
Age: 21 Days

Number of Studies/Number Data Sets: 11 / 21
Range of Study Dates: 06/01 - 04/05

Males

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Brain (g)	1.4397	0.04072	21	1.35826 / 1.52114	1.31754 / 1.56186	1.3451 / 1.4899
Spleen (g)	0.2058	0.03054	21	0.14472 / 0.26688	0.11418 / 0.29742	0.1471 / 0.2480
Thymus (g)	0.1963	0.02035	21	0.15560 / 0.23700	0.13525 / 0.25735	0.1617 / 0.2330

Females

Brain (g)	1.3931	0.03322	21	1.32666 / 1.45954	1.29344 / 1.49276	1.3142 / 1.4378
Spleen (g)	0.2020	0.03048	21	0.14104 / 0.26296	0.11056 / 0.29344	0.1471 / 0.2448
Thymus (g)	0.1987	0.02387	21	0.15096 / 0.24644	0.12709 / 0.27031	0.1669 / 0.2547

Version 2.3
24-Apr-06

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Male and Female Organ Weights (Necropsy)

Sex: M/F | Species: Rats | Number of Studies/Number Data Sets: 36 / 55
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 10/00 - 05/05

Males	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Age of Males at Necropsy (weeks)	22.2	4.20	27	13.80 / 30.60	9.60 / 34.80	16.4 / 30.6
Mean Seminal Vesicle/Coagulating Gland Weight (g)	2.21	0.169	36	1.872 / 2.548	1.703 / 2.717	1.82 / 2.57
Mean Prostate Weight (g)	1.07	0.102	22	0.866 / 1.274	0.764 / 1.376	0.76 / 1.27
Mean Right Testis Weight (g)	1.79	0.069	48	1.652 / 1.928	1.583 / 1.997	1.66 / 1.93
Mean Left Testis Weight (g)	1.80	0.077	48	1.646 / 1.954	1.569 / 2.031	1.67 / 2.09
Mean Right Epidymis Weight (g)	0.72	0.041	48	0.638 / 0.802	0.597 / 0.843	0.63 / 0.80
Mean Left Epidymis Weight (g)	0.72	0.041	48	0.638 / 0.802	0.597 / 0.843	0.62 / 0.78
Mean Right Cauda Epidymis Weight (g)	0.3275	0.02230	48	0.28290 / 0.37210	0.26060 / 0.39440	0.2629 / 0.3693
Mean Left Cauda Epidymis Weight (g)	0.3309	0.02064	48	0.28962 / 0.37218	0.26898 / 0.39282	0.2714 / 0.3706
Females						
Mean Age of Females at Necropsy (weeks)	23.2	5.03	19	13.14 / 33.26	8.11 / 38.29	16.0 / 32.0
Mean Combined Ovary Weight (g)	0.1448	0.03004	19	0.08472 / 0.20488	0.05468 / 0.23492	0.0926 / 0.1779

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Sperm Concentration and Morphology

Sex: Male | Species. Rats | Number of Studies/Control Groups: 32 / 44

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 10/00 - 05/05

Mean Sperm Concentration (millions/ gram of tissue)	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Left Testis	80.9	7.33	43	66.24 / 95.56	58.91 / 102.89	68.2 / 96.6
Left Epididymis	454.5	49.37	37	355.76 / 553 24	306.39 / 602.61	339.1 / 619.2
Left Cauda Epididymis	666.2	57.99	7	550.22 / 782.18	492.23 / 840.17	568.0 / 738.9
Mean Sperm Production Rate (millions/ gram of tissue/ day)	13.4	1.21	23	10.98 / 15.82	9.77 / 17.03	11.4 / 15.8
Mean Sperm Motility (%)	85.4	3.01	44	79.38 / 91.42	76.37 / 94.43	78.9 / 91.0
Mean Progressive Sperm Motility (%)	72.5	3.70	15	65.10 / 79.90	61.40 / 83.60	67.0 / 80.0
Sperm Morphology Differential Count (%)						
Normal	99.1	0.81	43	97.48 / 100.0	96.67 / 100.0	96.1 / 99.9
Normal Head Separated from Flagellum	0.4	0.40	43	0.00 / 1.20	0.00 / 1.60	0.0 / 1.8
Head Absent w/ Normal Flagellum	0.3	0.39	43	0.00 / 1.08	0.00 / 1.47	0.0 / 2.3
Head Absent w/ Abnormal Flagellum	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Misshapen Head w/ Normal Flagellum	0.0	0.17	43	0.00 / 0.34	0.00 / 0.51	0.0 / 1.1
Misshapen Head w/ Abnormal Flagellum	0.0	0.06	43	0.00 / 0.12	0.00 / 0.18	0.0 / 0.4
Degenerative Flagellar Defects w/ Normal Head	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Other Flagellar Defects w/ Normal Head	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0

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APPENDIX G

Study Protocol

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Study Number: WIL-187055

PROTOCOL AMENDMENT II

Sponsor: [redacted]

Sponsor No.: 06-010

A. Title:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **7.6.4 Determination of Estrous Cycles:**

In accordance with the Study Director Notification dated March 31, 2006, the vaginal lavage performed on the day of necropsy was collected immediately prior to euthanasia.

C. Reason for Protocol Modifications:

1) This change in procedure was made to allow a more accurate correlation of serum hormone levels with the stage of the estrous cycle.

Approved By:

[redacted]

21 June 2006
Date

Prepared By:
WIL Research Laboratories, LLC

[redacted]

20 June 2006
Date

[redacted]

20 June 2006
Date

Study Number: WIL-187055

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor No.: 06-010

A. Title:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **3** **STUDY SCHEDULE:**

Proposed Audited Report Date: June 14, 2006

2) **7.5.1** **Method and Frequency of Preparation:**

In accordance with the Study Director Notification dated March 10, 2006, the dosing formulations will be stored at room temperature.

3) **8** **HORMONE ANALYSIS:**

The following is added to this section:

Estradiol (E_2) and Lutenizing (LH) hormone concentration levels will be determined.

4) **9.1** **Macroscopic Examination:**

The following is added to this section:

The spleen, thymus and axillary lymph node are added to the list of tissues to be collected.

5) **9.2.2** **Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:**

The following is added to this section:

The spleen and thymus are added to the list of organs to be weighed.

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C. Reason for Protocol Modifications:

1) The proposed audited report date has been determined.

2) The storage requirement for dosing formulations has been added.

3) Additional hormones for analysis have been added.

4) The Sponsor has requested collection of additional tissues.

5) The additional tissues collected will be weighed.

Approved By:

[redacted]

[redacted]

20 March 2006
Date

WIL Research Laboratories, LLC

[redacted]

3/17/2006
Date

[redacted]

3/17/06
Date

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PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 06-010

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF), Law No. 82, 1948, Good Laboratory Practice (GLP) Standards. The study will be performed according to the protocol and WIL Standard Operating Procedures.

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2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[redacted]

2.2 Sponsor Alternate:

[redacted]

2.3 WIL Study Director:

[redacted]

2.4 WIL Deputy Director:

[redacted]

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2.5 WIL Departmental Responsibilities:

[redacted]

3 STUDY SCHEDULE:

Proposed Animal Receipt Date:	February 28, 2006
Proposed Experimental Start Date (Experimental Starting Date):	March 14, 2006
Proposed Experimental Termination/ Completion Date:	April 5, 2006
Proposed Audited Report Date:	To be determined

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4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

4.1.1 Lot Number:

[redacted]

4.1.2 Purity:

100%.

4.1.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.1.4 Physical Description:

To be determined

4.1.5 Storage Conditions:

Store at ambient conditions

4.1.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.1.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

4.2 Identification:

[redacted]

4.2.1 Lot Number:

[redacted]

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4.2.2 Purity:

100%.

4.2.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.2.4 Physical Description:

To be determined

4.2.5 Storage Conditions:

Store at ambient conditions

4.2.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.2.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Crl:CD(SD)

5.3 Source:

Charles River Laboratories
Raleigh, NC

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5.4 Number on Study:

One hundred-five females (maximum of 130 females and 13 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 6-8 days old upon receipt. Pups not expected to survive to the next observation period (moribund) will be euthanized by intraperitoneal injection of sodium pentobarbital (prior to PND 11) or by carbon dioxide inhalation (after PND 11) and the carcass discarded. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and the carcasses discarded.

5.5 Body Weight Range:

At randomization: 30-50 g for immature females. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal eartag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal. Following randomization the pups will be individually identified by an ear tag.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed-O'Cobs®). Following randomization, the juvenile female animals

will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. Control animals (Group 1) will be housed on a separate rack from exposed animals. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL standard operating procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol-specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Each lot utilized will be identified and recorded. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Acclimation:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately

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placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean. Each of 7 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses or incomplete dosing will be recorded.

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7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Vehicle	0	0	5	15
2	[redacted]	60	12	5	15
3		250	50	5	15
4		1000	200	5	15
5		60	12	5	15
6		250	50	5	15
7		1000	200	5	15

7.4.2 Vehicle Control Article:

Corn oil

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 of age and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, after 12:00 p.m., and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Material Preparations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This

visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration, if possible. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5 mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] c/o [redacted] for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The method employed will be:

[redacted] SOP: To be determined

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Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

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7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will be observed also approximately one hour following dosing and the observations will be recorded. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded. Findings noted outside of the scheduled observation time periods will be recorded at the time they are observed.

7.6.2 Body Weights:

Daily body weights will be recorded individually (to the nearest 0.1 gram, PND 22-42) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed once daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will be performed at approximately the same time each day and will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will be performed at approximately the same time each day and will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not

expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized by carbon dioxide inhalation and necropsied as described in section 9.

8 HOROMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples (target volume of 2 mL) will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH) Thyroxine (T4)

Serum not utilized for TSH and T4 concentrations will be stored frozen for possible future analysis (added by amendment).

9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized *in extremis*. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. Gross lesions (i.e., masses) will be collected and placed in 10% neutral-buffered formalin. The following tissues will be collected and placed in 10% neutral-buffered formalin at study termination:

Cervix and Uterine Body (one longitudinal section)	Thyroids with parathyroids
Ovaries	Uterine horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized in extremis.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in a round-robin

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order. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

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9.2.2 Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Ovaries and oviducts
Liver	Pituitary gland
Kidneys	Thyroids with parathyroids (following fixation)

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 Microscopic Examination:

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination. The vagina, ovaries, and thyroids with parathyroids from each animal will be similarly preserved.

Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

Ovaries	Thyroids with parathyroids
Cervix and Uterine Body (one longitudinal section)	Uterine Horns (four sections per horn)

10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, organ weights relative to final body weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age of first estrous, estrous cycle length and serum hormone concentrations will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the

results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol, protocol amendments and WIL Standard Operating Procedures. The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF) Law No. 82, 1948, Good Laboratory Practice (GLP) Standards. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report.

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One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional paper copies of the final report may result in additional charges.

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16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in

the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

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19 PROTOCOL APPROVAL:

Sponsor approval received via e-mail on February 24, 2006.

[redacted]

3 March 2006
Date

WIL Research Laboratories, LLC

[redacted]

3/1/2006
Date

[redacted]

3/1/2006
Date

Revised Draft

ABBREVIATED REVISED DRAFT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [ ] AND
[ ] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187056

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

3 March 2006

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

06-011

SPONSOR

[ ]

COMPLIANCE STATEMENT

This study, designated WIL-187056, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) Good Laboratory Practice Standards (11 Nousan No. 6283), 1 October 1999; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor. **A Certificate of Analysis was provided by the sponsor (presented in Appendix A); the characterization analyses were conducted according to Good Laboratory Practices (GLP).**

_____ _____

[ ] Date

Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] or [ ], in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to 3 groups each of 15 Crl:CD(SD) immature female rats. Dosage levels for each test article were 60, 250 and 1000 mg/kg/day, and the dosage volume was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director.

Dosing procedures were performed from 28 March 2006 through 18 April 2006, when the animals were 22 to 41 days of age; the start of dose administration was staggered, based on age. At the initiation of dose administration, individual body weights ranged from 39.2 g to 61.9 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[ ]	60	12	5	15
3	[ ]	250	50	5	15
4	[ ]	1000	200	5	15
5	[ ]	60	12	5	15
6	[ ]	250	50	5	15
7	[ ]	1000	200	5	15

Due to spacing constraints, the dosage group names are presented on the tables and figures as corn oil, [ ]/60, [ ]/250 and [ ]/1000 for the vehicle control,

60, 250 and 1000 mg/kg/day [ ] groups, respectively and [ ]/60, [ ]/250 and [ ]/1000 for the 60, 250 and 1000 mg/kg/day [ ] groups, respectively.

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (corn oil, exp. dates: 1 and 23 February 2007) was placed in a storage container and stirred throughout use. The [ ] and [ ] dosing formulations were prepared as follows. The appropriate amount of test article for each group was weighed into a tared, calibrated glass container. A stir bar and approximately 80% of the vehicle were added to each container, and the mixtures were stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The [ ] and [ ] dosing formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature. Three samples from the control group formulation and 3 sets of samples from the top, middle and bottom strata of the test article formulations were collected prior to the initiation of dose administration. Additional samples (3 sets) were collected for resuspension homogeneity from the same formulations following 10 days of room temperature storage. Two sets of samples for concentration verification were collected on each day of preparation and 2 sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and 6 sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC, for possible future analysis.

Thirteen dams with 10 or 11 female pups each (131 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on 14 March 2006. The pups were 6 to 8 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam for 14 to 16 days) during the acclimation period until randomization of the pups on postnatal day (PND) 21.

Following randomization, the female pups were weaned, identified by metal eartag and housed 3 per cage in plastic maternity cages; control group animals were housed in a separate rack than the test article-treated group animals. Environmental controls were set to maintain an average daily temperature of 71°F ± 5°F (22°C ±3°C) and an average daily relative humidity of 50% ± 20%. Actual mean daily temperatures ranged from 70.2°F to 70.6°F (21.2°C to 21.5°C) and mean daily relative humidity ranged from 37.9% to 49.6%. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse osmosis-purified water were offered ad libitum.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on PND 25 (Adams et al., 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (i.e., the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia). Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. As a result of mortality and clinical signs of overt toxicity, animals in the 1000 mg/kg/day [ ] group that were not found dead were euthanized by carbon dioxide inhalation (PND 23-25) and discarded without

further examination. A gross necropsy was performed only on animals that were found dead; at the scheduled euthanasia, organs that were weighed were also examined. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum thyroxine (T_4), thyroid stimulating hormone (TSH), estradiol (E_2) and luteinizing hormone (LH) levels. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, adrenal glands, pituitary gland, spleen, thymus gland and thyroid glands with parathyroid glands (following fixation) were weighed. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The ovaries, uterus (horns and body), cervix, vagina, pituitary gland, thyroid/parathyroid glands, spleen, thymus gland, axillary lymph nodes and gross lesions were retained from all necropsied females.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. In addition, percent change from control is presented for body weights, clinical pathology parameters and organ weights. Due to the different rounding conventions inherent in the types of software used, the means and standard deviations on the summary and individual tables may differ by ±1 in the last significant figure. Mean body weights, body weight changes, days of acquisition of vaginal patency, estrous cycle lengths, ages at the first occurrence of estrus, serum hormone levels, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
14 March 2006	Experimental starting date (animal receipt)
28 March 2006	Experimental start date (first day of dose administration)
28 March – 18 April 2006	Test article administration
27 April 2006	Experimental termination/completion date (last serum hormone analysis)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS - [ ]

One or 2 occurrences of clear material around the mouth were noted in 6 of 15 females in the 1000 mg/kg/day [ ] group 1 hour following dose administration. Salivation was also observed for 2 females in this group at the time of dose administration. These findings were attributed to the test article, but were not considered adverse because of the infrequent nature and because clear material around the mouth and salivation did not persist to the following day.

All females in the control, 60, 250 and 1000 mg/kg/day [ ] groups survived to the scheduled euthanasia. No test article-related macroscopic findings were noted at the scheduled necropsy on PND 42. Only the tissues that were retained were examined.

Slightly lower mean body weight gains in the 1000 mg/kg/day [ ] group relative to the control group values were noted during PND 25-26 through PND 28-29, with general reductions occurring during the remainder of the treatment period. The differences were statistically significant ($p<0.05$ or $p<0.01$) during PND 26-27 and when the entire treatment period (PND 22-42) was evaluated. Mean body weights in this group were 5.3% to 8.1% lower than the control group values from PND 33-42. The differences were statistically significant ($p<0.05$) on PND 40 and 42. Mean body weights and body weight gains in the 60 and 250 mg/kg/day [ ] groups were unaffected by test article administration. Although mean body weights and body weight gains in the 60 mg/kg/day [ ] group were generally lower than those in the control group throughout the study, there was no dose-response relationship compared to the higher dosage levels. The only statistically significant ($p<0.05$) differences from the control group were lower mean body weight gains in the 60 mg/kg/day [ ] group during PND 26-27 and 22-42 and a higher mean body weight gain in the 250 mg/kg/day [ ] group during PND 34-35. No dose-related trends were evident.

The mean age of attainment of vaginal patency was approximately 5 days earlier in the 250 and 1000 mg/kg/day [ ] groups compared to the concurrent control group value. The differences were statistically significant ($p<0.01$). The mean age of attainment of vaginal patency in the 60 mg/kg/day [ ] group was 1 day earlier than in the concurrent control group; the difference was not statistically significant. Mean ages of attainment were 32.7, 31.7, 26.9 and 26.5 days in the control, 60, 250 and 1000 mg/kg/day [ ] groups, respectively. Because the females were younger at the attainment of vaginal patency, mean body weights at the age of attainment in the 60, 250 and 1000 mg/kg/day [ ] groups were lower than the concurrent control group values; the differences were statistically significant ($p<0.01$). The mean ages and body weights at attainment of vaginal patency in all [ ]-treated groups were below the minimum mean values in the WIL historical control data (31.8 days and 102.1 g,

respectively). The early attainment of vaginal patency in the 60, 250 and 1000 mg/kg/day [ ] groups was attributed to the test article.

The ages of the first occurrence of estrus in the 60, 250 and 1000 mg/kg/day [ ] groups (32.6, 28.8 and 26.7 days, respectively) were earlier than in the control group (34.5 days of age); the differences were statistically significant ($p<0.01$) in the 250 and 1000 mg/kg/day [ ] groups. No test article-related differences in mean estrous cycle length were observed when the [ ]-treated groups were compared with the control group. Estrous cycle lengths in females of this age are highly variable. However, 7 females in the 250 mg/kg/day [ ] group had 3-5 consecutive days of estrus and all 15 females in the 1000 mg/kg/day [ ] group had 5-16 consecutive days of estrus, whereas no females in the control group had more than 2 consecutive days of estrus. The early age of occurrence of first observation of estrus in the 60, 250 and 1000 mg/kg/day [ ] groups and the persistent estrus observed in the 250 and 1000 mg/kg/day [ ] groups were attributed to the test article.

Mean total T_4 and TSH levels in the 60, 250 and 1000 mg/kg/day [ ] groups were generally similar to those in the control group; there was no dose-response relationship in these groups. A slightly lower mean estradiol level was observed in the 1000 mg/kg/day [ ] group. The difference from the control group was not statistically significant; however, all females in this group with lower estradiol levels were in persistent estrus. Therefore, the lower mean estradiol level in this group was considered test article-related. Mean estradiol levels in the 60 and 250 mg/kg/day [ ] groups and mean luteinizing hormone levels in the 60, 250 and 1000 mg/kg/day [ ] groups were unaffected by test article administration.

Mean absolute and relative (to final body weight) wet and blotted uterus weights and mean absolute luminal fluid weight in the 1000 mg/kg/day [ ] group were lower than the control group values; the differences were not statistically significant. However, when comparing individual uterus weights (wet and blotted) for females that were in

estrus (E) or proestrus (P) just prior to necropsy, the majority of the weights in the 1000 mg/kg/day [ ] group (7 females in E or P) were lower than some of the weights for females in the control group that were in diestrus (D) and markedly lower than the control group females that were in E or P at euthanasia. While luminal fluid weights were highly variable, the same trend noted for mean wet uterus weights was evident for luminal fluid weights in the 1000 mg/kg/day [ ] group. Mean absolute and relative ovary/oviduct weights in this group were also lower than the control group values; the difference was statistically significant ($p<0.05$) for the mean absolute weight. These reductions in mean absolute and relative uterus (wet and blotted) and ovary/oviduct weights and mean absolute luminal fluid weight in the 1000 mg/kg/day [ ] group were attributed to the test article. In the 1000 mg/kg/day [ ] group, mean absolute and relative thymus gland weights were lower than the control group values. Mean absolute and relative adrenal gland weights in the 1000 mg/kg/day [ ] group and mean absolute adrenal gland weight in the 250 mg/kg/day [ ] group were higher than the control group values. The differences were not statistically significant; however, these effects on organ weights were also considered test article-related. No other test article-related effects on organ weights were noted in the [ ]-treated groups. Differences from the control group were slight, attributed to lower mean body weights (relative organ weights), not statistically significant and/or did not occur in a dose-related manner.

1.6. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], administered orally to juvenile female rats resulted in estrogenic effects for females at 60, 250 and 1000 mg/kg/day as evidenced by earlier attainment of vaginal patency (with corresponding lower mean body weight on the day of attainment) and age at the first occurrence of estrus. In addition, estrous cycle disturbances were noted in the 250 and 1000 mg/kg/day [ ] groups with 7 and 15 females, respectively, exhibiting persistent estrus (3-16 consecutive days of estrus). A lower mean estradiol level was observed in the 1000 mg/kg/day [ ]

group. No test article-related effects on TSH, T_4 or luteinizing hormone were noted in the 60, 250 and 1000 mg/kg/day [ ] groups. Mean absolute and relative (to final body weight) wet and blotted uterus weights (and thus, luminal fluid weight), ovary/oviduct and thymus gland weights in the 1000 mg/kg/day [ ] group were lower than the control group values; mean absolute and/or relative adrenal gland weights in the 250 and 1000 mg/kg/day [ ] groups were higher than the control group values.

1.7. RESULTS - [ ]

Yellow material on the ventral abdomen and/or urogenital area, red material around the nose and an unkempt appearance were noted in the 1000 mg/kg/day [ ] group at the daily examinations. Two females in this group were lethargic 1 hour following dose administration (PND 24 or 25); these females were found dead on these same days. These findings were attributed to the test article. Increased incidences of salivation or evidence thereof (clear material around the mouth) were observed at the time of and 1 hour following dose administration in the 250 mg/kg/day [ ] group females. A slight increase in the incidence of salivation was also noted in this group at the time of dose administration. These findings in the 250 mg/kg/day [ ] group were attributed to the test article, but were not considered adverse. One female in the 250 mg/kg/day [ ] group was prostrate immediately prior to death. No test article-related clinical findings were noted in the 60 mg/kg/day [ ] group.

One and 3 females in the 250 and 1000 mg/kg/day [ ] groups, respectively, were found dead on PND 24 or 25 (1000 mg/kg/day [ ] group) or PND 35 (250 mg/kg/day [ ] group). Because of the mortality and other signs of overt toxicity (clinical findings and lower mean body weight gain and body weight loss) in the 1000 mg/kg/day [ ] group, all remaining females were euthanized and discarded on 31 March 2006 (PND 23-25), precluding all scheduled evaluations thereafter. All other animals survived to the scheduled euthanasia. No test article-related macroscopic findings were noted for the females that were found dead (complete necropsy) or at the scheduled necropsy (only the retained tissues were examined).

Test article-related, lower mean body weight gain or body weight losses were noted in the 1000 mg/kg/day [ ] group prior to euthanasia (PND 22-23 through 24-25). The differences were statistically significant ($p<0.01$) compared to the control group values. Mean body weights in this group were 7.9% to 20.9% lower than the control group values during PND 23-25; the differences were statistically significant ($p<0.01$) on PND 24 and 25. Further evaluation of body weight data for the 1000 mg/kg/day [ ]

group was precluded by euthanasia. Mean body weights and body weight gains in the 60 and 250 mg/kg/day [ ] groups were generally similar to those in the control group throughout the study; no test article-related effects were noted. The only statistically significant ($p<0.01$) difference noted was a transient reduction in mean body weight gain in the 250 mg/kg/day [ ] group during PND 33-34.

The mean ages of attainment of vaginal patency in the 60 and 250 mg/kg/day [ ] group were earlier than that in the control group; therefore, mean body weight at the age of attainment of patency in these groups was lower than that in the control group. The differences were statistically significant ($p<0.01$). Mean ages of attainment were 27.5 and 26.5 days in the 60 and 250 mg/kg/day [ ] groups, respectively, compared to 32.7 days in the control group. These effects were attributed to the test article.

The ages of the first occurrence of estrus in the 60 and 250 mg/kg/day [ ] groups (29.8 and 27.7 days of age, respectively) were earlier than in the control group (34.5 days of age). The differences were statistically significant ($p<0.01$). The early onset of estrus in these groups was attributed to the test article. Mean estrous cycle length in the 250 mg/kg/day [ ] group (5.9 days) was slightly longer than that in the control group (4.9 days); this increase was primarily due to a single female with an 11-day estrous cycle (10 days of diestrus). However, 12 females in this group had 3-8 consecutive days of estrus (E), whereas no females in the control group had more than 2 consecutive days of E. Two females in the 60 mg/kg/day [ ] group had 3-4 consecutive days of E. The early age of occurrence of first observation of estrus in the 60 and 250 mg/kg/day [ ] groups and the extended period of time in estrus in the 250 mg/kg/day [ ] group were attributed to the test article.

Mean T_4 and TSH levels in the 60 and 250 mg/kg/day [ ] groups were generally similar to the control group values. The mean T_4 level in the 250 mg/kg/day group (3.96 µg/dL) was statistically significantly ($p<0.05$) lower than the concurrent control group value (5.07 µg/dL). In addition, a corresponding increase (not statistically

significant) was noted in the mean TSH level in this group, as reduced circulating levels of T_4 following a chemical or physiological insult tend to induce a compensatory release of TSH (Goldman et al., 2000). Therefore, the reduction in mean T_4 level in the 250 mg/kg/day [ ] group was considered test article-related. Mean estradiol levels in the 60 and 250 mg/kg/day [ ] groups were lower than the control group values. The differences from the concurrent control group were not statistically significant. However, the lower mean estradiol levels in these groups were considered test article-related based on the test article-related effects on attainment of vaginal patency and estrous cycles in these groups. Mean luteinizing hormone levels in the 60 and 250 mg/kg/day [ ] groups were similar to the concurrent control group value.

Mean absolute and relative (to final body weight) liver weights in the 250 mg/kg/day [ ] group were higher than the control group values; the difference was statistically significant ($p<0.01$) for the relative value. Mean absolute and relative wet and blotted uterus weights and mean absolute luminal fluid weight in the 60 and 250 mg/kg/day [ ] groups were lower than the control group values; the differences were statistically significant ($p<0.01$) in the 250 mg/kg/day [ ] group. When comparing individual uterus weights (wet and blotted) for females that were in estrus (E) or proestrus (P), the majority of the weights in the 250 mg/kg/day [ ] group (6 females in E or P) were generally similar to or lower than the weights for females in the control group that were in diestrus (D) and lower than the control group females that were in E or P at euthanasia. Mean absolute and relative ovary/oviduct weights in this group were also lower than the control group values; the differences were statistically significant ($p<0.05$ or $p<0.01$). These reductions in mean absolute and relative uterus (wet and blotted) weights and mean absolute luminal fluid weight in the 60 and 250 mg/kg/day [ ] groups and mean absolute and relative ovary/oviduct weight in the 250 mg/kg/day [ ] groups were attributed to the test article. Mean absolute and relative thymus gland weights in the 60 and 250 mg/kg/day [ ] groups were lower than the control group values; the differences were statistically significant ($p<0.01$) in the 250 mg/kg/day [ ] group.

Mean absolute and relative adrenal gland weights in the 250 mg/kg/day [ ] group were higher ($p<0.05$ or $p<0.01$) than the control group values. These effects on organ weights were also considered test article-related. No other test article-related effects on organ weights were noted in the [ ]-treated groups. Differences from the control group were slight, not statistically significant and/or did not occur in a dose-related manner.

1.8. CONCLUSIONS - [ ]

Based on the results of this study, the test article, [ ], at a dosage level of 1000 mg/kg/day [ ], administered orally to juvenile female rats exceeded the maximum tolerated dose. Estrogenic effects were noted at 60 and 250 mg/kg/day as evidenced by earlier attainment of vaginal patency (with corresponding lower mean body weight on the day of attainment) and age at the first occurrence of estrus. In addition, estrous cycle disturbances were noted in the 250 mg/kg/day [ ] groups with 12 females having 3-8 consecutive days of estrus compared to no females in the control group with more than 2 consecutive days of estrus. Lower mean estradiol levels were observed in the 60 and 250 mg/kg/day [ ] groups; a lower mean T_4 level and a higher mean TSH level were noted at 250 mg/kg/day. No test article-related effects on luteinizing hormone were noted in the 60 and 250 mg/kg/day [ ] groups. Mean absolute and relative (to final body weight) wet and blotted uterus weights and thymus gland weights in the 60 and 250 mg/kg/day [ ] groups and mean absolute and relative ovary/oviduct weights in the 250 mg/kg/day [ ] group were lower than the control group values. Mean absolute and relative thymus gland weights were lower in the 60 and 250 mg/kg/day [ ] groups than in the control group. In the 250 mg/kg/day [ ] group, mean absolute and relative adrenal gland and liver weights were higher than the control group values.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____
[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____
[ ] Date
Senior Study Analyst

Report Reviewed By:

_____ _____
[ ] Date
Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Group Supervisor, Study Analysis and Reports

_____ _____
[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

[ ]	Manager, Clinical Pathology
[ ]	Senior Operations Manager, Vivarium
[ ]	Manager, Gross Pathology and Developmental Toxicology Laboratory
[ ]	Group Supervisor, Formulations Laboratory
[ ]	Director, Metabolism and Analytical Chemistry
[ ]	Operations Manager, Developmental, Reproductive and Neurotoxicology
[ ]	Manager, Reporting and Regulatory Technical Services

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
31-Mar-2006	Vaginal Perforation	31-Mar-2006	24-Apr-2006	[ ]
17-Apr-2006	Blood Collection	17-Apr-2006	23-May-2006	[ ]
15-Jun-2006, 26-Jun-2006	Study Records (I-1, I-2)	26-Jun-2006	25-Jul-2006	[ ]
26-Jun-2006	Study Records (I-1, Supplemental)	26-Jun-2006	25-Jul-2006	[ ]
15-Jun-2006, 26-Jun-2006	Study Records (N-1)	26-Jun-2006	25-Jul-2006	[ ]
26-Jun-2006	Study Records (C-1, C-2)	26-Jun-2006	25-Jul-2006	[ ]
26-Jun-2006	Study Records (Rx-1)	26-Jun-2006	25-Jul-2006	[ ]
23-Jun-2006, 26-Jun-2006, 29-Jun-2006	Draft Report	29-Jun-2006	25-Jul-2006	[ ]

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Part 792), the OECD Principles of Good Laboratory Practice, the Japanese MAFF Good Laboratory Practice Standards, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendments with the following exceptions. The data located in Appendices A (Certificates of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____
[ ] Date
Sponsor Specialist, Quality Assurance

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

Goldman, J.M.; Laws, S.C.; Balchak, S.K.; Cooper, R.L.; Kavlock, R.J. Endocrine-Disrupting Chemicals: Prepubertal Exposures and Effects on Sexual Maturation and Thyroid Activity in the Female Rat. A Focus on the EDSTAC Recommendations. *Critical Reviews in Toxicology* **2000**, 30(*2*), 135-196.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Sections 5.4, 7.2 and 7.4.1** state that 105 females (15 per group) would be placed on study. One female was added to the 1000 mg/kg/day [ ] group (Group 7) following the death of another female on PND 24. This resulted in 16 animals in Group 7 and a total of 106 females on study.
- **Protocol Section 6.1** states that the control group animals would be housed in a separate rack from the exposed animals following randomization. Documentation of separate housing for the control group was not recorded.
- **Protocol Section 7.6.4** states that vaginal lavages would be performed daily beginning on the day vaginal perforation was observed. The slide containing the vaginal lavage sample from female no. 22808-06 (60 mg/kg/day [ ] group; vaginal perforation noted on PND 30) on PND 33 could not located; therefore, no sample was available for that female on PND 33.
- **Protocol Section 9.1** states that tissues would be collected at study termination. Tissues were also collected from female no. 22803-03 (250 mg/kg/day [ ] group) that was found dead prior to study termination.
- **Protocol Section 9.2.2** states that thyroid gland weights (paired) would be recorded. At the time of trimming the fixed organs for weight collection, it was noted that the right and left thyroid gland from female nos. 22802-09 (250 mg/kg/day [ ] group) and 22801-05 (250 mg/kg/day [ ] group), respectively, were missing. Therefore, single organ weights for the thyroid glands were recorded for these females. The single organ weights are presented on the absolute weight tables, but are not included in calculations of the means.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

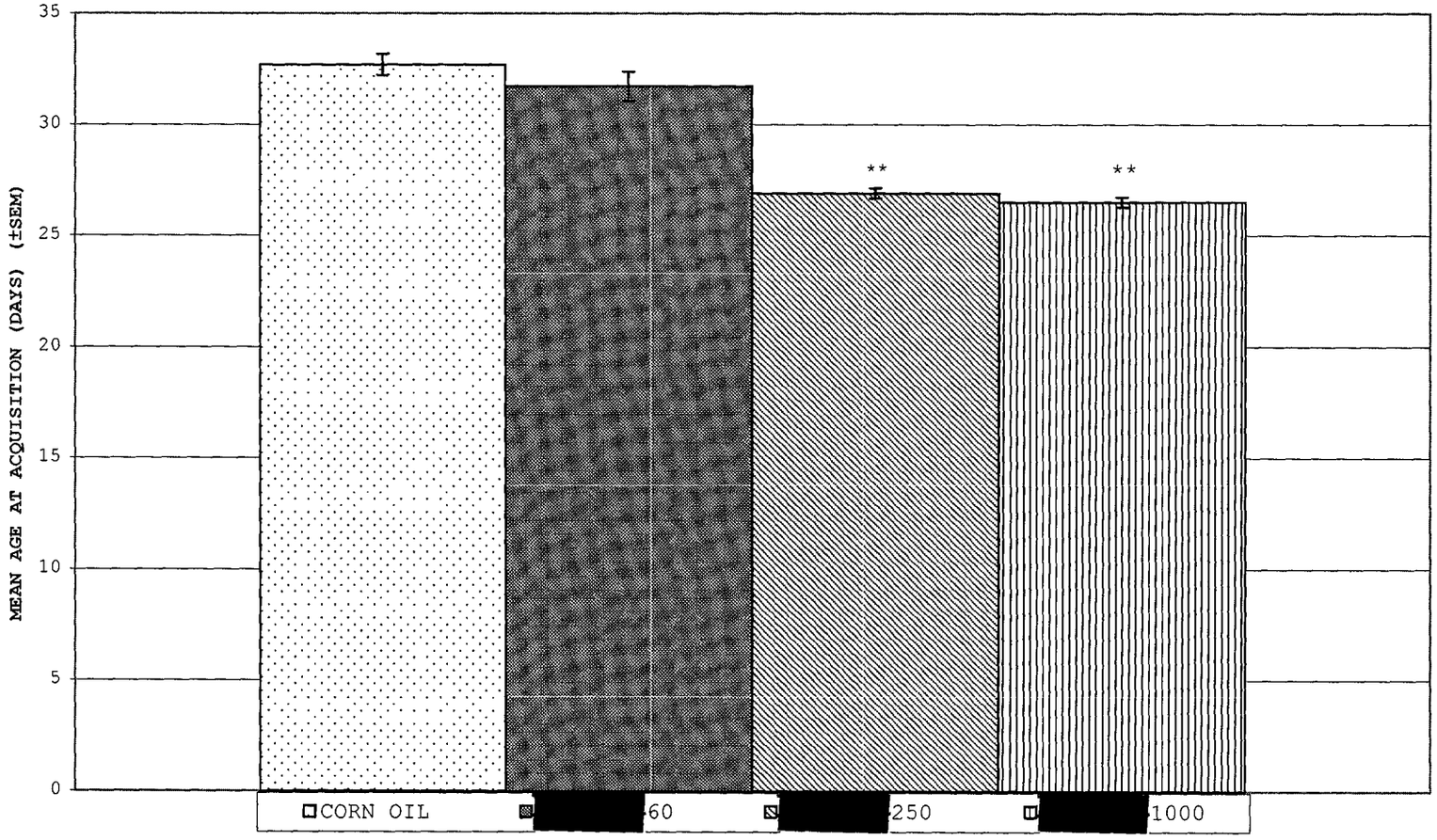
FIGURES 1-16

Revised Draft

Revised Draft

PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

PUBERTAL ASSAY OF [redacted] GURE [redacted] & [redacted] NISTERED ORALLY IN RATS
MEAN AGE (D [redacted] AC [redacted] ON OF VAGINAL PATENCY

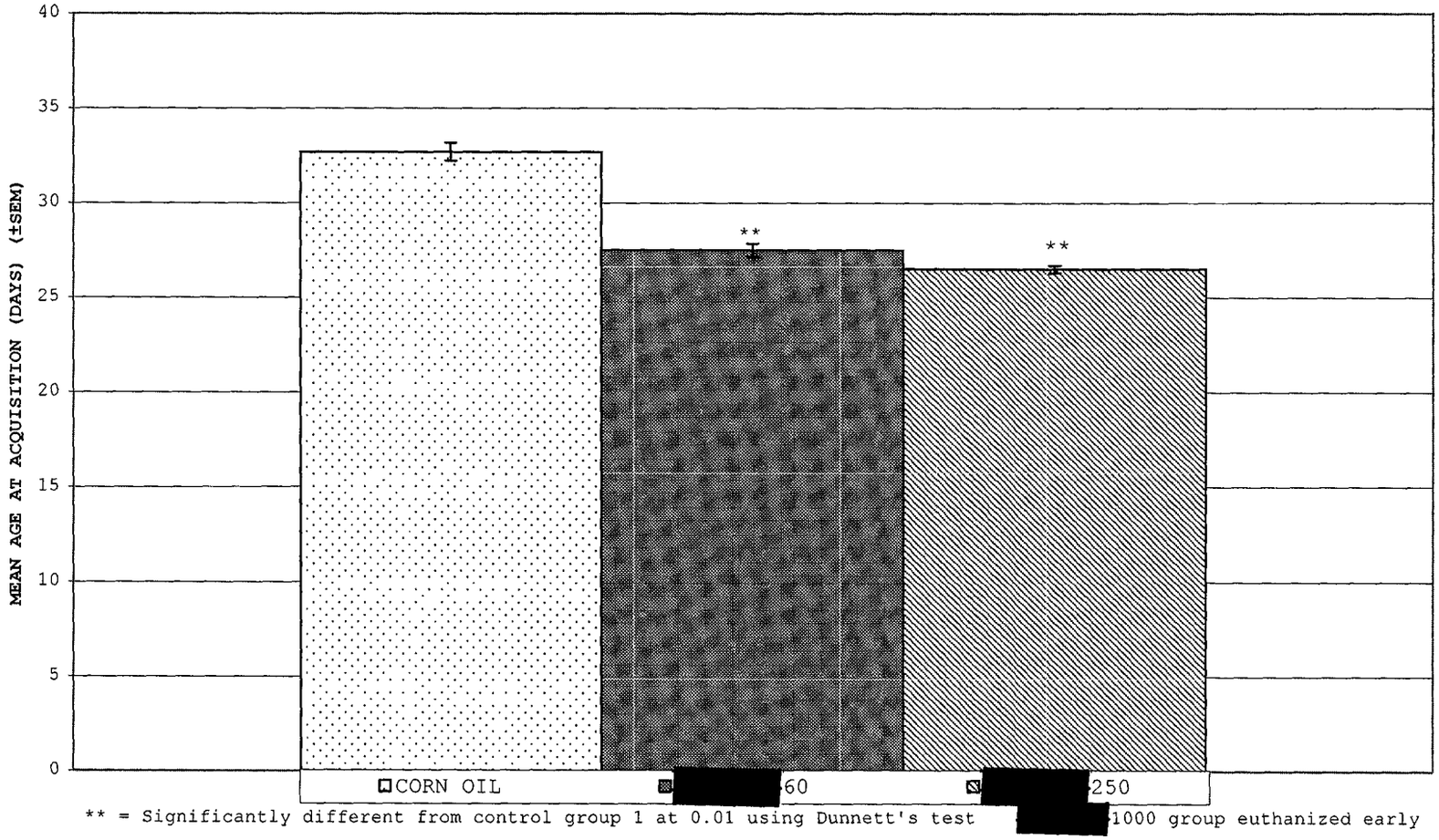


** = Significantly different from control group 1 at 0.01 using Dunnett's test

Revised Draft

PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

PUBERTAL ASSAY OF [redacted] GURE [redacted]
[redacted] & [redacted] NISTERED ORALLY IN RATS
MEAN AGE (D [redacted] AC [redacted] ON OF VAGINAL PATENCY

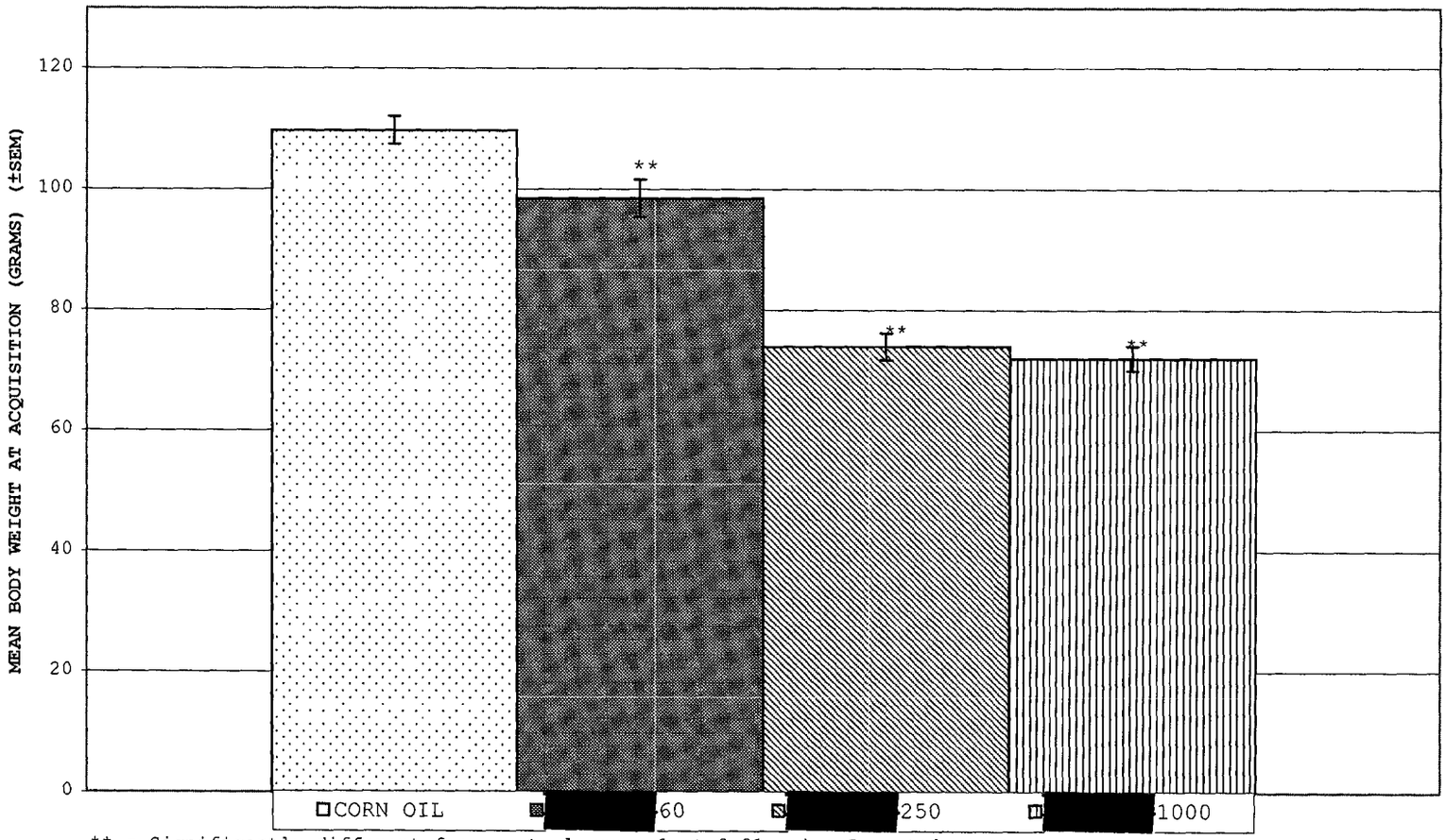


** = Significantly different from control group 1 at 0.01 using Dunnett's test [redacted]1000 group euthanized early

Revised Draft

PROJECT [redacted]-187056
SPONSOR [redacted]
SPONSOR [redacted]011

FIGURE 3 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN BODY WEIGHT [redacted]S) A[redacted]ISITION OF VAGINAL PATENCY

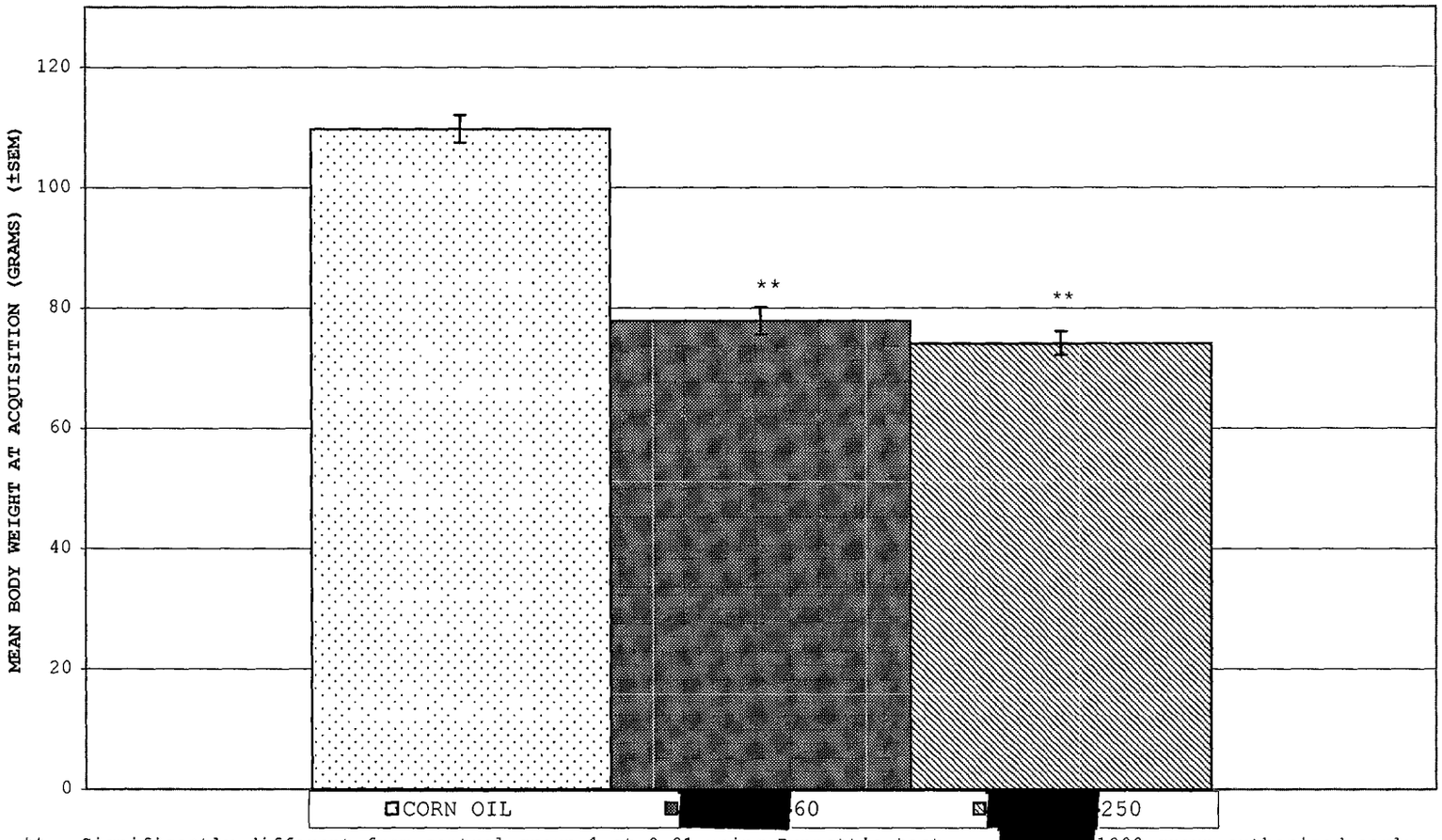


** = Significantly different from control group 1 at 0.01 using Dunnett's test

Revised Draft

PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

PUBERTAL ASSAY OF [redacted] GURE [redacted]
MEAN BODY WEIGHT [redacted]S) A [redacted]ISITION OF VAGINAL PATENCY



** - Significantly different from control group 1 at 0.01 using Dunnett's test

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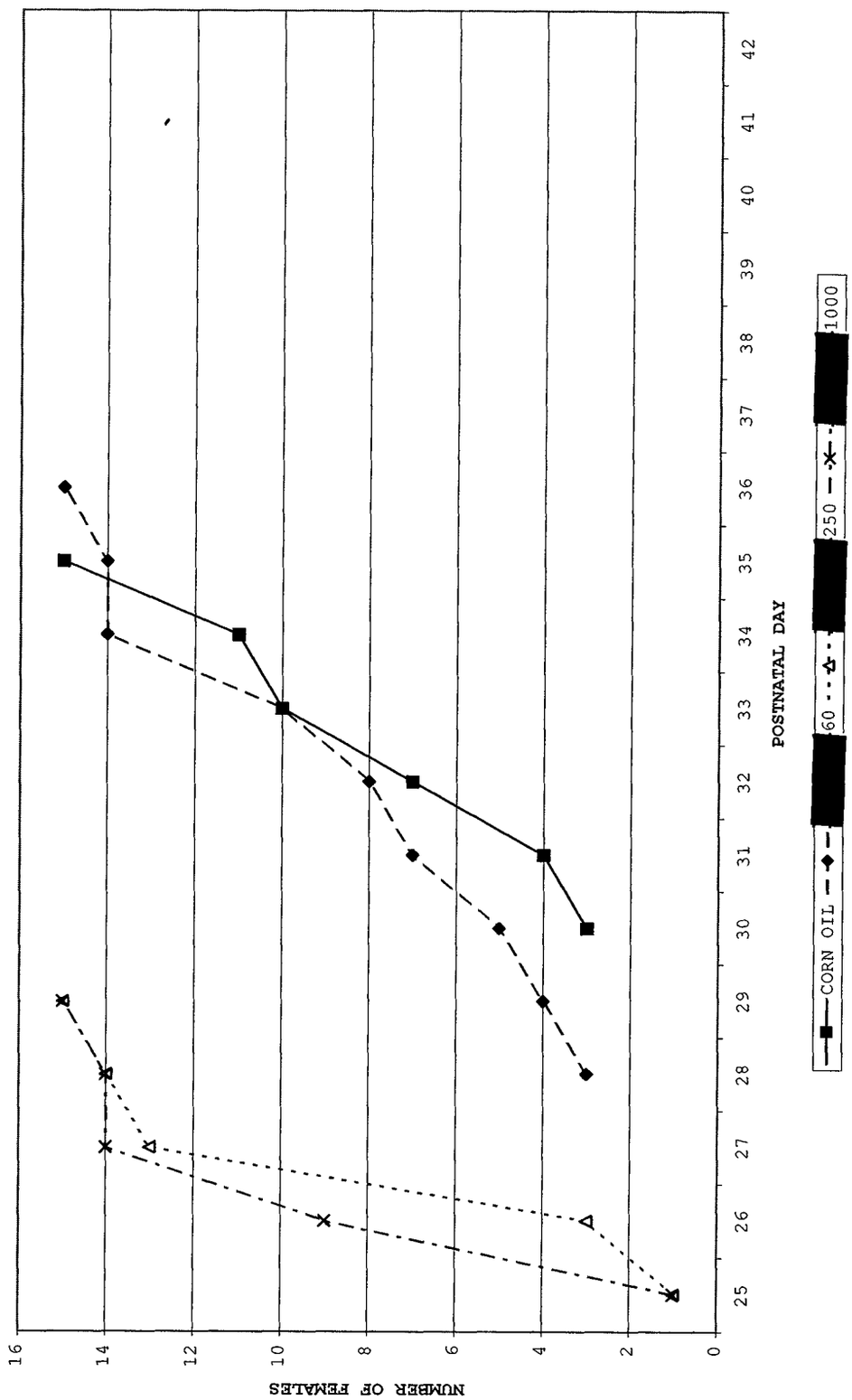
PROJECT -187056
SPONSOR: 011
SPONSOR

FIGURE 5 & PUBERTAL ASSAY OF CUMULATIVE OF ADMINISTERED ORALLY IN RATS WITH VAGINAL PATENCY



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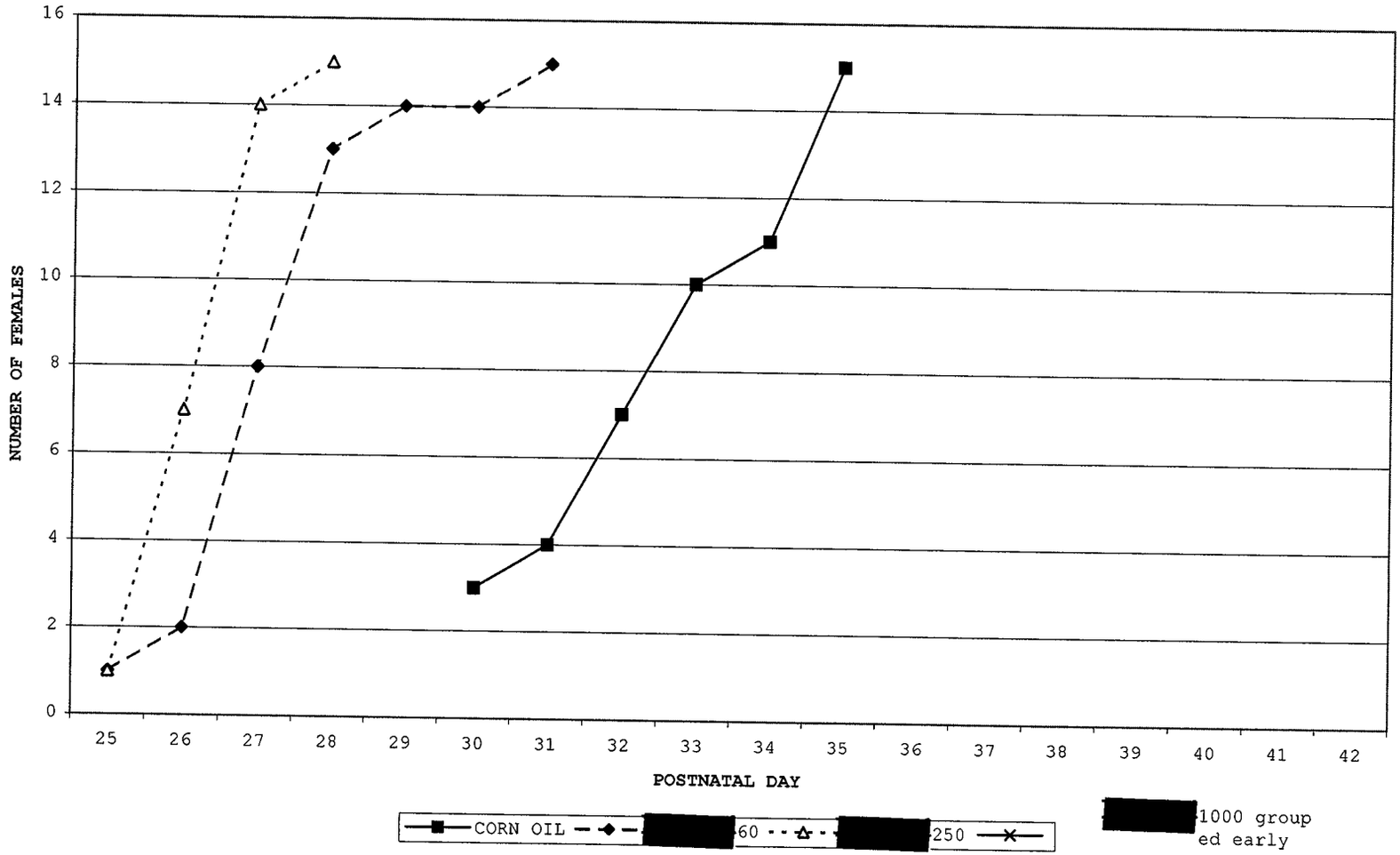
PROJECT -187056
SPONSOR:
SPONSOR 011

FIGURE 6 (
PUBERTAL ASSAY OF & ADMINISTERED ORALLY IN RATS
CUMULATIVE N OF F WITH VAGINAL PATENCY



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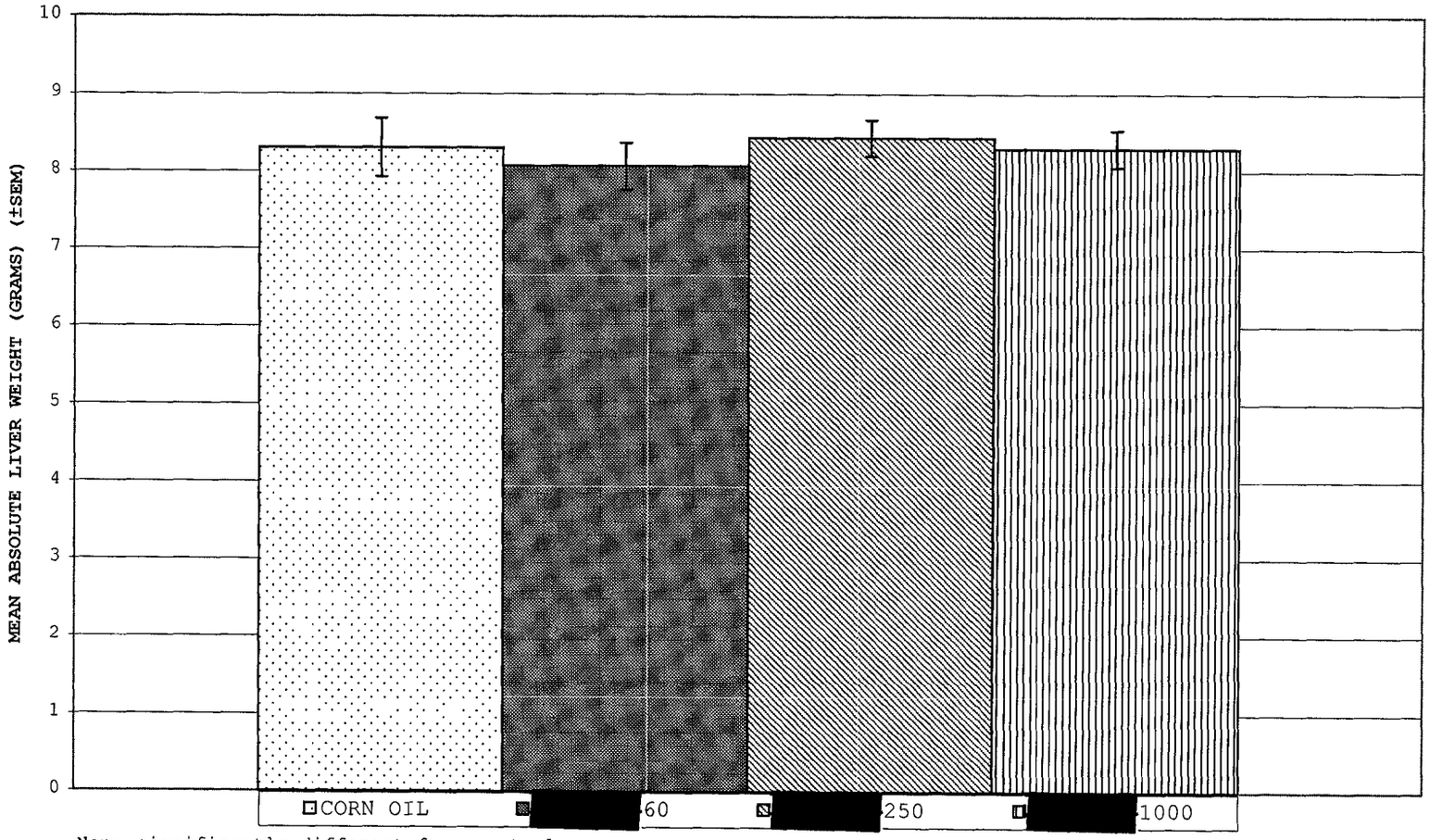
PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

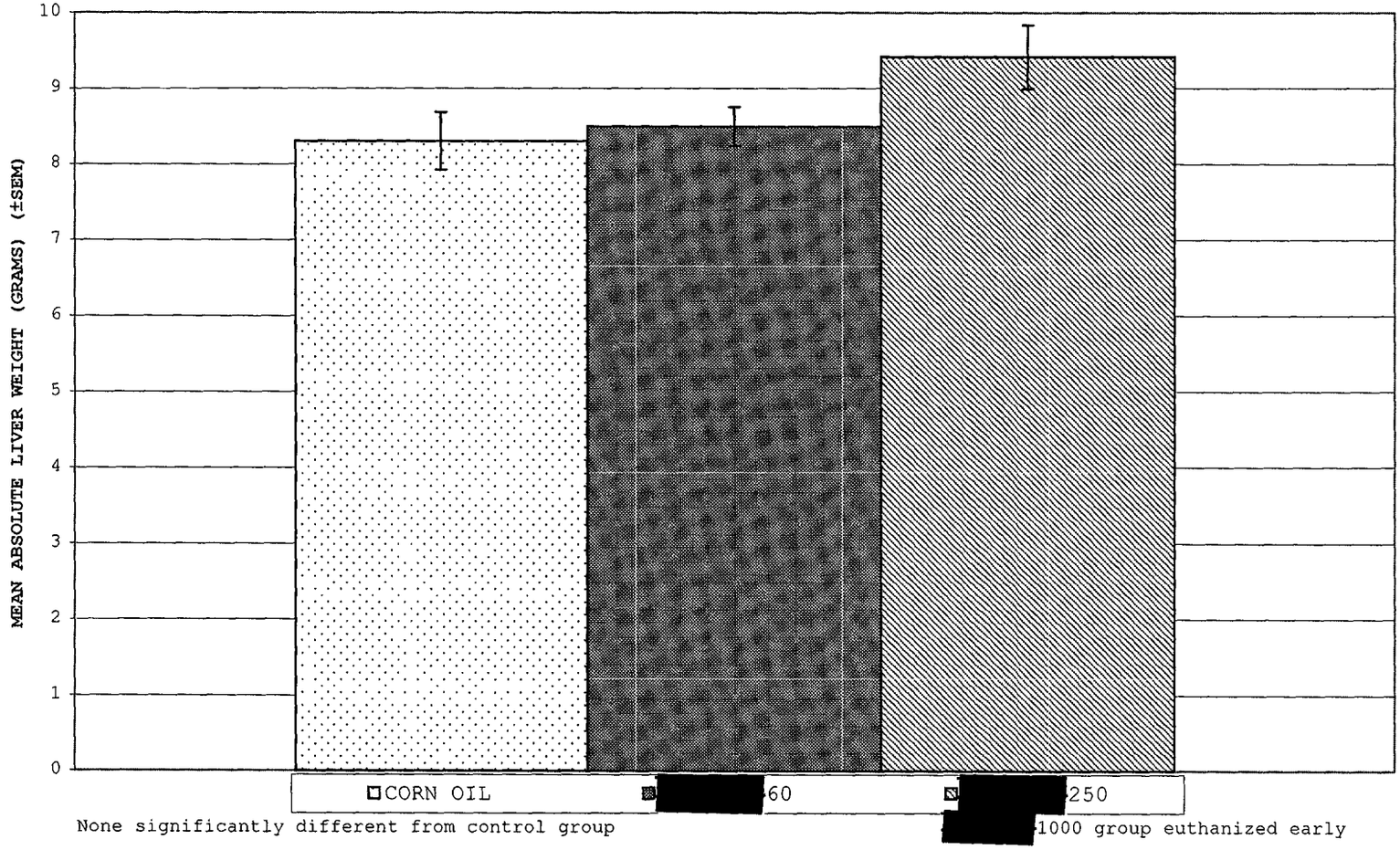
FIGURE 7 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN [redacted]UTE [redacted]WEIGHT (GRAMS)



None significantly different from control group

PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

FIGURE 8 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN [redacted]UTE [redacted]WEIGHT (GRAMS)



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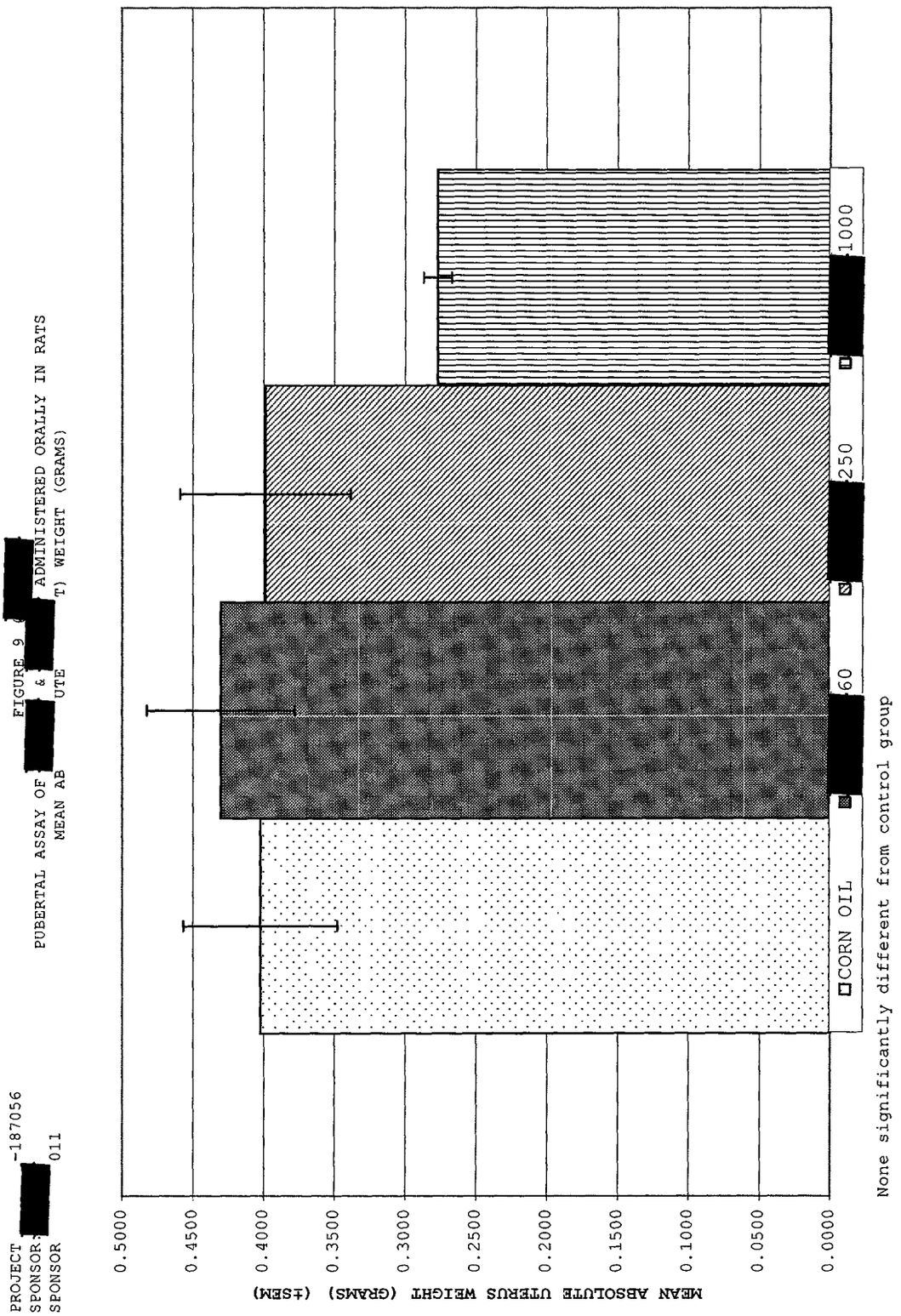

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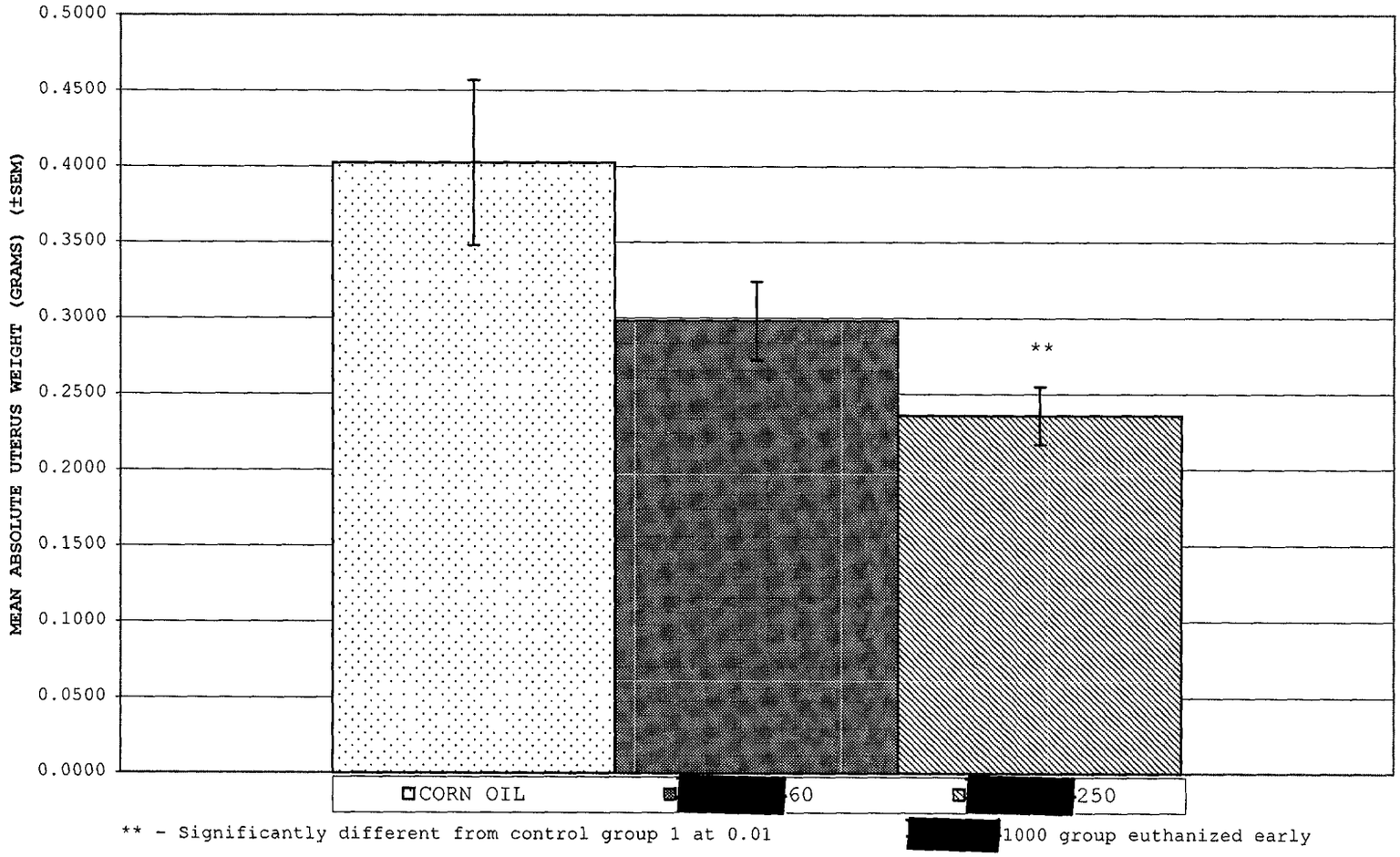
PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

FIGURE 10 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN AB[redacted]UTE [redacted]T) WEIGHT (GRAMS)



** - Significantly different from control group 1 at 0.01

[redacted]1000 group euthanized early

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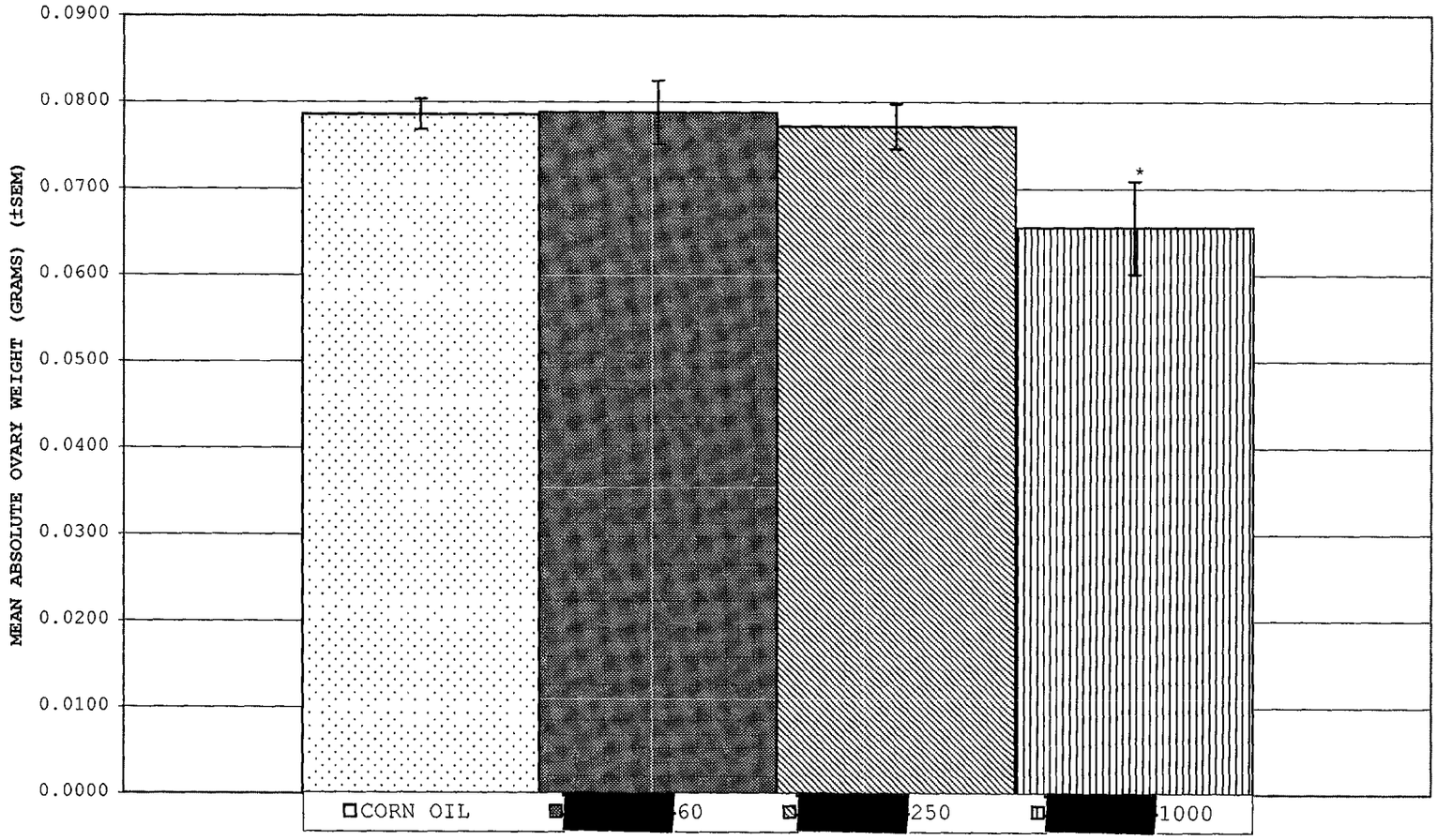
PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

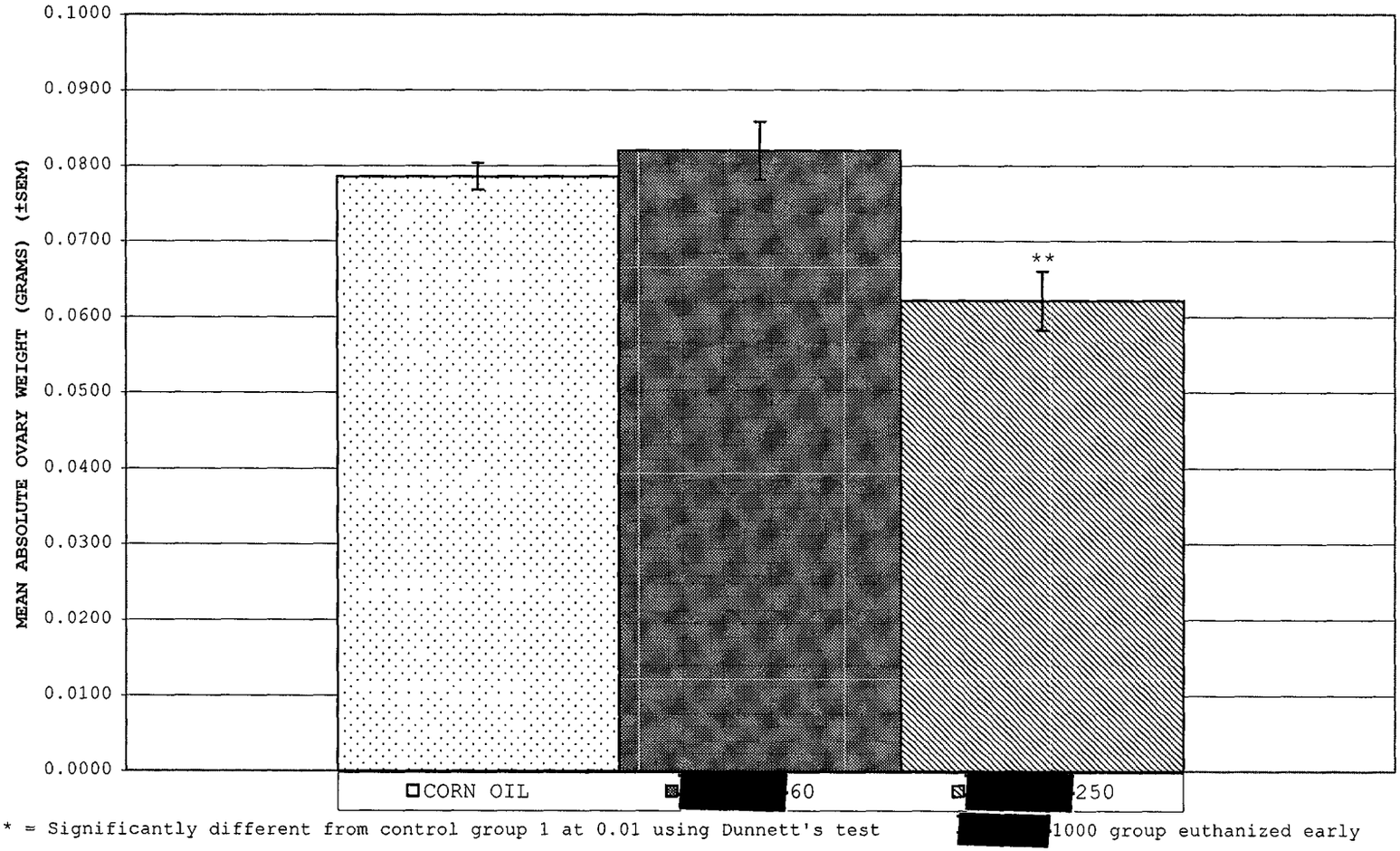
FIGURE 11 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN [redacted]TE [redacted]EIGHT (GRAMS)



* = Significantly different from control group 1 at 0.05 using Dunnett's test

PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

FIGURE 12 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN [redacted]UTE [redacted]WEIGHT (GRAMS)



** = Significantly different from control group 1 at 0.01 using Dunnett's test

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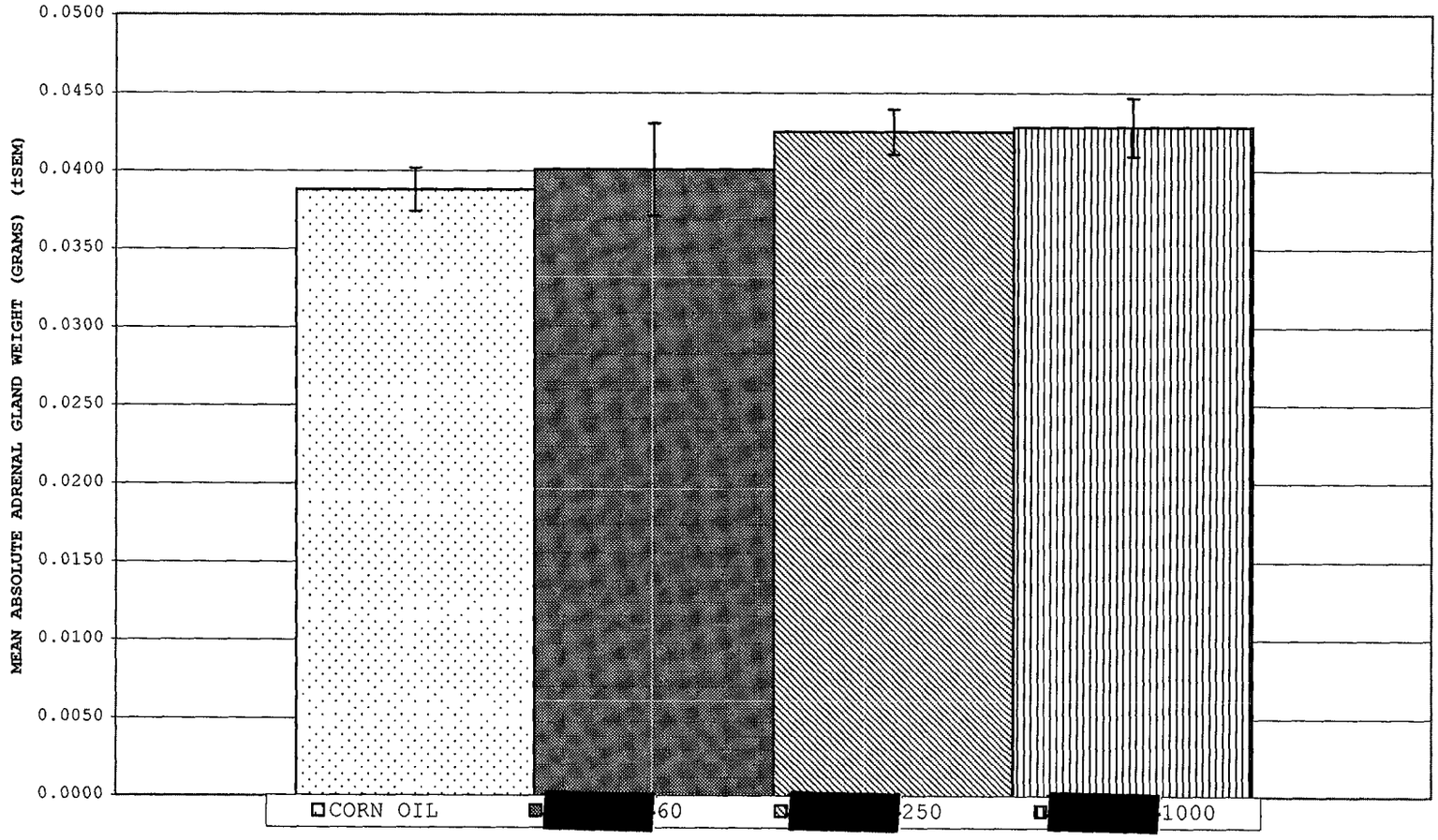
PROJECT NO.:WIL-187056
SPONSOR: [redacted]
SPONSOR [redacted] 011

FIGURE 13 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABS [redacted] ADRE [redacted] AND WEIGHT (GRAMS)



None significantly different from the control group

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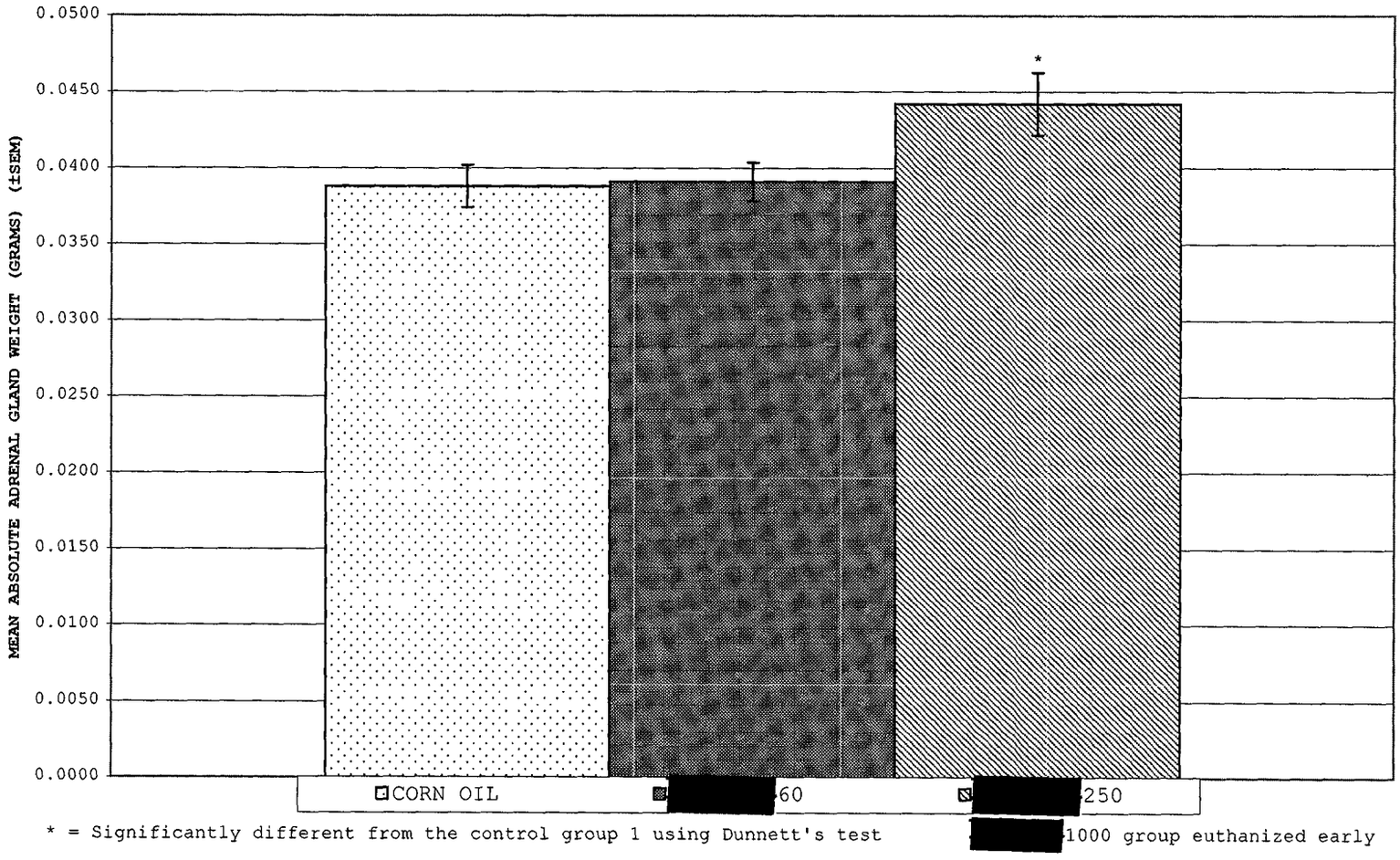
PROJECT [redacted]-187056
SPONSOR: [redacted] PUBERTAL ASSAY OF [redacted] URE [redacted]
SPONSOR [redacted]011 MEAN [redacted]TE A [redacted] ISTERED ORALLY IN RATS
WEIGHT (GRAMS)



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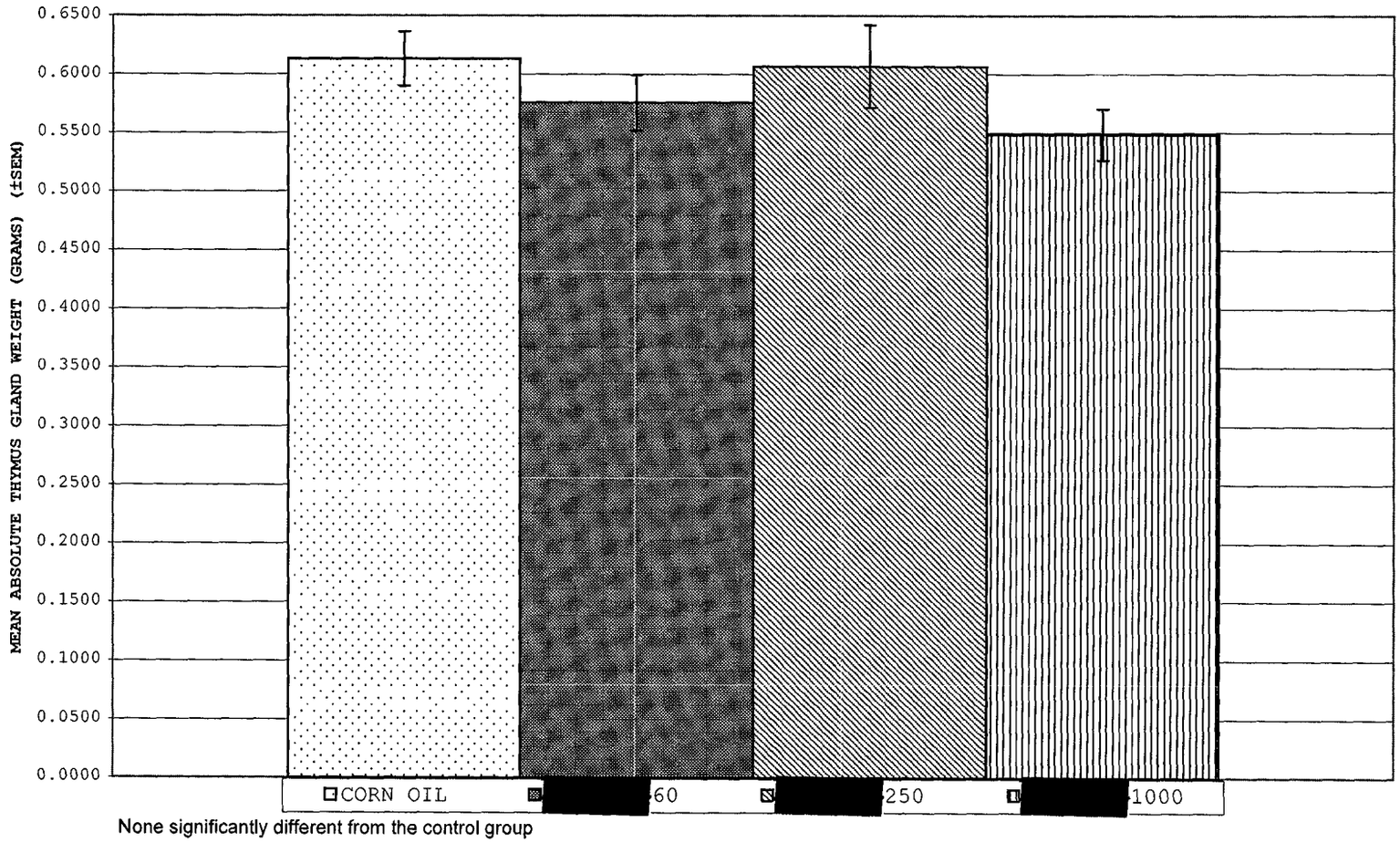
PROJECT [redacted]-187056
SPONSOR [redacted]
SPONSOR [redacted]011

FIGURE 15 ([redacted])
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN AB[redacted]THY[redacted]ND WEIGHT (GRAMS)



None significantly different from the control group

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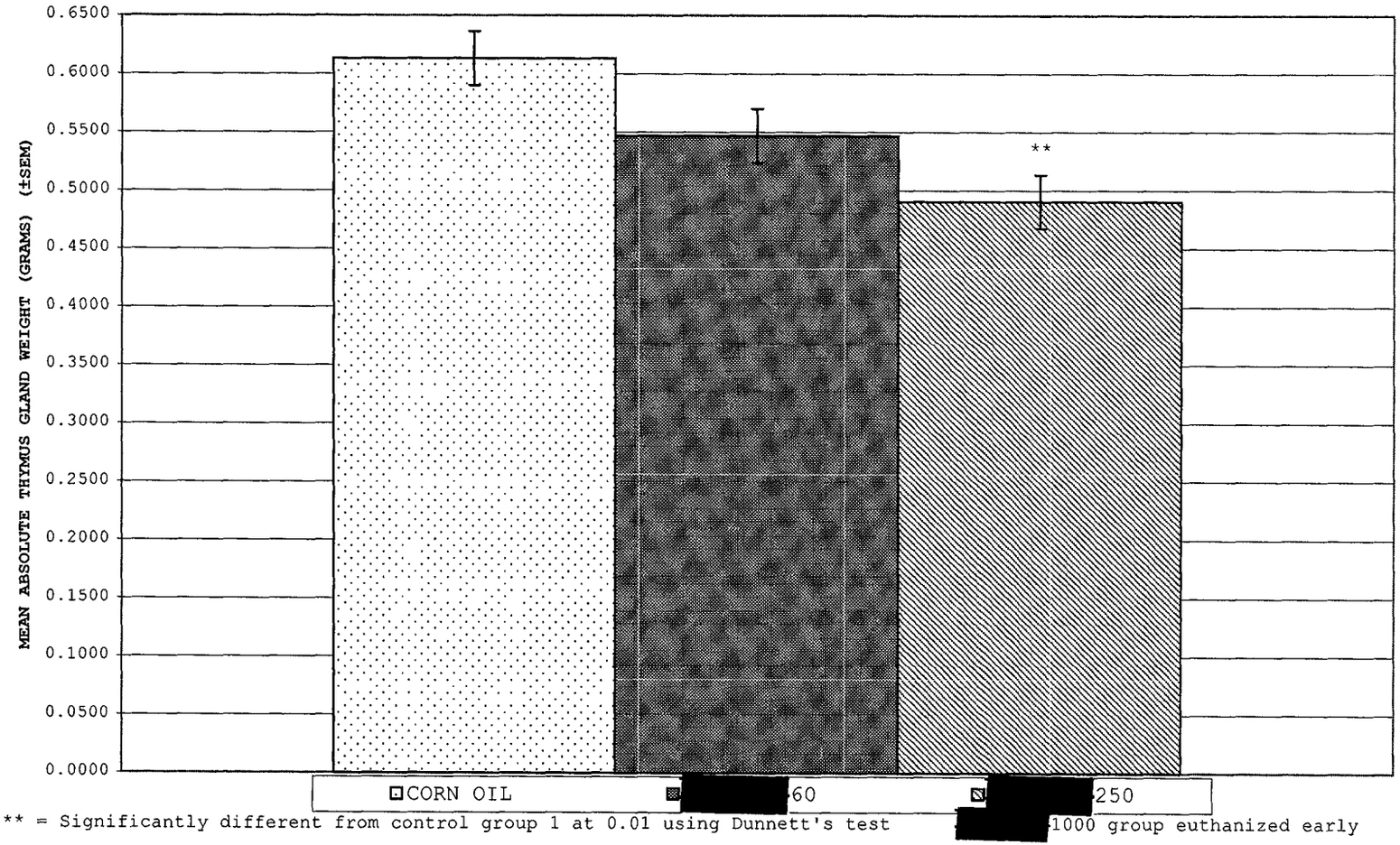
PROJECT [redacted]-187056
SPONSOR: [redacted]
SPONSOR [redacted]011

FIGURE 16 [redacted]
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
MEAN ABS THYM [redacted]ND WEIGHTS (GRAMS)



** = Significantly different from control group 1 at 0.01 using Dunnett's test

TABLES 1-25

Revised Draft

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TABLE 1

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	1				2				3				4			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
30	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
31	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
32	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
33	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
34	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
35	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
36	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
37	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
38	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
39	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
40	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
41	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000

Revised Draft

TABLE 1

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF SURVIVAL AND DISPOSITION

FEMALES

GROUP :	5				6				7			
DAY	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	16	0	0	0
23	15	0	0	0	15	0	0	0	12	0	4	0
24	15	0	0	0	15	0	0	0	6	1	5	0
25	15	0	0	0	15	0	0	0	0	2	4	0
26	15	0	0	0	15	0	0	0	0	0	0	0
27	15	0	0	0	15	0	0	0	0	0	0	0
28	15	0	0	0	15	0	0	0	0	0	0	0
29	15	0	0	0	15	0	0	0	0	0	0	0
30	15	0	0	0	15	0	0	0	0	0	0	0
31	15	0	0	0	15	0	0	0	0	0	0	0
32	15	0	0	0	15	0	0	0	0	0	0	0
33	15	0	0	0	15	0	0	0	0	0	0	0
34	15	0	0	0	15	0	0	0	0	0	0	0
35	15	0	0	0	14	1	0	0	0	0	0	0
36	15	0	0	0	14	0	0	0	0	0	0	0
37	15	0	0	0	14	0	0	0	0	0	0	0
38	15	0	0	0	14	0	0	0	0	0	0	0
39	15	0	0	0	14	0	0	0	0	0	0	0
40	15	0	0	0	14	0	0	0	0	0	0	0
41	15	0	0	0	14	0	0	0	0	0	0	0
42	0	0	0	15	0	0	0	14	0	0	0	0

DAY = DAY OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

5- [redacted]60 6- [redacted]250 7- [redacted]1000

PSURVv4.08
05/25/2006
R:05/31/2006

Revised Draft

Modified: 6/30/2006

PROJECT NO.:WIL-187056
SPONSOR: [redacted]
SPONSOR NO.:06-011

TABLE 2 (DAILY EXAMINATIONS)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	03-28-06 TO 04-19-06						
GROUP:	1	2	3	4	5	6	7
NORMAL							
-NO SIGNIFICANT CLINICAL OBSERVATIONS	315/15	315/15	315/15	315/15	312/15	307/15	21/16
DISPOSITION							
-FOUND DEAD	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1	3/ 3
-SCHEDULED EUTHANASIA	15/15	15/15	15/15	15/15	15/15	14/14	0/ 0
-EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	13/13
BEHAVIOR/CNS							
-PROSTRATE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0
BODY/INTEGUMENT							
-WET YELLOW MATERIAL VENTRAL ABDOMINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	6/ 6
-UNKEMPT APPEARANCE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	9/ 9
-WET YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	6/ 6
-DRIED YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	19/13
EYES/EARS/NOSE							
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	0/ 0	3/ 2	0/ 0	13/12

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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TABLE 2 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	03-28-06 TO 04-19-06						
GROUP:	1	2	3	4	5	6	7
EYES/EARS/NOSE							
-DRIED RED MATERIAL AROUND LEFT EYE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0
EXCRETA							
-SOFT STOOL	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
ORAL/DENTAL							
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
05/31/2006
R:06/07/2006

Revised Draft

PROJECT NO.:WIL-187056
SPONSOR: [redacted]
SPONSOR NO.:06-011

TABLE 3 (AT TIME OF DOSING)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE: 03-28-06 TO 04-18-06

GROUP:	1	2	3	4	5	6	7
ORAL/DENTAL -SALIVATION	0/ 0	0/ 0	0/ 0	4/ 2	0/ 0	10/ 5	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

PCSUv4.07
05/25/2006
R:05/30/2006

Revised Draft

Modified: 6/30/2006

PROJECT NO.:WIL-187056
SPONSOR:[redacted]
SPONSOR NO.:06-011

TABLE 4 (1 HOUR POST-DOSING)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE: 03-28-06 TO 04-18-06

GROUP:	1	2	3	4	5	6	7
BEHAVIOR/CNS							
-LETHARGIC	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
EYES/EARS/NOSE							
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-WET CLEAR MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0
ORAL/DENTAL							
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	9/ 6	1/ 1	66/14	2/ 2
-DRIED RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	3/ 3	0/ 0
-SALIVATION	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	15/ 8	0/ 0
-DRIED CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2	0/ 0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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05/25/2006
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TABLE 5

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22							
MEAN	51.2	50.9	50.1	51.1	51.3	51.4	50.7
% CHANGE		-0.6	-2.1	-0.2	0.2	0.4	-1.0
S.D.	5.16	5.40	5.58	5.26	4.34	6.33	5.04
N	15	15	15	15	15	15	16
PND 23							
MEAN	55.5	54.9	54.3	55.1	55.3	55.7	51.1
% CHANGE		-1.1	-2.2	-0.7	-0.4	0.4	-7.9
S.D.	5.54	5.49	5.64	5.84	4.64	6.52	5.94
N	15	15	15	15	15	15	16
PND 24							
MEAN	60.8	59.9	59.7	60.1	60.2	60.8	49.8d
% CHANGE		-1.5	-1.8	-1.2	-1.0	0.0	-18.1
S.D.	5.56	5.87	5.73	5.78	4.72	6.55	5.30
N	15	15	15	15	15	15	11
PND 25							
MEAN	65.9	64.7	64.0	64.8	65.4	65.9	52.1d
% CHANGE		-1.8	-2.9	-1.7	-0.8	0.0	-20.9
S.D.	6.14	6.16	5.89	5.69	4.94	7.12	7.01
N	15	15	15	15	15	15	4
PND 26							
MEAN	71.4	69.6	68.5	69.6	70.7	71.2	NA
% CHANGE		-2.5	-4.1	-2.5	-1.0	-0.3	
S.D.	6.48	6.28	5.86	5.99	5.56	7.52	
N	15	15	15	15	15	15	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

Revised Draft

Modified: 6/30/2006

TABLE 5

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF BODY WEIGHTS [G]

		FEMALES						
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000	
PND 27								
MEAN	76.9	74.2	74.4	74.1	75.3	76.1		NA
% CHANGE		-3.5	-3.3	-3.6	-2.1	-1.0		
S.D.	6.84	6.45	5.80	6.16	6.12	7.60		
N	15	15	15	15	15	15		
PND 28								
MEAN	82.5	79.2	79.5	78.6	80.3	82.1		NA
% CHANGE		-4.0	-3.6	-4.7	-2.7	-0.5		
S.D.	7.91	6.76	6.05	6.89	5.41	8.85		
N	15	15	15	15	15	15		
PND 29								
MEAN	88.2	84.8	84.6	83.5	85.4	86.6		NA
% CHANGE		-3.9	-4.1	-5.3	-3.2	-1.8		
S.D.	8.44	8.11	6.73	7.39	6.50	9.19		
N	15	15	15	15	15	15		
PND 30								
MEAN	94.0	90.8	91.3	90.2	92.1	93.6		NA
% CHANGE		-3.4	-2.9	-4.0	-2.0	-0.4		
S.D.	8.92	8.70	6.87	8.32	6.83	9.08		
N	15	15	15	15	15	15		
PND 31								
MEAN	99.8	95.8	97.1	94.7	97.8	99.2		NA
% CHANGE		-4.0	-2.7	-5.1	-2.0	-0.6		
S.D.	9.69	8.49	7.10	8.19	7.23	9.77		
N	15	15	15	15	15	15		

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
NA = NOT APPLICABLE

Revised Draft

Modified: 6/30/2006

TABLE 5

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-011

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 32								
	MEAN	106.0	100.7	101.9	101.1	103.9	104.5	NA
	% CHANGE		-5.0	-3.9	-4.6	-2.0	-1.4	
	S.D.	10.10	8.15	7.12	8.75	7.74	10.51	
	N	15	15	15	15	15	15	
PND 33								
	MEAN	112.4	107.1	107.4	106.4	110.0	110.7	NA
	% CHANGE		-4.7	-4.4	-5.3	-2.1	-1.5	
	S.D.	10.54	8.75	6.91	10.12	8.67	11.08	
	N	15	15	15	15	15	15	
PND 34								
	MEAN	119.4	112.4	113.4	111.3	115.6	114.9	NA
	% CHANGE		-5.9	-5.0	-6.8	-3.2	-3.8	
	S.D.	11.15	9.21	6.75	10.77	8.60	11.81	
	N	15	15	15	15	15	15	
PND 35								
	MEAN	123.8	116.9	120.7	115.7	120.2	120.7	NA
	% CHANGE		-5.6	-2.5	-6.5	-2.9	-2.5	
	S.D.	10.17	9.55	7.77	10.21	8.81	12.22	
	N	15	15	15	15	15	15	
PND 36								
	MEAN	129.2	122.9	124.5	120.1	127.1	125.5	NA
	% CHANGE		-4.9	-3.6	-7.0	-1.6	-2.9	
	S.D.	11.62	10.89	8.68	10.18	8.75	13.92	
	N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
None significantly different from control group
NA = NOT APPLICABLE

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TABLE 5

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-011

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 37								
	MEAN	135.6	128.8	129.9	125.9	131.8	130.2	NA
	% CHANGE		-5.0	-4.2	-7.2	-2.8	-4.0	
	S.D.	11.51	9.97	8.49	10.42	10.15	14.09	
	N	15	15	15	15	15	14	
PND 38								
	MEAN	139.2	133.6	135.4	130.4	137.6	135.6	NA
	% CHANGE		-4.0	-2.7	-6.3	-1.1	-2.6	
	S.D.	13.18	10.11	9.62	10.93	11.12	15.23	
	N	15	15	15	15	15	14	
PND 39								
	MEAN	144.5	137.1	140.3	134.8	140.9	141.0	NA
	% CHANGE		-5.1	-2.9	-6.7	-2.5	-2.4	
	S.D.	12.89	12.08	7.32	9.87	11.22	15.50	
	N	15	15	15	15	15	14	
PND 40								
	MEAN	148.6	140.4	144.9	137.6a	145.2	142.8	NA
	% CHANGE		-5.5	-2.5	-7.4	-2.3	-3.9	
	S.D.	13.47	11.13	8.62	10.88	11.21	15.28	
	N	15	15	15	15	15	14	
PND 41								
	MEAN	152.6	144.1	148.0	141.3	149.5	146.8	NA
	% CHANGE		-5.6	-3.0	-7.4	-2.0	-3.8	
	S.D.	15.29	11.81	8.74	8.99	12.92	15.34	
	N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
NA = NOT APPLICABLE

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TABLE 5

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF BODY WEIGHTS [G]

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 42							
MEAN	157.2	147.5	153.6	144.4a	153.7	150.9	NA
% CHANGE		-6.2	-2.3	-8.1	-2.2	-4.0	
S.D.	15.91	11.42	7.68	9.59	12.46	17.72	
N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
NA = NOT APPLICABLE

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06/07/2006

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TABLE 6

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-011 SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
	GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 22- 23								
	MEAN	4.3	3.9	4.2	4.0	4.0	4.3	0.4d
	S.D.	0.62	0.96	0.85	0.95	0.71	0.77	2.71
	N	15	15	15	15	15	15	16
PND 23- 24								
	MEAN	5.2	5.1	5.4	5.0	4.9	5.1	-2.4d
	S.D.	1.08	1.31	0.79	0.92	0.91	0.62	2.54
	N	15	15	15	15	15	15	11
PND 24- 25								
	MEAN	5.1	4.8	4.3	4.8	5.2	5.1	-0.3d
	S.D.	1.04	0.68	0.84	0.72	1.20	1.02	4.49
	N	15	15	15	15	15	15	4
PND 25- 26								
	MEAN	5.5	4.8	4.5	4.7	5.2	5.2	NA
	S.D.	1.05	1.18	0.92	1.02	0.98	1.48	
	N	15	15	15	15	15	15	
PND 26- 27								
	MEAN	5.5	4.6a	5.8	4.5a	4.6	5.0	NA
	S.D.	1.15	0.85	0.69	0.97	1.49	1.04	
	N	15	15	15	15	15	15	
PND 27- 28								
	MEAN	5.6	5.0	5.2	4.5	5.0	6.0	NA
	S.D.	1.76	1.70	1.19	2.10	1.21	1.92	
	N	15	15	15	15	15	15	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES
NA = NOT APPLICABLE

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TABLE 6

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 28- 29	MEAN	5.7	5.6	5.1	4.9	5.0	4.5	NA
	S.D.	1.65	2.38	1.83	1.93	2.36	1.36	
	N	15	15	15	15	15	15	
PND 29- 30	MEAN	5.8	6.0	6.7	6.7	6.7	7.1	NA
	S.D.	1.34	2.28	1.98	1.58	1.96	0.87	
	N	15	15	15	15	15	15	
PND 30- 31	MEAN	5.9	5.0	5.8	4.5	5.7	5.6	NA
	S.D.	2.00	2.34	1.97	5.01	2.33	1.40	
	N	15	15	15	15	15	15	
PND 31- 32	MEAN	6.1	4.9	4.8	6.3	6.2	5.3	NA
	S.D.	2.04	2.10	2.12	4.28	1.11	1.62	
	N	15	15	15	15	15	15	
PND 32- 33	MEAN	6.5	6.4	5.5	5.3	6.1	6.3	NA
	S.D.	1.84	2.34	1.56	3.58	2.53	1.40	
	N	15	15	15	15	15	15	
PND 33- 34	MEAN	7.0	5.2	6.1	5.0	5.6	4.2d	NA
	S.D.	1.89	2.22	2.36	2.27	2.73	2.06	
	N	15	15	15	15	15	15	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
d = Significantly different from control group 1 at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES
NA = NOT APPLICABLE

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TABLE 6

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 34- 35								
	MEAN	4.4	4.6	7.3a	4.3	4.6	5.8	NA
	S.D.	3.65	2.41	2.88	3.59	2.42	2.84	
	N	15	15	15	15	15	15	
PND 35- 36								
	MEAN	5.4	6.0	3.8	4.5	6.9	4.8	NA
	S.D.	3.46	3.53	3.83	2.17	2.41	2.85	
	N	15	15	15	15	15	14	
PND 36- 37								
	MEAN	6.4	5.9	5.4	5.8	4.8	4.7	NA
	S.D.	2.92	3.05	2.67	2.04	2.26	2.50	
	N	15	15	15	15	15	14	
PND 37- 38								
	MEAN	3.6	4.7	5.5	4.5	5.7	5.4	NA
	S.D.	5.08	4.53	4.75	2.37	3.98	3.02	
	N	15	15	15	15	15	14	
PND 38- 39								
	MEAN	5.3	3.6	4.9	4.4	3.4	5.3	NA
	S.D.	5.50	4.23	4.57	3.45	3.28	2.99	
	N	15	15	15	15	15	14	
PND 39- 40								
	MEAN	4.0	3.2	4.6	2.8	4.3	1.8	NA
	S.D.	6.54	3.44	3.50	2.42	4.06	3.62	
	N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES
NA = NOT APPLICABLE

Revised Draft

Modified: 6/30/2006

TABLE 6

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES						
GROUP:		CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PND 40- 41								
	MEAN	4.1	3.7	3.1	3.7	4.3	4.0	NA
	S.D.	4.12	3.85	4.90	3.42	3.69	4.06	
	N	15	15	15	15	15	14	
PND 41- 42								
	MEAN	4.6	3.4	5.7	3.1	4.2	4.1	NA
	S.D.	3.54	3.88	4.33	3.27	4.40	5.08	
	N	15	15	15	15	15	14	
PND 22- 42								
	MEAN	106.0	96.6a	103.5	93.3b	102.4	99.6	NA
	S.D.	13.60	10.13	8.44	8.25	9.03	13.38	
	N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
b = Significantly different from control group 1 at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES
NA = NOT APPLICABLE

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06/07/2006

Revised Draft

TABLE 7

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 60	[redacted] 250	[redacted] 1000
			FEMALES				
VAGINAL PATENCY (PND)							
MEAN	32.7	31.7	26.9b	26.5b	27.5d	26.5d	NA
S.D.	1.88	2.61	0.88	0.92	1.36	0.74	
N	15	15	15	15	15	15	
BODY WEIGHT (GRAMS)							
MEAN	109.7	98.5b	73.9b	71.9b	77.8d	74.1d	NA
S.D.	8.86	12.11	8.71	7.97	8.72	7.78	
N	15	15	15	15	15	15	

PND= POSTNATAL DAY
MODIFIED STATISTIC USED.
For statistical analysis, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5 and 6.
b = Significantly different from control group 1 at 0.01 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test

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PROJECT NO.:WIL-187056
SPONSOR: [redacted]
SPONSOR NO.:06-011

TABLE 8
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SUMMARY OF ESTROUS CYCLE DATA

GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 60	[redacted] 250	[redacted] 1000
			FEMALES				
ESTROUS CYCLE LENGTH (DAYS)							
MEAN	4.9	5.2	5.7	4.6	5.1	5.9	NA
S.D.	0.68	0.50	1.09	1.47	0.62	1.97	
N	12	12	15	10	14	13	
MEAN AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)							
MEAN	34.5	32.6	28.8b	26.7b	29.8d	27.7d	NA
S.D.	2.95	2.44	2.46	1.05	2.68	2.94	
N	15	15	15	15	15	15	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
b = Significantly different from control group 1 at 0.01 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

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05/25/2006
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TABLE 9

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF SERUM HORMONE VALUES

ANALYSIS	GROUP:	CORN OIL	[redacted] 60	[redacted] 250	[redacted] 1000	[redacted] 60	[redacted] 250	[redacted] 1000
		FEMALES						
TSH (ng/mL)								
DAY 42	MEAN	9.4	9.4	9.3	8.6	8.2	10.7	NA
	% CHANGE		0.0	-1.1	-8.5	-12.8	13.8	
	S.D.	2.03	2.53	2.49	1.81	2.03	3.23	
	N	15	15	15	15	15	14	
TOTAL T4 (ug/dL)								
DAY 42	MEAN	5.07	5.49	5.08	4.92	4.53	3.96c	NA
	% CHANGE		8.3	0.2	-3.0	-10.7	-21.9	
	S.D.	1.220	1.264	1.263	0.896	0.695	1.084	
	N	15	15	15	15	15	14	
ESTRADIOL (pg/mL)								
DAY 42	MEAN	155.00	161.47	147.56	134.01	139.23	118.31	NA
	% CHANGE		4.2	-4.8	-13.5	-10.2	-23.7	
	S.D.	32.116	34.324	31.952	30.002	43.335	46.399	
	N	15	15	15	15	15	14	
LUTEIN' HORMONE (ng/mL)								
DAY 42	MEAN	3.3	3.7	3.7	3.3	2.6	3.3	NA
	% CHANGE		12.1	12.1	0.0	-21.2	0.0	
	S.D.	1.22	1.21	2.27	2.07	1.08	1.83	
	N	15	14	15	15	15	14	

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
c = Significantly different from control group 1 at 0.05 using Dunnett's test
NA = NOT APPLICABLE

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05/31/2006
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PROJECT NO.:WIL-187056
SPONSOR: [redacted]
SPONSOR NO.:06-011

TABLE 10 (UNSCHEDULED DEATHS)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SUMMARY OF MACROSCOPIC FINDINGS

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

GROUP:	----- FEMALE ----- 1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	16
NUMBER OF ANIMALS EXAMINED	0	0	0	0	0	1	3
SKIN							
-MATTING, YELLOW	0	0	0	0	0	0	1
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	0	0	0	0	0	1	2

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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TABLE 11 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF MACROSCOPIC FINDINGS

SCHEDULED NECROPSY

	----- FEMALE -----						
GROUP:	1	2	3	4	5	6	7
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15	15	16
NUMBER OF ANIMALS EXAMINED	15	15	15	15	15	14	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	15	15	15	15	15	14	0

1- CORN OIL 2- [redacted]60 3- [redacted]250 4- [redacted]1000 5- [redacted]60 6- [redacted]250
7- [redacted]1000

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TABLE 12

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000	
				FEMALES				
ADRENAL GLANDS (G)								
MEAN	0.0388	0.0401	0.0425	0.0428	0.0391	0.0442c		NA
% CHANGE		3.4	9.5	10.3	0.8	13.9		
S.D.	0.00535	0.01142	0.00561	0.00722	0.00490	0.00774		
N	15	15	15	15	15	14		
KIDNEYS (G)								
MEAN	1.6043	1.5892	1.5487	1.5888	1.5934	1.6015		NA
% CHANGE		-0.9	-3.5	-1.0	-0.7	-0.2		
S.D.	0.16274	0.14625	0.10376	0.13261	0.20456	0.12534		
N	15	15	15	15	15	14		
LIVER (G)								
MEAN	8.3023	8.0670	8.4341	8.2934	8.4936	9.4150		NA
% CHANGE		-2.8	1.6	-0.1	2.3	13.4		
S.D.	1.45989	1.16940	0.89315	0.91458	0.98833	1.58380		
N	15	15	15	15	15	14		
OVARIES/OVIDUCTS (G)								
MEAN	0.0786	0.0788	0.0772	0.0655a	0.0820	0.0622d		NA
% CHANGE		0.3	-1.8	-16.7	4.3	-20.9		
S.D.	0.00672	0.01424	0.00998	0.02079	0.01479	0.01447		
N	15	15	15	15	15	14		
PITUITARY (G)								
MEAN	0.0091	0.0089	0.0091	0.0092	0.0088	0.0090		NA
% CHANGE		-2.2	0.0	1.1	-3.3	-1.1		
S.D.	0.00140	0.00185	0.00139	0.00188	0.00153	0.00195		
N	15	15	15	15	15	14		

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
c = Significantly different from control group 1 at 0.05 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

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TABLE 12

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
SPLEEN (G)							
MEAN	0.4430	0.4207	0.4127	0.4238	0.4815	0.4320	NA
% CHANGE		-5.0	-6.8	-4.3	8.7	-2.5	
S.D.	0.09289	0.07883	0.06680	0.07269	0.07952	0.09248	
N	15	15	15	15	15	14	
THYMUS (G)							
MEAN	0.6133	0.5755	0.6066	0.5484	0.5465	0.4905d	NA
% CHANGE		-6.2	-1.1	-10.6	-10.9	-20.0	
S.D.	0.08978	0.09243	0.13758	0.08426	0.08977	0.08513	
N	15	15	15	15	15	14	
THYROIDS/PARATHY (G)							
MEAN	0.0150	0.0144	0.0141	0.0148	0.0149	0.0138	NA
% CHANGE		-4.0	-6.0	-1.3	-0.7	-8.0	
S.D.	0.00329	0.00188	0.00194	0.00192	0.00284	0.00288	
N	15	15	14	15	15	13	
UTERUS- BLOTTED (G)							
MEAN	0.3052	0.3355	0.3091	0.2570	0.2612	0.2077d	NA
% CHANGE		9.9	1.3	-15.8	-14.4	-31.9	
S.D.	0.10385	0.08525	0.09022	0.03654	0.05974	0.03659	
N	15	15	15	15	15	14	
UTERUS- WET (G)							
MEAN	0.4023	0.4303	0.3987	0.2770	0.2982	0.2358d	NA
% CHANGE		7.0	-0.9	-31.1	-25.9	-41.4	
S.D.	0.21104	0.20239	0.23340	0.03879	0.10041	0.07079	
N	15	15	15	15	15	14	
UTERUS- LUM. FL. (G)							
MEAN	0.0971	0.0948	0.0896	0.0200	0.0370	0.0281c	NA
% CHANGE		2.4	-7.7	-79.4	-61.9	-71.1	
S.D.	0.11616	0.13995	0.15214	0.3654	0.04586	0.04142	
N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
c = Significantly different from control group 1 at 0.05 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

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TABLE 13

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
FINAL BODY WT (G)							
MEAN	157.	148.	154.	145.a	154.	151.	NA
S.D.	15.9	11.4	7.7	9.6	12.5	17.7	
N	15	15	15	15	15	14	
ADRENAL GLANDS (G/100 G FINAL BODY WEIGHT)							
MEAN	0.025	0.027	0.028	0.030	0.026	0.029d	NA
S.D.	0.0036	0.0085	0.0035	0.0041	0.0034	0.0032	
N	15	15	15	15	15	14	
KIDNEYS (G/100 G FINAL BODY WEIGHT)							
MEAN	1.023	1.077	1.008	1.099a	1.038	1.068	NA
S.D.	0.0862	0.0689	0.0577	0.0706	0.1132	0.0877	
N	15	15	15	15	15	14	
LIVER (G/100 G FINAL BODY WEIGHT)							
MEAN	5.252	5.444	5.475	5.724a	5.533	6.215d	NA
S.D.	0.5118	0.4877	0.3708	0.3486	0.5523	0.4970	
N	15	15	15	15	15	14	
OVARIES/OVIDUCTS (G/100 G FINAL BODY WEIGHT)							
MEAN	0.050	0.053	0.050	0.045	0.054	0.041c	NA
S.D.	0.0058	0.0073	0.0080	0.0138	0.0103	0.0083	
N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
a = Significantly different from control group 1 at 0.05 using Dunnett's test
c = Significantly different from control group 1 at 0.05 using Dunnett's test
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

Revised Draft

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TABLE 13

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-011

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
PITUITARY (G/100 G FINAL BODY WEIGHT)							
MEAN	0.006	0.006	0.006	0.006	0.006	0.006	NA
S.D.	0.0011	0.0012	0.0009	0.0014	0.0010	0.0011	
N	15	15	15	15	15	14	
SPLEEN (G/100 G FINAL BODY WEIGHT)							
MEAN	0.280	0.284	0.268	0.293	0.313	0.285	NA
S.D.	0.0418	0.0398	0.0398	0.0492	0.0449	0.0454	
N	15	15	15	15	15	14	
THYMUS (G/100 G FINAL BODY WEIGHT)							
MEAN	0.393	0.389	0.394	0.380	0.355	0.324d	NA
S.D.	0.0675	0.0503	0.0854	0.0545	0.0438	0.0364	
N	15	15	15	15	15	14	
THYROIDS/PARATHY (G/100 G FINAL BODY WEIGHT)							
MEAN	0.009	0.010	0.009	0.010	0.010	0.009	NA
S.D.	0.0021	0.0010	0.0011	0.0015	0.0017	0.0018	
N	15	15	14	15	15	13	
UTERUS- BLOTTED (G/100 G FINAL BODY WEIGHT)							
MEAN	0.195	0.227	0.200	0.178	0.169	0.138d	NA
S.D.	0.0672	0.0550	0.0537	0.0272	0.0341	0.0193	
N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

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TABLE 13

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT

		FEMALES					
GROUP:	CORN OIL	[redacted]60	[redacted]250	[redacted]1000	[redacted]60	[redacted]250	[redacted]1000
UTERUS- WET (G/100 G FINAL BODY WEIGHT)							
MEAN	0.257	0.292	0.257	0.192	0.193	0.156d	NA
S.D.	0.1331	0.1393	0.1412	0.0292	0.0595	0.0431	
N	15	15	15	15	15	14	

MODIFIED STATISTIC USED.
For statistical analyses, control group 1 was compared to groups 2, 3 and 4; control group 1 was compared to groups 5, 6 and 7.
d = Significantly different from control group 1 at 0.01 using Dunnett's test
NA = NOT APPLICABLE

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-011

TABLE RANGE: 03-28-06 TO 04-19-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22801-04	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22799-01	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22800-06	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22803-09	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22802-04	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22800-04	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22799-05	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22803-04	F	CORN OIL	DISPOSITION	04-17-06	7:56	P	SCHEDULED EUTHANASIA
22806-02	F	CORN OIL	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22807-07	F	CORN OIL	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22805-01	F	CORN OIL	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22804-04	F	CORN OIL	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22807-08	F	CORN OIL	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22808-05	F	CORN OIL	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22811-07	F	CORN OIL	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22801-06	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22800-03	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22803-07	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22799-08	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22802-02	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22802-06	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22801-03	F	[redacted]60	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22806-10	F	[redacted]60	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22804-09	F	[redacted]60	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22805-02	F	[redacted]60	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22807-01	F	[redacted]60	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22805-08	F	[redacted]60	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22806-01	F	[redacted]60	DISPOSITION	04-18-06	7:40	P	SCHEDULED EUTHANASIA
22811-03	F	[redacted]60	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-011

TABLE RANGE: 03-28-06 TO 04-19-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22808-06	F	[redacted]60	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22800-10	F	[redacted]250	DISPOSITION	04-17-06	7:57	P	SCHEDULED EUTHANASIA
22801-07	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22799-06	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22803-05	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22802-10	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22799-02	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22800-01	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22802-09	F	[redacted]250	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22805-03	F	[redacted]250	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22806-04	F	[redacted]250	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22804-10	F	[redacted]250	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22807-02	F	[redacted]250	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22805-06	F	[redacted]250	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22808-01	F	[redacted]250	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22811-08	F	[redacted]250	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22801-08	F	[redacted]1000	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22803-02	F	[redacted]1000	DISPOSITION	04-17-06	7:58	P	SCHEDULED EUTHANASIA
22799-10	F	[redacted]1000	DISPOSITION	04-17-06	7:59	P	SCHEDULED EUTHANASIA
22800-08	F	[redacted]1000	DISPOSITION	04-17-06	7:59	P	SCHEDULED EUTHANASIA
22802-08	F	[redacted]1000	DISPOSITION	04-17-06	7:59	P	SCHEDULED EUTHANASIA
22802-01	F	[redacted]1000	DISPOSITION	04-17-06	7:59	P	SCHEDULED EUTHANASIA
22801-10	F	[redacted]1000	DISPOSITION	04-17-06	7:59	P	SCHEDULED EUTHANASIA
22806-07	F	[redacted]1000	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22804-01	F	[redacted]1000	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22805-10	F	[redacted]1000	DISPOSITION	04-18-06	7:41	P	SCHEDULED EUTHANASIA
22807-04	F	[redacted]1000	DISPOSITION	04-18-06	7:42	P	SCHEDULED EUTHANASIA
22804-06	F	[redacted]1000	DISPOSITION	04-18-06	7:42	P	SCHEDULED EUTHANASIA
22811-02	F	[redacted]1000	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 03-28-06 TO 04-19-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22808-08	F	[redacted]1000	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22809-07	F	[redacted]1000	DISPOSITION	04-19-06	7:07	P	SCHEDULED EUTHANASIA
22801-02	F	[redacted]60	DISPOSITION	04-17-06	7:59	P	SCHEDULED EUTHANASIA
22800-05	F	[redacted]60	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22803-10	F	[redacted]60	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22803-10	F	[redacted]60	EYES/EARS/NOSE	04-16-06	7:27	1	DRIED RED MATERIAL AROUND NOSE
22799-07	F	[redacted]60	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22802-05	F	[redacted]60	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22800-09	F	[redacted]60	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22802-07	F	[redacted]60	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22806-09	F	[redacted]60	DISPOSITION	04-18-06	7:42	P	SCHEDULED EUTHANASIA
22805-04	F	[redacted]60	DISPOSITION	04-18-06	7:42	P	SCHEDULED EUTHANASIA
22804-05	F	[redacted]60	DISPOSITION	04-18-06	7:42	P	SCHEDULED EUTHANASIA
22807-03	F	[redacted]60	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA
22805-05	F	[redacted]60	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA
22804-07	F	[redacted]60	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA
22811-01	F	[redacted]60	DISPOSITION	04-19-06	7:08	P	SCHEDULED EUTHANASIA
22811-01	F	[redacted]60	EYES/EARS/NOSE	04-05-06	9:56	1	DRIED RED MATERIAL AROUND NOSE
				04-06-06	7:16	1	DRIED RED MATERIAL AROUND NOSE
22808-03	F	[redacted]60	DISPOSITION	04-19-06	7:08	P	SCHEDULED EUTHANASIA
22801-09	F	[redacted]250	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22800-07	F	[redacted]250	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22803-06	F	[redacted]250	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22799-04	F	[redacted]250	DISPOSITION	04-17-06	8:00	P	SCHEDULED EUTHANASIA
22802-11	F	[redacted]250	DISPOSITION	04-17-06	8:01	P	SCHEDULED EUTHANASIA
22801-05	F	[redacted]250	DISPOSITION	04-17-06	8:01	P	SCHEDULED EUTHANASIA
22803-03	F	[redacted]250	DISPOSITION	04-10-06	13:10	P	FOUND DEAD
22803-03	F	[redacted]250	BEHAVIOR/CNS	04-10-06	12:53	P	PROSTRATE
22806-05	F	[redacted]250	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 03-28-06 TO 04-19-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22804-03	F	[redacted] 250	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA
22805-09	F	[redacted] 250	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA
22807-05	F	[redacted] 250	DISPOSITION	04-18-06	7:43	P	SCHEDULED EUTHANASIA
22804-02	F	[redacted] 250	DISPOSITION	04-18-06	7:44	P	SCHEDULED EUTHANASIA
22806-08	F	[redacted] 250	DISPOSITION	04-18-06	7:44	P	SCHEDULED EUTHANASIA
22810-03	F	[redacted] 250	DISPOSITION	04-19-06	7:08	P	SCHEDULED EUTHANASIA
22810-03	F	[redacted] 250	EYES/EARS/NOSE	04-18-06	7:38	1	DRIED RED MATERIAL AROUND LEFT EYE
22811-06	F	[redacted] 250	DISPOSITION	04-19-06	7:08	P	SCHEDULED EUTHANASIA
22801-01	F	[redacted] 1000	DISPOSITION	03-31-06	16:40	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22801-01	F	[redacted] 1000	EYES/EARS/NOSE	03-31-06	10:30	1	DRIED RED MATERIAL AROUND NOSE
22799-09	F	[redacted] 1000	DISPOSITION	03-31-06	8:17	P	FOUND DEAD
22799-09	F	[redacted] 1000	BODY/INTEGUMENT	03-29-06	10:25	2	WET YELLOW MATERIAL VENTRAL ABDOMINAL AREA
				03-30-06	11:01	2	DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA
				03-29-06	10:24	3	WET YELLOW MATERIAL UROGENITAL AREA
				03-30-06	11:00	3	DRIED YELLOW MATERIAL UROGENITAL AREA
22799-09	F	[redacted] 1000	EYES/EARS/NOSE	03-30-06	11:01	1	DRIED RED MATERIAL AROUND NOSE
22803-01	F	[redacted] 1000	DISPOSITION	03-31-06	16:40	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22803-01	F	[redacted] 1000	BODY/INTEGUMENT	03-29-06	10:26	1	WET YELLOW MATERIAL UROGENITAL AREA
				03-30-06	11:02	1	DRIED YELLOW MATERIAL UROGENITAL AREA
				03-31-06	10:31	1	DRIED YELLOW MATERIAL UROGENITAL AREA
22803-01	F	[redacted] 1000	EYES/EARS/NOSE	03-31-06	10:31	1	DRIED RED MATERIAL AROUND NOSE
22800-02	F	[redacted] 1000	DISPOSITION	03-31-06	8:39	P	FOUND DEAD
22800-02	F	[redacted] 1000	BODY/INTEGUMENT	03-30-06	11:02	1	DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA
				03-30-06	11:02	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22800-02	F	[redacted] 1000	EYES/EARS/NOSE	03-30-06	11:02	1	DRIED RED MATERIAL AROUND NOSE
22802-03	F	[redacted] 1000	DISPOSITION	03-30-06	6:55	P	FOUND DEAD
22802-03	F	[redacted] 1000	BODY/INTEGUMENT	03-29-06	10:27	1	WET YELLOW MATERIAL UROGENITAL AREA
22803-08	F	[redacted] 1000	DISPOSITION	03-31-06	16:40	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22803-08	F	[redacted] 1000	BODY/INTEGUMENT	03-30-06	11:03	1	DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 03-28-06 TO 04-19-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22803-08	F	[redacted]1000	BODY/INTEGUMENT	03-31-06	10:32	P	UNKEMPT APPEARANCE
				03-30-06	11:03	2	DRIED YELLOW MATERIAL UROGENITAL AREA
				03-31-06	10:32	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22803-08	F	[redacted]1000	EYES/EARS/NOSE	03-30-06	11:03	1	DRIED RED MATERIAL AROUND NOSE
				03-31-06	10:32	1	DRIED RED MATERIAL AROUND NOSE
22803-08	F	[redacted]1000	EXCRETA	03-31-06	10:31	P	SOFT STOOL
22799-03	F	[redacted]1000	DISPOSITION	03-31-06	16:41	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22799-03	F	[redacted]1000	BODY/INTEGUMENT	03-31-06	10:33	P	UNKEMPT APPEARANCE
				03-29-06	10:27	1	WET YELLOW MATERIAL UROGENITAL AREA
				03-30-06	11:04	2	DRIED YELLOW MATERIAL UROGENITAL AREA
				03-31-06	10:33	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22799-03	F	[redacted]1000	EYES/EARS/NOSE	03-30-06	11:04	1	DRIED RED MATERIAL AROUND NOSE
22806-03	F	[redacted]1000	DISPOSITION	03-31-06	16:42	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22806-03	F	[redacted]1000	BODY/INTEGUMENT	03-31-06	10:34	P	UNKEMPT APPEARANCE
				03-31-06	10:34	3	DRIED YELLOW MATERIAL UROGENITAL AREA
22805-07	F	[redacted]1000	DISPOSITION	03-31-06	16:42	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22805-07	F	[redacted]1000	BODY/INTEGUMENT	03-31-06	10:35	P	UNKEMPT APPEARANCE
				03-30-06	11:05	1	DRIED YELLOW MATERIAL UROGENITAL AREA
				03-31-06	10:35	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22804-08	F	[redacted]1000	DISPOSITION	03-31-06	16:42	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22804-08	F	[redacted]1000	BODY/INTEGUMENT	03-31-06	10:36	1	DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA
				03-31-06	10:36	P	UNKEMPT APPEARANCE
				03-30-06	11:05	1	DRIED YELLOW MATERIAL UROGENITAL AREA
				03-31-06	10:36	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22804-08	F	[redacted]1000	EYES/EARS/NOSE	03-31-06	10:36	2	DRIED RED MATERIAL AROUND NOSE
22807-10	F	[redacted]1000	DISPOSITION	03-31-06	16:42	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22807-10	F	[redacted]1000	BODY/INTEGUMENT	03-31-06	10:37	P	UNKEMPT APPEARANCE
				03-30-06	11:06	1	WET YELLOW MATERIAL UROGENITAL AREA
				03-31-06	10:37	3	DRIED YELLOW MATERIAL UROGENITAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 6/30/2006

TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

TABLE RANGE: 03-28-06 TO 04-19-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22807-10	F	[redacted] 1000	EYES/EARS/NOSE	03-31-06	10:36	1	DRIED RED MATERIAL AROUND NOSE
22807-10	F	1000	EXCRETA	03-30-06	11:06	P	SOFT STOOL
22807-10	F	1000	ORAL/DENTAL	03-31-06	10:37	1	DRIED RED MATERIAL AROUND MOUTH
22807-06	F	1000	DISPOSITION	03-31-06	16:43	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22807-06	F	1000	BODY/INTEGUMENT	03-31-06	10:39	P	UNKEMPT APPEARANCE
				03-31-06	10:38	3	DRIED YELLOW MATERIAL UROGENITAL AREA
				03-30-06	11:07	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22807-06	F	[redacted] 1000	EYES/EARS/NOSE	03-31-06	10:38	1	DRIED RED MATERIAL AROUND NOSE
22811-04	F	1000	DISPOSITION	03-31-06	16:43	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22811-04	F	1000	BODY/INTEGUMENT	03-31-06	10:41	2	DRIED YELLOW MATERIAL UROGENITAL AREA
22808-02	F	1000	DISPOSITION	03-31-06	16:43	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22808-02	F	1000	BODY/INTEGUMENT	03-31-06	10:43	P	UNKEMPT APPEARANCE
				03-31-06	10:43	1	DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA
				03-31-06	10:42	3	DRIED YELLOW MATERIAL UROGENITAL AREA
22808-02	F	[redacted] 1000	EYES/EARS/NOSE	03-31-06	10:43	2	DRIED RED MATERIAL AROUND NOSE
22809-01	F	1000	DISPOSITION	03-31-06	16:43	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22809-01	F	1000	BODY/INTEGUMENT	03-31-06	10:43	1	DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA
				03-31-06	10:43	P	UNKEMPT APPEARANCE
				03-31-06	10:43	3	DRIED YELLOW MATERIAL UROGENITAL AREA
22809-01	F	[redacted] 1000	EYES/EARS/NOSE	03-31-06	10:44	1	DRIED RED MATERIAL AROUND NOSE
22810-01	F	1000	DISPOSITION	03-31-06	16:41	P	EUTHANIZED AND DISCARDED; EARLY GROUP TERMINATION
22810-01	F	1000	BODY/INTEGUMENT	03-31-06	10:45	1	WET YELLOW MATERIAL UROGENITAL AREA
22810-01	F	1000	EYES/EARS/NOSE	03-31-06	10:45	1	DRIED RED MATERIAL AROUND NOSE

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-28-06 TO 04-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22799-10	F	[redacted]1000	ORAL/DENTAL	04-11-06	12:50	2	SALIVATION
				04-14-06	12:47	1	SALIVATION
22804-01	F	[redacted]1000	ORAL/DENTAL	04-11-06	12:55	3	SALIVATION
				04-14-06	12:51	1	SALIVATION
22800-07	F	[redacted]250	ORAL/DENTAL	04-11-06	12:49	1	SALIVATION
				04-14-06	12:37	1	SALIVATION
22803-06	F	[redacted]250	ORAL/DENTAL	04-14-06	12:37	1	SALIVATION
22801-05	F	[redacted]250	ORAL/DENTAL	04-12-06	12:41	1	SALIVATION
				04-14-06	12:39	1	SALIVATION
22804-02	F	[redacted]250	ORAL/DENTAL	04-10-06	12:46	1	SALIVATION
				04-11-06	12:55	2	SALIVATION
				04-12-06	12:44	2	SALIVATION
				04-14-06	12:42	1	SALIVATION
22811-06	F	[redacted]250	ORAL/DENTAL	04-11-06	12:58	1	SALIVATION

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
05/25/2006

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TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-28-06 TO 04-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22803-02	F	[redacted]1000	ORAL/DENTAL	04-14-06	13:41	2	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	13:26	1	WET CLEAR MATERIAL AROUND MOUTH
22801-10	F	[redacted]1000	ORAL/DENTAL	04-02-06	14:27	1	WET CLEAR MATERIAL AROUND MOUTH
22806-07	F	[redacted]1000	ORAL/DENTAL	04-17-06	13:27	1	WET CLEAR MATERIAL AROUND MOUTH
22804-01	F	[redacted]1000	ORAL/DENTAL	04-03-06	14:06	2	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:27	1	WET CLEAR MATERIAL AROUND MOUTH
22805-10	F	[redacted]1000	ORAL/DENTAL	04-17-06	13:28	2	WET CLEAR MATERIAL AROUND MOUTH
22811-02	F	[redacted]1000	ORAL/DENTAL	04-03-06	14:06	1	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:28	1	WET CLEAR MATERIAL AROUND MOUTH
22801-02	F	[redacted]60	ORAL/DENTAL	04-02-06	14:28	1	WET CLEAR MATERIAL AROUND MOUTH
22801-09	F	[redacted]250	ORAL/DENTAL	04-10-06	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	13:47	2	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:43	2	WET CLEAR MATERIAL AROUND MOUTH
22800-07	F	[redacted]250	ORAL/DENTAL	04-09-06	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	13:45	1	SALIVATION
				04-11-06	13:48	2	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	13:35	1	SALIVATION
				04-12-06	13:35	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:33	2	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:44	1	SALIVATION
				04-15-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	13:28	2	WET CLEAR MATERIAL AROUND MOUTH
22803-06	F	[redacted]250	ORAL/DENTAL	04-14-06	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
22799-04	F	[redacted]250	ORAL/DENTAL	04-09-06	13:41	3	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-28-06 TO 04-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22799-04	F	[redacted]250	ORAL/DENTAL	04-11-06	13:48	1	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	13:35	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:44	1	WET CLEAR MATERIAL AROUND MOUTH
22802-11	F	[redacted]250	ORAL/DENTAL	04-10-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	13:36	1	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
22801-05	F	[redacted]250	ORAL/DENTAL	04-13-06	13:34	1	SALIVATION
				04-13-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:44	1	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
22806-05	F	[redacted]250	ORAL/DENTAL	04-09-06	13:41	3	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	13:46	1	DRIED RED MATERIAL AROUND MOUTH
				04-11-06	13:49	2	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	13:49	1	SALIVATION
				04-12-06	13:36	2	SALIVATION
				04-12-06	13:36	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:45	1	SALIVATION
				04-14-06	13:45	2	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	13:32	2	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	13:29	2	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:30	2	WET CLEAR MATERIAL AROUND MOUTH
22804-03	F	[redacted]250	ORAL/DENTAL	04-11-06	13:49	2	WET CLEAR MATERIAL AROUND MOUTH
				04-11-06	13:49	1	SALIVATION
				04-12-06	13:36	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:45	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:06-011
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-28-06 TO 04-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22804-03	F	[redacted] 250	ORAL/DENTAL	04-15-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	13:29	2	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:30	2	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:30	1	SALIVATION
22805-09	F	[redacted] 250	ORAL/DENTAL	04-11-06	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:30	1	WET CLEAR MATERIAL AROUND MOUTH
22807-05	F	[redacted] 250	ORAL/DENTAL	04-17-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
22804-02	F	[redacted] 250	EYES/EARS/NOSE	04-07-06	13:46	1	WET CLEAR MATERIAL AROUND NOSE
22804-02	F	[redacted] 250	ORAL/DENTAL	04-07-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				04-09-06	13:41	3	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	13:47	1	DRIED CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:35	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:35	1	SALIVATION
				04-14-06	13:46	2	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	13:30	1	DRIED RED MATERIAL AROUND MOUTH
				04-17-06	13:31	2	WET CLEAR MATERIAL AROUND MOUTH
22806-08	F	[redacted] 250	ORAL/DENTAL	04-07-06	13:47	1	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:36	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:36	1	SALIVATION
				04-14-06	13:47	2	SALIVATION
				04-14-06	13:47	2	WET CLEAR MATERIAL AROUND MOUTH
				04-16-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:31	2	SALIVATION
				04-17-06	13:32	3	WET CLEAR MATERIAL AROUND MOUTH
22810-03	F	[redacted] 250	ORAL/DENTAL	04-07-06	13:47	1	WET CLEAR MATERIAL AROUND MOUTH
				04-10-06	13:48	1	DRIED CLEAR MATERIAL AROUND MOUTH
				04-11-06	13:50	1	SALIVATION
				04-11-06	13:50	1	WET CLEAR MATERIAL AROUND MOUTH
				04-12-06	13:37	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 03-28-06 TO 04-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
22810-03	F	[redacted]250	ORAL/DENTAL	04-13-06	13:35	1	WET CLEAR MATERIAL AROUND MOUTH
				04-15-06	13:34	1	DRIED RED MATERIAL AROUND MOUTH
				04-17-06	13:31	2	WET CLEAR MATERIAL AROUND MOUTH
				04-18-06	15:45	1	WET CLEAR MATERIAL AROUND MOUTH
22811-06	F	[redacted]250	ORAL/DENTAL	04-10-06	13:48	1	SALIVATION
				04-10-06	13:48	2	WET CLEAR MATERIAL AROUND MOUTH
				04-13-06	13:36	1	WET CLEAR MATERIAL AROUND MOUTH
				04-14-06	13:46	2	WET CLEAR MATERIAL AROUND MOUTH
				04-17-06	13:32	2	WET CLEAR MATERIAL AROUND MOUTH
				04-18-06	15:45	2	WET CLEAR MATERIAL AROUND MOUTH
22800-02	F	[redacted]1000	ORAL/DENTAL	03-28-06	14:28	1	WET CLEAR MATERIAL AROUND MOUTH
22803-08	F	[redacted]1000	ORAL/DENTAL	03-31-06	14:32	1	WET CLEAR MATERIAL AROUND MOUTH
22799-03	F	[redacted]1000	BEHAVIOR/CNS	03-31-06	14:34	P	LETHARGIC
22806-03	F	[redacted]1000	BEHAVIOR/CNS	03-31-06	14:35	P	LETHARGIC
22804-08	F	[redacted]1000	EYES/EARS/NOSE	03-31-06	14:35	1	DRIED RED MATERIAL AROUND NOSE

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

PCRDv4.1
05/25/2006

Revised Draft

Modified: 6/30/2006

TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: CORN OIL												
22801-04	56.5	60.0	65.9	71.7	78.3	84.8	89.6	96.8	103.2	110.6	117.3	124.3
22799-01	51.9	56.2	63.4	69.4	74.7	81.9	87.4	94.3	100.2	109.6	111.8	117.8
22800-06	49.5	53.1	59.3	64.9	70.1	75.4	80.5	85.9	91.8	99.8	103.7	113.6
22803-09	48.5	52.5	57.2	60.0	64.3	70.6	75.9	79.3	85.2	91.4	98.0	102.3
22802-04	42.5	46.7	50.8	56.0	60.7	66.5	70.0	76.9	82.8	86.2	92.2	100.4
22800-04	43.9	48.1	53.5	57.5	62.8	67.4	73.3	77.4	84.8	87.7	95.1	101.9
22799-05	51.5	55.9	60.5	67.0	71.8	77.1	84.8	89.8	93.2	100.0	105.8	110.7
22803-04	54.7	59.2	65.0	71.2	75.0	81.1	90.7	93.1	99.7	106.0	112.1	118.2
22806-02	41.7	44.9	51.6	56.4	62.8	69.0	72.5	79.6	82.7	90.0	95.5	100.3
22807-07	51.3	56.1	61.2	65.9	73.0	78.1	82.6	88.0	95.0	99.7	108.2	115.3
22805-01	52.7	56.7	60.1	64.2	69.1	72.2	76.0	80.2	85.4	88.5	94.5	100.7
22804-04	56.9	62.3	68.4	74.1	81.5	87.5	95.5	102.6	110.6	117.3	124.3	134.2
22807-08	58.2	63.5	68.6	74.9	80.5	87.4	93.8	101.8	107.7	111.1	121.5	126.7
22808-05	54.3	59.2	63.1	67.9	73.0	77.6	83.5	88.7	94.0	101.3	108.3	112.0
22811-07	54.3	58.7	63.1	67.4	73.9	77.6	81.8	88.8	93.4	98.3	101.3	108.2
MEAN	51.2	55.5	60.8	65.9	71.4	76.9	82.5	88.2	94.0	99.8	106.0	112.4
S.D.	5.16	5.54	5.56	6.14	6.48	6.84	7.91	8.44	8.92	9.69	10.10	10.54
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/30/2006

TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: CORN OIL									
22801-04	131.6	136.7	139.0	145.8	153.2	158.8	164.0	171.4	179.8
22799-01	121.3	129.4	133.1	141.7	139.6	153.9	146.5	150.0	150.2
22800-06	119.2	125.4	129.3	132.4	137.1	141.3	146.5	147.4	152.6
22803-09	111.8	118.8	124.0	131.5	130.6	135.1	140.2	144.1	148.6
22802-04	108.3	117.6	122.1	126.9	136.0	139.9	149.2	157.4	159.9
22800-04	109.0	115.3	122.4	126.8	132.4	137.3	142.0	146.4	148.6
22799-05	118.1	122.0	123.2	129.5	133.8	133.3	139.8	133.0	144.4
22803-04	127.4	132.5	137.4	144.3	150.2	163.3	156.6	165.0	171.0
22806-02	105.7	105.5	113.4	119.3	118.8	127.7	132.3	130.2	136.5
22807-07	120.9	127.0	134.4	137.9	147.4	151.7	156.9	161.8	162.0
22805-01	106.0	111.0	115.8	123.1	126.7	129.7	135.4	141.1	143.4
22804-04	142.5	144.3	157.0	159.6	171.3	171.2	179.8	185.3	191.1
22807-08	136.4	130.7	142.4	149.7	148.8	142.3	159.7	164.8	175.2
22808-05	120.5	124.8	128.1	142.9	135.8	147.8	151.5	155.3	155.9
22811-07	113.0	116.4	117.0	122.8	125.9	134.5	128.0	136.2	138.8
MEAN	119.4	123.8	129.2	135.6	139.2	144.5	148.6	152.6	157.2
S.D.	11.15	10.17	11.62	11.51	13.18	12.89	13.47	15.29	15.91
N	15	15	15	15	15	15	15	15	15

Revised Draft

TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: [redacted]60												
22801-06	55.7	58.5	62.8	67.3	72.0	76.2	80.0	86.0	93.7	96.2	96.7	108.2
22800-03	53.9	57.2	63.7	68.3	75.4	80.2	85.8	94.6	99.4	106.0	112.7	119.1
22803-07	48.3	50.9	56.1	60.1	64.6	69.6	76.6	78.7	83.2	91.2	96.8	103.6
22799-08	48.2	51.3	57.9	62.2	67.4	73.1	80.6	86.8	90.1	97.7	101.9	107.9
22802-02	40.9	44.4	49.8	54.1	58.0	62.6	67.4	72.1	79.2	85.3	89.9	96.6
22802-06	43.7	47.9	53.8	57.1	62.4	67.5	72.3	75.4	79.3	85.8	90.0	94.1
22801-03	55.8	59.2	65.0	70.6	76.2	82.7	89.9	95.3	100.0	107.6	111.9	116.7
22806-10	46.5	50.9	55.1	60.0	63.6	68.0	72.1	77.5	81.9	84.6	92.5	97.9
22804-09	51.0	54.9	59.9	65.3	71.0	76.0	80.2	88.9	95.2	100.0	101.3	112.8
22805-02	50.6	55.3	60.3	65.6	68.5	71.9	77.7	80.9	87.4	93.3	98.5	103.8
22807-01	57.0	62.4	67.4	72.7	78.2	82.2	83.2	91.7	103.7	105.0	108.6	114.2
22805-08	50.8	55.6	58.1	62.7	67.0	70.2	74.2	75.3	83.6	84.9	92.5	96.4
22806-01	47.0	52.7	55.5	61.5	67.6	71.6	76.4	83.2	88.4	95.4	101.0	106.9
22811-03	61.4	65.8	73.1	78.0	80.9	85.8	92.7	98.7	106.1	109.1	114.6	122.9
22808-06	53.0	55.8	60.3	65.3	70.6	74.8	79.0	86.4	90.2	94.4	101.6	106.1
MEAN	50.9	54.9	59.9	64.7	69.6	74.2	79.2	84.8	90.8	95.8	100.7	107.1
S.D.	5.40	5.49	5.87	6.16	6.28	6.45	6.76	8.11	8.70	8.49	8.15	8.75
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: [redacted]60									
22801-06	116.1	120.5	132.5	136.6	143.3	150.4	157.7	154.6	147.6
22800-03	123.8	129.2	133.6	142.6	149.8	151.0	152.7	159.7	161.1
22803-07	112.4	113.8	122.5	127.7	135.2	140.7	139.7	143.4	153.8
22799-08	114.1	121.2	124.5	132.2	133.6	139.3	141.0	142.5	144.6
22802-02	103.7	106.1	111.9	120.0	128.7	129.3	136.8	137.8	143.6
22802-06	100.0	103.8	107.4	116.8	123.5	123.5	129.2	136.0	140.1
22801-03	122.0	125.9	137.4	137.1	146.4	149.4	146.4	159.6	164.8
22806-10	99.0	101.9	109.3	112.8	124.6	116.4	124.6	129.6	133.7
22804-09	118.6	126.2	131.9	135.5	144.1	147.5	152.9	158.4	160.8
22805-02	108.4	111.2	114.2	124.3	121.3	126.5	128.0	128.3	130.5
22807-01	120.1	125.5	134.9	142.4	144.6	154.6	157.6	159.5	163.8
22805-08	101.7	105.8	112.0	115.6	119.3	122.7	127.7	130.6	134.9
22806-01	108.9	115.8	119.0	124.3	127.5	130.6	136.3	137.0	145.8
22811-03	129.0	130.0	137.3	139.7	136.3	142.6	142.7	149.2	151.1
22808-06	107.5	117.0	115.7	124.6	125.2	132.3	132.1	134.6	136.3
MEAN	112.4	116.9	122.9	128.8	133.6	137.1	140.4	144.1	147.5
S.D.	9.21	9.55	10.89	9.97	10.11	12.08	11.13	11.81	11.42
N	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/30/2006

TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: [redacted]250												
22800-10	56.8	62.3	68.8	72.1	77.2	83.1	87.2	95.6	104.1	110.4	114.5	118.3
22801-07	52.9	56.0	61.3	64.6	70.0	74.6	80.4	84.8	91.6	98.0	100.9	108.5
22799-06	48.7	52.6	58.9	62.6	67.7	74.1	80.8	82.6	92.7	101.1	105.9	111.5
22803-05	47.2	51.1	55.4	59.9	63.3	68.9	72.6	78.3	83.7	91.8	94.2	98.6
22802-10	39.2	43.8	49.5	52.6	58.0	64.6	69.3	74.1	81.7	87.5	92.1	98.5
22799-02	45.7	50.2	55.2	59.5	64.6	71.1	76.7	81.3	87.3	95.3	100.6	107.4
22800-01	51.1	55.3	61.4	64.5	68.6	74.2	79.9	81.2	90.3	98.8	98.1	100.5
22802-09	42.3	45.9	51.5	56.8	61.5	67.5	73.9	78.5	87.8	91.3	97.8	102.5
22805-03	47.4	53.5	58.0	63.3	66.6	72.7	76.1	81.4	86.2	88.7	95.5	103.1
22806-04	47.0	51.4	56.8	61.0	66.8	72.2	78.2	84.8	90.4	94.9	102.0	105.5
22804-10	52.6	56.2	61.6	66.2	69.2	75.4	79.3	86.1	93.6	98.8	106.0	110.7
22807-02	60.6	65.5	70.4	75.8	81.0	86.9	93.7	100.3	106.9	111.4	117.0	122.4
22805-06	51.4	55.0	60.1	64.7	68.9	73.0	77.2	82.5	85.9	90.3	95.1	102.2
22808-01	54.8	57.8	64.6	69.8	74.3	80.7	84.9	89.0	94.3	101.8	105.5	111.0
22811-08	54.1	58.2	62.3	67.3	70.5	76.3	82.8	88.7	92.9	96.5	103.0	109.6
MEAN	50.1	54.3	59.7	64.0	68.5	74.4	79.5	84.6	91.3	97.1	101.9	107.4
S.D.	5.58	5.64	5.73	5.89	5.86	5.80	6.05	6.73	6.87	7.10	7.12	6.91
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: [redacted]250									
22800-10	127.1	137.7	143.1	142.1	149.2	148.1	157.5	163.2	166.0
22801-07	116.5	124.5	126.2	128.0	134.4	144.9	144.1	148.3	155.8
22799-06	113.8	125.6	133.0	140.7	136.3	146.5	149.6	160.9	158.1
22803-05	104.2	115.7	113.3	122.0	129.3	134.7	146.2	145.3	149.6
22802-10	104.6	110.4	118.2	124.1	128.5	140.9	142.4	149.2	153.5
22799-02	113.4	118.3	120.0	124.7	131.8	136.5	140.1	144.2	154.2
22800-01	110.0	113.6	114.4	118.9	122.6	128.6	131.3	130.8	137.4
22802-09	110.8	118.4	124.1	130.9	135.2	143.5	146.0	152.0	156.3
22805-03	110.1	120.0	116.4	119.1	128.7	131.7	137.1	139.1	149.6
22806-04	113.5	116.8	125.7	131.0	136.5	139.9	148.2	156.0	155.1
22804-10	117.1	121.3	129.7	134.4	147.6	146.9	153.9	150.3	163.9
22807-02	125.6	135.0	136.4	144.6	157.9	154.0	161.9	154.5	161.5
22805-06	105.0	112.1	115.5	121.4	124.2	131.0	132.7	140.7	142.8
22808-01	117.2	124.4	129.5	138.1	136.3	143.0	144.3	146.7	154.8
22811-08	112.2	116.6	122.6	128.5	131.8	134.2	137.8	138.5	146.1
MEAN	113.4	120.7	124.5	129.9	135.4	140.3	144.9	148.0	153.6
S.D.	6.75	7.77	8.68	8.49	9.62	7.32	8.62	8.74	7.68
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: [redacted]1000												
22801-08	56.6	60.0	64.4	68.9	73.6	77.9	82.2	87.0	93.7	98.1	104.9	106.2
22803-02	50.5	53.2	58.0	63.7	67.7	72.3	75.6	79.1	86.5	88.9	96.7	102.2
22799-10	50.4	54.0	59.0	64.1	69.9	73.6	73.9	76.3	84.9	98.1	99.8	101.2
22800-08	45.7	50.0	54.9	60.1	66.0	71.6	77.2	82.5	90.4	85.4	101.4	109.1
22802-08	45.2	48.5	53.3	58.0	61.6	66.1	70.3	74.9	80.0	86.3	90.5	95.9
22802-01	42.1	44.8	50.5	56.1	60.1	65.9	68.9	75.0	79.9	94.6	93.1	94.7
22801-10	55.1	59.3	62.0	67.0	70.0	75.2	77.4	80.2	86.9	85.0	96.1	97.7
22806-07	48.2	50.9	55.4	59.9	65.1	69.5	78.0	79.0	84.3	88.4	93.2	98.8
22804-01	49.8	54.8	59.7	62.9	68.8	72.7	77.7	84.5	91.5	97.7	99.6	107.2
22805-10	54.0	58.5	63.2	68.4	73.2	78.6	82.8	88.7	97.0	101.6	108.3	114.1
22807-04	61.9	67.7	73.2	77.3	84.0	89.5	94.5	100.6	110.5	114.8	123.2	128.4
22804-06	52.3	57.5	62.3	67.8	72.2	76.9	83.5	89.4	96.1	101.0	108.5	111.4
22811-02	57.0	61.5	66.9	71.8	75.5	80.0	86.9	93.9	99.4	98.6	109.1	124.2
22808-08	51.5	55.1	62.2	67.0	71.8	74.5	80.5	84.1	90.4	96.1	100.9	108.9
22809-07	46.3	50.5	56.2	59.7	64.4	67.0	69.3	77.3	81.3	86.1	90.6	95.9
MEAN	51.1	55.1	60.1	64.8	69.6	74.1	78.6	83.5	90.2	94.7	101.1	106.4
S.D.	5.26	5.84	5.78	5.69	5.99	6.16	6.89	7.39	8.32	8.19	8.75	10.12
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: [redacted]1000									
22801-08	113.0	118.9	122.4	127.6	133.5	138.0	142.8	143.4	146.6
22803-02	106.0	110.0	117.4	126.5	126.8	126.6	128.5	134.8	139.5
22799-10	104.5	109.7	112.7	118.7	124.8	131.7	134.6	139.9	139.5
22800-08	114.5	115.7	126.1	132.5	139.7	143.0	144.6	147.3	154.8
22802-08	102.5	105.2	110.9	119.2	126.3	131.3	133.6	143.1	144.9
22802-01	101.7	105.4	111.0	117.6	119.3	129.5	130.1	139.1	140.7
22801-10	104.2	109.0	110.1	111.8	117.9	126.1	126.8	132.4	135.9
22806-07	102.3	106.4	110.2	114.8	117.0	119.2	118.3	125.9	129.7
22804-01	111.7	117.2	121.8	126.1	132.2	135.3	137.1	141.9	148.5
22805-10	120.1	126.2	129.6	136.3	140.6	141.6	146.0	148.2	145.0
22807-04	135.3	141.2	145.3	149.8	155.3	156.0	161.7	161.5	165.8
22804-06	117.0	125.1	129.1	132.7	139.2	145.0	149.2	150.5	150.4
22811-02	130.9	124.1	127.2	135.8	136.4	145.1	144.4	144.3	154.1
22808-08	107.4	115.7	119.3	126.2	131.5	130.8	138.5	138.3	140.9
22809-07	99.1	105.2	109.0	113.2	115.8	123.5	127.9	128.5	130.0
MEAN	111.3	115.7	120.1	125.9	130.4	134.8	137.6	141.3	144.4
S.D.	10.77	10.21	10.18	10.42	10.93	9.87	10.88	8.99	9.59
N	15	15	15	15	15	15	15	15	15

187056 RD

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Modified: 6/30/2006

TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: [redacted]60												
22801-02	54.2	58.1	62.1	68.4	72.8	78.4	81.2	90.0	95.2	102.0	108.7	112.9
22800-05	52.7	57.6	61.3	67.2	71.5	78.4	83.8	83.0	92.0	99.0	106.9	113.6
22803-10	51.5	56.2	61.6	66.2	71.3	76.6	80.0	86.2	91.4	100.7	106.5	110.2
22799-07	47.1	50.2	56.5	59.7	65.6	69.3	76.3	79.6	83.8	93.3	99.7	105.8
22802-05	45.2	49.3	53.4	58.3	62.5	67.5	72.7	77.1	83.8	88.7	94.2	101.5
22800-09	50.0	52.6	56.5	61.7	66.5	70.2	75.7	80.9	87.5	93.5	97.2	99.9
22802-07	49.1	52.4	56.3	62.4	68.1	70.8	76.0	80.1	91.0	92.1	98.5	104.0
22806-09	42.4	46.7	51.8	57.8	61.4	65.3	72.0	75.2	80.7	83.3	89.0	97.5
22805-04	50.8	54.7	60.8	65.8	71.4	74.5	80.1	86.4	91.3	95.3	101.8	105.9
22804-05	56.3	60.3	64.7	67.9	73.3	79.1	84.3	88.6	97.2	104.2	110.2	117.5
22807-03	58.9	63.3	68.5	74.3	81.6	89.1	92.0	98.6	107.7	111.2	118.1	131.3
22805-05	53.3	57.5	61.6	64.7	70.6	75.1	80.5	84.5	91.3	95.5	101.1	106.3
22804-07	49.3	52.7	58.1	64.0	69.0	74.3	79.3	84.0	91.8	98.4	103.0	109.5
22811-01	55.5	60.7	66.2	72.7	79.4	81.8	87.5	94.3	100.0	107.1	113.7	117.9
22808-03	53.2	57.8	63.9	70.3	75.1	78.7	83.3	91.8	96.6	102.4	110.4	116.7
MEAN	51.3	55.3	60.2	65.4	70.7	75.3	80.3	85.4	92.1	97.8	103.9	110.0
S.D.	4.34	4.64	4.72	4.94	5.56	6.12	5.41	6.50	6.83	7.23	7.74	8.67
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: [redacted]60									
22801-02	120.5	126.1	132.2	137.2	144.8	148.0	149.8	159.5	165.4
22800-05	117.5	120.4	127.9	132.3	138.0	135.5	143.3	151.2	151.5
22803-10	117.9	121.6	127.0	132.9	137.1	141.7	147.4	150.6	151.8
22799-07	110.6	113.2	124.8	128.9	134.3	136.8	143.6	147.0	151.1
22802-05	107.1	110.1	117.9	122.5	125.5	127.7	135.5	138.5	136.9
22800-09	104.1	114.3	121.4	121.6	131.0	141.1	136.9	138.7	151.4
22802-07	111.9	113.5	124.4	130.8	128.7	137.3	145.7	145.4	151.8
22806-09	102.8	108.4	110.9	117.0	118.9	120.1	125.6	126.9	132.0
22805-04	114.1	117.7	121.2	122.4	133.5	135.1	132.3	141.2	142.3
22804-05	117.4	122.2	130.8	136.8	138.5	144.7	151.7	152.7	154.1
22807-03	134.5	142.2	147.0	156.0	165.9	166.8	173.1	182.2	181.8
22805-05	112.2	115.0	121.2	124.9	133.9	135.0	142.5	140.9	153.8
22804-07	113.5	121.3	127.7	130.5	142.2	143.6	149.4	151.8	153.2
22811-01	129.4	131.7	139.2	146.6	151.4	157.7	158.0	164.8	172.0
22808-03	120.8	125.1	132.2	136.9	139.6	142.5	143.4	150.7	156.0
MEAN	115.6	120.2	127.1	131.8	137.6	140.9	145.2	149.5	153.7
S.D.	8.60	8.81	8.75	10.15	11.12	11.22	11.21	12.92	12.46
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 6: [redacted]250												
22801-09	60.7	64.6	69.3	74.0	80.7	85.1	92.7	95.0	101.0	109.0	112.2	119.3
22800-07	53.6	56.8	61.0	66.2	70.3	74.9	79.5	82.5	90.3	93.9	100.6	105.4
22803-06	48.2	52.7	57.1	62.6	66.3	71.9	76.8	81.6	88.0	93.7	97.6	103.7
22799-04	47.1	51.0	56.1	60.7	66.3	72.4	77.1	81.1	88.5	93.0	96.9	102.4
22802-11	44.3	48.6	54.1	59.3	64.2	69.7	75.5	79.8	88.4	96.1	101.9	109.7
22801-05	49.3	54.2	58.6	63.9	69.1	74.6	79.0	83.6	89.3	94.9	98.1	103.9
22803-03	52.2	56.8	62.2	67.9	72.9	78.2	83.0	88.6	96.1	101.9	106.2	109.6
22806-05	43.9	48.5	54.5	57.9	63.8	67.6	75.8	77.2	84.0	89.2	95.5	103.0
22804-03	49.1	52.8	58.1	61.8	66.8	72.9	77.5	82.6	89.6	94.1	97.9	104.5
22805-09	51.4	56.2	61.1	66.3	71.4	75.2	81.5	86.8	93.6	98.2	104.8	109.3
22807-05	61.2	65.6	71.3	77.0	83.8	88.2	99.0	103.6	111.9	117.1	125.5	134.1
22804-02	58.4	64.5	69.5	74.4	82.4	86.5	94.6	101.3	107.0	114.9	121.0	128.8
22806-08	40.4	44.1	49.5	53.8	60.3	63.2	67.5	72.8	80.0	84.8	88.7	94.5
22810-03	58.9	63.4	69.7	77.4	81.5	87.8	93.8	99.4	106.3	112.7	119.2	125.0
22811-06	52.4	55.3	59.8	65.8	67.7	73.8	78.1	82.6	90.3	94.2	101.0	107.9
MEAN	51.4	55.7	60.8	65.9	71.2	76.1	82.1	86.6	93.6	99.2	104.5	110.7
S.D.	6.33	6.52	6.55	7.12	7.52	7.60	8.85	9.19	9.08	9.77	10.51	11.08
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 6: [redacted]250									
22801-09	123.6	127.7	132.5	133.1	140.1	145.0	145.6	143.8	149.5
22800-07	111.2	119.2	121.9	126.5	134.5	145.7	138.0	148.0	152.3
22803-06	108.0	114.8	117.7	124.0	129.8	138.9	137.5	138.8	149.8
22799-04	103.5	111.1	116.3	119.0	120.9	125.2	129.1	135.8	132.7
22802-11	114.6	117.7	123.7	124.6	136.2	139.9	140.4	147.3	149.5
22801-05	104.8	110.6	115.1	116.6	120.6	123.8	125.7	127.5	131.3
22803-03	115.5	120.2							
22806-05	106.1	113.5	111.3	117.2	122.3	126.7	130.6	132.2	131.5
22804-03	105.7	110.4	117.2	126.9	130.5	137.3	141.6	142.0	154.3
22805-09	113.0	119.3	122.1	127.4	128.8	133.8	136.3	139.1	136.0
22807-05	137.1	148.7	153.8	159.2	165.2	168.1	169.0	177.5	183.4
22804-02	133.7	142.0	149.2	153.9	164.5	166.9	169.2	173.5	178.7
22806-08	99.1	104.6	108.6	113.9	118.4	118.8	121.7	131.3	131.2
22810-03	132.8	132.3	141.9	148.0	151.8	160.0	162.3	159.9	171.9
22811-06	114.8	117.7	125.6	132.2	135.1	143.4	152.2	158.1	160.5
MEAN	114.9	120.7	125.5	130.2	135.6	141.0	142.8	146.8	150.9
S.D.	11.81	12.22	13.92	14.09	15.23	15.50	15.28	15.34	17.72
N	15	15	14	14	14	14	14	14	14

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 7: [redacted]1000												
22801-01	55.8	60.2	60.7	58.0								
22799-09	53.7	49.9	47.0	NA								
22803-01	49.5	49.2	52.1	58.3								
22800-02	45.0	47.9	44.6	NA								
22802-03	39.9	38.0	NA									
22803-08	51.2	55.4	50.9	47.1								
22799-03	50.9	49.8	45.9	45.1								
22806-03	46.3	47.9	46.1									
22805-07	49.2	50.3	48.7									
22804-08	54.2	58.6	57.6									
22807-10	57.5	55.1	49.7									
22807-06	49.8	49.6	44.3									
22811-04	59.3	61.4										
22808-02	54.1	50.6										
22809-01	49.3	48.0										
22810-01	45.6	45.0										
MEAN	50.7	51.1	49.8	52.1								
S.D.	5.04	5.94	5.30	7.01								
N	16	16	11	4								

NA = NOT APPLICABLE

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TABLE 17

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 7: [redacted]1000									
NO DATA FOR THESE INTERVALS									

PJTBWv4.22
06/07/2006

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TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: CORN OIL												
22801-04	3.5	5.9	5.8	6.6	6.5	4.8	7.2	6.4	7.4	6.7	7.0	7.3
22799-01	4.3	7.2	6.0	5.3	7.2	5.5	6.9	5.9	9.4	2.2	6.0	3.5
22800-06	3.6	6.2	5.6	5.2	5.3	5.1	5.4	5.9	8.0	3.9	9.9	5.6
22803-09	4.0	4.7	2.8	4.3	6.3	5.3	3.4	5.9	6.2	6.6	4.3	9.5
22802-04	4.2	4.1	5.2	4.7	5.8	3.5	6.9	5.9	3.4	6.0	8.2	7.9
22800-04	4.2	5.4	4.0	5.3	4.6	5.9	4.1	7.4	2.9	7.4	6.8	7.1
22799-05	4.4	4.6	6.5	4.8	5.3	7.7	5.0	3.4	6.8	5.8	4.9	7.4
22803-04	4.5	5.8	6.2	3.8	6.1	9.6	2.4	6.6	6.3	6.1	6.1	9.2
22806-02	3.2	6.7	4.8	6.4	6.2	3.5	7.1	3.1	7.3	5.5	4.8	5.4
22807-07	4.8	5.1	4.7	7.1	5.1	4.5	5.4	7.0	4.7	8.5	7.1	5.6
22805-01	4.0	3.4	4.1	4.9	3.1	3.8	4.2	5.2	3.1	6.0	6.2	5.3
22804-04	5.4	6.1	5.7	7.4	6.0	8.0	7.1	8.0	6.7	7.0	9.9	8.3
22807-08	5.3	5.1	6.3	5.6	6.9	6.4	8.0	5.9	3.4	10.4	5.2	9.7
22808-05	4.9	3.9	4.8	5.1	4.6	5.9	5.2	5.3	7.3	7.0	3.7	8.5
22811-07	4.4	4.4	4.3	6.5	3.7	4.2	7.0	4.6	4.9	3.0	6.9	4.8
MEAN	4.3	5.2	5.1	5.5	5.5	5.6	5.7	5.8	5.9	6.1	6.5	7.0
S.D.	0.62	1.08	1.04	1.05	1.15	1.76	1.65	1.34	2.00	2.04	1.84	1.89
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: CORN OIL									
22801-04	5.1	2.3	6.8	7.4	5.6	5.2	7.4	8.4	123.3
22799-01	8.1	3.7	8.6	-2.1	14.3	-7.4	3.5	0.2	98.3
22800-06	6.2	3.9	3.1	4.7	4.2	5.2	0.9	5.2	103.1
22803-09	7.0	5.2	7.5	-0.9	4.5	5.1	3.9	4.5	100.1
22802-04	9.3	4.5	4.8	9.1	3.9	9.3	8.2	2.5	117.4
22800-04	6.3	7.1	4.4	5.6	4.9	4.7	4.4	2.2	104.7
22799-05	3.9	1.2	6.3	4.3	-0.5	6.5	-6.8	11.4	92.9
22803-04	5.1	4.9	6.9	5.9	13.1	-6.7	8.4	6.0	116.3
22806-02	-0.2	7.9	5.9	-0.5	8.9	4.6	-2.1	6.3	94.8
22807-07	6.1	7.4	3.5	9.5	4.3	5.2	4.9	0.2	110.7
22805-01	5.0	4.8	7.3	3.6	3.0	5.7	5.7	2.3	90.7
22804-04	1.8	12.7	2.6	11.7	-0.1	8.6	5.5	5.8	134.2
22807-08	-5.7	11.7	7.3	-0.9	-6.5	17.4	5.1	10.4	117.0
22808-05	4.3	3.3	14.8	-7.1	12.0	3.7	3.8	0.6	101.6
22811-07	3.4	0.6	5.8	3.1	8.6	-6.5	8.2	2.6	84.5
MEAN	4.4	5.4	6.4	3.6	5.3	4.0	4.1	4.6	106.0
S.D.	3.65	3.46	2.92	5.08	5.50	6.54	4.12	3.54	13.60
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: [redacted]60												
22801-06	2.8	4.3	4.5	4.7	4.2	3.8	6.0	7.7	2.5	0.5	11.5	7.9
22800-03	3.3	6.5	4.6	7.1	4.8	5.6	8.8	4.8	6.6	6.7	6.4	4.7
22803-07	2.6	5.2	4.0	4.5	5.0	7.0	2.1	4.5	8.0	5.6	6.8	8.8
22799-08	3.1	6.6	4.3	5.2	5.7	7.5	6.2	3.3	7.6	4.2	6.0	6.2
22802-02	3.5	5.4	4.3	3.9	4.6	4.8	4.7	7.1	6.1	4.6	6.7	7.1
22802-06	4.2	5.9	3.3	5.3	5.1	4.8	3.1	3.9	6.5	4.2	4.1	5.9
22801-03	3.4	5.8	5.6	5.6	6.5	7.2	5.4	4.7	7.6	4.3	4.8	5.3
22806-10	4.4	4.2	4.9	3.6	4.4	4.1	5.4	4.4	2.7	7.9	5.4	1.1
22804-09	3.9	5.0	5.4	5.7	5.0	4.2	8.7	6.3	4.8	1.3	11.5	5.8
22805-02	4.7	5.0	5.3	2.9	3.4	5.8	3.2	6.5	5.9	5.2	5.3	4.6
22807-01	5.4	5.0	5.3	5.5	4.0	1.0	8.5	12.0	1.3	3.6	5.6	5.9
22805-08	4.8	2.5	4.6	4.3	3.2	4.0	1.1	8.3	1.3	7.6	3.9	5.3
22806-01	5.7	2.8	6.0	6.1	4.0	4.8	6.8	5.2	7.0	5.6	5.9	2.0
22811-03	4.4	7.3	4.9	2.9	4.9	6.9	6.0	7.4	3.0	5.5	8.3	6.1
22808-06	2.8	4.5	5.0	5.3	4.2	4.2	7.4	3.8	4.2	7.2	4.5	1.4
MEAN	3.9	5.1	4.8	4.8	4.6	5.0	5.6	6.0	5.0	4.9	6.4	5.2
S.D.	0.96	1.31	0.68	1.18	0.85	1.70	2.38	2.28	2.34	2.10	2.34	2.22
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: [redacted]60									
22801-06	4.4	12.0	4.1	6.7	7.1	7.3	-3.1	-7.0	91.9
22800-03	5.4	4.4	9.0	7.2	1.2	1.7	7.0	1.4	107.2
22803-07	1.4	8.7	5.2	7.5	5.5	-1.0	3.7	10.4	105.5
22799-08	7.1	3.3	7.7	1.4	5.7	1.7	1.5	2.1	96.4
22802-02	2.4	5.8	8.1	8.7	0.6	7.5	1.0	5.8	102.7
22802-06	3.8	3.6	9.4	6.7	0.0	5.7	6.8	4.1	96.4
22801-03	3.9	11.5	-0.3	9.3	3.0	-3.0	13.2	5.2	109.0
22806-10	2.9	7.4	3.5	11.8	-8.2	8.2	5.0	4.1	87.2
22804-09	7.6	5.7	3.6	8.6	3.4	5.4	5.5	2.4	109.8
22805-02	2.8	3.0	10.1	-3.0	5.2	1.5	0.3	2.2	79.9
22807-01	5.4	9.4	7.5	2.2	10.0	3.0	1.9	4.3	106.8
22805-08	4.1	6.2	3.6	3.7	3.4	5.0	2.9	4.3	84.1
22806-01	6.9	3.2	5.3	3.2	3.1	5.7	0.7	8.8	98.8
22811-03	1.0	7.3	2.4	-3.4	6.3	0.1	6.5	1.9	89.7
22808-06	9.5	-1.3	8.9	0.6	7.1	-0.2	2.5	1.7	83.3
MEAN	4.6	6.0	5.9	4.7	3.6	3.2	3.7	3.4	96.6
S.D.	2.41	3.53	3.05	4.53	4.23	3.44	3.85	3.88	10.13
N	15	15	15	15	15	15	15	15	15

Revised Draft

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 5
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: [redacted]250												
22800-10	5.5	6.5	3.3	5.1	5.9	4.1	8.4	8.5	6.3	4.1	3.8	8.8
22801-07	3.1	5.3	3.3	5.4	4.6	5.8	4.4	6.8	6.4	2.9	7.6	8.0
22799-06	3.9	6.3	3.7	5.1	6.4	6.7	1.8	10.1	8.4	4.8	5.6	2.3
22803-05	3.9	4.3	4.5	3.4	5.6	3.7	5.7	5.4	8.1	2.4	4.4	5.6
22802-10	4.6	5.7	3.1	5.4	6.6	4.7	4.8	7.6	5.8	4.6	6.4	6.1
22799-02	4.5	5.0	4.3	5.1	6.5	5.6	4.6	6.0	8.0	5.3	6.8	6.0
22800-01	4.2	6.1	3.1	4.1	5.6	5.7	1.3	9.1	8.5	-0.7	2.4	9.5
22802-09	3.6	5.6	5.3	4.7	6.0	6.4	4.6	9.3	3.5	6.5	4.7	8.3
22805-03	6.1	4.5	5.3	3.3	6.1	3.4	5.3	4.8	2.5	6.8	7.6	7.0
22806-04	4.4	5.4	4.2	5.8	5.4	6.0	6.6	5.6	4.5	7.1	3.5	8.0
22804-10	3.6	5.4	4.6	3.0	6.2	3.9	6.8	7.5	5.2	7.2	4.7	6.4
22807-02	4.9	4.9	5.4	5.2	5.9	6.8	6.6	6.6	4.5	5.6	5.4	3.2
22805-06	3.6	5.1	4.6	4.2	4.1	4.2	5.3	3.4	4.4	4.8	7.1	2.8
22808-01	3.0	6.8	5.2	4.5	6.4	4.2	4.1	5.3	7.5	3.7	5.5	6.2
22811-08	4.1	4.1	5.0	3.2	5.8	6.5	5.9	4.2	3.6	6.5	6.6	2.6
MEAN	4.2	5.4	4.3	4.5	5.8	5.2	5.1	6.7	5.8	4.8	5.5	6.1
S.D.	0.85	0.79	0.84	0.92	0.69	1.19	1.83	1.98	1.97	2.12	1.56	2.36
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/30/2006

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: [redacted]250									
22800-10	10.6	5.4	-1.0	7.1	-1.1	9.4	5.7	2.8	109.2
22801-07	8.0	1.7	1.8	6.4	10.5	-0.8	4.2	7.5	102.9
22799-06	11.8	7.4	7.7	-4.4	10.2	3.1	11.3	-2.8	109.4
22803-05	11.5	-2.4	8.7	7.3	5.4	11.5	-0.9	4.3	102.4
22802-10	5.8	7.8	5.9	4.4	12.4	1.5	6.8	4.3	114.3
22799-02	4.9	1.7	4.7	7.1	4.7	3.6	4.1	10.0	108.5
22800-01	3.6	0.8	4.5	3.7	6.0	2.7	-0.5	6.6	86.3
22802-09	7.6	5.7	6.8	4.3	8.3	2.5	6.0	4.3	114.0
22805-03	9.9	-3.6	2.7	9.6	3.0	5.4	2.0	10.5	102.2
22806-04	3.3	8.9	5.3	5.5	3.4	8.3	7.8	-0.9	108.1
22804-10	4.2	8.4	4.7	13.2	-0.7	7.0	-3.6	13.6	111.3
22807-02	9.4	1.4	8.2	13.3	-3.9	7.9	-7.4	7.0	100.9
22805-06	7.1	3.4	5.9	2.8	6.8	1.7	8.0	2.1	91.4
22808-01	7.2	5.1	8.6	-1.8	6.7	1.3	2.4	8.1	100.0
22811-08	4.4	6.0	5.9	3.3	2.4	3.6	0.7	7.6	92.0
MEAN	7.3	3.8	5.4	5.5	4.9	4.6	3.1	5.7	103.5
S.D.	2.88	3.83	2.67	4.75	4.57	3.50	4.90	4.33	8.44
N	15	15	15	15	15	15	15	15	15

187056 RD

Revised Draft

Modified: 6/30/2006

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-011

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: [redacted]1000												
22801-08	3.4	4.4	4.5	4.7	4.3	4.3	4.8	6.7	4.4	6.8	1.3	6.8
22803-02	2.7	4.8	5.7	4.0	4.6	3.3	3.5	7.4	2.4	7.8	5.5	3.8
22799-10	3.6	5.0	5.1	5.8	3.7	0.3	2.4	8.6	13.2	1.7	1.4	3.3
22800-08	4.3	4.9	5.2	5.9	5.6	5.6	5.3	7.9	-5.0	16.0	7.7	5.4
22802-08	3.3	4.8	4.7	3.6	4.5	4.2	4.6	5.1	6.3	4.2	5.4	6.6
22802-01	2.7	5.7	5.6	4.0	5.8	3.0	6.1	4.9	14.7	-1.5	1.6	7.0
22801-10	4.2	2.7	5.0	3.0	5.2	2.2	2.8	6.7	-1.9	11.1	1.6	6.5
22806-07	2.7	4.5	4.5	5.2	4.4	8.5	1.0	5.3	4.1	4.8	5.6	3.5
22804-01	5.0	4.9	3.2	5.9	3.9	5.0	6.8	7.0	6.2	1.9	7.6	4.5
22805-10	4.5	4.7	5.2	4.8	5.4	4.2	5.9	8.3	4.6	6.7	5.8	6.0
22807-04	5.8	5.5	4.1	6.7	5.5	5.0	6.1	9.9	4.3	8.4	5.2	6.9
22804-06	5.2	4.8	5.5	4.4	4.7	6.6	5.9	6.7	4.9	7.5	2.9	5.6
22811-02	4.5	5.4	4.9	3.7	4.5	6.9	7.0	5.5	-0.8	10.5	15.1	6.7
22808-08	3.6	7.1	4.8	4.8	2.7	6.0	3.6	6.3	5.7	4.8	8.0	-1.5
22809-07	4.2	5.7	3.5	4.7	2.6	2.3	8.0	4.0	4.8	4.5	5.3	3.2
MEAN	4.0	5.0	4.8	4.7	4.5	4.5	4.9	6.7	4.5	6.3	5.3	5.0
S.D.	0.95	0.92	0.72	1.02	0.97	2.10	1.93	1.58	5.01	4.28	3.58	2.27
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-011

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: [redacted]1000									
22801-08	5.9	3.5	5.2	5.9	4.5	4.8	0.6	3.2	90.0
22803-02	4.0	7.4	9.1	0.3	-0.2	1.9	6.3	4.7	89.0
22799-10	5.2	3.0	6.0	6.1	6.9	2.9	5.3	-0.4	89.1
22800-08	1.2	10.4	6.4	7.2	3.3	1.6	2.7	7.5	109.1
22802-08	2.7	5.7	8.3	7.1	5.0	2.3	9.5	1.8	99.7
22802-01	3.7	5.6	6.6	1.7	10.2	0.6	9.0	1.6	98.6
22801-10	4.8	1.1	1.7	6.1	8.2	0.7	5.6	3.5	80.8
22806-07	4.1	3.8	4.6	2.2	2.2	-0.9	7.6	3.8	81.5
22804-01	5.5	4.6	4.3	6.1	3.1	1.8	4.8	6.6	98.7
22805-10	6.1	3.4	6.7	4.3	1.0	4.4	2.2	-3.2	91.0
22807-04	5.9	4.1	4.5	5.5	0.7	5.7	-0.2	4.3	103.9
22804-06	8.1	4.0	3.6	6.5	5.8	4.2	1.3	-0.1	98.1
22811-02	-6.8	3.1	8.6	0.6	8.7	-0.7	-0.1	9.8	97.1
22808-08	8.3	3.6	6.9	5.3	-0.7	7.7	-0.2	2.6	89.4
22809-07	6.1	3.8	4.2	2.6	7.7	4.4	0.6	1.5	83.7
MEAN	4.3	4.5	5.8	4.5	4.4	2.8	3.7	3.1	93.3
S.D.	3.59	2.17	2.04	2.37	3.45	2.42	3.42	3.27	8.25
N	15	15	15	15	15	15	15	15	15

Revised Draft

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 9
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: [redacted]60												
22801-02	3.9	4.0	6.3	4.4	5.6	2.8	8.8	5.2	6.8	6.7	4.2	7.6
22800-05	4.9	3.7	5.9	4.3	6.9	5.4	-0.8	9.0	7.0	7.9	6.7	3.9
22803-10	4.7	5.4	4.6	5.1	5.3	3.4	6.2	5.2	9.3	5.8	3.7	7.7
22799-07	3.1	6.3	3.2	5.9	3.7	7.0	3.3	4.2	9.5	6.4	6.1	4.8
22802-05	4.1	4.1	4.9	4.2	5.0	5.2	4.4	6.7	4.9	5.5	7.3	5.6
22800-09	2.6	3.9	5.2	4.8	3.7	5.5	5.2	6.6	6.0	3.7	2.7	4.2
22802-07	3.3	3.9	6.1	5.7	2.7	5.2	4.1	10.9	1.1	6.4	5.5	7.9
22806-09	4.3	5.1	6.0	3.6	3.9	6.7	3.2	5.5	2.6	5.7	8.5	5.3
22805-04	3.9	6.1	5.0	5.6	3.1	5.6	6.3	4.9	4.0	6.5	4.1	8.2
22804-05	4.0	4.4	3.2	5.4	5.8	5.2	4.3	8.6	7.0	6.0	7.3	-0.1
22807-03	4.4	5.2	5.8	7.3	7.5	2.9	6.6	9.1	3.5	6.9	13.2	3.2
22805-05	4.2	4.1	3.1	5.9	4.5	5.4	4.0	6.8	4.2	5.6	5.2	5.9
22804-07	3.4	5.4	5.9	5.0	5.3	5.0	4.7	7.8	6.6	4.6	6.5	4.0
22811-01	5.2	5.5	6.5	6.7	2.4	5.7	6.8	5.7	7.1	6.6	4.2	11.5
22808-03	4.6	6.1	6.4	4.8	3.6	4.6	8.5	4.8	5.8	8.0	6.3	4.1
MEAN	4.0	4.9	5.2	5.2	4.6	5.0	5.0	6.7	5.7	6.2	6.1	5.6
S.D.	0.71	0.91	1.20	0.98	1.49	1.21	2.36	1.96	2.33	1.11	2.53	2.73
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/30/2006

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: [redacted]60									
22801-02	5.6	6.1	5.0	7.6	3.2	1.8	9.7	5.9	111.2
22800-05	2.9	7.5	4.4	5.7	-2.5	7.8	7.9	0.3	98.8
22803-10	3.7	5.4	5.9	4.2	4.6	5.7	3.2	1.2	100.3
22799-07	2.6	11.6	4.1	5.4	2.5	6.8	3.4	4.1	104.0
22802-05	3.0	7.8	4.6	3.0	2.2	7.8	3.0	-1.6	91.7
22800-09	10.2	7.1	0.2	9.4	10.1	-4.2	1.8	12.7	101.4
22802-07	1.6	10.9	6.4	-2.1	8.6	8.4	-0.3	6.4	102.7
22806-09	5.6	2.5	6.1	1.9	1.2	5.5	1.3	5.1	89.6
22805-04	3.6	3.5	1.2	11.1	1.6	-2.8	8.9	1.1	91.5
22804-05	4.8	8.6	6.0	1.7	6.2	7.0	1.0	1.4	97.8
22807-03	7.7	4.8	9.0	9.9	0.9	6.3	9.1	-0.4	122.9
22805-05	2.8	6.2	3.7	9.0	1.1	7.5	-1.6	12.9	100.5
22804-07	7.8	6.4	2.8	11.7	1.4	5.8	2.4	1.4	103.9
22811-01	2.3	7.5	7.4	4.8	6.3	0.3	6.8	7.2	116.5
22808-03	4.3	7.1	4.7	2.7	2.9	0.9	7.3	5.3	102.8
MEAN	4.6	6.9	4.8	5.7	3.4	4.3	4.3	4.2	102.4
S.D.	2.42	2.41	2.26	3.98	3.28	4.06	3.69	4.40	9.03
N	15	15	15	15	15	15	15	15	15

187056 RD

Revised Draft

Modified: 6/30/2006

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 6: [redacted]250												
22801-09	3.9	4.7	4.7	6.7	4.4	7.6	2.3	6.0	8.0	3.2	7.1	4.3
22800-07	3.2	4.2	5.2	4.1	4.6	4.6	3.0	7.8	3.6	6.7	4.8	5.8
22803-06	4.5	4.4	5.5	3.7	5.6	4.9	4.8	6.4	5.7	3.9	6.1	4.3
22799-04	3.9	5.1	4.6	5.6	6.1	4.7	4.0	7.4	4.5	3.9	5.5	1.1
22802-11	4.3	5.5	5.2	4.9	5.5	5.8	4.3	8.6	7.7	5.8	7.8	4.9
22801-05	4.9	4.4	5.3	5.2	5.5	4.4	4.6	5.7	5.6	3.2	5.8	0.9
22803-03	4.6	5.4	5.7	5.0	5.3	4.8	5.6	7.5	5.8	4.3	3.4	5.9
22806-05	4.6	6.0	3.4	5.9	3.8	8.2	1.4	6.8	5.2	6.3	7.5	3.1
22804-03	3.7	5.3	3.7	5.0	6.1	4.6	5.1	7.0	4.5	3.8	6.6	1.2
22805-09	4.8	4.9	5.2	5.1	3.8	6.3	5.3	6.8	4.6	6.6	4.5	3.7
22807-05	4.4	5.7	5.7	6.8	4.4	10.8	4.6	8.3	5.2	8.4	8.6	3.0
22804-02	6.1	5.0	4.9	8.0	4.1	8.1	6.7	5.7	7.9	6.1	7.8	4.9
22806-08	3.7	5.4	4.3	6.5	2.9	4.3	5.3	7.2	4.8	3.9	5.8	4.6
22810-03	4.5	6.3	7.7	4.1	6.3	6.0	5.6	6.9	6.4	6.5	5.8	7.8
22811-06	2.9	4.5	6.0	1.9	6.1	4.3	4.5	7.7	3.9	6.8	6.9	6.9
MEAN	4.3	5.1	5.1	5.2	5.0	6.0	4.5	7.1	5.6	5.3	6.3	4.2
S.D.	0.77	0.62	1.02	1.48	1.04	1.92	1.36	0.87	1.40	1.62	1.40	2.06
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Draft

Modified: 6/30/2006

TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 6: [redacted]250									
22801-09	4.1	4.8	0.6	7.0	4.9	0.6	-1.8	5.7	88.8
22800-07	8.0	2.7	4.6	8.0	11.2	-7.7	10.0	4.3	98.7
22803-06	6.8	2.9	6.3	5.8	9.1	-1.4	1.3	11.0	101.6
22799-04	7.6	5.2	2.7	1.9	4.3	3.9	6.7	-3.1	85.6
22802-11	3.1	6.0	0.9	11.6	3.7	0.5	6.9	2.2	105.2
22801-05	5.8	4.5	1.5	4.0	3.2	1.9	1.8	3.8	82.0
22803-03	4.7								
22806-05	7.4	-2.2	5.9	5.1	4.4	3.9	1.6	-0.7	87.6
22804-03	4.7	6.8	9.7	3.6	6.8	4.3	0.4	12.3	105.2
22805-09	6.3	2.8	5.3	1.4	5.0	2.5	2.8	-3.1	84.6
22807-05	11.6	5.1	5.4	6.0	2.9	0.9	8.5	5.9	122.2
22804-02	8.3	7.2	4.7	10.6	2.4	2.3	4.3	5.2	120.3
22806-08	5.5	4.0	5.3	4.5	0.4	2.9	9.6	-0.1	90.8
22810-03	-0.5	9.6	6.1	3.8	8.2	2.3	-2.4	12.0	113.0
22811-06	2.9	7.9	6.6	2.9	8.3	8.8	5.9	2.4	108.1
MEAN	5.8	4.8	4.7	5.4	5.3	1.8	4.0	4.1	99.6
S.D.	2.84	2.85	2.50	3.02	2.99	3.62	4.06	5.08	13.38
N	15	14	14	14	14	14	14	14	14

187056 RD

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TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 7: [redacted]1000												
22801-01	4.4	0.5	-2.7									
22799-09	-3.8	-2.9	NA									
22803-01	-0.3	2.9	6.2									
22800-02	2.9	-3.3	NA									
22802-03	-1.9	NA										
22803-08	4.2	-4.5	-3.8									
22799-03	-1.1	-3.9	-0.8									
22806-03	1.6	-1.8										
22805-07	1.1	-1.6										
22804-08	4.4	-1.0										
22807-10	-2.4	-5.4										
22807-06	-0.2	-5.3										
22811-04	2.1											
22808-02	-3.5											
22809-01	-1.3											
22810-01	-0.6											
MEAN	0.4	-2.4	-0.3									
S.D.	2.71	2.54	4.49									
N	16	11	4									

NA = NOT APPLICABLE

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TABLE 18

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 14
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 7: [redacted]1000									

NO DATA FOR THESE INTERVALS

PJTBWv4.22
06/07/2006

Revised Draft

Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-011

GROUP: CORN OIL SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22801-04	31	108.4	N	N	N	N	N	N	Y					
22799-01	33	115.3	N	N	N	N	N	N	N	N	Y			
22800-06	32	101.4	N	N	N	N	N	N	N	Y				
22803-09	32	98.7	N	N	N	N	N	N	N	Y				
22802-04	35	114.5	N	N	N	N	N	N	N	N	N	N	Y	
22800-04	35	116.5	N	N	N	N	N	N	N	N	N	N	Y	
22799-05	32	104.8	N	N	N	N	N	N	N	Y				
22803-04	33	121.3	N	N	N	N	N	N	N	N	Y			
22806-02	35	108.3	N	N	N	N	N	N	N	N	N	N	Y	
22807-07	34	119.6	N	N	N	N	N	N	N	N	N	Y		
22805-01	33	102.1	N	N	N	N	N	N	N	N	Y			
22804-04	30	108.0	N	N	N	N	N	Y						
22807-08	30	108.9	N	N	N	N	N	Y						
22808-05	35	124.6	N	N	N	N	N	N	N	N	N	N	Y	
22811-07	30	93.4	N	N	N	N	N	Y						
MEAN	32.7	109.7												
S.D.	1.88	8.86												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Draft

Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-011

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22801-06	28	80.4	N	N	N	Y								
22800-03	28	85.5	N	N	N	Y								
22803-07	32	98.2	N	N	N	N	N	N	N	Y				
22799-08	31	97.3	N	N	N	N	N	N	Y					
22802-02	34	102.6	N	N	N	N	N	N	N	N	N	Y		
22802-06	34	100.0	N	N	N	N	N	N	N	N	N	Y		
22801-03	28	88.1	N	N	N	Y								
22806-10	31	85.5	N	N	N	N	N	N	Y					
22804-09	29	88.4	N	N	N	N	Y							
22805-02	34	106.6	N	N	N	N	N	N	N	N	N	Y		
22807-01	33	117.3	N	N	N	N	N	N	N	N	Y			
22805-08	36	111.3	N	N	N	N	N	N	N	N	N	N	N	Y
22806-01	33	106.5	N	N	N	N	N	N	N	N	Y			
22811-03	34	119.6	N	N	N	N	N	N	N	N	N	Y		
22808-06	30	90.5	N	N	N	N	N	Y						
MEAN	31.7	98.5												
S.D.	2.61	12.11												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

Revised Draft

Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22800-10	27	83.1	N	N	Y									
22801-07	26	69.5	N	Y										
22799-06	27	72.5	N	N	Y									
22803-05	27	67.2	N	N	Y									
22802-10	26	57.9	N	Y										
22799-02	27	68.9	N	N	Y									
22800-01	27	74.7	N	N	Y									
22802-09	27	66.4	N	N	Y									
22805-03	27	71.8	N	N	Y									
22806-04	28	80.2	N	N	N	Y								
22804-10	25	65.1	Y											
22807-02	27	88.5	N	N	Y									
22805-06	27	73.9	N	N	Y									
22808-01	27	80.0	N	N	Y									
22811-08	29	88.1	N	N	N	N	Y							
MEAN	26.9	73.9												
S.D.	0.88	8.71												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-011

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22801-08	26	72.8	N	Y										
22803-02	26	69.1	N	Y										
22799-10	26	69.1	N	Y										
22800-08	26	67.1	N	Y										
22802-08	26	61.8	N	Y										
22802-01	26	59.7	N	Y										
22801-10	26	70.6	N	Y										
22806-07	27	70.4	N	N	Y									
22804-01	29	83.1	N	N	N	N	Y							
22805-10	25	68.6	Y											
22807-04	27	90.2	N	N	Y									
22804-06	27	77.3	N	N	Y									
22811-02	27	80.2	N	N	Y									
22808-08	26	71.7	N	Y										
22809-07	27	66.8	N	N	Y									
MEAN	26.5	71.9												
S.D.	0.92	7.97												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-011

GROUP: [redacted]60 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22801-02	28	83.8	N	N	N	Y								
22800-05	28	83.5	N	N	N	Y								
22803-10	28	80.5	N	N	N	Y								
22799-07	27	68.9	N	N	Y									
22802-05	28	72.8	N	N	N	Y								
22800-09	27	71.1	N	N	Y									
22802-07	31	90.7	N	N	N	N	N	N	Y					
22806-09	27	65.2	N	N	Y									
22805-04	28	79.8	N	N	N	Y								
22804-05	25	68.4	Y											
22807-03	27	86.7	N	N	Y									
22805-05	26	68.8	N	Y										
22804-07	27	74.9	N	N	Y									
22811-01	29	93.7	N	N	N	N	Y							
22808-03	27	78.1	N	N	Y									
MEAN	27.5	77.8												
S.D.	1.36	8.72												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-011

GROUP: [redacted]250 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22801-09	26	80.4	N	Y										
22800-07	26	70.5	N	Y										
22803-06	26	66.7	N	Y										
22799-04	27	71.7	N	N	Y									
22802-11	27	70.8	N	N	Y									
22801-05	27	74.0	N	N	Y									
22803-03	27	77.8	N	N	Y									
22806-05	27	68.5	N	N	Y									
22804-03	25	62.0	Y											
22805-09	28	82.1	N	N	N	Y								
22807-05	26	83.3	N	Y										
22804-02	27	86.7	N	N	Y									
22806-08	27	63.7	N	N	Y									
22810-03	26	83.7	N	Y										
22811-06	26	69.2	N	Y										
MEAN	26.5	74.1												
S.D.	0.74	7.78												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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Modified: 6/30/2006

TABLE 19

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-011

GROUP: [redacted]1000 SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 25	26	27	28	29	30	31	32	33	34	35	36
22801-01	RESPONSE NOT EXHIBITED BY DAY 25, DAY OF DEATH													
22803-01	RESPONSE NOT EXHIBITED BY DAY 25, DAY OF DEATH													
22803-08	RESPONSE NOT EXHIBITED BY DAY 25, DAY OF DEATH													
22799-03	RESPONSE NOT EXHIBITED BY DAY 25, DAY OF DEATH													
MEAN		NA	NA											
S.D.														
N														

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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05/25/2006
R:05/30/2006

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Modified: 6/30/2006

TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 1: CORN OIL

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
22801-04	N N N N N E D D D P E D D D D D D	5.0
22799-01	N N N N N N N E D D D E E D D D E	5.0
22800-06	N N N N N N D D D D E E D D D E D	4.0
22803-09	N N N N N N D D D E D D D E D D P	4.0
22802-04	N N N N N N N N N E D D D D D D D	A
22800-04	N N N N N N N N N D D D P E D D P	A
22799-05	N N N N N N D D D P E D D D P P D	5.0
22803-04	N N N N N N N D P E D D D P E D D	5.0
22806-02	N N N N N N N N N N E D D D D P E D	6.0
22807-07	N N N N N N N N N P D D D P E E D D	6.0
22805-01	N N N N N N N N N E D D D D E D D E	5.0
22804-04	N N N N N E D D D P E D D D E E D D	5.0
22807-08	N N N N N E D D D E E D D P E D D P	4.5
22808-05	N N N N N N N N N N N D D P E D D D E	A
22811-07	N N N N N N D P E D D P E D D P E D D	4.0
	MEAN	4.9
	S.D.	0.68
	N	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

Revised Draft

TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-011

FEMALES FROM GROUP 2: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
22801-06	N N D D E D D D D D D D D D D D D	A
22800-03	N N D D E D D D D E D D D E E D D	5.0
22803-07	N N N N N N E D D D E E D D D E D	4.5
22799-08	N N N N N P E D D D P E D D D E E	5.0
22802-02	N N N N N N N N E D D D E E D D I	5.0
22802-06	N N N N N N N N E D D D P E D D D	5.0
22801-03	N N P E D D D P E D D D E E D D P	5.0
22806-10	N N N N N N D P E D D D D E E D D D	6.0
22804-09	N N N N D E D D D P E D D D P E D D	5.0
22805-02	N N N N N N N N N E D D D D E E D D	6.0
22807-01	N N N N N N N N E D D D D P E D D D	6.0
22805-08	N N N N N N N N N N E D D D D P E	A
22806-01	N N N N N N N N E D D D P E D D P E	5.0
22811-03	N N N N N N N N N N D D D P E D D D E	A
22808-06	N N N N N N P E D N D P E D D D P E D	5.0
	MEAN	5.2
	S.D.	0.50
	N	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE: CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED, I = INSUFFICIENT CELLS PRESENT

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TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-011

FEMALES FROM GROUP 3: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
22800-10	N D D D E E D D D D P E D D D E E	6.0
22801-07	E E E E E D D D D P E D D D E E D	5.5
22799-06	N D D D D D D P E D D D P E D D D	5.0
22803-05	N D D E D D E E D D D D E E D D D	5.0
22802-10	D D D D P E E E D D D P E D D D P	5.0
22799-02	N D D D P E E D D D P E P D D D P	6.0
22800-01	N E E E D D D D P E E D D D E E D	6.0
22802-09	N E D D E E D D D P E D D D E E D	4.7
22805-03	N N D D D D P E E D D D D P E E D D	7.0
22806-04	N N N E D D P P E E E E D D D D P E	8.0
22804-10	E D E E E E D P D P E D D P P E D D	3.8
22807-02	N N E D P E E D D D P E D D D P E D	4.7
22805-06	N N E E E D D D D D P E E D D D P E D	6.0
22808-01	N N N D D E E E E D D D D P E E D D D	7.0
22811-08	N N N N N E D D D D E E D D D D E E D	6.0
	MEAN	5.7
	S.D.	1.09
	N	15

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
N = NOT ENTERED

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TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-011

FEMALES FROM GROUP 4: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
22801-08	E E E E E E D E E E D D D D D D D	4.0
22803-02	E E E E P E E E E E E E E E D D D	A
22799-10	D E E E E E E D D D D E D D D P E	5.0
22800-08	E E E E E D D D P P D D D D D E D	5.5
22802-08	E E E E E E E P D D D D D D E D P	7.0
22802-01	E E E E E E D E E E E E D P D P E D	3.3
22801-10	E E E E E E P P P E E E E E P D D	A
22806-07	N N E E E E E E E E E E E E E E E E	A
22804-01	N N N N D E E E E E E E E E E E E E	A
22805-10	D E E E E E E D D D D P E D D D D D D	6.0
22807-04	N N E E E E E E D P D E E D D D P E D	3.3
22804-06	N N E E E E E D D E D E E E E E E E E	3.0
22811-02	N N N E E E E E E E E D D D D D E D D D	6.0
22808-08	N N E E E E E E E D P D D D E D D D P E	3.0
22809-07	N N N E E E E E E E E E E E E E E E E	A
	MEAN	4.6
	S.D.	1.47
	N	10

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

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Modified: 6/30/2006

TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-011

FEMALES FROM GROUP 5: [redacted]60

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
22801-02	N N E E E D D D P E D D D P E D D	5.0
22800-05	N N E E D D D P E D D D P E D D P	5.0
22803-10	N N D D D D E E D D D D P E D D D	6.0
22799-07	N D D D D D D E E D D D D E E D D	6.0
22802-05	N N D D D P E E D D D I D D E D D	A
22800-09	N D D E E D D D D P E D D D P E D	5.5
22802-07	N N N N N D D D P E D D D D E D D	5.0
22806-09	N N D D D D P E E D D D D P E D D D	6.0
22805-04	N N N D E E D D D P E D D D D E D D	5.0
22804-05	E D D D E E D D D E D D D E D D D E	4.3
22807-03	N N E D D D P D P E D D D P E D D E	4.0
22805-05	N D E E E E D D D P E D D D D D E D	5.5
22804-07	N N D D D P E E D D D P E D D D E D	4.5
22811-01	N N N N N P E D D D P E D D D P E D D	5.0
22808-03	N N N D P E E D D D P E D D D P E D D	5.0
	MEAN	5.1
	S.D.	0.62
	N	14

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED, I = INSUFFICIENT CELLS PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-011

FEMALES FROM GROUP 6: [redacted]250

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
22801-09	E D D E E E P E E D E D D D E E D	5.0
22800-07	E E E E E E P E E D D D D E E D D	6.0
22803-06	E E D E E E E E P E E E E E D E D	7.0
22799-04	N D D D E D D D D D D D D D D E D	11.0
22802-11	N E E E E D D E E E P E E D P P D	5.5
22801-05	N E E P E E E E E E P P E E D D D	A
22803-03	N D D D E E E E E D	A
22806-05	N N E E E E D E E E E D E D E D D E	3.0
22804-03	E E E D D D E E D D D D D E D D D P	5.5
22805-09	N N N D D D P D D D D D E D D D D P	6.0
22807-05	N D E E E D E E E E D D D D D E E E	4.0
22804-02	N N E E E E D D D D E D D D P E D D	5.0
22806-08	N N D E E D D P E E D D D D E E D D	5.5
22810-03	N N E E E E E E E E E D D E E E D E E E	5.0
22811-06	N N E E E E D D D D D D D E D D D D E	8.0
	MEAN	5.9
	S.D.	1.97
	N	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
N = NOT ENTERED

Revised Draft

Modified: 6/30/2006

TABLE 20

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-011

FEMALES FROM GROUP 7: [redacted]1000

FEMALE NUMBER	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)

THERE WERE NO FEMALES IN THIS GROUP SURVIVING TO ESTROUS CYCLE DETERMINATIONS; NONE ATTAINED VAGINAL PATENCY PRIOR TO DEATH/EUTHANASIA.

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS

PCYCv5.23
05/25/2006
R:06/07/2006

Revised Draft

TABLE 21

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-011

ANIMAL	TSH	TOTAL T4	ESTRA-DIOL	LUTEIN' HORMONE
	ng/mL	ug/dL	pg/mL	ng/mL
GROUP:	CORN OIL	FEMALES		
22801-04	8.2	4.70	104.00	2.7
22799-01	10.3	5.40	210.00	2.2
22800-06	8.5	5.00	116.00	4.0
22803-09	10.7	4.20	178.00	3.6
22802-04	10.6	7.80	128.00	3.3
22800-04	8.4	5.50	170.00	2.9
22799-05	8.8	5.60	134.00	1.8
22803-04	8.0	5.90	152.00	2.9
22806-02	7.2	2.50	164.00	5.6
22807-07	7.7	5.70	217.00	2.2
22805-01	13.1	5.10	150.00	2.7
22804-04	13.8	3.20	141.00	1.7
22807-08	9.1	5.60	156.00	4.1
22808-05	9.2	4.50	177.00	5.7
22811-07	6.7	5.40	128.00	3.7
MEAN	9.4	5.07	155.00	3.3
S.D.	2.03	1.220	32.116	1.22
N	15	15	15	15

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

TABLE 21

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-011

ANIMAL	TSH	TOTAL T4	ESTRA-DIOL	LUTEIN' HORMONE
	ng/mL	ug/dL	pg/mL	ng/mL
GROUP: [redacted]60	FEMALES			
22801-06	11.4	4.80	218.00	4.1
22800-03	8.1	3.50	161.00	3.2
22803-07	9.5	4.30	138.00	2.1
22799-08	10.8	6.50	104.00	4.3
22802-02	9.9	7.50	123.00	2.0
22802-06	12.2	4.70	155.00	5.3
22801-03	10.4	6.80	230.00	3.2
22806-10	10.3	6.90	173.00	3.7
22804-09	7.7	6.60	191.00	2.5
22805-02	8.0	3.80	132.00	3.0
22807-01	7.2	4.50	147.00	4.3
22805-08	15.7	5.80	176.00	RU
22806-01	6.4	6.00	142.00	6.4
22811-03	6.3	6.20	182.00	4.0
22808-06	7.3	4.40	150.00	3.0
MEAN	9.4	5.49	161.47	3.7
S.D.	2.53	1.264	34.324	1.21
N	15	15	15	14

RU = RESULT UNOBTAINABLE

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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Modified: 6/30/2006

TABLE 21

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-011

ANIMAL	TSH	TOTAL T4	ESTRA-DIOL	LUTEIN' HORMONE
	ng/mL	ug/dL	pg/mL	ng/mL
GROUP: [redacted]250		FEMALES		
22800-10	8.4	4.30	199.00	2.6
22801-07	9.8	3.70	139.00	2.9
22799-06	9.8	4.70	125.00	1.9
22803-05	10.1	3.50	118.00	2.9
22802-10	11.4	7.20	87.40	5.2
22799-02	15.7	6.70	155.00	11.1
22800-01	6.9	4.90	164.00	4.4
22802-09	10.3	6.40	134.00	2.5
22805-03	6.1	4.30	143.00	4.6
22806-04	6.4	7.00	204.00	3.7
22804-10	6.9	4.60	127.00	2.9
22807-02	7.6	5.50	179.00	4.4
22805-06	9.8	4.60	156.00	2.8
22808-01	8.3	5.50	167.00	2.3
22811-08	11.4	3.30	116.00	2.0
MEAN	9.3	5.08	147.56	3.7
S.D.	2.49	1.263	31.952	2.27
N	15	15	15	15

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Draft

Modified: 6/30/2006

TABLE 21

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-011

ANIMAL	TSH	TOTAL T4	ESTRA-DIOL	LUTEIN' HORMONE
	ng/mL	ug/dL	pg/mL	ng/mL
GROUP: [redacted]1000	FEMALES			
22801-08	11.5	2.80	153.00	1.2
22803-02	8.7	3.80	82.10	1.8
22799-10	8.5	5.70	140.00	1.6
22800-08	8.6	5.90	116.00	1.8
22802-08	8.8	4.90	128.00	2.6
22802-01	7.7	5.70	101.00	2.0
22801-10	8.4	4.10	159.00	9.0
22806-07	6.3	3.90	175.00	6.7
22804-01	10.9	5.50	117.00	3.9
22805-10	7.0	5.20	157.00	3.3
22807-04	12.7	4.80	168.00	2.6
22804-06	7.3	5.70	131.00	3.6
22811-02	8.1	4.90	102.00	4.1
22808-08	6.9	5.40	104.00	2.5
22809-07	7.3	5.50	177.00	3.2
MEAN	8.6	4.92	134.01	3.3
S.D.	1.81	0.896	30.002	2.07
N	15	15	15	15

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-011

ANIMAL	TSH	TOTAL T4	ESTRA-DIOL	LUTEIN' HORMONE
	ng/mL	ug/dL	pg/mL	ng/mL
GROUP: [redacted]60		FEMALES		
22801-02	8.5	3.10	97.20	2.6
22800-05	8.1	4.60	144.00	1.6
22803-10	9.1	4.90	208.00	3.2
22799-07	10.5	4.60	132.00	3.0
22802-05	7.7	3.60	140.00	1.7
22800-09	6.9	4.50	144.00	2.7
22802-07	9.1	4.10	140.00	2.1
22806-09	6.4	5.00	151.00	3.0
22805-04	7.1	4.20	153.00	2.2
22804-05	5.9	4.00	9.30	5.7
22807-03	14.1	5.00	183.00	3.2
22805-05	6.9	4.40	155.00	1.0
22804-07	6.7	5.40	138.00	3.1
22811-01	7.9	5.90	137.00	1.9
22808-03	8.0	4.70	157.00	2.1
MEAN	8.2	4.53	139.23	2.6
S.D.	2.03	0.695	43.335	1.08
N	15	15	15	15

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 6
SPONSOR: [redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-011

ANIMAL	TSH	TOTAL T4	ESTRA-DIOL	LUTEIN' HORMONE
	ng/mL	ug/dL	pg/mL	ng/mL
GROUP: [redacted]250	FEMALES			
22801-09	11.5	1.70	13.80	3.8
22800-07	8.6	4.50	140.00	1.7
22803-06	8.6	3.60	142.00	2.3
22799-04	11.8	2.80	112.00	3.8
22802-11	15.7	4.50	145.00	1.9
22801-05	8.0	4.30	114.00	3.1
22806-05	7.2	3.70	127.00	2.2
22804-03	12.2	3.90	102.00	4.6
22805-09	9.4	4.60	154.00	8.7
22807-05	14.9	3.00	17.50	4.6
22804-02	7.7	4.10	148.00	2.7
22806-08	7.3	4.30	140.00	2.5
22810-03	10.2	3.90	145.00	3.0
22811-06	16.9	6.50	156.00	1.7
MEAN	10.7	3.96	118.31	3.3
S.D.	3.23	1.084	46.399	1.83
N	14	14	14	14

ug/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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05/31/2006
R:05/31/2006

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22803-03 GROUP 6: [redacted]250 FEMALE FOUND DEAD 04/10/06 DATE OF DEATH: 04/10/06

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-09 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 03/31/06 DATE OF DEATH: 03/31/06

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-02 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 03/31/06 DATE OF DEATH: 03/31/06

			GRADE		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
		HEART	INTESTINE	KIDNEYS	LIVER
		LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
		OVARIES	PANCREAS	PITUITARY	SPINAL CORD
		SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
		THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
		UTERUS	CERVIX	VAGINA	LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 4
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22802-03 GROUP 7: [redacted]1000 FEMALE FOUND DEAD 03/30/06 DATE OF DEATH: 03/30/06

			GRADE
SKIN	GROSS: MATTING, YELLOW		P
	UROGENITAL		
NO SIGNIFICANT CHANGES OBSERVED	GROSS:		

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPINAL CORD
SAL. GLAND MAND	SPLEEN	STOMACH	THYMUS
THYROID GLANDS	TRACHEA	URINARY BLADDER	UTERUS
CERVIX	VAGINA	LYMPH NODE, AXIL	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.54
06/07/2006

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22801-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2337	0.130	
UTERUS- BLOTTED	0.2112	0.117	
LIVER	10.5891	5.883	
KIDNEYS	1.6864	0.937	
SPLEEN	0.5322	0.296	
OVARIES/OVIDUCTS	0.0899	0.050	
THYMUS	0.7779	0.432	
ADRENAL GLANDS	0.0416	0.023	
PITUITARY	0.0102	0.006	
THYROIDS/PARA	0.0180	0.010	
FINAL BODY WT(G)	180.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5520	0.368	
UTERUS- BLOTTED	0.3962	0.264	
LIVER	6.8915	4.594	
KIDNEYS	1.3660	0.911	
SPLEEN	0.3945	0.263	
OVARIES/OVIDUCTS	0.0684	0.046	
THYMUS	0.7873	0.525	
ADRENAL GLANDS	0.0383	0.026	
PITUITARY	0.0084	0.006	
THYROIDS/PARA	0.0169	0.011	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-06 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2046	0.134	
UTERUS- BLOTTED	0.1885	0.123	
LIVER	7.3052	4.775	
KIDNEYS	1.6735	1.094	
SPLEEN	0.3364	0.220	
OVARIES/OVIDUCTS	0.0779	0.051	
THYMUS	0.6124	0.400	
ADRENAL GLANDS	0.0304	0.020	
PITUITARY	0.0067	0.004	
THYROIDS/PARA	0.0191	0.012	
FINAL BODY WT(G)	153.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22803-09 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4112	0.276
UTERUS- BLOTTED	0.3308	0.222
LIVER	7.8932	5.297
KIDNEYS	1.5714	1.055
SPLEEN	0.4464	0.300
OVARIES/OVIDUCTS	0.0821	0.055
THYMUS	0.5205	0.349
ADRENAL GLANDS	0.0348	0.023
PITUITARY	0.0091	0.006
THYROIDS/PARA	0.0124	0.008
FINAL BODY WT(G)	149.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2320	0.145		
UTERUS- BLOTTED	0.2103	0.131		
LIVER	10.4901	6.556		
KIDNEYS	1.9001	1.188		
SPLEEN	0.5394	0.337		
OVARIES/OVIDUCTS	0.0814	0.051		
THYMUS	0.6192	0.387		
ADRENAL GLANDS	0.0368	0.023		
PITUITARY	0.0122	0.008		
THYROIDS/PARA	0.0146	0.009		
FINAL BODY WT(G)	160.			

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.6545	0.439	
UTERUS- BLOTTED	0.4833	0.324	
LIVER	7.4390	4.993	
KIDNEYS	1.5594	1.047	
SPLEEN	0.5019	0.337	
OVARIES/OVIDUCTS	0.0811	0.054	
THYMUS	0.5870	0.394	
ADRENAL GLANDS	0.0444	0.030	
PITUITARY	0.0105	0.007	
THYROIDS/PARA	0.0148	0.010	
FINAL BODY WT(G)	149.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 7
SPONSOR: [redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-05 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2593	0.180		
UTERUS- BLOTTED	0.2377	0.165		
LIVER	7.0779	4.915		
KIDNEYS	1.6258	1.129		
SPLEEN	0.4444	0.309		
OVARIES/OVIDUCTS	0.0919	0.064		
THYMUS	0.6739	0.468		
ADRENAL GLANDS	0.0409	0.028		
PITUITARY	0.0094	0.007		
THYROIDS/PARA	0.0194	0.013		
FINAL BODY WT(G)	144.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 8

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22803-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3375	0.197	NO SIGNIFICANT
UTERUS- BLOTTED	0.3076	0.180	CHANGES OBSERVED
LIVER	9.6839	5.663	
KIDNEYS	1.6599	0.971	
SPLEEN	0.5814	0.340	
OVARIES/OVIDUCTS	0.0817	0.048	
THYMUS	0.5248	0.307	
ADRENAL GLANDS	0.0413	0.024	
PITUITARY	0.0082	0.005	
THYROIDS/PARA	0.0160	0.009	
FINAL BODY WT(G)	171.		

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22806-02 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2130	0.155
UTERUS- BLOTTED	0.1932	0.141
LIVER	7.0444	5.142
KIDNEYS	1.5259	1.114
SPLEEN	0.3401	0.248
OVARIES/OVIDUCTS	0.0763	0.056
THYMUS	0.6494	0.474
ADRENAL GLANDS	0.0328	0.024
PITUITARY	0.0073	0.005
THYROIDS/PARA	0.0115	0.008
FINAL BODY WT(G)	137.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22807-07 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2170	0.134	GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.1960	0.121		OVARIES	PANCREAS	PITUITARY	SPLEEN
LIVER	8.7588	5.407		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.5908	0.982		VAGINA	LYMPH NODE, AXIL		
SPLEEN	0.4253	0.263					
OVARIES/OVIDUCTS	0.0710	0.044					
THYMUS	0.6764	0.418					
ADRENAL GLANDS	0.0330	0.020					
PITUITARY	0.0082	0.005					
THYROIDS/PARA	0.0179	0.011					
FINAL BODY WT(G)	162.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22805-01 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.6509	0.455		
UTERUS- BLOTTED	0.3873	0.271		
LIVER	7.2350	5.059		
KIDNEYS	1.4115	0.987		
SPLEEN	0.3347	0.234		
OVARIES/OVIDUCTS	0.0762	0.053		
THYMUS	0.4878	0.341		
ADRENAL GLANDS	0.0378	0.026		
PITUITARY	0.0079	0.006		
THYROIDS/PARA	0.0136	0.010		
FINAL BODY WT(G)	143.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22804-04 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3475	0.182	
UTERUS- BLOTTED	0.3282	0.172	
LIVER	10.5373	5.517	
KIDNEYS	1.8488	0.968	
SPLEEN	0.6120	0.320	
OVARIES/OVIDUCTS	0.0772	0.040	
THYMUS	0.5241	0.274	
ADRENAL GLANDS	0.0367	0.019	
PITUITARY	0.0104	0.005	
THYROIDS/PARA	0.0077	0.004	
FINAL BODY WT(G)	191.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 13

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22807-08 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.8840	0.505		
UTERUS- BLOTTED	0.4830	0.276		
LIVER	9.3358	5.335		
KIDNEYS	1.7935	1.025		
SPLEEN	0.4276	0.244		
OVARIES/OVIDUCTS	0.0791	0.045		
THYMUS	0.6152	0.352		
ADRENAL GLANDS	0.0517	0.030		
PITUITARY	0.0094	0.005		
THYROIDS/PARA	0.0174	0.010		
FINAL BODY WT(G)	175.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22808-05 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.5751	0.369		
UTERUS- BLOTTED	0.3862	0.248		
LIVER	7.7421	4.963		
KIDNEYS	1.3735	0.880		
SPLEEN	0.4065	0.261		
OVARIES/OVIDUCTS	0.0770	0.049		
THYMUS	0.5386	0.345		
ADRENAL GLANDS	0.0431	0.028		
PITUITARY	0.0095	0.006		
THYROIDS/PARA	0.0129	0.008		
FINAL BODY WT(G)	156.			

GROSS:				
	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22811-07 GROUP 1: CORN OIL FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2629	0.189	GROSS:	
UTERUS- BLOTTED	0.2388	0.172		
LIVER	6.5107	4.684		
KIDNEYS	1.4780	1.063		
SPLEEN	0.3229	0.232		
OVARIES/OVIDUCTS	0.0679	0.049		
THYMUS	0.6055	0.436		
ADRENAL GLANDS	0.0391	0.028		
PITUITARY	0.0091	0.007		
THYROIDS/PARA	0.0121	0.009		
FINAL BODY WT(G)	139.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22801-06 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4271	0.289	
UTERUS- BLOTTED	0.3995	0.270	
LIVER	8.8807	6.000	
KIDNEYS	1.7544	1.185	
SPLEEN	0.4315	0.292	
OVARIES/OVIDUCTS	0.0972	0.066	
THYMUS	0.5503	0.372	
ADRENAL GLANDS	0.0477	0.032	
PITUITARY	0.0090	0.006	
THYROIDS/PARA	0.0134	0.009	
FINAL BODY WT(G)	148.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-03 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2872	0.178	
UTERUS- BLOTTED	0.2632	0.163	
LIVER	9.2161	5.724	
KIDNEYS	1.6124	1.001	
SPLEEN	0.4728	0.294	
OVARIES/OVIDUCTS	0.0914	0.057	
THYMUS	0.7722	0.480	
ADRENAL GLANDS	0.0350	0.022	
PITUITARY	0.0104	0.006	
THYROIDS/PARA	0.0179	0.011	
FINAL BODY WT(G)	161.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22803-07 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3036	0.197	
UTERUS- BLOTTED	0.2755	0.179	
LIVER	8.7970	5.712	
KIDNEYS	1.6048	1.042	
SPLEEN	0.4044	0.263	
OVARIES/OVIDUCTS	0.0982	0.064	
THYMUS	0.5154	0.335	
ADRENAL GLANDS	0.0396	0.026	
PITUITARY	0.0124	0.008	
THYROIDS/PARA	0.0161	0.010	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 19
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-08 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3497	0.241	
UTERUS- BLOTTED	0.3256	0.225	
LIVER	7.9492	5.482	
KIDNEYS	1.5421	1.064	
SPLEEN	0.3529	0.243	
OVARIES/OVIDUCTS	0.0860	0.059	
THYMUS	0.6492	0.448	
ADRENAL GLANDS	0.0458	0.032	
PITUITARY	0.0124	0.009	
THYROIDS/PARA	0.0141	0.010	
FINAL BODY WT(G)	145.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-02 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4339	0.301	
UTERUS- BLOTTED	0.3682	0.256	
LIVER	7.5336	5.232	
KIDNEYS	1.5308	1.063	
SPLEEN	0.4097	0.285	
OVARIES/OVIDUCTS	0.0701	0.049	
THYMUS	0.4821	0.335	
ADRENAL GLANDS	0.0288	0.020	
PITUITARY	0.0086	0.006	
THYROIDS/PARA	0.0142	0.010	
FINAL BODY WT(G)	144.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-06 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4372	0.312	
UTERUS- BLOTTED	0.4088	0.292	
LIVER	8.4987	6.071	
KIDNEYS	1.6861	1.204	
SPLEEN	0.4675	0.334	
OVARIES/OVIDUCTS	0.0727	0.052	
THYMUS	0.5678	0.406	
ADRENAL GLANDS	0.0341	0.024	
PITUITARY	0.0094	0.007	
THYROIDS/PARA	0.0138	0.010	
FINAL BODY WT(G)	140.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22801-03 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.7403	0.449	
UTERUS- BLOTTED	0.4700	0.285	
LIVER	8.7817	5.322	
KIDNEYS	1.6614	1.007	
SPLEEN	0.5466	0.331	
OVARIES/OVIDUCTS	0.1016	0.062	
THYMUS	0.5929	0.359	
ADRENAL GLANDS	0.0454	0.028	
PITUITARY	0.0091	0.006	
THYROIDS/PARA	0.0162	0.010	
FINAL BODY WT(G)	165.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

187056 RD

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22806-10 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3335	0.249		
UTERUS- BLOTTED	0.2995	0.224		
LIVER	6.9946	5.220		
KIDNEYS	1.4190	1.059		
SPLEEN	0.3654	0.273		
OVARIES/OVIDUCTS	0.0647	0.048		
THYMUS	0.5247	0.392		
ADRENAL GLANDS	0.0321	0.024		
PITUITARY	0.0068	0.005		
THYROIDS/PARA	0.0145	0.011		
FINAL BODY WT(G)	134.			

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22804-09 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2593	0.161	NO SIGNIFICANT
UTERUS- BLOTTED	0.2393	0.149	CHANGES OBSERVED
LIVER	10.1247	6.289	
KIDNEYS	1.6955	1.053	
SPLEEN	0.5345	0.332	
OVARIES/OVIDUCTS	0.0741	0.046	
THYMUS	0.5671	0.352	
ADRENAL GLANDS	0.0380	0.024	
PITUITARY	0.0081	0.005	
THYROIDS/PARA	0.0177	0.011	
FINAL BODY WT(G)	161.		

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22805-02 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2033	0.155	
UTERUS- BLOTTED	0.1903	0.145	
LIVER	5.9587	4.549	
KIDNEYS	1.3926	1.063	
SPLEEN	0.3271	0.250	
OVARIES/OVIDUCTS	0.0564	0.043	
THYMUS	0.4477	0.342	
ADRENAL GLANDS	0.0300	0.023	
PITUITARY	0.0063	0.005	
THYROIDS/PARA	0.0117	0.009	
FINAL BODY WT(G)	131.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22807-01 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4829	0.294		
UTERUS- BLOTTED	0.4243	0.259		
LIVER	9.4682	5.773		
KIDNEYS	1.8719	1.141		
SPLEEN	0.5438	0.332		
OVARIES/OVIDUCTS	0.0901	0.055		
THYMUS	0.6989	0.426		
ADRENAL GLANDS	0.0353	0.022		
PITUITARY	0.0093	0.006		
THYROIDS/PARA	0.0118	0.007		
FINAL BODY WT(G)	164.			

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PANCREAS, PITUITARY, SPLEEN
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 27
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22805-08 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.8718	0.646		
UTERUS- BLOTTED	0.4051	0.300		
LIVER	6.7799	5.022		
KIDNEYS	1.3963	1.034		
SPLEEN	0.3795	0.281		
OVARIES/OVIDUCTS	0.0649	0.048		
THYMUS	0.5939	0.440		
ADRENAL GLANDS	0.0373	0.028		
PITUITARY	0.0071	0.005		
THYROIDS/PARA	0.0128	0.009		
FINAL BODY WT(G)	135.			

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22806-01 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3195	0.219	
UTERUS- BLOTTED	0.2993	0.205	
LIVER	7.9143	5.421	
KIDNEYS	1.7362	1.189	
SPLEEN	0.3925	0.269	
OVARIES/OVIDUCTS	0.0765	0.052	
THYMUS	0.6514	0.446	
ADRENAL GLANDS	0.0318	0.022	
PITUITARY	0.0069	0.005	
THYROIDS/PARA	0.0142	0.010	
FINAL BODY WT(G)	146.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22811-03 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.7513	0.498		
UTERUS- BLOTTED	0.4283	0.284		
LIVER	7.2881	4.827		
KIDNEYS	1.5100	1.000		
SPLEEN	0.2860	0.189		
OVARIES/OVIDUCTS	0.0644	0.043		
THYMUS	0.5909	0.391		
ADRENAL GLANDS	0.0456	0.030		
PITUITARY	0.0082	0.005		
THYROIDS/PARA	0.0151	0.010		
FINAL BODY WT(G)	151.			

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22808-06 GROUP 2: [redacted]60 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2539	0.187	NO SIGNIFICANT
UTERUS- BLOTTED	0.2360	0.174	CHANGES OBSERVED
LIVER	6.8201	5.015	
KIDNEYS	1.4243	1.047	
SPLEEN	0.3967	0.292	
OVARIES/OVIDUCTS	0.0738	0.054	
THYMUS	0.4285	0.315	
ADRENAL GLANDS	0.0750	0.055	
PITUITARY	0.0100	0.007	
THYROIDS/PARA	0.0131	0.010	
FINAL BODY WT(G)	136.		

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-10 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	1.0375	0.625	
UTERUS- BLOTTED	0.5000	0.301	
LIVER	9.3528	5.634	
KIDNEYS	1.6606	1.000	
SPLEEN	0.4517	0.272	
OVARIES/OVIDUCTS	0.0759	0.046	
THYMUS	0.7679	0.463	
ADRENAL GLANDS	0.0455	0.027	
PITUITARY	0.0090	0.005	
THYROIDS/PARA	0.0135	0.008	
FINAL BODY WT(G)	166.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22801-07 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2617	0.168	
UTERUS- BLOTTED	0.2454	0.157	
LIVER	8.6404	5.539	
KIDNEYS	1.5257	0.978	
SPLEEN	0.3942	0.253	
OVARIES/OVIDUCTS	0.0701	0.045	
THYMUS	0.6447	0.413	
ADRENAL GLANDS	0.0457	0.029	
PITUITARY	0.0088	0.006	
THYROIDS/PARA	0.0118	0.008	
FINAL BODY WT(G)	156.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-06 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4076	0.258
UTERUS- BLOTTED	0.3639	0.230
LIVER	8.3155	5.263
KIDNEYS	1.6845	1.066
SPLEEN	0.5035	0.319
OVARIES/OVIDUCTS	0.0797	0.050
THYMUS	0.6125	0.388
ADRENAL GLANDS	0.0420	0.027
PITUITARY	0.0087	0.006
THYROIDS/PARA	0.0176	0.011
FINAL BODY WT(G)	158.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 34
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22803-05 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2985	0.199	
UTERUS- BLOTTED	0.2687	0.179	
LIVER	7.9083	5.272	
KIDNEYS	1.4534	0.969	
SPLEEN	0.3629	0.242	
OVARIES/OVIDUCTS	0.0726	0.048	
THYMUS	0.4328	0.289	
ADRENAL GLANDS	0.0382	0.025	
PITUITARY	0.0083	0.006	
THYROIDS/PARA	0.0139	0.009	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-10 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.6931	0.450	
UTERUS- BLOTTED	0.4761	0.309	
LIVER	9.3577	6.076	
KIDNEYS	1.6317	1.060	
SPLEEN	0.5036	0.327	
OVARIES/OVIDUCTS	0.0801	0.052	
THYMUS	0.8934	0.580	
ADRENAL GLANDS	0.0548	0.036	
PITUITARY	0.0107	0.007	
THYROIDS/PARA	0.0134	0.009	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-02 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.7222	0.469	
UTERUS- BLOTTED	0.4036	0.262	
LIVER	8.0982	5.259	
KIDNEYS	1.5176	0.985	
SPLEEN	0.3867	0.251	
OVARIES/OVIDUCTS	0.0868	0.056	
THYMUS	0.7401	0.481	
ADRENAL GLANDS	0.0480	0.031	
PITUITARY	0.0075	0.005	
THYROIDS/PARA	0.0171	0.011	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22800-01 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.2600	0.190		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2429	0.177		OVARIES	PANCREAS	PITUITARY	SPLEEN
LIVER	6.9194	5.051		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.5395	1.124		VAGINA	LYMPH NODE, AXIL		
SPLEEN	0.3016	0.220					
OVARIES/OVIDUCTS	0.1012	0.074					
THYMUS	0.5248	0.383					
ADRENAL GLANDS	0.0408	0.030					
PITUITARY	0.0101	0.007					
THYROIDS/PARA	0.0135	0.010					
FINAL BODY WT(G)	137.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-09 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.3072	0.197	GENERAL COMMENT	GROSS: ORGAN WEIGHT THYROID/PARATHYROID, LEFT: 0.0068 G	P
UTERUS- BLOTTED	0.2861	0.183	GENERAL COMMENT	GROSS: ORGAN LOST AT NECROPSY THYROID/PARATHYROID, RIGHT	P
LIVER	8.8348	5.663			
KIDNEYS	1.5826	1.014	NO SIGNIFICANT		
SPLEEN	0.4142	0.266	CHANGES OBSERVED	GROSS:	
OVARIES/OVIDUCTS	0.0879	0.056			
THYMUS	0.7517	0.482			
ADRENAL GLANDS	0.0437	0.028			
PITUITARY	0.0125	0.008			
FINAL BODY WT(G)	156.				

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR: [redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22805-03 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2583	0.172	
UTERUS- BLOTTED	0.2414	0.161	
LIVER	7.0695	4.713	
KIDNEYS	1.4675	0.978	
SPLEEN	0.3386	0.226	
OVARIES/OVIDUCTS	0.0613	0.041	
THYMUS	0.5764	0.384	
ADRENAL GLANDS	0.0356	0.024	
PITUITARY	0.0074	0.005	
THYROIDS/PARA	0.0120	0.008	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22806-04 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3951	0.255	
UTERUS- BLOTTED	0.3661	0.236	
LIVER	8.6690	5.593	
KIDNEYS	1.6219	1.046	
SPLEEN	0.4763	0.307	
OVARIES/OVIDUCTS	0.0829	0.053	
THYMUS	0.6804	0.439	
ADRENAL GLANDS	0.0416	0.027	
PITUITARY	0.0101	0.007	
THYROIDS/PARA	0.0151	0.010	
FINAL BODY WT(G)	155.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

INDIVIDUAL MACROSCOPIC FINDINGS

PROJECT NO.:WIL-187056
SPONSOR:[redacted]
SPONSOR NO.:06-011

ANIMAL NO.22804-10 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2704	0.165
UTERUS- BLOTTED	0.2502	0.153
LIVER	9.9129	6.044
KIDNEYS	1.5848	0.966
SPLEEN	0.4103	0.250
OVARIES/OVIDUCTS	0.0792	0.048
THYMUS	0.4635	0.283
ADRENAL GLANDS	0.0441	0.027
PITUITARY	0.0093	0.006
THYROIDS/PARA	0.0129	0.008
FINAL BODY WT(G)	164.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22807-02 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2705	0.167		
UTERUS- BLOTTED	0.2536	0.157		
LIVER	9.4365	5.825		
KIDNEYS	1.5850	0.978		
SPLEEN	0.3301	0.204		
OVARIES/OVIDUCTS	0.0707	0.044		
THYMUS	0.4814	0.297		
ADRENAL GLANDS	0.0374	0.023		
PITUITARY	0.0098	0.006		
THYROIDS/PARA	0.0142	0.009		
FINAL BODY WT(G)	162.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22805-06 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2402	0.168	
UTERUS- BLOTTED	0.2256	0.158	
LIVER	7.3044	5.108	
KIDNEYS	1.2563	0.879	
SPLEEN	0.3751	0.262	
OVARIES/OVIDUCTS	0.0750	0.052	
THYMUS	0.4678	0.327	
ADRENAL GLANDS	0.0310	0.022	
PITUITARY	0.0075	0.005	
THYROIDS/PARA	0.0131	0.009	
FINAL BODY WT(G)	143.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22808-01 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2925	0.189	
UTERUS- BLOTTED	0.2677	0.173	
LIVER	8.6371	5.572	
KIDNEYS	1.5789	1.019	
SPLEEN	0.5159	0.333	
OVARIES/OVIDUCTS	0.0667	0.043	
THYMUS	0.4752	0.307	
ADRENAL GLANDS	0.0445	0.029	
PITUITARY	0.0086	0.006	
THYROIDS/PARA	0.0174	0.011	
FINAL BODY WT(G)	155.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22811-08 GROUP 3: [redacted]250 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2655	0.182	
UTERUS- BLOTTED	0.2456	0.168	
LIVER	8.0548	5.517	
KIDNEYS	1.5406	1.055	
SPLEEN	0.4258	0.292	
OVARIES/OVIDUCTS	0.0684	0.047	
THYMUS	0.5861	0.401	
ADRENAL GLANDS	0.0445	0.030	
PITUITARY	0.0080	0.005	
THYROIDS/PARA	0.0125	0.009	
FINAL BODY WT(G)	146.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22801-08 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3008	0.205	
UTERUS- BLOTTED	0.2757	0.188	
LIVER	8.1377	5.536	
KIDNEYS	1.5980	1.087	
SPLEEN	0.4059	0.276	
OVARIES/OVIDUCTS	0.0807	0.055	
THYMUS	0.5390	0.367	
ADRENAL GLANDS	0.0502	0.034	
PITUITARY	0.0128	0.009	
THYROIDS/PARA	0.0165	0.011	
FINAL BODY WT(G)	147.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)
PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
INDIVIDUAL MACROSCOPIC FINDINGS

PROJECT NO.:WIL-187056
SPONSOR:[redacted]
SPONSOR NO.:06-011

ANIMAL NO.22803-02 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06 GRADE

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2709	0.194
UTERUS- BLOTTED	0.2455	0.175
LIVER	7.7733	5.552
KIDNEYS	1.3894	0.992
SPLEEN	0.4037	0.288
OVARIES/OVIDUCTS	0.0695	0.050
THYMUS	0.4888	0.349
ADRENAL GLANDS	0.0505	0.036
PITUITARY	0.0100	0.007
THYROIDS/PARA	0.0149	0.011
FINAL BODY WT(G)	140.	

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22799-10 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3154	0.225		
UTERUS- BLOTTED	0.2940	0.210		
LIVER	8.0046	5.718		
KIDNEYS	1.7281	1.234		
SPLEEN	0.3780	0.270		
OVARIES/OVIDUCTS	0.1043	0.075		
THYMUS	0.5023	0.359		
ADRENAL GLANDS	0.0485	0.035		
PITUITARY	0.0123	0.009		
THYROIDS/PARA	0.0173	0.012		
FINAL BODY WT(G)	140.			

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22800-08 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3035	0.196
UTERUS- BLOTTED	0.2781	0.179
LIVER	9.6245	6.209
KIDNEYS	1.7245	1.113
SPLEEN	0.5038	0.325
OVARIES/OVIDUCTS	0.0834	0.054
THYMUS	0.5274	0.340
ADRENAL GLANDS	0.0490	0.032
PITUITARY	0.0101	0.007
THYROIDS/PARA	0.0194	0.013
FINAL BODY WT(G)	155.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-08 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2363	0.163	
UTERUS- BLOTTED	0.2213	0.153	
LIVER	8.9123	6.146	
KIDNEYS	1.6505	1.138	
SPLEEN	0.5988	0.413	
OVARIES/OVIDUCTS	0.0718	0.050	
THYMUS	0.7469	0.515	
ADRENAL GLANDS	0.0404	0.028	
PITUITARY	0.0088	0.006	
THYROIDS/PARA	0.0149	0.010	
FINAL BODY WT(G)	145.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22802-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1971	0.140
UTERUS- BLOTTED	0.1826	0.130
LIVER	8.4710	6.008
KIDNEYS	1.5923	1.129
SPLEEN	0.4936	0.350
OVARIES/OVIDUCTS	0.0505	0.036
THYMUS	0.5801	0.411
ADRENAL GLANDS	0.0345	0.024
PITUITARY	0.0086	0.006
THYROIDS/PARA	0.0147	0.010
FINAL BODY WT(G)	141.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22801-10 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2690	0.198
UTERUS- BLOTTED	0.2482	0.182
LIVER	6.8139	5.010
KIDNEYS	1.4313	1.052
SPLEEN	0.3543	0.261
OVARIES/OVIDUCTS	0.0365	0.027
THYMUS	0.4087	0.301
ADRENAL GLANDS	0.0366	0.027
PITUITARY	0.0064	0.005
THYROIDS/PARA	0.0141	0.010
FINAL BODY WT(G)	136.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22806-07 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2850	0.219		
UTERUS- BLOTTED	0.2563	0.197		
LIVER	7.5832	5.833		
KIDNEYS	1.5617	1.201		
SPLEEN	0.3112	0.239		
OVARIES/OVIDUCTS	0.0399	0.031		
THYMUS	0.4892	0.376		
ADRENAL GLANDS	0.0327	0.025		
PITUITARY	0.0069	0.005		
THYROIDS/PARA	0.0149	0.011		
FINAL BODY WT(G)	130.			

GROSS:				
	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22804-01 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2443	0.164
UTERUS- BLOTTED	0.2278	0.153
LIVER	8.7445	5.869
KIDNEYS	1.6035	1.076
SPLEEN	0.3339	0.224
OVARIES/OVIDUCTS	0.0374	0.025
THYMUS	0.6071	0.407
ADRENAL GLANDS	0.0384	0.026
PITUITARY	0.0091	0.006
THYROIDS/PARA	0.0137	0.009
FINAL BODY WT(G)	149.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22805-10 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2949	0.203	
UTERUS- BLOTTED	0.2772	0.191	
LIVER	7.5022	5.174	
KIDNEYS	1.5887	1.096	
SPLEEN	0.4451	0.307	
OVARIES/OVIDUCTS	0.0758	0.052	
THYMUS	0.6143	0.424	
ADRENAL GLANDS	0.0399	0.028	
PITUITARY	0.0075	0.005	
THYROIDS/PARA	0.0140	0.010	
FINAL BODY WT(G)	145.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 56
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22807-04 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2392	0.144	
UTERUS- BLOTTED	0.2237	0.135	
LIVER	9.9362	5.986	
KIDNEYS	1.7080	1.029	
SPLEEN	0.4213	0.254	
OVARIES/OVIDUCTS	0.0849	0.051	
THYMUS	0.4891	0.295	
ADRENAL GLANDS	0.0549	0.033	
PITUITARY	0.0079	0.005	
THYROIDS/PARA	0.0119	0.007	
FINAL BODY WT(G)	166.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22804-06 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3602	0.240	
UTERUS- BLOTTED	0.3382	0.225	
LIVER	8.6447	5.763	
KIDNEYS	1.7785	1.186	
SPLEEN	0.4079	0.272	
OVARIES/OVIDUCTS	0.0519	0.035	
THYMUS	0.6270	0.418	
ADRENAL GLANDS	0.0340	0.023	
PITUITARY	0.0100	0.007	
THYROIDS/PARA	0.0154	0.010	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22811-02 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2716	0.176	
UTERUS- BLOTTED	0.2497	0.162	
LIVER	9.2545	6.009	
KIDNEYS	1.6344	1.061	
SPLEEN	0.4535	0.294	
OVARIES/OVIDUCTS	0.0643	0.042	
THYMUS	0.6241	0.405	
ADRENAL GLANDS	0.0498	0.032	
PITUITARY	0.0105	0.007	
THYROIDS/PARA	0.0142	0.009	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22808-08 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2949	0.209
UTERUS- BLOTTED	0.2792	0.198
LIVER	8.0544	5.712
KIDNEYS	1.5448	1.096
SPLEEN	0.3912	0.277
OVARIES/OVIDUCTS	0.0856	0.061
THYMUS	0.4894	0.347
ADRENAL GLANDS	0.0450	0.032
PITUITARY	0.0097	0.007
THYROIDS/PARA	0.0117	0.008
FINAL BODY WT(G)	141.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22809-07 GROUP 4: [redacted]1000 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2719	0.209	
UTERUS- BLOTTED	0.2576	0.198	
LIVER	6.9443	5.342	
KIDNEYS	1.2977	0.998	
SPLEEN	0.4555	0.350	
OVARIES/OVIDUCTS	0.0467	0.036	
THYMUS	0.4930	0.379	
ADRENAL GLANDS	0.0379	0.029	
PITUITARY	0.0071	0.005	
THYROIDS/PARA	0.0146	0.011	
FINAL BODY WT(G)	130.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PANCREAS	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA	LYMPH NODE, AXIL			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 61

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22801-02 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2785	0.169		
UTERUS- BLOTTED	0.2614	0.158		
LIVER	9.0757	5.500		
KIDNEYS	1.5136	0.917		
SPLEEN	0.5089	0.308		
OVARIES/OVIDUCTS	0.0914	0.055		
THYMUS	0.5882	0.356		
ADRENAL GLANDS	0.0371	0.022		
PITUITARY	0.0086	0.005		
THYROIDS/PARA	0.0156	0.009		
FINAL BODY WT(G)	165.			

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-05 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5767	0.379	
UTERUS- BLOTTED	0.4014	0.264	
LIVER	7.8430	5.160	
KIDNEYS	1.5755	1.037	
SPLEEN	0.5522	0.363	
OVARIES/OVIDUCTS	0.0891	0.059	
THYMUS	0.5866	0.386	
ADRENAL GLANDS	0.0407	0.027	
PITUITARY	0.0081	0.005	
THYROIDS/PARA	0.0140	0.009	
FINAL BODY WT(G)	152.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22803-10 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2600	0.171	
UTERUS- BLOTTED	0.2431	0.160	
LIVER	8.8692	5.835	
KIDNEYS	1.5057	0.991	
SPLEEN	0.4449	0.293	
OVARIES/OVIDUCTS	0.0631	0.042	
THYMUS	0.4747	0.312	
ADRENAL GLANDS	0.0316	0.021	
PITUITARY	0.0087	0.006	
THYROIDS/PARA	0.0129	0.008	
FINAL BODY WT(G)	152.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22799-07 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2206	0.146	
UTERUS- BLOTTED	0.2015	0.133	
LIVER	7.2695	4.814	
KIDNEYS	1.5501	1.027	
SPLEEN	0.3988	0.264	
OVARIES/OVIDUCTS	0.0802	0.053	
THYMUS	0.5499	0.364	
ADRENAL GLANDS	0.0392	0.026	
PITUITARY	0.0077	0.005	
THYROIDS/PARA	0.0144	0.010	
FINAL BODY WT(G)	151.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-05 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2340	0.171	
UTERUS- BLOTTED	0.2142	0.156	
LIVER	8.5490	6.240	
KIDNEYS	1.6661	1.216	
SPLEEN	0.4519	0.330	
OVARIES/OVIDUCTS	0.0893	0.065	
THYMUS	0.5231	0.382	
ADRENAL GLANDS	0.0411	0.030	
PITUITARY	0.0096	0.007	
THYROIDS/PARA	0.0149	0.011	
FINAL BODY WT(G)	137.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22800-09 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2313	0.153	
UTERUS- BLOTTED	0.2105	0.139	
LIVER	7.6439	5.062	
KIDNEYS	1.4839	0.983	
SPLEEN	0.5138	0.340	
OVARIES/OVIDUCTS	0.0747	0.049	
THYMUS	0.5422	0.359	
ADRENAL GLANDS	0.0406	0.027	
PITUITARY	0.0104	0.007	
THYROIDS/PARA	0.0133	0.009	
FINAL BODY WT(G)	151.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 67
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-07 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2977	0.196		
UTERUS- BLOTTED	0.2788	0.183		
LIVER	9.3386	6.144		
KIDNEYS	1.7318	1.139		
SPLEEN	0.5900	0.388		
OVARIES/OVIDUCTS	0.1047	0.069		
THYMUS	0.4800	0.316		
ADRENAL GLANDS	0.0446	0.029		
PITUITARY	0.0115	0.008		
THYROIDS/PARA	0.0174	0.011		
FINAL BODY WT(G)	152.			

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22806-09 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2292	0.174		
UTERUS- BLOTTED	0.2052	0.155		
LIVER	6.6798	5.060		
KIDNEYS	1.2628	0.957		
SPLEEN	0.4156	0.315		
OVARIES/OVIDUCTS	0.0595	0.045		
THYMUS	0.5157	0.391		
ADRENAL GLANDS	0.0371	0.028		
PITUITARY	0.0076	0.006		
THYROIDS/PARA	0.0095	0.007		
FINAL BODY WT(G)	132.			

GRADE

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22805-04 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2614	0.184	
UTERUS- BLOTTED	0.2399	0.169	
LIVER	8.2011	5.775	
KIDNEYS	1.5882	1.118	
SPLEEN	0.3881	0.273	
OVARIES/OVIDUCTS	0.1019	0.072	
THYMUS	0.5376	0.379	
ADRENAL GLANDS	0.0386	0.027	
PITUITARY	0.0061	0.004	
THYROIDS/PARA	0.0175	0.012	
FINAL BODY WT(G)	142.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22804-05 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3517	0.228	
UTERUS- BLOTTED	0.3324	0.216	
LIVER	9.8745	6.412	
KIDNEYS	1.6803	1.091	
SPLEEN	0.4771	0.310	
OVARIES/OVIDUCTS	0.0790	0.051	
THYMUS	0.4910	0.319	
ADRENAL GLANDS	0.0429	0.028	
PITUITARY	0.0085	0.006	
THYROIDS/PARA	0.0159	0.010	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22807-03 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4742	0.261
UTERUS- BLOTTED	0.3565	0.196
LIVER	9.0925	4.996
KIDNEYS	1.8004	0.989
SPLEEN	0.4899	0.269
OVARIES/OVIDUCTS	0.0708	0.039
THYMUS	0.7770	0.427
ADRENAL GLANDS	0.0381	0.021
PITUITARY	0.0103	0.006
THYROIDS/PARA	0.0132	0.007
FINAL BODY WT(G)	182.	

GRADE

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22805-05 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2546	0.165	
UTERUS- BLOTTED	0.2402	0.156	
LIVER	7.3927	4.800	
KIDNEYS	1.2005	0.780	
SPLEEN	0.3752	0.244	
OVARIES/OVIDUCTS	0.0684	0.044	
THYMUS	0.3779	0.245	
ADRENAL GLANDS	0.0302	0.020	
PITUITARY	0.0074	0.005	
THYROIDS/PARA	0.0141	0.009	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22804-07 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2300	0.150		
UTERUS- BLOTTED	0.2078	0.136		
LIVER	9.4668	6.187		
KIDNEYS	1.7450	1.141		
SPLEEN	0.4109	0.269		
OVARIES/OVIDUCTS	0.0905	0.059		
THYMUS	0.5616	0.367		
ADRENAL GLANDS	0.0422	0.028		
PITUITARY	0.0093	0.006		
THYROIDS/PARA	0.0142	0.009		
FINAL BODY WT(G)	153.			

GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22811-01 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3001	0.174	GROSS:	
UTERUS- BLOTTED	0.2749	0.160		
LIVER	9.8924	5.751		
KIDNEYS	2.0351	1.183		
SPLEEN	0.6357	0.370		
OVARIES/OVIDUCTS	0.1015	0.059		
THYMUS	0.6614	0.385		
ADRENAL GLANDS	0.0491	0.029		
PITUITARY	0.0110	0.006		
THYROIDS/PARA	0.0225	0.013		
FINAL BODY WT(G)	172.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PANCREAS PITUITARY SPLEEN
THYMUS THYROID GLANDS UTERUS CERVIX
VAGINA LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22808-03 GROUP 5: [redacted]60 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2734	0.175	
UTERUS- BLOTTED	0.2507	0.161	
LIVER	8.2147	5.266	
KIDNEYS	1.5626	1.002	
SPLEEN	0.5692	0.365	
OVARIES/OVIDUCTS	0.0657	0.042	
THYMUS	0.5311	0.340	
ADRENAL GLANDS	0.0338	0.022	
PITUITARY	0.0073	0.005	
THYROIDS/PARA	0.0144	0.009	
FINAL BODY WT(G)	156.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22801-09 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2157	0.144	
UTERUS- BLOTTED	0.1988	0.133	
LIVER	8.6036	5.736	
KIDNEYS	1.5543	1.036	
SPLEEN	0.4259	0.284	
OVARIES/OVIDUCTS	0.0716	0.048	
THYMUS	0.4692	0.313	
ADRENAL GLANDS	0.0497	0.033	
PITUITARY	0.0107	0.007	
THYROIDS/PARA	0.0152	0.010	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 77

SPONSOR:[redacted]

SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22800-07 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2253	0.148	
UTERUS- BLOTTED	0.2061	0.136	
LIVER	9.3863	6.175	
KIDNEYS	1.5303	1.007	
SPLEEN	0.4820	0.317	
OVARIES/OVIDUCTS	0.0716	0.047	
THYMUS	0.5327	0.350	
ADRENAL GLANDS	0.0496	0.033	
PITUITARY	0.0081	0.005	
THYROIDS/PARA	0.0109	0.007	
FINAL BODY WT(G)	152.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22803-06 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.1925	0.128	
UTERUS- BLOTTED	0.1766	0.118	
LIVER	10.0103	6.674	
KIDNEYS	1.6602	1.107	
SPLEEN	0.4058	0.271	
OVARIES/OVIDUCTS	0.0507	0.034	
THYMUS	0.4950	0.330	
ADRENAL GLANDS	0.0450	0.030	
PITUITARY	0.0125	0.008	
THYROIDS/PARA	0.0170	0.011	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22799-04 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.1798	0.135	
UTERUS- BLOTTED	0.1709	0.128	
LIVER	8.5069	6.396	
KIDNEYS	1.4889	1.119	
SPLEEN	0.3692	0.278	
OVARIES/OVIDUCTS	0.0586	0.044	
THYMUS	0.4090	0.308	
ADRENAL GLANDS	0.0386	0.029	
PITUITARY	0.0086	0.006	
THYROIDS/PARA	0.0140	0.011	
FINAL BODY WT(G)	133.		

NO SIGNIFICANT CHANGES OBSERVED GROSS:

ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
SPONSOR NO.:06-011

INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22802-11 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2080	0.139	
UTERUS- BLOTTED	0.1952	0.130	
LIVER	10.5294	7.020	
KIDNEYS	1.7419	1.161	
SPLEEN	0.5073	0.338	
OVARIES/OVIDUCTS	0.0613	0.041	
THYMUS	0.6077	0.405	
ADRENAL GLANDS	0.0376	0.025	
PITUITARY	0.0098	0.007	
THYROIDS/PARA	0.0142	0.009	
FINAL BODY WT(G)	150.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22801-05 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/17/06 DATE OF DEATH: 04/17/06

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.1542	0.118			
UTERUS- BLOTTED	0.1444	0.110	GENERAL COMMENT	GROSS: ORGAN WEIGHT THYROID/PARATHYROID, RIGHT: 0.0092 G	P
LIVER	7.7283	5.899	GENERAL COMMENT	GROSS: ORGAN LOST AT NECROPSY THYROID/PARATHYROID, LEFT	P
KIDNEYS	1.6725	1.277	NO SIGNIFICANT		
SPLEEN	0.3175	0.242	CHANGES OBSERVED	GROSS:	
OVARIES/OVIDUCTS	0.0571	0.044			
THYMUS	0.4314	0.329			
ADRENAL GLANDS	0.0369	0.028			
PITUITARY	0.0069	0.005			
FINAL BODY WT(G)	131.				

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22806-05 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2117	0.160	
UTERUS- BLOTTED	0.1985	0.150	
LIVER	7.9606	6.031	
KIDNEYS	1.4133	1.071	
SPLEEN	0.4479	0.339	
OVARIES/OVIDUCTS	0.0458	0.035	
THYMUS	0.3685	0.279	
ADRENAL GLANDS	0.0429	0.033	
PITUITARY	0.0089	0.007	
THYROIDS/PARA	0.0111	0.008	
FINAL BODY WT(G)	132.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22804-03 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4456	0.289	
UTERUS- BLOTTED	0.2761	0.179	
LIVER	9.8002	6.364	
KIDNEYS	1.6395	1.065	
SPLEEN	0.3586	0.233	
OVARIES/OVIDUCTS	0.0689	0.045	
THYMUS	0.5302	0.344	
ADRENAL GLANDS	0.0442	0.029	
PITUITARY	0.0077	0.005	
THYROIDS/PARA	0.0102	0.007	
FINAL BODY WT(G)	154.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC FINDINGS
SPONSOR NO.:06-011

ANIMAL NO.22805-09 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2770	0.204	
UTERUS- BLOTTED	0.2388	0.176	
LIVER	7.5919	5.582	
KIDNEYS	1.4949	1.099	
SPLEEN	0.3042	0.224	
OVARIES/OVIDUCTS	0.0516	0.038	
THYMUS	0.4246	0.312	
ADRENAL GLANDS	0.0330	0.024	
PITUITARY	0.0066	0.005	
THYROIDS/PARA	0.0118	0.009	
FINAL BODY WT(G)	136.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22807-05 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2648	0.145	
UTERUS- BLOTTED	0.2466	0.135	
LIVER	12.1610	6.645	
KIDNEYS	1.7077	0.933	
SPLEEN	0.4299	0.235	
OVARIES/OVIDUCTS	0.0524	0.029	
THYMUS	0.5897	0.322	
ADRENAL GLANDS	0.0533	0.029	
PITUITARY	0.0114	0.006	
THYROIDS/PARA	0.0111	0.006	
FINAL BODY WT(G)	183.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 86
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22804-02 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2618	0.146	
UTERUS- BLOTTED	0.2362	0.132	
LIVER	12.5816	7.029	
KIDNEYS	1.8507	1.034	
SPLEEN	0.5664	0.316	
OVARIES/OVIDUCTS	0.0773	0.043	
THYMUS	0.6561	0.367	
ADRENAL GLANDS	0.0558	0.031	
PITUITARY	0.0079	0.004	
THYROIDS/PARA	0.0167	0.009	
FINAL BODY WT(G)	179.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXIL

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22806-08 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/18/06 DATE OF DEATH: 04/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.1719	0.131	
UTERUS- BLOTTED	0.1637	0.125	
LIVER	7.8900	6.023	
KIDNEYS	1.4196	1.084	
SPLEEN	0.3188	0.243	
OVARIES/OVIDUCTS	0.0470	0.036	
THYMUS	0.4085	0.312	
ADRENAL GLANDS	0.0319	0.024	
PITUITARY	0.0060	0.005	
THYROIDS/PARA	0.0127	0.010	
FINAL BODY WT(G)	131.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

Revised Draft

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 88
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL MACROSCOPIC FINDINGS

ANIMAL NO.22810-03 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.2524	0.147		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2322	0.135		OVARIES	PANCREAS	PITUITARY	SPLEEN
LIVER	10.2972	5.987		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.6375	0.952		VAGINA	LYMPH NODE, AXIL		
SPLEEN	0.5342	0.311					
OVARIES/OVIDUCTS	0.0573	0.033					
THYMUS	0.4361	0.254					
ADRENAL GLANDS	0.0476	0.028					
PITUITARY	0.0108	0.006					
THYROIDS/PARA	0.0142	0.008					
FINAL BODY WT(G)	172.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

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Modified: 6/30/2006

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC FINDINGS

SPONSOR NO.:06-011

ANIMAL NO.22811-06 GROUP 6: [redacted]250 FEMALE SCHEDULED EUTH 04/19/06 DATE OF DEATH: 04/19/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2400	0.149	
UTERUS- BLOTTED	0.2235	0.139	
LIVER	8.7628	5.443	
KIDNEYS	1.6100	1.000	
SPLEEN	0.5801	0.360	
OVARIES/OVIDUCTS	0.0992	0.062	
THYMUS	0.5086	0.316	
ADRENAL GLANDS	0.0533	0.033	
PITUITARY	0.0103	0.006	
THYROIDS/PARA	0.0199	0.012	
FINAL BODY WT(G)	161.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA	LYMPH NODE, AXIL		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

PGRHv4.54
06/07/2006

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TABLE 24

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-011

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-04	180.	0.2337	0.2112	0.0225	10.5891	1.6864	0.5322	0.0899	0.7779	0.0416	0.0102	0.0180
22799-01	150.	0.5520	0.3962	0.1558	6.8915	1.3660	0.3945	0.0684	0.7873	0.0383	0.0084	0.0169
22800-06	153.	0.2046	0.1885	0.0161	7.3052	1.6735	0.3364	0.0779	0.6124	0.0304	0.0067	0.0191
22803-09	149.	0.4112	0.3308	0.0804	7.8932	1.5714	0.4464	0.0821	0.5205	0.0348	0.0091	0.0124
22802-04	160.	0.2320	0.2103	0.0217	10.4901	1.9001	0.5394	0.0814	0.6192	0.0368	0.0122	0.0146
22800-04	149.	0.6545	0.4833	0.1712	7.4390	1.5594	0.5019	0.0811	0.5870	0.0444	0.0105	0.0148
22799-05	144.	0.2593	0.2377	0.0216	7.0779	1.6258	0.4444	0.0919	0.6739	0.0409	0.0094	0.0194
22803-04	171.	0.3375	0.3076	0.0299	9.6839	1.6599	0.5814	0.0817	0.5248	0.0413	0.0082	0.0160
22806-02	137.	0.2130	0.1932	0.0198	7.0444	1.5259	0.3401	0.0763	0.6494	0.0328	0.0073	0.0115
22807-07	162.	0.2170	0.1960	0.0210	8.7588	1.5908	0.4253	0.0710	0.6764	0.0330	0.0082	0.0179
22805-01	143.	0.6509	0.3873	0.2636	7.2350	1.4115	0.3347	0.0762	0.4878	0.0378	0.0079	0.0136
22804-04	191.	0.3475	0.3282	0.0193	10.5373	1.8488	0.6120	0.0772	0.5241	0.0367	0.0104	0.0077
22807-08	175.	0.8840	0.4830	0.4010	9.3358	1.7935	0.4276	0.0791	0.6152	0.0517	0.0094	0.0174
22808-05	156.	0.5751	0.3862	0.1889	7.7421	1.3735	0.4065	0.0770	0.5386	0.0431	0.0095	0.0129
22811-07	139.	0.2629	0.2388	0.0241	6.5107	1.4780	0.3229	0.0679	0.6055	0.0391	0.0091	0.0121
MEAN	157.	0.4023	0.3052	0.0971	8.3023	1.6043	0.4430	0.0786	0.6133	0.0388	0.0091	0.0150
S.D.	15.9	0.21104	0.10385	0.11616	1.45989	0.16274	0.09289	0.00672	0.08978	0.00535	0.00140	0.00329
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

TABLE 24

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-06	148.	0.4271	0.3995	0.0276	8.8807	1.7544	0.4315	0.0972	0.5503	0.0477	0.0090	0.0134
22800-03	161.	0.2872	0.2632	0.0240	9.2161	1.6124	0.4728	0.0914	0.7722	0.0350	0.0104	0.0179
22803-07	154.	0.3036	0.2755	0.0281	8.7970	1.6048	0.4044	0.0982	0.5154	0.0396	0.0124	0.0161
22799-08	145.	0.3497	0.3256	0.0241	7.9492	1.5421	0.3529	0.0860	0.6492	0.0458	0.0124	0.0141
22802-02	144.	0.4339	0.3682	0.0657	7.5336	1.5308	0.4097	0.0701	0.4821	0.0288	0.0086	0.0142
22802-06	140.	0.4372	0.4088	0.0284	8.4987	1.6861	0.4675	0.0727	0.5678	0.0341	0.0094	0.0138
22801-03	165.	0.7403	0.4700	0.2703	8.7817	1.6614	0.5466	0.1016	0.5929	0.0454	0.0091	0.0162
22806-10	134.	0.3335	0.2995	0.0340	6.9946	1.4190	0.3654	0.0647	0.5247	0.0321	0.0068	0.0145
22804-09	161.	0.2593	0.2393	0.0200	10.1247	1.6955	0.5345	0.0741	0.5671	0.0380	0.0081	0.0177
22805-02	131.	0.2033	0.1903	0.0130	5.9587	1.3926	0.3271	0.0564	0.4477	0.0300	0.0063	0.0117
22807-01	164.	0.4829	0.4243	0.0586	9.4682	1.8719	0.5438	0.0901	0.6989	0.0353	0.0093	0.0118
22805-08	135.	0.8718	0.4051	0.4667	6.7799	1.3963	0.3795	0.0649	0.5939	0.0373	0.0071	0.0128
22806-01	146.	0.3195	0.2993	0.0202	7.9143	1.7362	0.3925	0.0765	0.6514	0.0318	0.0069	0.0142
22811-03	151.	0.7513	0.4283	0.3230	7.2881	1.5100	0.2860	0.0644	0.5909	0.0456	0.0082	0.0151
22808-06	136.	0.2539	0.2360	0.0179	6.8201	1.4243	0.3967	0.0738	0.4285	0.0750	0.0100	0.0131
MEAN	148.	0.4303	0.3355	0.0948	8.0670	1.5892	0.4207	0.0788	0.5755	0.0401	0.0089	0.0144
S.D.	11.4	0.20239	0.08525	0.13995	1.16940	0.14625	0.07883	0.01424	0.09243	0.01142	0.00185	0.00188
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 6/30/2006

TABLE 24

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22800-10	166.	1.0375	0.5000	0.5375	9.3528	1.6606	0.4517	0.0759	0.7679	0.0455	0.0090	0.0135
22801-07	156.	0.2617	0.2454	0.0163	8.6404	1.5257	0.3942	0.0701	0.6447	0.0457	0.0088	0.0118
22799-06	158.	0.4076	0.3639	0.0437	8.3155	1.6845	0.5035	0.0797	0.6125	0.0420	0.0087	0.0176
22803-05	150.	0.2985	0.2687	0.0298	7.9083	1.4534	0.3629	0.0726	0.4328	0.0382	0.0083	0.0139
22802-10	154.	0.6931	0.4761	0.2170	9.3577	1.6317	0.5036	0.0801	0.8934	0.0548	0.0107	0.0134
22799-02	154.	0.7222	0.4036	0.3186	8.0982	1.5176	0.3867	0.0868	0.7401	0.0480	0.0075	0.0171
22800-01	137.	0.2600	0.2429	0.0171	6.9194	1.5395	0.3016	0.1012	0.5248	0.0408	0.0101	0.0135
22802-09	156.	0.3072	0.2861	0.0211	8.8348	1.5826	0.4142	0.0879	0.7517	0.0437	0.0125	0.0068-A
22805-03	150.	0.2583	0.2414	0.0169	7.0695	1.4675	0.3386	0.0613	0.5764	0.0356	0.0074	0.0120
22806-04	155.	0.3951	0.3661	0.0290	8.6690	1.6219	0.4763	0.0829	0.6804	0.0416	0.0101	0.0151
22804-10	164.	0.2704	0.2502	0.0202	9.9129	1.5848	0.4103	0.0792	0.4635	0.0441	0.0093	0.0129
22807-02	162.	0.2705	0.2536	0.0169	9.4365	1.5850	0.3301	0.0707	0.4814	0.0374	0.0098	0.0142
22805-06	143.	0.2402	0.2256	0.0146	7.3044	1.2563	0.3751	0.0750	0.4678	0.0310	0.0075	0.0131
22808-01	155.	0.2925	0.2677	0.0248	8.6371	1.5789	0.5159	0.0667	0.4752	0.0445	0.0086	0.0174
22811-08	146.	0.2655	0.2456	0.0199	8.0548	1.5406	0.4258	0.0684	0.5861	0.0445	0.0080	0.0125
MEAN	154.	0.3987	0.3091	0.0896	8.4341	1.5487	0.4127	0.0772	0.6066	0.0425	0.0091	0.0141
S.D.	7.7	0.23340	0.09022	0.15214	0.89315	0.10376	0.06680	0.00998	0.13758	0.00561	0.00139	0.00194
N	15	15	15	15	15	15	15	15	15	15	15	14

FBW = FINAL BODY WEIGHT
A = SINGLE ORGAN WEIGHT; NOT INCLUDED IN CALCULATIONS

Revised Draft

Modified: 6/30/2006

TABLE 24

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-011

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-08	147.	0.3008	0.2757	0.0251	8.1377	1.5980	0.4059	0.0807	0.5390	0.0502	0.0128	0.0165
22803-02	140.	0.2709	0.2455	0.0254	7.7733	1.3894	0.4037	0.0695	0.4888	0.0505	0.0100	0.0149
22799-10	140.	0.3154	0.2940	0.0214	8.0046	1.7281	0.3780	0.1043	0.5023	0.0485	0.0123	0.0173
22800-08	155.	0.3035	0.2781	0.0254	9.6245	1.7245	0.5038	0.0834	0.5274	0.0490	0.0101	0.0194
22802-08	145.	0.2363	0.2213	0.0150	8.9123	1.6505	0.5988	0.0718	0.7469	0.0404	0.0088	0.0149
22802-01	141.	0.1971	0.1826	0.0145	8.4710	1.5923	0.4936	0.0505	0.5801	0.0345	0.0086	0.0147
22801-10	136.	0.2690	0.2482	0.0208	6.8139	1.4313	0.3543	0.0365	0.4087	0.0366	0.0064	0.0141
22806-07	130.	0.2850	0.2563	0.0287	7.5832	1.5617	0.3112	0.0399	0.4892	0.0327	0.0069	0.0149
22804-01	149.	0.2443	0.2278	0.0165	8.7445	1.6035	0.3339	0.0374	0.6071	0.0384	0.0091	0.0137
22805-10	145.	0.2949	0.2772	0.0177	7.5022	1.5887	0.4451	0.0758	0.6143	0.0399	0.0075	0.0140
22807-04	166.	0.2392	0.2237	0.0155	9.9362	1.7080	0.4213	0.0849	0.4891	0.0549	0.0079	0.0119
22804-06	150.	0.3602	0.3382	0.0220	8.6447	1.7785	0.4079	0.0519	0.6270	0.0340	0.0100	0.0154
22811-02	154.	0.2716	0.2497	0.0219	9.2545	1.6344	0.4535	0.0643	0.6241	0.0498	0.0105	0.0142
22808-08	141.	0.2949	0.2792	0.0157	8.0544	1.5448	0.3912	0.0856	0.4894	0.0450	0.0097	0.0117
22809-07	130.	0.2719	0.2576	0.0143	6.9443	1.2977	0.4555	0.0467	0.4930	0.0379	0.0071	0.0146
MEAN	145.	0.2770	0.2570	0.0200	8.2934	1.5888	0.4238	0.0655	0.5484	0.0428	0.0092	0.0148
S.D.	9.6	0.03879	0.03654	0.00474	0.91458	0.13261	0.07269	0.02079	0.08426	0.00722	0.00188	0.00192
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/30/2006

TABLE 24

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-02	165.	0.2785	0.2614	0.0171	9.0757	1.5136	0.5089	0.0914	0.5882	0.0371	0.0086	0.0156
22800-05	152.	0.5767	0.4014	0.1753	7.8430	1.5755	0.5522	0.0891	0.5866	0.0407	0.0081	0.0140
22803-10	152.	0.2600	0.2431	0.0169	8.8692	1.5057	0.4449	0.0631	0.4747	0.0316	0.0087	0.0129
22799-07	151.	0.2206	0.2015	0.0191	7.2695	1.5501	0.3988	0.0802	0.5499	0.0392	0.0077	0.0144
22802-05	137.	0.2340	0.2142	0.0198	8.5490	1.6661	0.4519	0.0893	0.5231	0.0411	0.0096	0.0149
22800-09	151.	0.2313	0.2105	0.0208	7.6439	1.4839	0.5138	0.0747	0.5422	0.0406	0.0104	0.0133
22802-07	152.	0.2977	0.2788	0.0189	9.3386	1.7318	0.5900	0.1047	0.4800	0.0446	0.0115	0.0174
22806-09	132.	0.2292	0.2052	0.0240	6.6798	1.2628	0.4156	0.0595	0.5157	0.0371	0.0076	0.0095
22805-04	142.	0.2614	0.2399	0.0215	8.2011	1.5882	0.3881	0.1019	0.5376	0.0386	0.0061	0.0175
22804-05	154.	0.3517	0.3324	0.0193	9.8745	1.6803	0.4771	0.0790	0.4910	0.0429	0.0085	0.0159
22807-03	182.	0.4742	0.3565	0.1177	9.0925	1.8004	0.4899	0.0708	0.7770	0.0381	0.0103	0.0132
22805-05	154.	0.2546	0.2402	0.0144	7.3927	1.2005	0.3752	0.0684	0.3779	0.0302	0.0074	0.0141
22804-07	153.	0.2300	0.2078	0.0222	9.4668	1.7450	0.4109	0.0905	0.5616	0.0422	0.0093	0.0142
22811-01	172.	0.3001	0.2749	0.0252	9.8924	2.0351	0.6357	0.1015	0.6614	0.0491	0.0110	0.0225
22808-03	156.	0.2734	0.2507	0.0227	8.2147	1.5626	0.5692	0.0657	0.5311	0.0338	0.0073	0.0144
MEAN	154.	0.2982	0.2612	0.0370	8.4936	1.5934	0.4815	0.0820	0.5465	0.0391	0.0088	0.0149
S.D.	12.5	0.10041	0.05974	0.04586	0.98833	0.20456	0.07952	0.01479	0.08977	0.00490	0.00153	0.00284
N	15	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/30/2006

TABLE 24

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-09	150.	0.2157	0.1988	0.0169	8.6036	1.5543	0.4259	0.0716	0.4692	0.0497	0.0107	0.0152
22800-07	152.	0.2253	0.2061	0.0192	9.3863	1.5303	0.4820	0.0716	0.5327	0.0496	0.0081	0.0109
22803-06	150.	0.1925	0.1766	0.0159	10.0103	1.6602	0.4058	0.0507	0.4950	0.0450	0.0125	0.0170
22799-04	133.	0.1798	0.1709	0.0089	8.5069	1.4889	0.3692	0.0586	0.4090	0.0386	0.0086	0.0140
22802-11	150.	0.2080	0.1952	0.0128	10.5294	1.7419	0.5073	0.0613	0.6077	0.0376	0.0098	0.0142
22801-05	131.	0.1542	0.1444	0.0098	7.7283	1.6725	0.3175	0.0571	0.4314	0.0369	0.0069	0.0092-A
22806-05	132.	0.2117	0.1985	0.0132	7.9606	1.4133	0.4479	0.0458	0.3685	0.0429	0.0089	0.0111
22804-03	154.	0.4456	0.2761	0.1695	9.8002	1.6395	0.3586	0.0689	0.5302	0.0442	0.0077	0.0102
22805-09	136.	0.2770	0.2388	0.0382	7.5919	1.4949	0.3042	0.0516	0.4246	0.0330	0.0066	0.0118
22807-05	183.	0.2648	0.2466	0.0182	12.1610	1.7077	0.4299	0.0524	0.5897	0.0533	0.0114	0.0111
22804-02	179.	0.2618	0.2362	0.0256	12.5816	1.8507	0.5664	0.0773	0.6561	0.0558	0.0079	0.0167
22806-08	131.	0.1719	0.1637	0.0082	7.8900	1.4196	0.3188	0.0470	0.4085	0.0319	0.0060	0.0127
22810-03	172.	0.2524	0.2322	0.0202	10.2972	1.6375	0.5342	0.0573	0.4361	0.0476	0.0108	0.0142
22811-06	161.	0.2400	0.2235	0.0165	8.7628	1.6100	0.5801	0.0992	0.5086	0.0533	0.0103	0.0199
MEAN	151.	0.2358	0.2077	0.0281	9.4150	1.6015	0.4320	0.0622	0.4905	0.0442	0.0090	0.0138
S.D.	17.7	0.07079	0.03659	0.04142	1.58380	0.12534	0.09248	0.01447	0.08513	0.00774	0.00195	0.00288
N	14	14	14	14	14	14	14	14	14	14	14	13

FBW = FINAL BODY WEIGHT
A = SINGLE ORGAN WEIGHT; NOT INCLUDED IN CALCULATIONS

POFBWv4.14
05/25/2006
R:06/30/2006

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Modified: 6/30/2006

TABLE 25

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: CORN OIL

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-04	180.	0.130	0.117	5.883	0.937	0.296	0.050	0.432	0.023	0.006	0.010
22799-01	150.	0.368	0.264	4.594	0.911	0.263	0.046	0.525	0.026	0.006	0.011
22800-06	153.	0.134	0.123	4.775	1.094	0.220	0.051	0.400	0.020	0.004	0.012
22803-09	149.	0.276	0.222	5.297	1.055	0.300	0.055	0.349	0.023	0.006	0.008
22802-04	160.	0.145	0.131	6.556	1.188	0.337	0.051	0.387	0.023	0.008	0.009
22800-04	149.	0.439	0.324	4.993	1.047	0.337	0.054	0.394	0.030	0.007	0.010
22799-05	144.	0.180	0.165	4.915	1.129	0.309	0.064	0.468	0.028	0.007	0.013
22803-04	171.	0.197	0.180	5.663	0.971	0.340	0.048	0.307	0.024	0.005	0.009
22806-02	137.	0.155	0.141	5.142	1.114	0.248	0.056	0.474	0.024	0.005	0.008
22807-07	162.	0.134	0.121	5.407	0.982	0.263	0.044	0.418	0.020	0.005	0.011
22805-01	143.	0.455	0.271	5.059	0.987	0.234	0.053	0.341	0.026	0.006	0.010
22804-04	191.	0.182	0.172	5.517	0.968	0.320	0.040	0.274	0.019	0.005	0.004
22807-08	175.	0.505	0.276	5.335	1.025	0.244	0.045	0.352	0.030	0.005	0.010
22808-05	156.	0.369	0.248	4.963	0.880	0.261	0.049	0.345	0.028	0.006	0.008
22811-07	139.	0.189	0.172	4.684	1.063	0.232	0.049	0.436	0.028	0.007	0.009
MEAN	157.	0.257	0.195	5.252	1.023	0.280	0.050	0.393	0.025	0.006	0.009
S.D.	15.9	0.1331	0.0672	0.5118	0.0862	0.0418	0.0058	0.0675	0.0036	0.0011	0.0021
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/30/2006

TABLE 25

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-06	148.	0.289	0.270	6.000	1.185	0.292	0.066	0.372	0.032	0.006	0.009
22800-03	161.	0.178	0.163	5.724	1.001	0.294	0.057	0.480	0.022	0.006	0.011
22803-07	154.	0.197	0.179	5.712	1.042	0.263	0.064	0.335	0.026	0.008	0.010
22799-08	145.	0.241	0.225	5.482	1.064	0.243	0.059	0.448	0.032	0.009	0.010
22802-02	144.	0.301	0.256	5.232	1.063	0.285	0.049	0.335	0.020	0.006	0.010
22802-06	140.	0.312	0.292	6.071	1.204	0.334	0.052	0.406	0.024	0.007	0.010
22801-03	165.	0.449	0.285	5.322	1.007	0.331	0.062	0.359	0.028	0.006	0.010
22806-10	134.	0.249	0.224	5.220	1.059	0.273	0.048	0.392	0.024	0.005	0.011
22804-09	161.	0.161	0.149	6.289	1.053	0.332	0.046	0.352	0.024	0.005	0.011
22805-02	131.	0.155	0.145	4.549	1.063	0.250	0.043	0.342	0.023	0.005	0.009
22807-01	164.	0.294	0.259	5.773	1.141	0.332	0.055	0.426	0.022	0.006	0.007
22805-08	135.	0.646	0.300	5.022	1.034	0.281	0.048	0.440	0.028	0.005	0.009
22806-01	146.	0.219	0.205	5.421	1.189	0.269	0.052	0.446	0.022	0.005	0.010
22811-03	151.	0.498	0.284	4.827	1.000	0.189	0.043	0.391	0.030	0.005	0.010
22808-06	136.	0.187	0.174	5.015	1.047	0.292	0.054	0.315	0.055	0.007	0.010
MEAN	148.	0.292	0.227	5.444	1.077	0.284	0.053	0.389	0.027	0.006	0.010
S.D.	11.4	0.1393	0.0550	0.4877	0.0689	0.0398	0.0073	0.0503	0.0085	0.0012	0.0010
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

TABLE 25

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22800-10	166.	0.625	0.301	5.634	1.000	0.272	0.046	0.463	0.027	0.005	0.008
22801-07	156.	0.168	0.157	5.539	0.978	0.253	0.045	0.413	0.029	0.006	0.008
22799-06	158.	0.258	0.230	5.263	1.066	0.319	0.050	0.388	0.027	0.006	0.011
22803-05	150.	0.199	0.179	5.272	0.969	0.242	0.048	0.289	0.025	0.006	0.009
22802-10	154.	0.450	0.309	6.076	1.060	0.327	0.052	0.580	0.036	0.007	0.009
22799-02	154.	0.469	0.262	5.259	0.985	0.251	0.056	0.481	0.031	0.005	0.011
22800-01	137.	0.190	0.177	5.051	1.124	0.220	0.074	0.383	0.030	0.007	0.010
22802-09	156.	0.197	0.183	5.663	1.014	0.266	0.056	0.482	0.028	0.008	NA
22805-03	150.	0.172	0.161	4.713	0.978	0.226	0.041	0.384	0.024	0.005	0.008
22806-04	155.	0.255	0.236	5.593	1.046	0.307	0.053	0.439	0.027	0.007	0.010
22804-10	164.	0.165	0.153	6.044	0.966	0.250	0.048	0.283	0.027	0.006	0.008
22807-02	162.	0.167	0.157	5.825	0.978	0.204	0.044	0.297	0.023	0.006	0.009
22805-06	143.	0.168	0.158	5.108	0.879	0.262	0.052	0.327	0.022	0.005	0.009
22808-01	155.	0.189	0.173	5.572	1.019	0.333	0.043	0.307	0.029	0.006	0.011
22811-08	146.	0.182	0.168	5.517	1.055	0.292	0.047	0.401	0.030	0.005	0.009
MEAN	154.	0.257	0.200	5.475	1.008	0.268	0.050	0.394	0.028	0.006	0.009
S.D.	7.7	0.1412	0.0537	0.3708	0.0577	0.0398	0.0080	0.0854	0.0035	0.0009	0.0011
N	15	15	15	15	15	15	15	15	15	15	14

FBW = FINAL BODY WEIGHT
NA = NOT APPLICABLE

Revised Draft

Modified: 6/30/2006

TABLE 25

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR: [redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-011

FEMALE GROUP: [redacted]1000

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-08	147.	0.205	0.188	5.536	1.087	0.276	0.055	0.367	0.034	0.009	0.011
22803-02	140.	0.194	0.175	5.552	0.992	0.288	0.050	0.349	0.036	0.007	0.011
22799-10	140.	0.225	0.210	5.718	1.234	0.270	0.075	0.359	0.035	0.009	0.012
22800-08	155.	0.196	0.179	6.209	1.113	0.325	0.054	0.340	0.032	0.007	0.013
22802-08	145.	0.163	0.153	6.146	1.138	0.413	0.050	0.515	0.028	0.006	0.010
22802-01	141.	0.140	0.130	6.008	1.129	0.350	0.036	0.411	0.024	0.006	0.010
22801-10	136.	0.198	0.183	5.010	1.052	0.261	0.027	0.301	0.027	0.005	0.010
22806-07	130.	0.219	0.197	5.833	1.201	0.239	0.031	0.376	0.025	0.005	0.011
22804-01	149.	0.164	0.153	5.869	1.076	0.224	0.025	0.407	0.026	0.006	0.009
22805-10	145.	0.203	0.191	5.174	1.096	0.307	0.052	0.424	0.028	0.005	0.010
22807-04	166.	0.144	0.135	5.986	1.029	0.254	0.051	0.295	0.033	0.005	0.007
22804-06	150.	0.240	0.225	5.763	1.186	0.272	0.035	0.418	0.023	0.007	0.010
22811-02	154.	0.176	0.162	6.009	1.061	0.294	0.042	0.405	0.032	0.007	0.009
22808-08	141.	0.209	0.198	5.712	1.096	0.277	0.061	0.347	0.032	0.007	0.008
22809-07	130.	0.209	0.198	5.342	0.998	0.350	0.036	0.379	0.029	0.005	0.011
MEAN	145.	0.192	0.178	5.724	1.099	0.293	0.045	0.380	0.030	0.006	0.010
S.D.	9.6	0.0292	0.0272	0.3486	0.0706	0.0492	0.0138	0.0545	0.0041	0.0014	0.0015
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/30/2006

TABLE 25

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-011

FEMALE GROUP: [redacted]60

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-02	165.	0.169	0.158	5.500	0.917	0.308	0.055	0.356	0.022	0.005	0.009
22800-05	152.	0.379	0.264	5.160	1.037	0.363	0.059	0.386	0.027	0.005	0.009
22803-10	152.	0.171	0.160	5.835	0.991	0.293	0.042	0.312	0.021	0.006	0.008
22799-07	151.	0.146	0.133	4.814	1.027	0.264	0.053	0.364	0.026	0.005	0.010
22802-05	137.	0.171	0.156	6.240	1.216	0.330	0.065	0.382	0.030	0.007	0.011
22800-09	151.	0.153	0.139	5.062	0.983	0.340	0.049	0.359	0.027	0.007	0.009
22802-07	152.	0.196	0.183	6.144	1.139	0.388	0.069	0.316	0.029	0.008	0.011
22806-09	132.	0.174	0.155	5.060	0.957	0.315	0.045	0.391	0.028	0.006	0.007
22805-04	142.	0.184	0.169	5.775	1.118	0.273	0.072	0.379	0.027	0.004	0.012
22804-05	154.	0.228	0.216	6.412	1.091	0.310	0.051	0.319	0.028	0.006	0.010
22807-03	182.	0.261	0.196	4.996	0.989	0.269	0.039	0.427	0.021	0.006	0.007
22805-05	154.	0.165	0.156	4.800	0.780	0.244	0.044	0.245	0.020	0.005	0.009
22804-07	153.	0.150	0.136	6.187	1.141	0.269	0.059	0.367	0.028	0.006	0.009
22811-01	172.	0.174	0.160	5.751	1.183	0.370	0.059	0.385	0.029	0.006	0.013
22808-03	156.	0.175	0.161	5.266	1.002	0.365	0.042	0.340	0.022	0.005	0.009
MEAN	154.	0.193	0.169	5.533	1.038	0.313	0.054	0.355	0.026	0.006	0.010
S.D.	12.5	0.0595	0.0341	0.5523	0.1132	0.0449	0.0103	0.0438	0.0034	0.0010	0.0017
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Draft

Modified: 6/30/2006

TABLE 25

PROJECT NO.:WIL-187056 PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS
SPONSOR:[redacted]
SPONSOR NO.:06-011
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: [redacted]250

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	OVARIES/OVIDUCTS	THYMUS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARATHY
22801-09	150.	0.144	0.133	5.736	1.036	0.284	0.048	0.313	0.033	0.007	0.010
22800-07	152.	0.148	0.136	6.175	1.007	0.317	0.047	0.350	0.033	0.005	0.007
22803-06	150.	0.128	0.118	6.674	1.107	0.271	0.034	0.330	0.030	0.008	0.011
22799-04	133.	0.135	0.128	6.396	1.119	0.278	0.044	0.308	0.029	0.006	0.011
22802-11	150.	0.139	0.130	7.020	1.161	0.338	0.041	0.405	0.025	0.007	0.009
22801-05	131.	0.118	0.110	5.899	1.277	0.242	0.044	0.329	0.028	0.005	NA
22806-05	132.	0.160	0.150	6.031	1.071	0.339	0.035	0.279	0.033	0.007	0.008
22804-03	154.	0.289	0.179	6.364	1.065	0.233	0.045	0.344	0.029	0.005	0.007
22805-09	136.	0.204	0.176	5.582	1.099	0.224	0.038	0.312	0.024	0.005	0.009
22807-05	183.	0.145	0.135	6.645	0.933	0.235	0.029	0.322	0.029	0.006	0.006
22804-02	179.	0.146	0.132	7.029	1.034	0.316	0.043	0.367	0.031	0.004	0.009
22806-08	131.	0.131	0.125	6.023	1.084	0.243	0.036	0.312	0.024	0.005	0.010
22810-03	172.	0.147	0.135	5.987	0.952	0.311	0.033	0.254	0.028	0.006	0.008
22811-06	161.	0.149	0.139	5.443	1.000	0.360	0.062	0.316	0.033	0.006	0.012
MEAN	151.	0.156	0.138	6.215	1.068	0.285	0.041	0.324	0.029	0.006	0.009
S.D.	17.7	0.0431	0.0193	0.4970	0.0877	0.0454	0.0083	0.0364	0.0032	0.0011	0.0018
N	14	14	14	14	14	14	14	14	14	14	13

FBW = FINAL BODY WEIGHT
NA = NOT APPLICABLE

POFBWv4.14
05/25/2006
R:06/07/2006

APPENDIX A

Certificates Of Analysis (Sponsor-Provided Data)

Revised Draft

[redacted]

Test Substance Certificate

Revised Draft

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark amber very viscous liquid

Storage Conditions
Ambient

Expiration Date
1 December 2006

Additional Comments
None

[redacted]

27 February 2006
Date

[redacted]

Test Substance Certificate

Revised Draft

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Dark brown viscous liquid

Storage Conditions
Ambient

Expiration Date
1 March 2007

Additional Comments
None

[redacted]

27 February 2006
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

Revised Draft

APPENDIX C

Animal Room Environmental Conditions

Revised Draft

Revised Draft

Modified: 5/27/2006

PUBERTAL ASSAY OF [redacted] & [redacted] ADMINISTERED ORALLY IN RATS

PROJECT NO [redacted] 187056 TEMPERATURE [redacted] ITY [redacted] Y SUMMARY REPORT BY STUDY

SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187056

DATE IN: 03/14/06 TIME IN: 11:00
DATE OUT: 04/19/06 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
14-Mar-06	70.4	21.3	40.3
15-Mar-06	70.5	21.4	40.0
16-Mar-06	70.5	21.4	39.2
17-Mar-06	70.5	21.4	40.6
18-Mar-06	70.5	21.4	40.0
19-Mar-06	70.4	21.3	40.4
20-Mar-06	70.2	21.2	41.0
21-Mar-06	70.5	21.4	40.3
22-Mar-06	70.5	21.4	40.5
23-Mar-06	70.5	21.4	40.3
24-Mar-06	70.5	21.4	40.5
25-Mar-06	70.4	21.3	41.8
26-Mar-06	70.5	21.4	40.0
27-Mar-06	70.5	21.4	41.2
28-Mar-06	70.5	21.4	39.5
29-Mar-06	70.5	21.4	40.8
30-Mar-06	70.5	21.4	40.0
31-Mar-06	70.5	21.4	46.8
01-Apr-06	70.6	21.4	41.5
02-Apr-06	70.5	21.4	39.8
03-Apr-06	70.5	21.4	45.4
04-Apr-06	70.6	21.4	39.7
05-Apr-06	70.5	21.4	38.7

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
5/27/2006 12:50

Revised Draft

Modified: 5/27/2006

STUDY SPECIFICATIONS: 187056

DATE IN: 03/14/06 TIME IN: 11:00
DATE OUT: 04/19/06 TIME OUT: 8:00

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
06-Apr-06	70.5	21.4	38.4
07-Apr-06	70.5	21.4	49.6
08-Apr-06	70.5	21.4	38.2
09-Apr-06	70.4	21.3	39.0
10-Apr-06	70.6	21.5	39.1
11-Apr-06	70.5	21.4	37.9
12-Apr-06	70.5	21.4	40.2
13-Apr-06	70.5	21.4	38.4
14-Apr-06	70.5	21.4	42.2
15-Apr-06	70.6	21.4	39.6
16-Apr-06	70.5	21.4	39.3
17-Apr-06	70.5	21.4	40.1
18-Apr-06	70.6	21.5	38.3
19-Apr-06	70.4	21.4	38.9

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.2	70.6
TEMPERATURE °C	21.4	21.2	21.5
HUMIDITY (%RH)	40.5	37.9	49.6
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
NOTE: - = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
5/27/2006 12:50

Revised Draft

Modified: 5/27/2006

ROOM SPECIFICATIONS: B ROOM 73
SPECIES: RAT
LOW TEMPERATURE: 66.0
HIGH TEMPERATURE: 76.0
LOW HUMIDITY: 30.0
HIGH HUMIDITY: 70.0
DATE IN: 03/14/06
TIME IN: 11:00
DATE OUT: 04/19/06
TIME OUT: 8:00

ROOM B ROOM 73 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	40.5
MIN	68.6	31.1
MAX	72.8	75.6
SD	0.34	3.67
N SAMPLES	861	861
FIRST DAY	03/14/06	
LAST DAY	04/19/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

REPORT 5
VERSION 1.10
5/27/2006 12:51

Revised Draft

STUDY 187056 SUMMARY

MEAN	70.5	40.5
MIN	68.6	31.1
MAX	72.8	75.6
SD	0.34	3.67
N SAMPLES	861	861
FIRST DAY	03/14/06	
LAST DAY	04/19/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

REPORT 5
VERSION 1.10
5/27/2006 12:51

APPENDIX D

Clinical Pathology Methods, Procedures And References

Revised Draft

CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Immunoassay- DPC Immulite®

Estradiol (estradiol-17β) - Competitive Immunoassay for the quantitative measurement of estradiol in serum. Default unit: pg/mL.

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

Revised Draft

Immunoassay-GAMMA-C12 Gamma Counter

Rat Luteinizing Hormone (rLH) - ^{125}I radioimmunoassay system for the quantitative determination of (rLH) DPC GAMMA C-12 gamma counter. Default unit: mIU/mL. Biotrak™ rat luteinizing hormone [^{125}I] assay system©. Amersham Life Science Ltd. Package Insert.

Rat Thyroid Stimulating Hormone (rTSH) - ^{125}I assay system with magnetic separation for the quantitative measurement of (rTSH). DPC GAMMA C-12 gamma counter. Biotrak™ rat thyroid stimulating hormone ^{125}I assay system. Amersham Pharmacia Biotech. Package insert.

References:

Immulite®. Diagnostics Products Corporation. Package Insert.

APPENDIX E

WIL Female Pubertal Assay Historical Control Data Version 1.0 [Crl:CD(SD) Rats]

Revised Draft

Modified: 3/13/2006

Revised Draft

WIL Research Laboratories, LLC Historical Control

FEMALE PUBERTAL ASSAYS - Crl:CD(SD) RATS

	Grand Mean	SD	N	Min	Max	25th Quartile	75th Quartile
Vaginal Patency (PND)	34.0	1.3	9	31.8	36.5	33.5	34.5
Body Weight At Patency (g)	111.0	4.9	9	102.1	116.4	107.2	114.3
Estrous Cycle Length (days)	5.1	0.4	8	4.8	6.1	4.875	5.25
Age At First Estrus (PND)	35.8	1.4	9	34.1	38.0	35.1	37.1
T4 (µg/dL)	4.4	0.5	5	3.89	5.23	4.06	4.53
TSH (ng/mL)	9.3	1.9	5	7.7	11.4	7.8	11.3
Uterus - Wet (g)	0.3413	0.0492	9	0.2932	0.44	0.3132	0.3424
Uterus - Blotted (g)	0.2884	0.0307	9	0.2621	0.361	0.2763	0.283
Luminal Fluid (g)	0.0537	0.0227	9	0.0306	0.0924	0.038	0.061
Liver (g)	7.4265	0.4693	9	6.69	7.978	7.16	7.9285
Kidney (g)	1.6066	0.0369	5	1.5682	1.6541	1.5704	1.6237
Ovaries/Oviducts (g)	0.0841	0.0051	8	0.0769	0.094	0.0821	0.0859
Adrenal Glands (g)	0.0381	0.0039	9	0.0321	0.0428	0.0352	0.0415
Pituitary (g)	0.0085	0.0009	9	0.0074	0.0101	0.0079	0.0092
Thyroid Glands (g)	0.0171	0.0031	5	0.0129	0.0213	0.0158	0.0179

Version 1.0 - 23 January 2006

APPENDIX F

WIL Reproductive Historical Control Data Version 2.3 [Crl:CD(SD) Rats]

Revised Draft

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Reproductive Performance

Sex: M/F | Species: Rats | Number of Studies/Control Groups: 61 / 92
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Total	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Number of Males in Control Group	1622						
Male Mating Index (%)		96.8	3.69	61	89.42 / 100.0	85.73 / 100.0	86.7 / 100.0
Male Fertility Index (%)		89.6	7.06	61	75.48 / 100.0	68.42 / 100.0	72.0 / 100.0
Male Copulation Index (%)		92.6	6.33	61	79.94 / 100.0	73.61 / 100.0	75.0 / 100.0
Number of Females in Control Group	2266						
Female Mating Index (%)		97.8	3.24	74	91.32 / 100.0	88.08 / 100.0	86.7 / 100.0
Female Fertility Index (%)		91.2	7.37	83	76.46 / 100.0	69.09 / 100.0	72.0 / 100.0
Female Conception Index (%)		92.8	6.01	74	80.78 / 100.0	74.77 / 100.0	75.0 / 100.0
Number of Females Selected to Deliver	1243						
Number that Delivered	1101						
Number that did not Deliver	137						
Number with Total Litter Loss	10						
Number with Dystocia	3						

Version 2.2
02-Mar-06

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Reproductive Performance

Sex: Female | Species: Rats | Number of Studies/Control Groups: 63 / 97

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Mean Estrous Cycle Length (days)	4.5	0.41	62	3.68 / 5.32	3.27 / 5.73	4.0 / 5.8
Mean Pre-Coital Interval (days)	3.0	0.53	75	1.94 / 4.06	1.41 / 4.59	1.8 / 4.7
Mean Gestation Length (days)	21.9	0.19	44	21.52 / 22.28	21.33 / 22.47	21.5 / 22.3
Mean Number of Pups Born	14.3	0.93	44	12.44 / 16.16	11.51 / 17.09	12.2 / 16.0
Mean Viable Litter Size (PND 0)	14.1	0.95	44	12.20 / 16.00	11.25 / 16.95	12.0 / 16.0
Mean % Males/ Litter	50.1	2.77	57	44.56 / 55.64	41.79 / 58.41	42.7 / 58.5
Mean % Females/ Litter	49.9	2.77	57	44.36 / 55.44	41.59 / 58.21	41.5 / 57.3
Mean No. of Former Implantation Sites at Weaning	15.2	0.89	42	13.42 / 16.98	12.53 / 17.87	13.2 / 17.1
Mean No. of Sites Unaccounted for at Weaning	0.8	0.24	42	0.32 / 1.28	0.08 / 1.52	0.4 / 1.4
Mean No. of Corpora Lutea at Laparohysterectomy	16.3	1.17	25	13.96 / 18.64	12.79 / 19.81	12.9 / 17.9
Mean No. of Implantation Sites at Laparohysterectomy	15.2	1.19	40	12.82 / 17 58	11.63 / 18.77	11.1 / 16.8
Mean Viable Fetuses at Laparohysterectomy (GD 15)	14.9	0.73	10	13.44 / 16.36	12.71 / 17.09	13.6 / 16.1
Mean Viable Fetuses at Laparohysterectomy (GD 20)	13.9	1.56	14	10.78 / 17.02	9.22 / 18.58	10.5 / 15.6
Mean Fetal Body Weight (GD 20) (g)	3.6	0.15	12	3.30 / 3.90	3.15 / 4.05	3.4 / 3.8
Mean Primordial Follical Count of 10 Sections/Dam	115.2	31.74	11	51.72 / 178.68	19.98 / 210.42	50.4 / 148.8

Version 2.2
03-Mar-06

Revised Draft

Modified: 7/14/2006

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Body Weights (g)

Sex: M/F | Study Type. All | Number of Studies/Data Sets· 28 / 44
Species: Rats | Age Range: 1 - 28 Days | Range of Study Dates: 08/00 - 09/05
Strain: Crl:CD(SD)

Males (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	7.1	0.25	44	6.60 / 7.60	6.35 / 7.85	6.7 / 7.6
PND 4	10.0	0.57	43	8.86 / 11.14	8.29 / 11.71	9.0 / 11.4
PND 7	15.3	1.22	42	12 86 / 17.74	11.64 / 18.96	11.9 / 17.5
PND 14	30.2	3.76	34	22.68 / 37.72	18.92 / 41.48	20.2 / 35.3
PND 21	47.3	5.23	39	36 84 / 57.76	31.61 / 62.99	32.8 / 56.7
PND 28 (weaned PND 28)	82.0	6.86	15	68.28 / 95.72	61.42 / 102.58	69.8 / 94

Females (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	6.7	0.24	44	6.22 / 7.18	5.98 / 7.42	6.3 / 7.3
PND 4	9.5	0.54	43	8.42 / 10.58	7.88 / 11.12	8.6 / 10.9
PND 7	14.5	1.15	42	12.20 / 16.80	11.05 / 17.95	11.3 / 16.5
PND 14	29.1	3.50	34	22.10 / 36.10	18.60 / 39.60	20.3 / 33.9
PND 21	45.4	4.77	39	35.86 / 54.94	31.09 / 59.71	32.8 / 53.5
PND 28 (weaned PND 28)	75.8	6.11	15	63.58 / 88.02	57.47 / 94.13	66.7 / 86.2

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03-Mar-06

Revised Draft

Modified: 7/14/2006

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Survival Indices (%)

Sex: M/F | Study Type: All | Number of Studies/Data Sets: 28 / 44
Species: Rats | Age Range: 0 - 21 Days | Range of Study Dates: 08/00 - 09/05
Strain: Crl:CD(SD)

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Number of Pups Born	14.3	0.93	44	12.44 / 16.16	11.51 / 17.09	12.2 / 16.0
Survival (%)						
PND 0 (Relative to No. Born)	98.0	1.56	44	94.88 / 100.00	93.32 / 100.00	93.3 / 100.0
PND 0 to PND 1	99.1	0.90	44	97.30 / 100.00	96.40 / 100.00	95.8 / 100.0
PND 1 to PND 4 (Before Selection)	98 8	1.17	43	96.46 / 100.00	95.29 / 100.00	95.2 / 100.0
PND 4 (After Selection) to PND 7	98.8	1.79	42	95.22 / 100.00	93.43 / 100.00	91.7 / 100.0
PND 7 to PND 14	99.3	1.49	39	96.32 / 100.00	94.83 / 100.00	93.5 / 100.0
PND 14 to PND 21	99.5	1.13	39	97.24 / 100.00	96.11 / 100.00	94.7 / 100.0
Birth to PND 4 (Before Selection)	95.9	2.25	41	91.40 / 100.00	89.15 / 100.00	86.6 / 98.7
PND 4 (After Selection) to PND 21	97.8	2.55	38	92.70 / 100.00	90.15 / 100.00	91.1 / 100.0

Version 2.2
02-Mar-06

Revised Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Developmental Landmarks

Sex: M/F | Species: Rats | Number of Studies/Control Groups: 27 / 35

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates. 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Male Anogenital Distance (PND1) (mm)	4.02	0.724	8	2.572 / 5.468	1.848 / 6.192	2.45 / 4.66
Mean Female Anogenital Distance (PND1) (mm)	2.18	0.420	8	1.340 / 3.020	0.920 / 3.440	1.34 / 2.57
Mean Day of Balanopreputial Separation	44.8	1.32	30	42.16 / 47.44	40.84 / 48.76	42.0 / 49.0
Mean Body Weight at Aquisition (g)	225.33	9.432	30	206.466 / 244.194	197.034 / 253.626	203.7 / 246.8
Mean Day of Vaginal Patency	33.6	1.07	30	31.46 / 35.74	30.39 / 36.81	31.7 / 37.0
Mean Body Weight at Aquisition (g)	111.87	6 527	30	98.816 / 124.924	92.289 / 131.451	99.5 / 127.4
Mean Day of Surface Righting Response						
Males	5.0	0.06	3	4.88 / 5.12	4.82 / 5.18	5.0 / 5.1
Females	5.2	0.10	3	5.00 / 5.40	4.90 / 5.50	5.1 / 5.3
Mean Day of Pinnal Detachment						
Males	4.1	0.15	4	3.80 / 4.40	3.65 / 4.55	4.0 / 4.3
Females	4.1	0.10	4	3.90 / 4.30	3.80 / 4.40	4.0 / 4.2
Mean Day of Eye Opening						
Males	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Females	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Mean Day of Air Drop Righting Reflex						
Males	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Females	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Mean Day of Hair Growth						
Males	13.5	1.43	4	10.64 / 16.36	9.21 / 17.79	11.7 / 15.0
Females	13.6	1.51	4	10.58 / 16.62	9.07 / 18.13	11.8 / 15.2
Mean Day of Incisor Eruption						
Males	9.9	0.41	5	9.08 / 10.72	8.67 / 11.13	9.3 / 10.4
Females	9.9	0.34	5	9.22 / 10.58	8.88 / 10.92	9.3 / 10.2

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02-Mar-06

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Modified: 7/14/2006

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Organ Weights (PND 21)

Sex: M/F
Species: Rats
Strain: Crl:CD(SD)

Study Type: All
Age: 21 Days

Number of Studies/Number Data Sets: 13 / 22
Range of Study Dates: 06/01 - 09/05

Males

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Brain (g)	1.4380	0.04128	19	1.35544 / 1.52056	1.31416 / 1.56184	1.3451 / 1.4899
Spleen (g)	0.2029	0.03069	19	0.14152 / 0.26428	0.11083 / 0.29497	0.1471 / 0.2480
Thymus (g)	0.1938	0.01956	19	0.15468 / 0.23292	0.13512 / 0.25248	0.1617 / 0.2330

Females

Brain (g)	1.3899	0.03333	19	1.32324 / 1.45656	1.28991 / 1.48989	1.3142 / 1.4378
Spleen (g)	0.1982	0.02939	19	0.13942 / 0.25698	0.11003 / 0.28637	0.1471 / 0.2408
Thymus (g)	0.1943	0.01983	19	0.15464 / 0.23396	0.13481 / 0.25379	0.1669 / 0.2363

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Male and Female Organ Weights (Necropsy)

Sex: M/F | Species: Rats | Number of Studies/Number Data Sets: 39 / 57
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 10/00 - 05/05

Males	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Age of Males at Necropsy (weeks)	21.9	4.29	26	13.32 / 30.48	9.03 / 34.77	16.4 / 30.6
Mean Seminal Vesicle/Coagulating Gland Weight (g)	2.20	0.196	35	1.808 / 2.592	1.612 / 2.788	1.65 / 2.57
Mean Prostate Weight (g)	1.06	0.114	21	0.832 / 1.288	0.718 / 1.402	0.76 / 1.27
Mean Right Testis Weight (g)	1.79	0.069	47	1.652 / 1.928	1.583 / 1.997	1.66 / 1.93
Mean Left Testis Weight (g)	1.79	0.066	47	1.658 / 1.922	1.592 / 1.988	1.67 / 1.94
Mean Right Epidymis Weight (g)	0.72	0.042	47	0.636 / 0.804	0.594 / 0.846	0.63 / 0.80
Mean Left Epidymis Weight (g)	0.72	0.042	47	0.636 / 0.804	0.594 / 0.846	0.62 / 0.78
Mean Right Cauda Epidymis Weight (g)	0.3262	0.02419	47	0.27782 / 0.37458	0.25363 / 0.39877	0.2629 / 0.3693
Mean Left Cauda Epidymis Weight (g)	0.3294	0.02310	47	0.28320 / 0.37560	0.26010 / 0.39870	0.2628 / 0.3706
Females						
Mean Age of Females at Necropsy (weeks)	23.1	5.33	17	12.44 / 33.76	7.11 / 39.09	16.0 / 32.0
Mean Combined Ovary Weight (g)	0.1472	0.03091	17	0.08538 / 0.20902	0.05447 / 0.23993	0.0926 / 0.1779

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Sperm Concentration and Morphology

Sex: Male | Species: Rats | Number of Studies/Control Groups: 31 / 42
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 10/00 - 05/05

Mean Sperm Concentration (millions/ gram of tissue)	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Left Testis	81.2	7.40	41	66.40 / 96.00	59.00 / 103.40	68.2 / 96.6
Left Epididymis	452.6	49.36	35	353.88 / 551.32	304.52 / 600 68	339.1 / 619.2
Left Cauda Epididymis	666.2	57.99	7	550.22 / 782.18	492.23 / 840.17	568.0 / 738.9
Mean Sperm Production Rate (millions/ gram of tissue/ day)	13.4	1.21	23	10.98 / 15.82	9.77 / 17.03	11.4 / 15.8
Mean Sperm Motility (%)	85 4	3.02	42	79.36 / 91.44	76.34 / 94.46	78.9 / 91.0
Mean Progressive Sperm Motility (%)	72.6	3.71	13	65.18 / 80.02	61.47 / 83.73	67.0 / 80.0
Sperm Morphology Differential Count (%)						
Normal	99.1	0.81	41	97.48 / 100.0	96.67 / 100.0	96.1 / 99.9
Normal Head Separated from Flagellum	0.4	0.40	41	0.00 / 1.20	0.00 / 1.60	0.0 / 1.8
Head Absent w/ Normal Flagellum	0.3	0.40	41	0.00 / 1.10	0.00 / 1.50	0.0 / 2.3
Head Absent w/ Abnormal Flagellum	0.0	0.00	41	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Misshapen Head w/ Normal Flagellum	0.0	0.18	41	0.00 / 0.36	0.00 / 0.54	0.0 / 1 1
Misshapen Head w/ Abnormal Flagellum	0.0	0.07	41	0.00 / 0.14	0.00 / 0.21	0.0 / 0.4
Degenerative Flagellar Defects w/ Normal Head	0.0	0.00	41	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Other Flagellar Defects w/ Normal Head	0.0	0.00	41	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0

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APPENDIX G

Study Protocol

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PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] AND [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 06-011

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

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1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test articles to induce effects on pubertal development in the intact juvenile female rat.

The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF), Law No. 82, 1948, Good Laboratory Practice (GLP) Standards. The study will be performed according to the protocol and WIL Standard Operating Procedures.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

2.2 Sponsor Alternate:

2.3 WIL Study Director:

2.4 WIL Deputy Director:

2.5 WIL Departmental Responsibilities:

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3 STUDY SCHEDULE:

Proposed Animal Receipt Date:	March 14, 2006
Proposed Experimental Start Date (Experimental Starting Date):	March 28, 2006
Proposed Experimental Termination/ Completion Date:	April 19, 2006
Proposed Audited Report Date:	To be determined

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

4.1.1 Lot Number:

[redacted]

4.1.2 Purity:

100%.

4.1.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.1.4 Physical Description:

To be determined

4.1.5 Storage Conditions:

Store at ambient conditions.

4.1.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.1.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

4.2 Identification:

[redacted]

4.2.1 Lot Number:

[redacted]

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4.2.2 Purity:

100%.

4.2.3 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.2.4 Physical Description:

To be determined

4.2.5 Storage Conditions:

Store at ambient conditions

4.2.6 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.2.7 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Crl:CD(SD)

5.3 Source:

Charles River Laboratories
Raleigh, NC

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5.4 Number on Study:

One hundred five females (maximum of 130 females and 13 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 6-8 days old upon receipt. Pups not expected to survive to the next observation period (moribund) will be euthanized by intraperitoneal injection of sodium pentobarbital (prior to PND 11) or by carbon dioxide inhalation (after PND 11) and the carcass discarded. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and the carcasses discarded.

5.5 Body Weight Range:

At randomization: 30-50 g for immature females. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal eartag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal. Following randomization the pups will be individually identified by an ear tag.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed-O'Cobs®). Following randomization, the juvenile female animals

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will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. Control animals (Group 1) will be housed on a separate rack from exposed animals. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL standard operating procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol-specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL standard operating procedures. The municipal water supplying the laboratory is analyzed according to WIL standard operating procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Each lot utilized will be identified and recorded. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Acclimation:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately

placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean. Each of 7 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses or incomplete dosing will be recorded.

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7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Vehicle	0	0	5	15
2	[redacted]	60	12	5	15
3		250	50	5	15
4		1000	200	5	15
5		60	12	5	15
6		250	50	5	15
7		1000	200	5	15

7.4.2 Vehicle Control Article:

Corn oil

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 of age and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, after 12:00 p.m., and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Material Preparations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are

visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration, if possible. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5 mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted], for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The method employed will be:

[redacted] SOP: To be determined

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Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted]. This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

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7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will be observed also approximately one hour following dosing and the observations will be recorded. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded. Findings noted outside of the scheduled observation time periods will be recorded at the time they are observed.

7.6.2 Body Weights:

Daily body weights will be recorded individually (to the nearest 0.1 gram, PND 22-42) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed once daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will be performed at approximately the same time each day and will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will be performed at approximately the same time each day and will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not

expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized by carbon dioxide inhalation and necropsied as described in section 9.

8 HOROMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples (target volume of 2 mL) will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH) Thyroxine (T4)

Serum not utilized for TSH and T4 concentrations will be stored frozen for possible future analysis (added by amendment).

9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized *in extremis*. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. Gross lesions (i.e., masses) will be collected and placed in 10% neutral-buffered formalin. The following tissues will be collected and placed in 10% neutral-buffered formalin at study termination:

Cervix and Uterine Body (one longitudinal section)	Thyroids with parathyroids
Ovaries	Uterine horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized in extremis.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in a round-robin

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order. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

Revised Draft

9.2.2 Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Ovaries and oviducts
Liver	Pituitary gland
Kidneys	Thyroids with parathyroids (following fixation)

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 Microscopic Examination:

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination. The vagina, ovaries, and thyroids with parathyroids from each animal will be similarly preserved.

Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

Ovaries	Thyroids with parathyroids
Cervix and Uterine Body (one longitudinal section)	Uterine Horns (four sections per horn)

10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, organ weights relative to final body weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age of first estrous, estrous cycle length and serum hormone concentrations will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the

results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol, protocol amendments and WIL Standard Operating Procedures. The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF) Law No. 82, 1948, Good Laboratory Practice (GLP) Standards. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report.

Revised Draft

One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for additional paper copies of the final report may result in additional charges.

Revised Draft

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in

the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via e-mail on March 2, 2006.

[redacted]

03/13/2006
Date

WIL Research Laboratories, LLC

[redacted]

3/3/2006
Date

[redacted]

3/3/2006
Date

Revised Draft

Study Number: WIL-187056

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor No.: 06-011

A. Title:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **3** **STUDY SCHEDULE:**

Proposed Audited Report Date: June 28, 2006

2) **7.5.1** **Method and Frequency of Preparation:**

The following is added to this section:

The dosing formulations will be stored at room temperature.

3) **8** **HORMONE ANALYSIS:**

The following is added to this section:

Estradiol (E_2) and Lutenizing (LH) hormone concentration levels will be determined.

4) **9.1** **Macroscopic Examination:**

The following is added to this section:

The spleen, thymus and axillary lymph node are added to the list of tissues to be collected.

5) **9.2.2** **Ovary, Liver, Kidney, Pituitary, Thyroid and Adrenal Weights:**

The following is added to this section:

The spleen and thymus are added to the list of organs to be weighed.

Revised Draft

Revised Draft

C. Reason for Protocol Modifications:

1) The proposed audited report date has been determined.

2) The storage requirement for dosing formulations has been added.

3) Additional hormones for analysis have been added.

4) The Sponsor has requested collection of additional tissues.

5) The additional tissues collected will be weighed.

Approved By:

[redacted]

March 21, 2006
Date

Prepared By:

WIL Research Laboratories, LLC

[redacted]

3/20/2006
Date

[redacted]

3/20/2006
Date

Revised Draft

Study Number: WIL-187056

PROTOCOL AMENDMENT II

Sponsor: [redacted]

Sponsor No.: 06-011

A. Title:

A Female Pubertal Assay of [redacted] and [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **7.6.4 Determination of Estrous Cycles:**

In accordance with the Study Director Notification dated April 11, 2006, the vaginal lavage performed on the day of necropsy was collected immediately prior to euthanasia.

C. Reason for Protocol Modifications:

1) This change in procedure was made to allow a more accurate correlation of serum hormone levels with the stage of the estrous cycle.

Approved By:

[redacted]

16 June 2006
Date

Prepared By:
WIL Research Laboratories, LLC

[redacted]

15 June 2006
Date

[redacted]

15 June 2006
Date

307491

COMPANY SANITIZED

REVISED ABBREVIATED AUDITED DRAFT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [ ]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187060

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

7 September 2006

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

06-023

SPONSOR

COMPLIANCE STATEMENT

This study, designated WIL-187060, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) Good Laboratory Practice Standards Law No. 82, 1984; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor. **A Certificate of Analysis was provided by the sponsor (presented in Appendix A); the characterization analyses were conducted according to Good Laboratory Practices (GLP) [sponsor-supplied documentation required]. Stability of the test article to be addressed by the sponsor.**

_____ _____

[ ] Date

Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

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I. Study Protocol

1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test article to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[ ] in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to 4 groups each of 15 Crl:CD(SD) immature female rats. Dosage levels were 10, 50, 200 and 800 mg/kg/day, and the dosage volume was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director. **Stability of the test article to be addressed by the sponsor.**

Dosing procedures were performed from 26 September 2006 through 17 October 2006, when the animals were 22 to 41 days of age; the start of dose administration was staggered, based on age. At the initiation of dose administration, individual body weights ranged from 40.5 g to 63.7 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2		10	2	5	15
3		50	10	5	15
4		200	40	5	15
5		800	160	5	15

Preparation, storage and sampling of the control and test article formulations were conducted as follows. For the control group, the appropriate amount of the vehicle (corn oil, exp. dates: 23 October 2007 and 16 November 2007) was placed in a glass storage container and stirred throughout use. The test article formulations were prepared as follows. The appropriate amount of test article for each group was weighed into a tared,

calibrated glass container. A stir bar and approximately 80% of the vehicle were added to each container, and the mixtures were stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The test article formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature. Three samples from the middle stratum of the control group formulation and 3 sets of samples from the top, middle and bottom strata of the test article formulations were collected prior to the initiation of dose administration. Additional samples (3 sets) were collected for resuspension homogeneity from the same formulations following 10 days of room temperature storage. Two sets of samples for concentration verification were collected on each day of preparation and 2 sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and 6 sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC for possible future analysis.

Ten dams with 10 female pups each (100 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on 12 September 2006. The pups were 6 to 8 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam for 14 to 16 days) during the acclimation period until randomization of the pups on postnatal day (PND) 21. Following randomization, the female pups were weaned, identified by metal eartag and housed in plastic maternity cages. Environmental controls were set to maintain an average daily temperature of 71°F ± 5°F and an average daily relative humidity of 50% ± 20%. Actual mean daily temperatures ranged from 70.3°F to 71.0°F (21.3°C to 21.7°C) and mean daily relative humidity ranged from 36.9% to 47.7%. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes

per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse osmosis-purified water were offered ad libitum.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on PND 23 (Adams et al., 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (i.e., the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia). Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A complete gross necropsy was performed only on animals that were found dead. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum estradiol (E_2), luteinizing hormone (LH), thyroxine (T_4) and thyroid stimulating hormone (TSH) levels. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, pituitary gland, spleen, adrenal glands, thymus gland and thyroid glands (with parathyroid glands) were weighed at the scheduled euthanasia. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus weight. The adrenal glands, axillary lymph nodes, ovaries, oviducts, uterus (horns and body), cervix, vagina, kidneys, liver, spleen, thymus gland, pituitary gland, thyroid glands (with parathyroid glands) and internal gross lesions were examined from all

females, including those found dead; all of these tissues were retained with the exception of the adrenal glands, kidneys and liver.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. In addition, percent difference from control is presented for body weights, clinical pathology parameters and organ weights. Statistical analyses were not conducted if the number of animals was 2 or less. Due to the different rounding conventions inherent in the types of software used, the means and standard deviations on the summary and individual tables may differ by ±1 in the last significant figure. Mean body weights, body weight changes, days of acquisition of vaginal patency, estrous cycle lengths, ages at the first occurrence of estrus, serum hormone levels, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
12 September 2006	Experimental starting date (animal receipt)
26 September 2006	Experimental start date (first day of dose administration)
26 September – 17 October 2006	Test article administration
15 November 2006	Last serum hormone analysis
[redacted]	Experimental termination/completion date ([redacted])

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test article, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS

Brown material on various body surfaces (primarily the anogenital and urogenital areas) was noted in the 800 mg/kg/day group females beginning as early as PND 24. Clear material around the mouth was noted in the 200 and 800 mg/kg/day group females 1 hour following dose administration beginning as early as PND 29 and 27, respectively. This finding was attributed to the test article, but was not considered adverse because they did not persist to the daily examinations. Salivation prior to dose administration was also noted in the 50, 200 and 800 mg/kg/day group females beginning as early as PND 39, 28 and 28, respectively; however, this finding was not considered adverse because it generally did not persist to the daily examinations on the following day.

Eight females in the 800 mg/kg/day were found dead at 23, 25 or 26 days of age as a result of test article administration. Three females in this group were found dead at approximately 1-2 hours following dose administration; the remaining 5 females were found dead on the morning following their last dose. In addition to the findings noted above, 5 of the 8 females in the 800 mg/kg/day group that were found dead had a hunched posture on the day prior to or the day of death; 1 of these females was observed rocking, lurching or swaying while ambulating. A hunched posture was also noted for 1 female in the 800 mg/kg/day group that survived to the scheduled necropsy. At the

necropsy of the females that were found dead, 1 female had dark red discoloration in the lungs and another female had clear fluid contents in the uterus. No other internal findings were noted for females in the 800 mg/kg/day group that died prematurely. All other animals survived to the scheduled euthanasia.

Test article-related lower mean body weight gains and body weight losses in the 800 mg/kg/day group were noted during the first 4 days of dose administration. The differences were statistically significant ($p<0.01$) compared to the control group. Throughout the remainder of the dosing period (following the deaths of the most sensitive animals) mean body weight gains in this group were sporadically lower than the control group; the difference was statistically significant ($p<0.01$) during PND 27-28. However, when the entire treatment period (PND 22-42) was evaluated, mean body weight gain in the 800 mg/kg/day group was lower (not statistically significant) compared to the control group value. As a result of the decrements in mean body weight gains, mean body weights in the 800 mg/kg/day group were 9.7% to 16.1% lower than the control group values during PND 24-42. The differences were statistically significant ($p<0.05$ or $p<0.01$) from PND 24-40. Mean body weight gains in the 200 mg/kg/day group were similar to those in the control group during PND 22-23 through PND 27-28. Thereafter, mean body weight gain in this group was generally lower than that noted in the control group; the difference was statistically significant ($p<0.01$) during PND 39-40. Mean body weight gain in the 200 mg/kg/day group was lower (not statistically significant) than the control group value when the entire treatment period (PND 22-42) was evaluated. The decrements in mean body weight gain in this group were attributed to the test article and resulted in mean body weights that were 5.5% to 8.8% lower (not statistically significant) than the control group values during PND 35-42. Mean body weights and body weight gains in the 10 and 50 mg/kg/day groups were generally similar to those in the control group throughout the study; none of the differences were statistically significant.

The mean age of attainment of vaginal patency was earlier in the 50, 200 and 800 mg/kg/day groups; this change was attributed to the test article. The differences from the concurrent control group were statistically significant ($p<0.01$). Mean ages of attainment were 32.5, 33.3, 28.3, 28.2 and 28.9 days in the control, 10, 50, 200 and 800 mg/kg/day groups, respectively. The values in the 50, 200 and 800 mg/kg/day groups were also lower than the mean minimum value in the WIL historical control data for female pubertal studies (31.8 days of age). Mean body weights at the age of attainment (85.4 g, 83.4 g and 73.9 g) in the 50, 200 and 800 mg/kg/day groups, respectively, were statistically significantly ($p<0.01$) lower than the concurrent control group value; the values were also below the minimum mean value in the WIL historical control data (102.1 g).

Consistent with an earlier age of attainment of vaginal patency, the ages of the first occurrence of estrus in the 50, 200 and 800 mg/kg/day groups (32.1, 31.2 and 28.9 days of age, respectively) were earlier than in the concurrent control group (34.4 days of age); the differences in the 200 and 800 mg/kg/day groups were statistically significant ($p<0.05$ or $p<0.01$). These values were also lower than the minimum mean value in the WIL historical control data (34.1 days of age). Estrous cycle lengths could only be determined for 5/15, 8/15, 13/15, 7/15 and 1/7 females in the control, 10, 50, 200 and 800 mg/kg/day groups, respectively, due to a high number of females with incomplete cycles. No differences in estrous cycle lengths were noted in the 10, 50 and 200 mg/kg/day groups with number of cycling animals available for evaluation. Estrous cycle lengths in females of this age are highly variable. Abnormal estrous cycles ($\geq$3 consecutive days estrus [E]) were noted in 12/15 and 6/7 females in the 200 and 800 mg/kg/day groups, respectively, as presented in the following table.

Text Table 1: Number of Females with Abnormal Estrous Cycles

Group (mg/kg/day)	Number with Extended D	Number with Extended E	Number with Both Extended E and D
0	6/15	0/15	0/15
10	4/15	0/15	0/15
50	6/15	1/15	0/15
200	5/15	12/15	2/15
800	2/7	6/7	1/7

The majority of females in the control, 10 and 50 mg/kg/day groups with abnormal estrous cycles had extended diestrus, whereas a shift toward extended estrus was noted in the 200 and 800 mg/kg/day groups. The persistent estrus noted at the 2 highest dosage levels was consistent with the earlier attainment (3.2 and 5.5 days earlier, respectively) of vaginal patency in these groups.

There were no test article-related effects in thyroid hormone levels (total T_4 and TSH) at any dosage level. In addition, E_2 and LH were unaffected by test article administration at all dosage levels. A high LH value was noted for 1 control group female, resulting in a higher-than-average mean for this group; this sample was re-analyzed and the re-tested value was similar. No statistically significant differences from the control group were noted.

Test article-related, generally statistically significant ($p<0.05$ or $p<0.01$) increases in mean absolute and relative (to final body weight) liver weights (800 mg/kg/day group) and decreases in mean absolute and relative spleen (800 mg/kg/day group), luminal fluid (absolute only), wet and blotted uterus and thymus gland (200 and 800 mg/kg/day groups) and ovary/oviduct weights (50, 200 and 800 mg/kg/day groups) were observed compared to the control group values. The following table presents these changes.

Text Table 2: Summary of Test Article-Related Effects on Absolute Organ Weights [G] with Percent Difference from the Control Group

Organ	0 mg/kg/day	10 mg/kg/day	50 mg/kg/day	200 mg/kg/day	800 mg/kg/day
Liver	8.2487	7.8837 (-4.4%)	7.9892 (-3.1%)	8.3159 (+0.8%)	12.1045** (+46.7%)
Spleen	0.4681	0.4643 (-0.8%)	0.4877 (+4.2%)	0.4209 (-10.1%)	0.3611** (-22.9%)
Wet Uterus	0.4201	0.3760 (-10.5%)	0.4013 (-4.5%)	0.2177** (-48.2%)	0.2143** (-49.0%)
Blot. Uterus	0.3371	0.3277 (-2.8%)	0.3083 (-8.5%)	0.2022** (-40.0%)	0.1992** (-40.9%)
Luminal Fluid	0.0829	0.0482 (-41.9%)	0.0930 (+12.2%)	0.0155 (-81.3%)	0.0151 (-81.8%)
Thymus	0.5948	0.5867 (-1.4%)	0.5768 (-3.0%)	0.4598** (-22.7%)	0.3105** (-47.8%)
Ovary	0.0936	0.0855 (-8.7%)	0.0787* (-15.9%)	0.0548** (-41.5%)	0.0393** (-58.0%)

Blot. = Blotted, Ovary = Ovaries/Oviducts
* = $p<0.05$ ** = $p<0.01$

One and 2 females in the 200 and 800 mg/kg/day groups had small ovaries at necropsy, and 1 of the 800 mg/kg/day group females had small oviducts, corresponding to the lower ovary/oviduct weights noted in these groups. The mean relative liver weight in the 200 mg/kg/day group was statistically significantly ($p<0.05$) higher than the control group value; however, the absolute value was comparable to that in the control group. Therefore, the increase in relative liver weight in this group was not considered test article-related.

Microscopically, 14/15 rats from the 800 mg/kg/day group had absent corpora lutea. This effect was accompanied by moderate (9/15 rats) to severe (6/15 rats) granulosa cell necrosis, and moderate (10/15 rats) to severe (5/15 rats) oocyte degeneration. In the 200 mg/kg/day group, there were 9 rats with absent corpora. Fourteen rats from this group had mild granulosa cell necrosis, and 1 rat had moderate granulosa cell necrosis.

The uterus of 7 rats from the 800 mg/kg/day group that were found dead had mild (4/14 rats) to severe (3/14 rats) atrophy, consisting of decreased endometrial and myometrial thickness as well as a reduced number of endometrial glands. The atrophic glandular

epithelial cells had an inactive appearance with a reduced amount of cytoplasm. All the examined tissues from the control group were microscopically normal.

Text Table 3. Incidence Of Selected Histopathologic Findings

	0 mg/kg/day	200 mg/kg/day	800 mg/kg/day
Ovaries [a]	15	15	15
Corpora lutea absent, bilateral	0	9	14
Necrosis, granulosa cell, bilateral	0	15	15
Mild	0	14	0
Moderate	0	1	9
Severe	0	0	6
Degeneration, oocyte, bilateral	0	15	15
Mild	0	14	0
Moderate	0	1	10
Severe	0	0	5
Uterus[a]	15	15	14[b,c]
Atrophy	0	0	7
Mild	0	0	4
Severe	0	0	3

[a] = Number of tissues examined from each group.
[b] = Missing 1 uterus and cervix at trimming.
[c] = Only noted for females that were found dead.

Mild follicular cell hypertrophy was noted in the thyroid gland of 3 rats from the 800 mg/kg/day group. The relationship of this finding to the test article was unclear. Also in the 800 mg/kg/day group, there was mild focal necrosis in ectopic thymic tissue that was present in the thryoid gland section of 1 rat that was found dead, and minimal focal lymphocytic infiltration was present in the thyroid gland of 1 rat from the 800 mg/kg/day group that was euthanized at the scheduled termination. Remaining histologic changes were considered to be incidental findings, manifestations of spontaneous diseases, or related to some aspect of experimental manipulation other than administration of the test article. There was no test article-related alteration in the incidence, severity or histologic character of those incidental and spontaneous tissue alterations.

1.6. CONCLUSIONS

Based on the results of this study, [ ] administered orally to juvenile female rats resulted in estrogenic effects for females at 50, 200 and 800 mg/kg/day as evidenced by earlier attainment of vaginal patency (with corresponding lower mean body weight on the day of attainment) and at 200 and 800 mg/kg/day by earlier age at the first occurrence of estrus. In addition, estrous cycle disturbances were noted in the 200 and 800 mg/kg/day groups with 12/15 and 6/7 females, respectively, exhibiting persistent estrus (≥3 consecutive days of estrus). No test article-related effects on mean serum E_2, LH, T_4 or TSH levels were observed at any dosage level. Mean absolute and relative (to final body weight) spleen weight in the 800 mg/kg/day group and mean absolute and relative wet and blotted uterus weights (and thus, luminal fluid weight) and thymus gland weights in the 200 and 800 mg/kg/day groups were lower than the control group values. Lower mean absolute and relative ovary/oviduct weights were observed in the 50, 200 and 800 mg/kg/day groups. Mean absolute and relative liver weights in the 800 mg/kg/day groups were higher than the control group values. Microscopic findings corresponding to the lower mean ovary and uterus weights were observed in the 800 mg/kg/day group. The 800 mg/kg/day dosage level resulted in complete absence of corpora lutea in 14 of 15 rats. All ovaries in this group had moderate to severe granulosa cell necrosis and moderate to severe oocyte degeneration. Mild or severe atrophy of the uterus was present in 7 rats from the 800 mg/kg/day group that were found dead. In the 200 mg/kg/day group, similar but milder morphologic changes in ovaries were present.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____

[ ] Date

Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____

[ ] Date

Senior Study Analyst

Report Reviewed By:

_____ _____

[ ] Date

Director, Developmental and
Reproductive Toxicology

_____ _____

[ ] Date

Associate Director, Developmental and
Reproductive Toxicology

_____ _____

[ ] Date

Senior Study Analyst

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

Manager, Clinical Pathology
Senior Operations Manager, Vivarium
Manager, Gross Pathology and Developmental Toxicology Laboratory
Group Manager, Formulations Laboratory
Director, Metabolism and Analytical Chemistry
Operations Manager, Developmental and Reproductive Toxicology and the Formulations Laboratory
Manager, Reporting and Regulatory Technical Services

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
25-Sep-2006	Test Article Preparation	25-Sep-2006	18-Oct-2006	
26-Sep-2006	Test Article Administration	26-Sep-2006	18-Oct-2006	
10-Nov-2006	Study Records (I-2)	10-Nov-2006	20-Dec-2006	
06-Nov-2006, 07-Nov-2006, 08-Nov-2006, 09-Nov-2006, 10-Nov-2006	Study Records (I-1)	10-Nov-2006	20-Dec-2006	
10-Nov-2006	Study Records (Rx-1)	10-Nov-2006	20-Dec-2006	
13-Nov-2006	Study Records (N-1)	13-Nov-2006	20-Dec-2006	
20-Nov-2006, 21-Nov-2006	Study Records (C-2)	21-Nov-2006	20-Dec-2006	
20-Nov-2006, 21-Nov-2006	Study Records (C-1)	21-Nov-2006	20-Dec-2006	
20-Dec-2006, 21-Dec-2006, 22-Dec-2006	Draft Report (without Clinical Pathology Appendix)	22-Dec-2006	30-Jan-2007	
22-Dec-2006	Draft Report (Clinical Pathology Appendix)	22-Dec-2006	30-Jan-2007	
15-Mar-2007	Study Records (P-1)	15-Mar-2007	23-Apr-2007	
15-Mar-2007	Study Records (H-1)	15-Mar-2007	23-Apr-2007	
01-May-2007	Study Records (P-1 Supplemental)	01-May-2007	__-Jun-2007	
01-May-2007, 02-May-2007	Revised Draft Report	02-May-2007	__-Jun-2007	
01-May-2007, 02-May-2007	Draft Report (Combined Clinical Pathology and Pathology Appendix)	02-May-2007	__-Jun-2007	

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Part 792), the OECD Principles of Good Laboratory Practice, the Japanese MAFF Good Laboratory Practice Standards, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendment with the following exceptions. The data located in Appendices A (Certificate of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____

[ ] Date

Group Supervisor, Quality Assurance

Report Released By:

_____ _____

[ ] Date

Manager, Quality Assurance

4. REFERENCES

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985**, *7*, 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 5.5** states that the females would weigh 30 g to 50 g at the time of randomization and that body weights for all animals assigned to the study would be within approximately ±5 g of the mean. The upper limit was extended to 60 g in order to obtain a sufficient number of females for the study. The animals assigned to study were -8.4 g to +11.4 g of the mean.
- **Protocol Section 6.1** states that animals would be housed 3 per cage in plastic maternity cages following weaning. Although PND 21 females were randomized into treatment groups and placed into plastic maternity cages, there is no documentation that females were housed 3 per cage.
- **Protocol Section 7.6.1** states that animals would be observed approximately 1 hour following dose administration. On 29 September 2006, 3 control group females were observed 1 hour and 16 minutes or 1 hour and 17 minutes following dose administration. On 9 October 2006, 8 females in the 10 mg/kg/day group were observed 1 hour and 16 minutes to 1 hour and 20 minutes following dose administration.
- **Protocol Section 7.7** states that the time of euthanasia would be recorded for each animal. On 18 October 2006, times of euthanasia were recorded for each animal; however, it is unclear whether the time recorded was at the initiation or completion of euthanasia.
- **Protocol Section 9.1** states that the ovaries from each animal would be preserved. The oviducts were also retained.
- **Protocol Section 9.3** states that the cervix, uterine body and horns, ovaries and thyroids/parathyroids would be examined microscopically for females in the control, 200 and 800 mg/kg/day groups. The oviducts for female no. 38696-10 in the 800 mg/kg/day group were also examined microscopically.
- **Protocol Section 9.3** states that the uterus, vagina, ovaries and thyroids/parathyroids would be retained for microscopic examination. Lung tissue for female no. 38703-07 in the 800 mg/kg/day group (collected due to a gross lesion) was also processed for microscopic examination, but was not examined.

- **Protocol Section 9.3** states that microscopic examinations would be performed on specified tissues. Although not specified by protocol, a peer review of the study pathologist's findings was also conducted.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1-8

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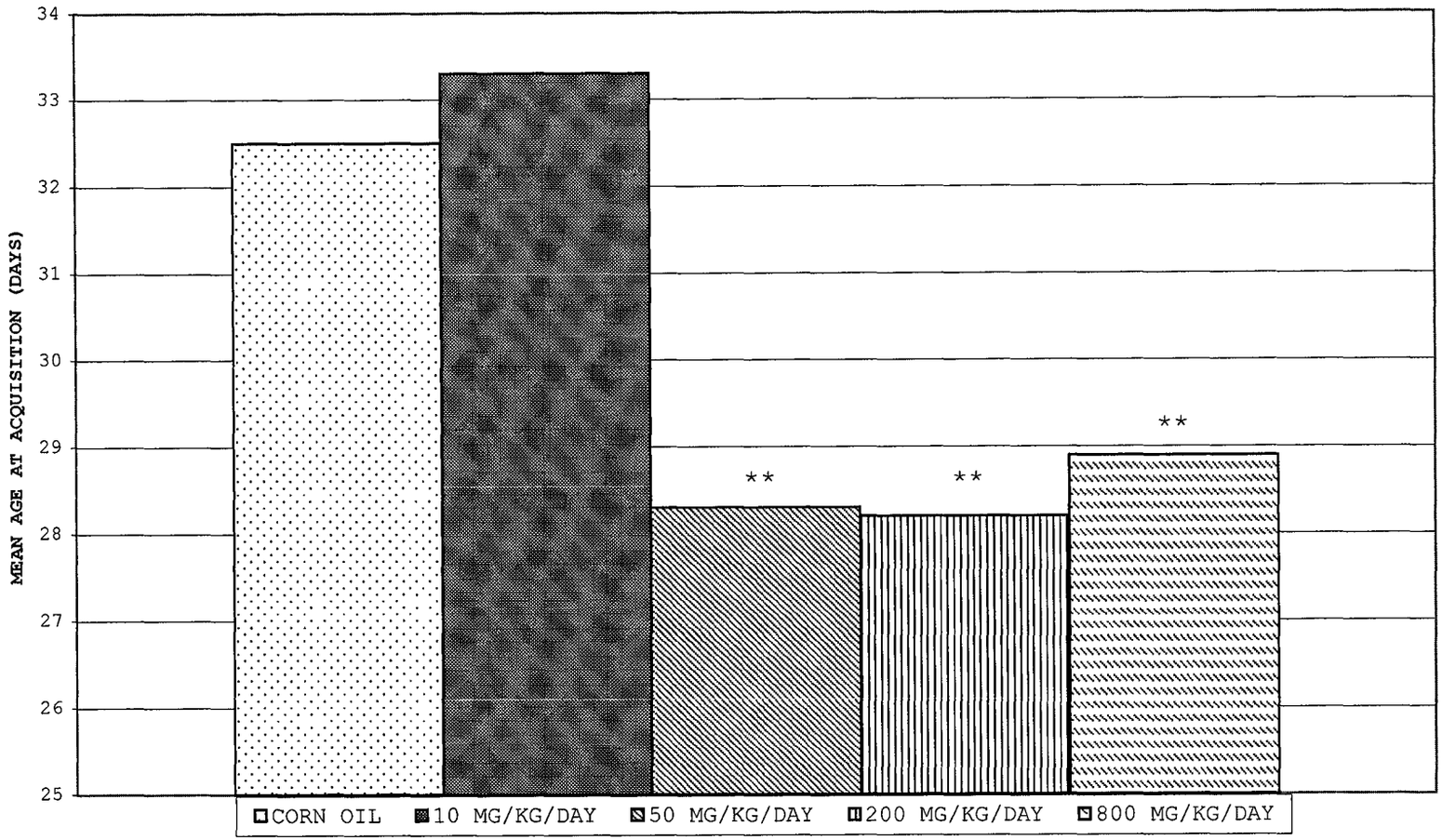
PROJECT [redacted]-187060
SPONSOR [redacted]
SPONSOR [redacted]023

FIGURE 1
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN AGE (DAYS) AT A [redacted]INAL PATENCY



** = Significantly different from control group at 0.01 using Dunnett's test

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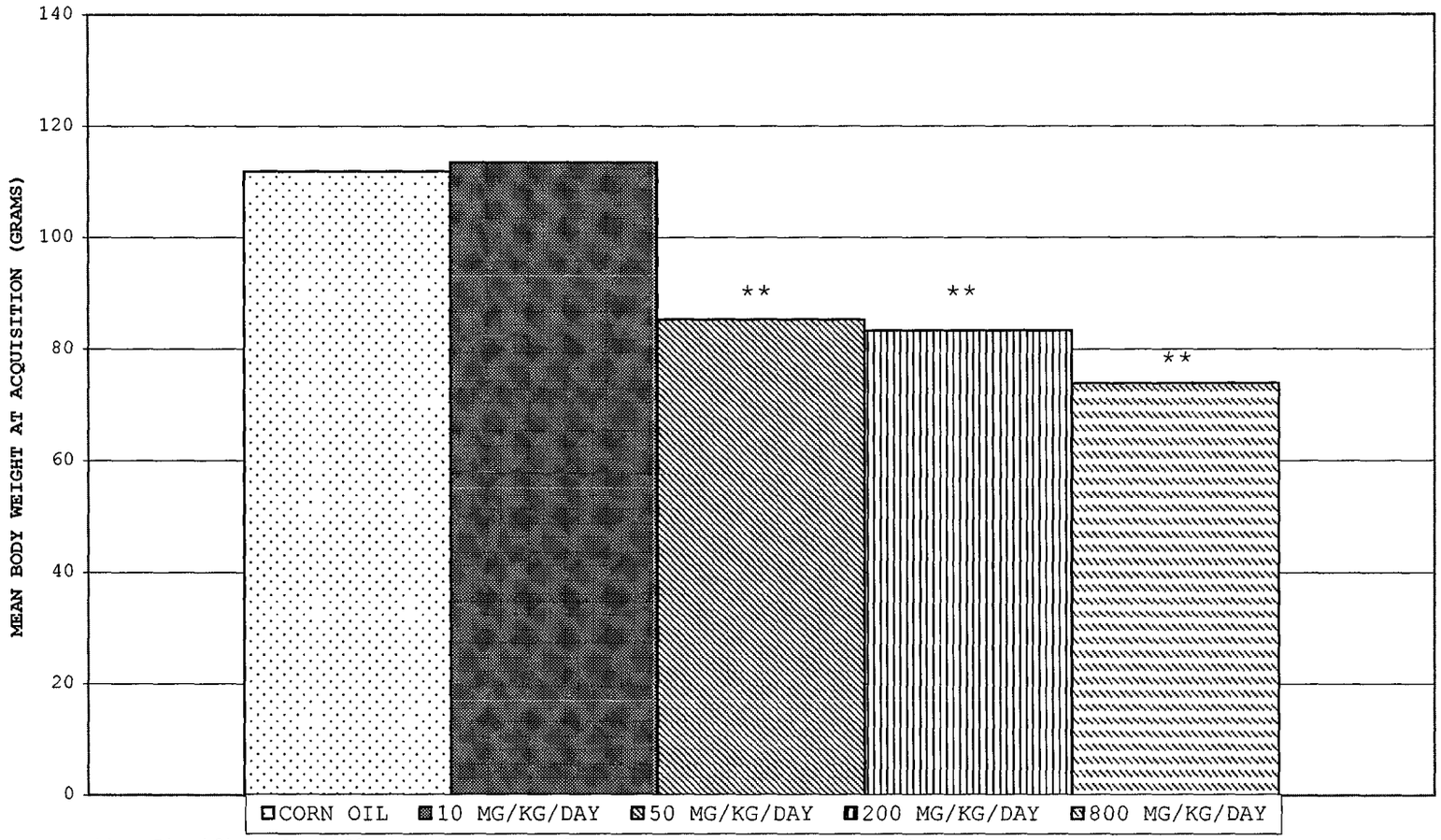
PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR [redacted]023

FIGURE 2
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN BODY WEIGHT (GRAMS) F VAGINAL PATENCY



** = Significantly different from control group at 0.01 using Dunnett's test

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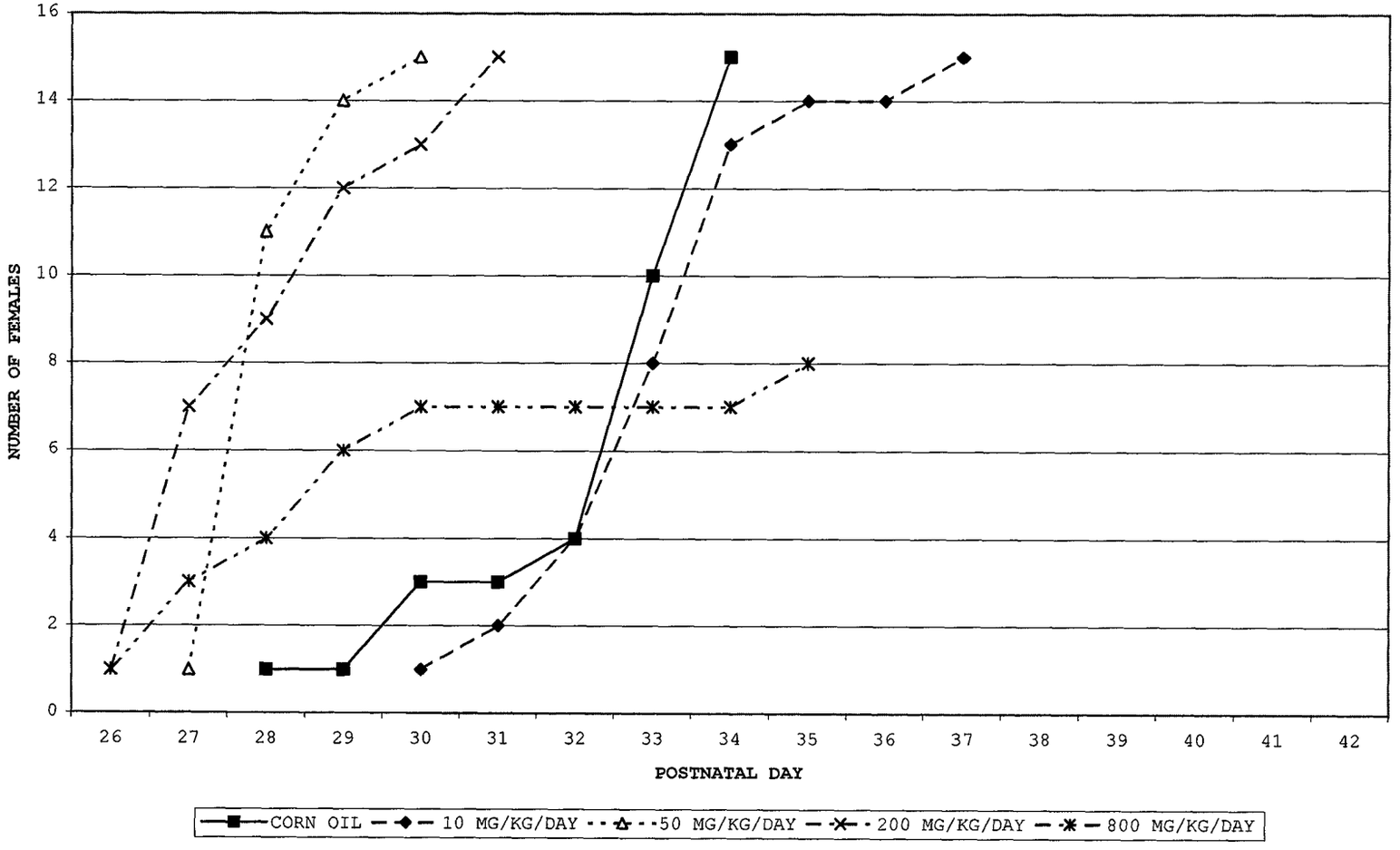
PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR [redacted]023

FIGURE 3
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
CUMULATIVE NUMBER OF [redacted] INAL PATENCY



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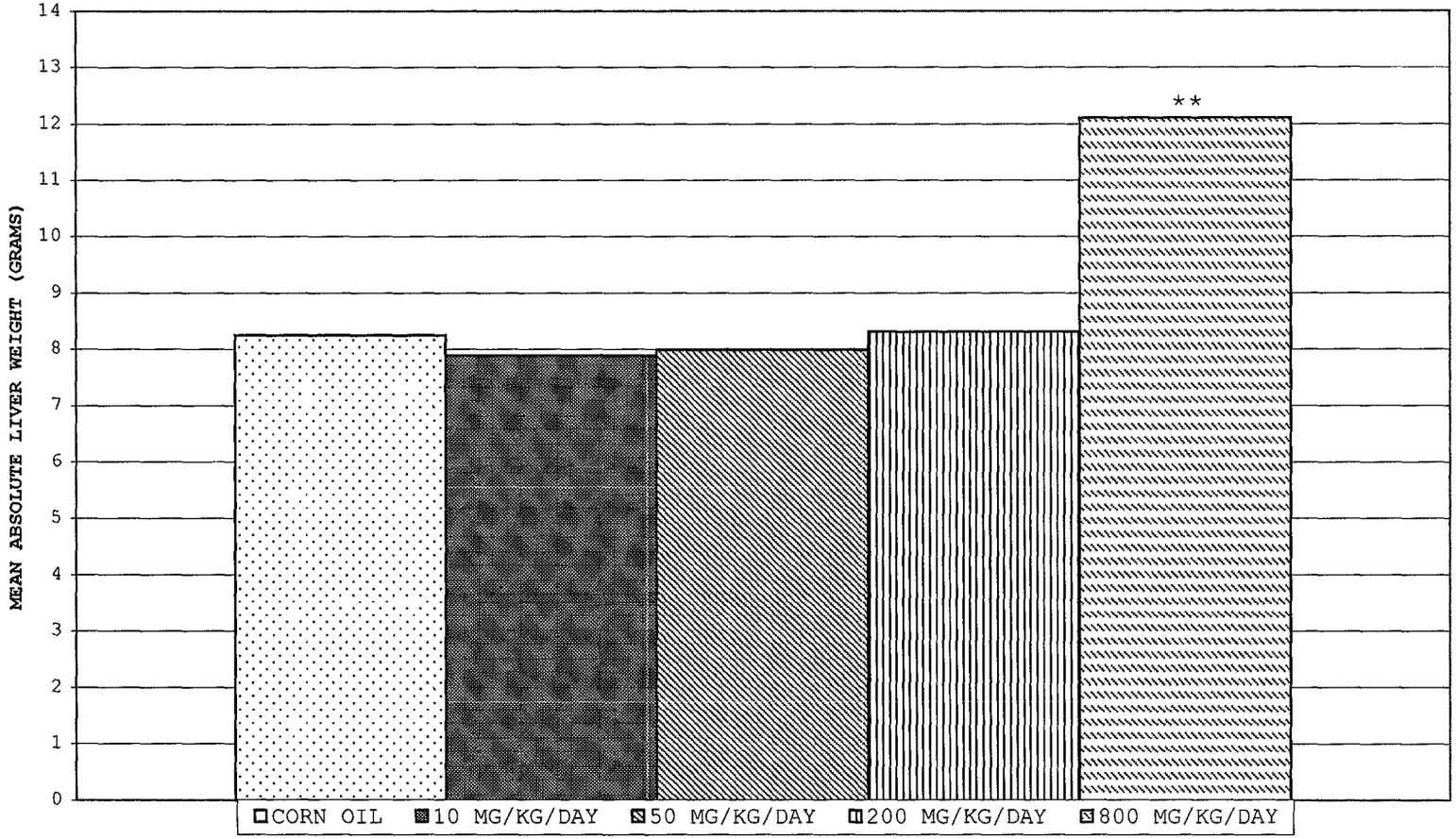
PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR [redacted]023

FIGURE 4
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN ABSOLUTE [redacted]RAMS)



** = Significantly different from control group at 0.01 using Dunnett's test

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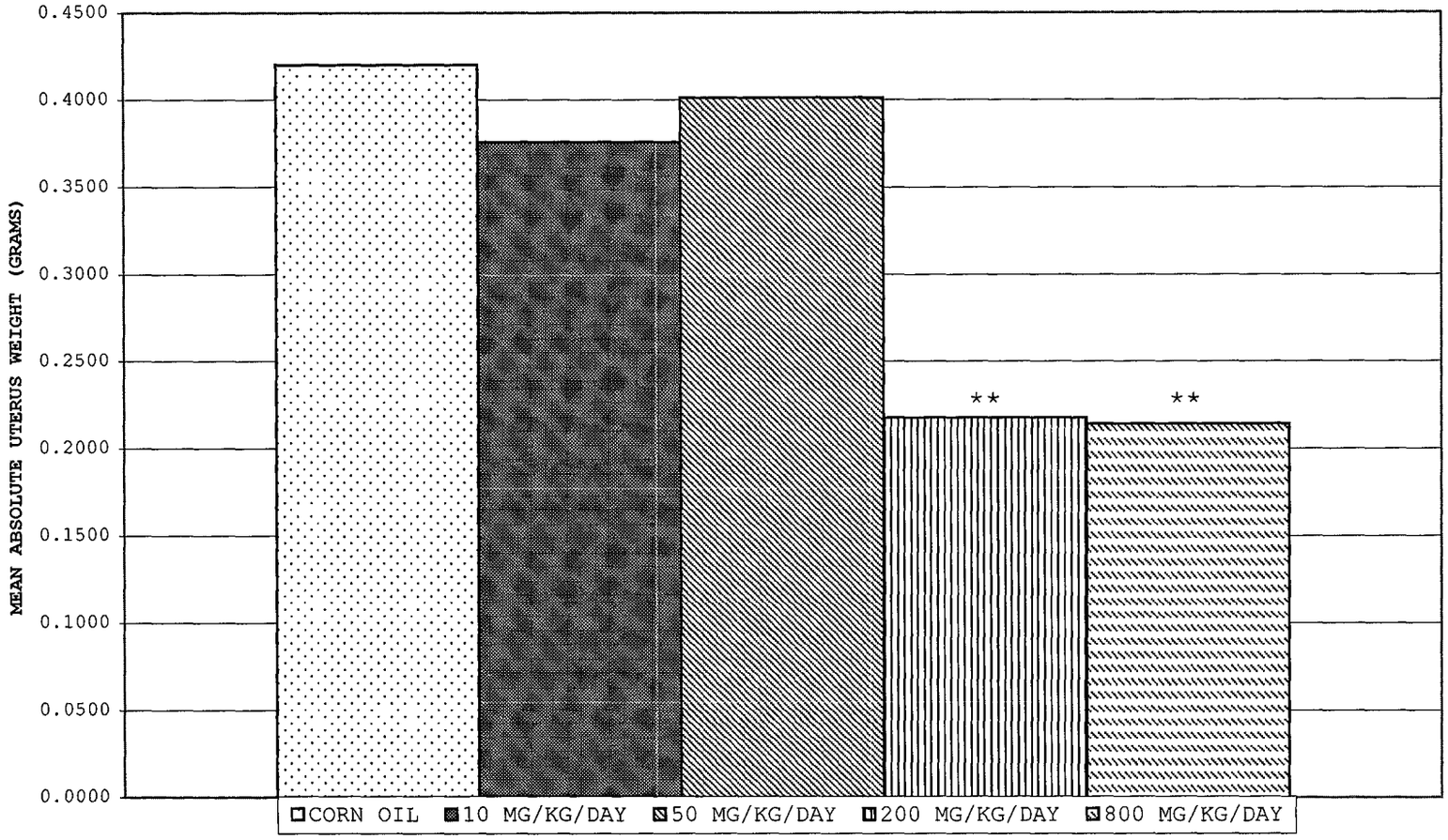
PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR [redacted]023

FIGURE 5

FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN ABSOLUTE UT (GRAMS)



** = Significantly different from control group at 0.01 using Dunnett's test

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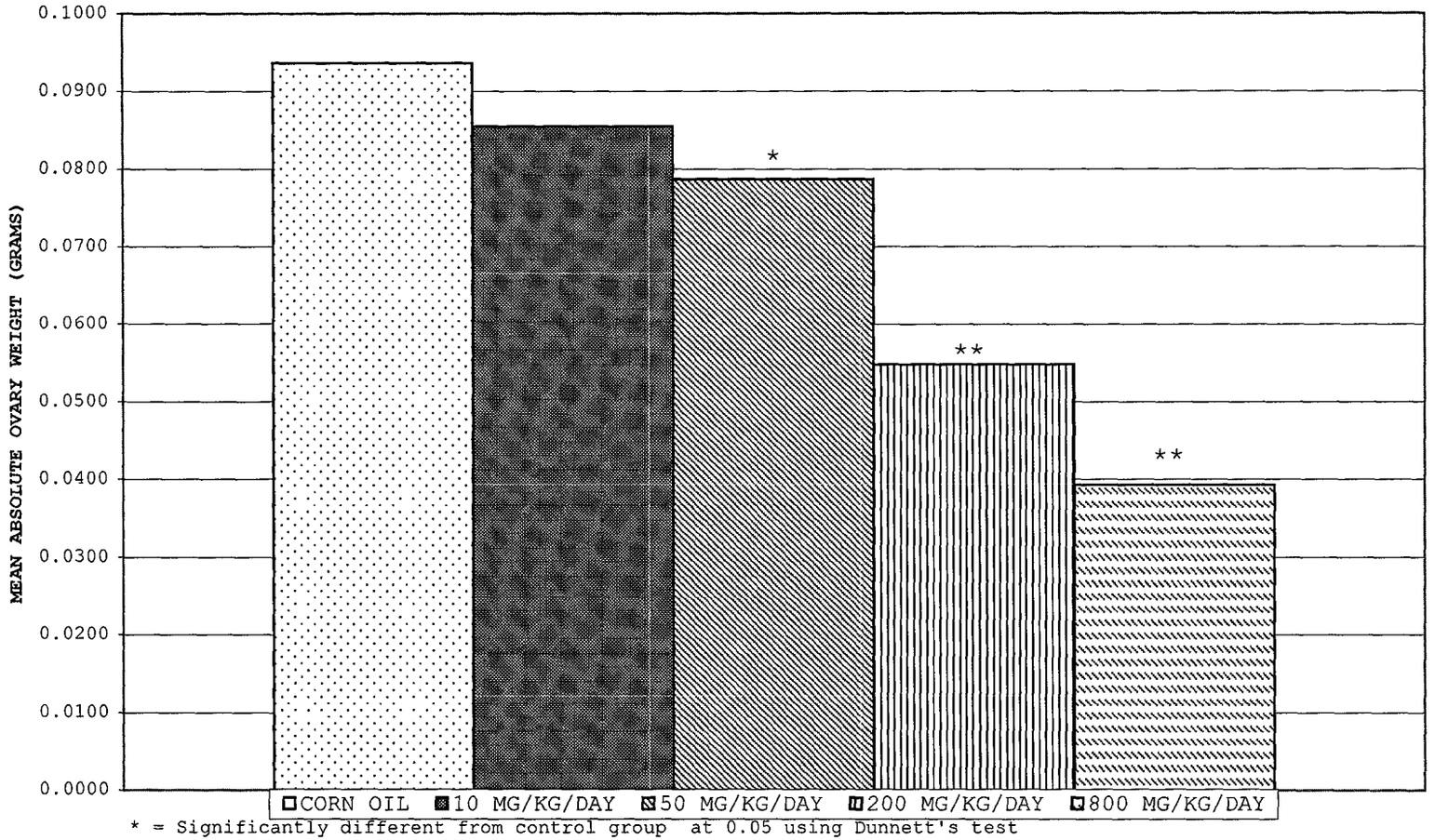
PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR 023

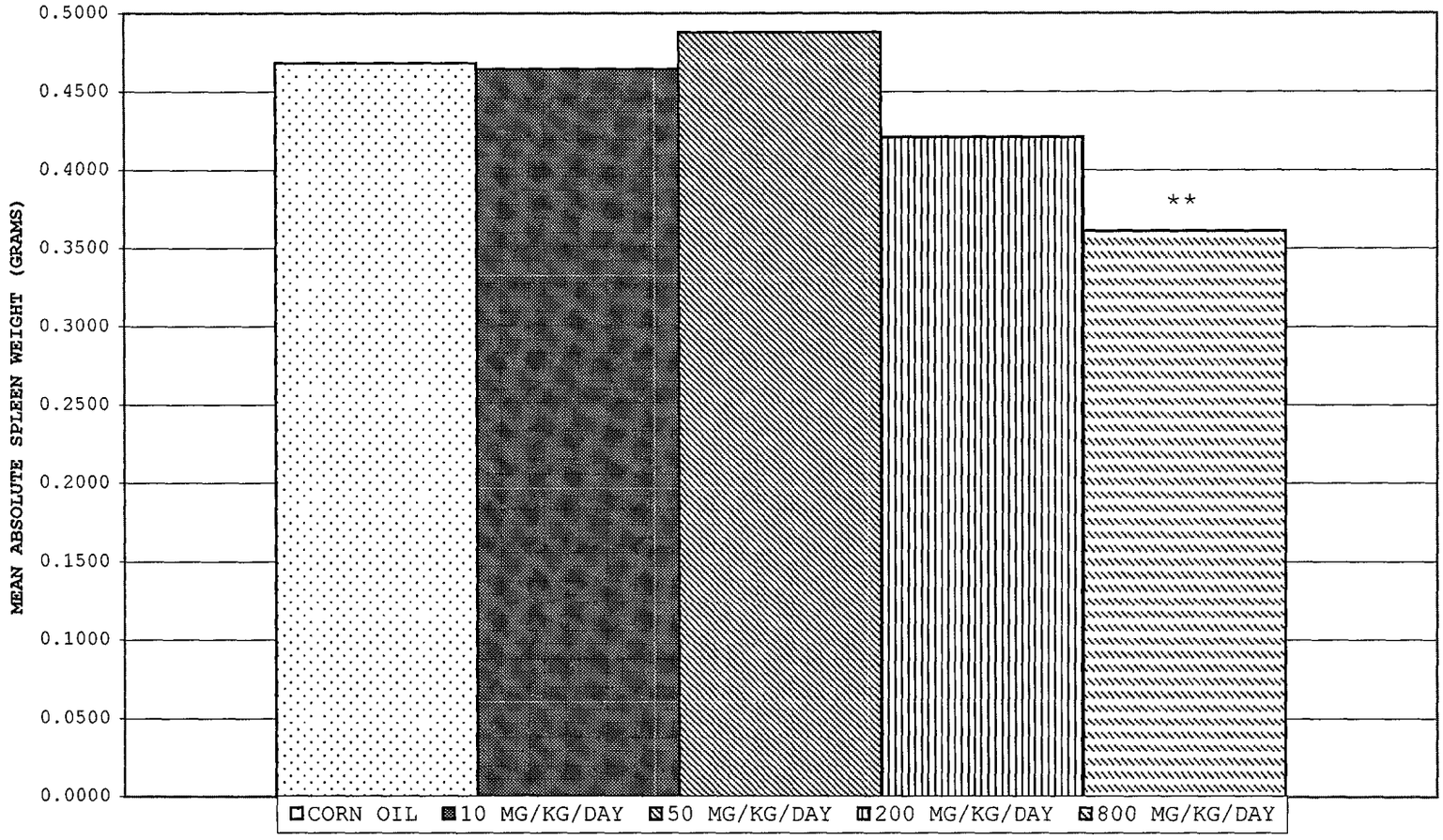
FIGURE 6
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN ABSOLUTE AMS)



* = Significantly different from control group at 0.05 using Dunnett's test
** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR [redacted]023

FIGURE 7
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN ABSOLUTE [redacted] RAMS)



** = Significantly different from control group at 0.01 using Dunnett's test

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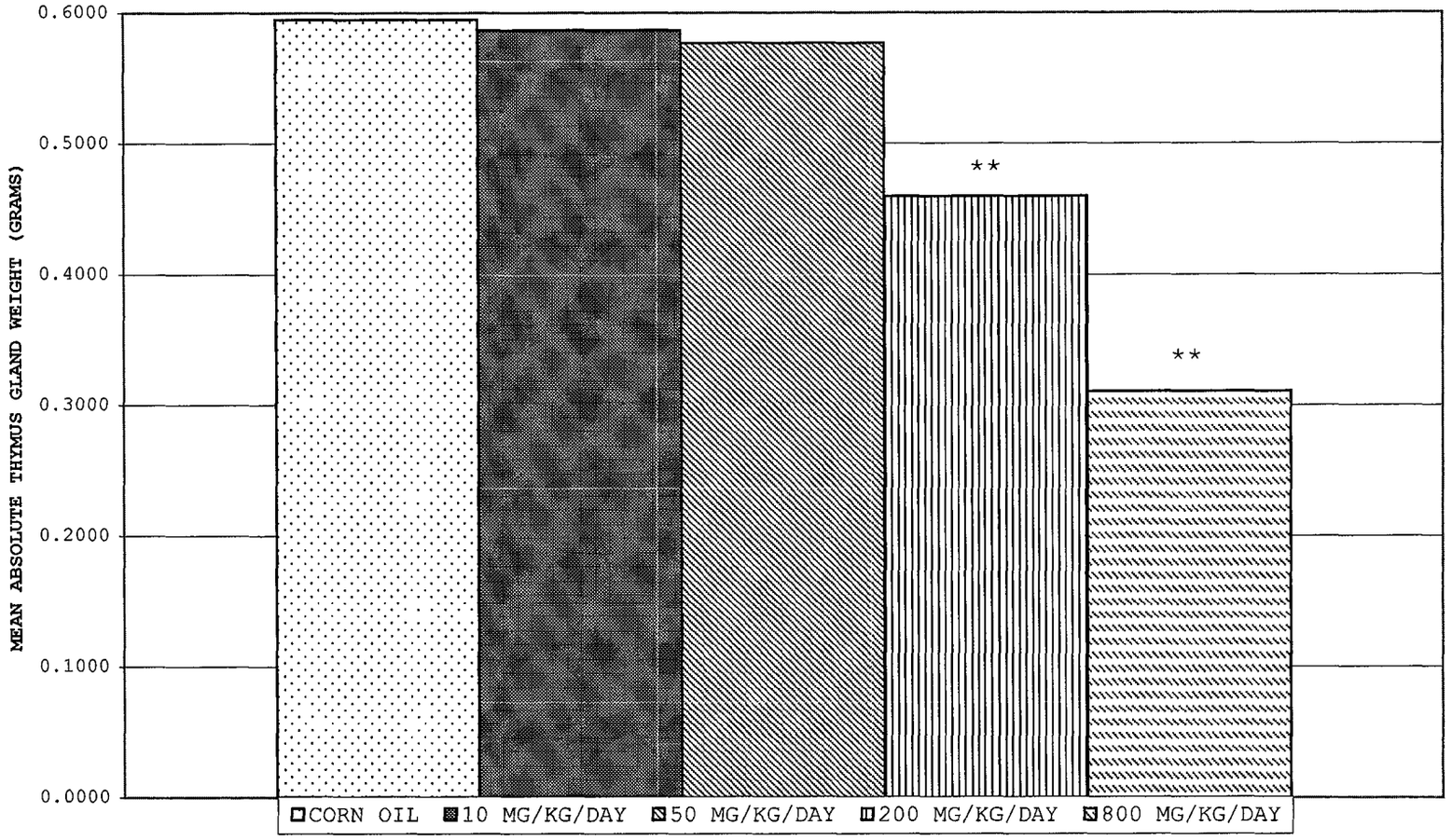
PROJECT [redacted]-187060
SPONSOR: [redacted]
SPONSOR [redacted]023

FIGURE 8
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
MEAN ABSOLUTE TH (GRAMS)



** = Significantly different from control group at 0.01 using Dunnett's test

TABLES 1-25

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TABLE 1

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SUMMARY OF SURVIVAL AND DISPOSITION
SPONSOR NO.:06-023

FEMALES

GROUP :	1				2				3				4				5			
PND	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	14	1	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	14	0	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	10	4	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	3	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
30	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
31	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
32	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
33	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
34	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
35	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
36	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
37	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
38	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
39	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
40	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
41	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	7

PND = POSTNATAL DAY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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TABLE 2 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:06-023

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-18-06				
GROUP:	1	2	3	4	5
NORMAL					
-NO SIGNIFICANT CLINICAL OBSERVATIONS	315/15	313/15	315/15	315/15	141/15
DISPOSITION					
-FOUND DEAD	0/ 0	0/ 0	0/ 0	0/ 0	8/ 8
-SCHEDULED EUTHANASIA	15/15	15/15	15/15	15/15	7/ 7
BEHAVIOR/CNS					
-HUNCHED POSTURE	0/ 0	0/ 0	0/ 0	0/ 0	6/ 6
-ROCKS, LURCHES, OR SWAYS AS IT WALKS	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
BODY/INTEGUMENT					
-DRIED BROWN MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	14/ 8
-WET BROWN MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	14/ 8
-WET BROWN MATERIAL RIGHT INGUINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	6/ 3
-WET BROWN MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	9/ 7
-WET BROWN MATERIAL LEFT INGUINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	3/ 2
-WET BROWN MATERIAL BASE OF TAIL	0/ 0	0/ 0	0/ 0	0/ 0	2/ 1
-DRIED BROWN MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
-SCABBING MEDIAL PORTION OF TAIL	0/ 0	2/ 1	0/ 0	0/ 0	0/ 0

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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11/09/2006

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TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

SPONSOR NO.:06-023

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-17-06				
GROUP:	1	2	3	4	5
ORAL/DENTAL					
-SALIVATION PRIOR TO DOSING	0/ 0	0/ 0	8/ 4	43/11	34/ 7
-SALIVATION	0/ 0	1/ 1	0/ 0	0/ 0	6/ 4

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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11/09/2006
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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:06-023

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-17-06				
GROUP:	1	2	3	4	5
BEHAVIOR/CNS					
-HUNCHED POSTURE	0/ 0	0/ 0	0/ 0	0/ 0	4/ 4
BODY/INTEGUMENT					
-BODY COOL TO TOUCH	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-LIMBS COOL TO TOUCH	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-WET CLEAR MATERIAL FACIAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-WET CLEAR MATERIAL DORSAL HEAD	0/ 0	0/ 0	0/ 0	0/ 0	2/ 1
-WET CLEAR MATERIAL DORSAL ABDOMINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-WET CLEAR MATERIAL DORSAL NECK	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-WET CLEAR MATERIAL DORSAL THORACIC AREA	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-WET CLEAR MATERIAL VENTRAL NECK	0/ 0	0/ 0	0/ 0	0/ 0	2/ 1
ORAL/DENTAL					
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	45/ 9	77/ 7
-WET RED MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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11/09/2006
R:11/13/2006

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Modified: 5/4/2007

TABLE 5

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 1
SPONSOR: [redacted]
SPONSOR NO.:06-023
SUMMARY OF BODY WEIGHTS [G]

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 22					
MEAN	51.7	50.4	51.5	52.0	51.7
% DIFFERENCE		-2.5	-0.4	0.6	0.0
S.D.	5.74	5.13	5.72	5.14	5.77
N	15	15	15	15	15
PND 23					
MEAN	56.6	55.2	56.5	56.7	54.6
% DIFFERENCE		-2.5	-0.2	0.2	-3.5
S.D.	5.94	5.48	6.32	6.18	6.90
N	15	15	15	15	15
PND 24					
MEAN	61.5	60.5	61.7	61.7	53.2**
% DIFFERENCE		-1.6	0.3	0.3	-13.5
S.D.	5.86	5.76	6.30	5.95	8.40
N	15	15	15	15	14
PND 25					
MEAN	66.1	65.3	66.8	66.4	55.8**
% DIFFERENCE		-1.2	1.1	0.5	-15.6
S.D.	5.82	6.49	6.71	6.39	9.07
N	15	15	15	15	11
PND 26					
MEAN	72.6	71.0	72.2	71.9	60.9**
% DIFFERENCE		-2.2	-0.6	-1.0	-16.1
S.D.	6.46	6.68	6.74	7.07	9.44
N	15	15	15	15	8

** = Significantly different from the control group at 0.01 using Dunnett's test

Revised Audited Draft

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TABLE 5

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 2
SPONSOR: [redacted]
SPONSOR NO.:06-023 SUMMARY OF BODY WEIGHTS [G]

		FEMALES				
	GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 27						
	MEAN	78.0	76.2	78.3	77.7	68.6*
	% DIFFERENCE		-2.3	0.4	-0.4	-12.1
	S.D.	7.03	7.14	7.45	7.71	7.44
	N	15	15	15	15	7
PND 28						
	MEAN	83.9	81.3	84.0	82.7	72.4**
	% DIFFERENCE		-3.1	0.1	-1.4	-13.7
	S.D.	6.95	7.56	8.11	8.38	8.16
	N	15	15	15	15	7
PND 29						
	MEAN	89.4	87.4	89.8	87.5	77.4**
	% DIFFERENCE		-2.2	0.4	-2.1	-13.4
	S.D.	7.71	8.27	8.52	8.73	7.44
	N	15	15	15	15	7
PND 30						
	MEAN	95.9	93.5	95.8	93.3	82.4**
	% DIFFERENCE		-2.5	-0.1	-2.7	-14.1
	S.D.	7.95	9.07	8.95	9.68	8.73
	N	15	15	15	15	7
PND 31						
	MEAN	102.0	99.6	102.5	99.1	89.1*
	% DIFFERENCE		-2.4	0.5	-2.8	-12.6
	S.D.	8.44	9.32	9.50	11.01	9.05
	N	15	15	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 3
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 32					
MEAN	108.8	107.0	109.3	104.7	95.4*
% DIFFERENCE		-1.7	0.5	-3.8	-12.3
S.D.	9.98	10.04	10.10	11.15	9.56
N	15	15	15	15	7
PND 33					
MEAN	115.2	112.8	115.5	110.5	99.3**
% DIFFERENCE		-2.1	0.3	-4.1	-13.8
S.D.	10.79	11.09	9.98	11.53	9.80
N	15	15	15	15	7
PND 34					
MEAN	121.8	119.2	122.2	115.8	103.9**
% DIFFERENCE		-2.1	0.3	-4.9	-14.7
S.D.	11.19	11.44	10.73	12.53	10.43
N	15	15	15	15	7
PND 35					
MEAN	127.8	126.1	129.2	120.8	110.7*
% DIFFERENCE		-1.3	1.1	-5.5	-13.4
S.D.	12.33	11.85	10.72	13.37	10.58
N	15	15	15	15	7
PND 36					
MEAN	133.8	132.3	135.4	126.3	115.6**
% DIFFERENCE		-1.1	1.2	-5.6	-13.6
S.D.	12.11	12.45	11.12	14.65	11.76
N	15	15	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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Modified: 5/4/2007

TABLE 5

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 4
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF BODY WEIGHTS [G]

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 37					
MEAN	138.7	137.4	138.6	130.0	120.8*
% DIFFERENCE		-0.9	-0.1	-6.3	-12.9
S.D.	14.27	13.39	11.04	14.06	13.24
N	15	15	15	15	7
PND 38					
MEAN	144.6	142.5	143.8	134.1	125.2*
% DIFFERENCE		-1.5	-0.6	-7.3	-13.4
S.D.	15.14	14.23	10.07	15.46	13.80
N	15	15	15	15	7
PND 39					
MEAN	149.7	148.4	149.3	138.6	130.5*
% DIFFERENCE		-0.9	-0.3	-7.4	-12.8
S.D.	15.92	14.90	10.69	15.97	14.87
N	15	15	15	15	7
PND 40					
MEAN	156.3	154.0	154.3	142.6	136.9*
% DIFFERENCE		-1.5	-1.3	-8.8	-12.4
S.D.	17.06	15.69	11.08	16.60	16.46
N	15	15	15	15	7
PND 41					
MEAN	159.2	158.2	157.7	146.9	141.8
% DIFFERENCE		-0.6	-0.9	-7.7	-10.9
S.D.	17.15	15.82	11.16	17.45	16.67
N	15	15	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF BODY WEIGHTS [G]

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
			FEMALES		
PND 42					
MEAN	160.3	161.1	159.6	149.5	144.7
% DIFFERENCE		0.5	-0.4	-6.7	-9.7
S.D.	17.58	17.06	11.52	17.17	15.77
N	15	15	15	15	7

None significantly different from control group

PJTBWSUv5.14
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TABLE 6

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

FEMALES

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 22- 23					
MEAN	4.9	4.8	5.1	4.7	2.9**
S.D.	1.30	0.87	1.01	1.40	1.79
N	15	15	15	15	15
PND 23- 24					
MEAN	4.9	5.2	5.2	5.0	-0.7**
S.D.	0.68	1.19	0.83	1.03	3.32
N	15	15	15	15	14
PND 24- 25					
MEAN	4.6	4.8	5.1	4.8	-0.3**
S.D.	0.96	1.30	1.18	1.10	4.18
N	15	15	15	15	11
PND 25- 26					
MEAN	6.5	5.7	5.4	5.5	1.6**
S.D.	1.33	0.88	1.01	1.41	4.88
N	15	15	15	15	8
PND 26- 27					
MEAN	5.4	5.2	6.1	5.8	5.5
S.D.	1.38	1.20	1.39	1.22	0.56
N	15	15	15	15	7
PND 27- 28					
MEAN	5.9	5.2	5.7	5.1	3.9**
S.D.	0.53	1.06	1.11	1.26	2.50
N	15	15	15	15	7

** = Significantly different from the control group at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

187060 RAD

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TABLE 6

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES				
	GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 28- 29						
	MEAN	5.5	6.1	5.8	4.8	5.0
	S.D.	1.56	1.39	0.86	0.98	3.13
	N	15	15	15	15	7
PND 29- 30						
	MEAN	6.5	6.0	6.0	5.8	4.9
	S.D.	0.54	1.46	0.92	1.66	2.92
	N	15	15	15	15	7
PND 30- 31						
	MEAN	6.1	6.1	6.7	5.8	6.8
	S.D.	1.71	1.34	1.59	1.76	1.28
	N	15	15	15	15	7
PND 31- 32						
	MEAN	6.8	7.4	6.8	5.7	6.2
	S.D.	2.79	1.26	2.02	1.30	1.95
	N	15	15	15	15	7
PND 32- 33						
	MEAN	6.4	5.8	6.2	5.8	3.9
	S.D.	2.68	2.63	1.70	1.47	1.75
	N	15	15	15	15	7
PND 33- 34						
	MEAN	6.6	6.4	6.7	5.3	4.6
	S.D.	1.51	2.17	1.61	2.08	1.54
	N	15	15	15	15	7

None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

		FEMALES				
GROUP:		0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 34- 35						
	MEAN	5.9	6.9	6.9	4.9	6.9
	S.D.	2.77	1.56	1.57	2.19	2.63
	N	15	15	15	15	7
PND 35- 36						
	MEAN	6.0	6.2	6.2	5.6	4.8
	S.D.	2.39	1.93	2.40	2.77	2.66
	N	15	15	15	15	7
PND 36- 37						
	MEAN	5.0	5.2	3.2	3.7	5.2
	S.D.	3.29	2.32	3.57	3.06	2.49
	N	15	15	15	15	7
PND 37- 38						
	MEAN	5.8	5.1	5.2	4.1	4.4
	S.D.	4.22	3.37	3.72	2.64	2.45
	N	15	15	15	15	7
PND 38- 39						
	MEAN	5.1	5.8	5.5	4.6	5.4
	S.D.	2.06	2.54	2.87	2.14	2.98
	N	15	15	15	15	7
PND 39- 40						
	MEAN	6.6	5.7	5.0	4.0**	6.4
	S.D.	2.99	1.78	1.94	1.89	2.44
	N	15	15	15	15	7

** = Significantly different from the control group at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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Modified: 5/4/2007

TABLE 6

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

		FEMALES				
GROUP:		0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PND 40- 41						
	MEAN	2.9	4.2	3.4	4.3	4.9
	S.D.	2.94	2.08	3.06	2.12	1.91
	N	15	15	15	15	7
PND 41- 42						
	MEAN	1.1	2.8	1.9	2.6	3.0
	S.D.	4.75	3.66	4.55	2.62	3.05
	N	15	15	15	15	7
PND 22- 42						
	MEAN	108.7	110.6	108.1	97.5	92.9
	S.D.	15.81	14.70	9.49	14.21	15.58
	N	15	15	15	15	7

None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.14
11/09/2006

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TABLE 7

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 1
SPONSOR: [redacted]
SPONSOR NO.:06-023 SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

FEMALES

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
VAGINAL PATENCY (PND)					
MEAN	32.5	33.3	28.3**	28.2**	28.9**
S.D.	1.81	1.67	0.70	1.57	2.80
N	15	15	15	15	8
BODY WEIGHT (GRAMS)					
MEAN	111.9	113.5	85.4**	83.4**	73.9**
S.D.	9.13	8.96	9.65	11.93	17.27
N	15	15	15	15	8

PND= POSTNATAL DAY
** = Significantly different from the control group at 0.01 using Dunnett's test

PJTBBv1.16
11/09/2006
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TABLE 8

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF ESTROUS CYCLE DATA

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
ESTROUS CYCLE LENGTH (DAYS)					
MEAN	4.8	4.9	5.2	4.8	2.0
S.D.	0.45	0.64	0.81	2.34	0.00
N	5	8	13	7	1
AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)					
MEAN	34.4	35.6	32.1	31.2*	28.9**
S.D.	3.33	2.98	2.77	3.23	3.02
N	13	14	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

PCYCv5.24
11/09/2006
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TABLE 9

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR: [redacted]
SUMMARY OF SERUM HORMONE VALUES
SPONSOR NO.:06-023

ANALYSIS GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
	FEMALES				
TOTAL T4 (uG/dL)					
DAY 42 MEAN	6.65	6.47	6.55	6.54	5.49
% DIFFERENCE		-2.7	-1.5	-1.7	-17.4
S.D.	0.898	1.023	0.978	1.215	1.027
N	15	15	15	15	7
ESTRADIOL (pg/mL)					
DAY 42 MEAN	101.79	111.29	106.22	82.85	125.69
% DIFFERENCE		9.3	4.4	-18.6	23.5
S.D.	23.573	24.432	25.435	30.205	23.825
N	15	15	15	15	7
TSH (ng/mL)					
DAY 42 MEAN	8.16	7.39	7.37	9.07	10.97
% DIFFERENCE		-9.4	-9.7	11.2	34.4
S.D.	2.903	1.925	2.277	2.558	3.720
N	15	15	15	15	7
LUTEIN' HORMONE (ng/mL)					
DAY 42 MEAN	3.1	1.8	1.7	1.7	1.0
% DIFFERENCE		-41.9	-45.2	-45.2	-67.7
S.D.	6.34	0.70	0.63	0.51	0.38
N	15	15	15	15	6

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

None significantly different from control group

PCPSv5.23
11/16/2006
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TABLE 10 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF MACROSCOPIC FINDINGS

SPONSOR NO.:06-023

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- FEMALE -----				
GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	0	0	0	0	8
LUNGS					
-DISCOLORATION, DARK RED	0	0	0	0	1
UTERUS					
-CONTENTS, CLEAR FLUID	0	0	0	0	1
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	0	0	0	0	6

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

PGRSI2v4.07
04/25/2007
R:05/03/2007

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TABLE 10A (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	0	0	0	0	8
CERVIX					
TOTAL NUMBER EXAMINED	0	NA	NA	0	7
EXAMINED, UNREMARKABLE	0	NA	NA	0	6
NOT EXAMINED	0	NA	NA	0	1
-EDEMA, SUBMUCOSAL	0	NA	NA	0	1
MILD	NONE	NA	NA	NONE	1
OVARIES					
TOTAL NUMBER EXAMINED	0	NA	NA	0	8
EXAMINED, UNREMARKABLE	0	NA	NA	0	0
-CORPORA LUTEA ABSENT, BILATERAL	0	NA	NA	0	8
-DEGENERATION, OOCYTE, BILATERAL	0	NA	NA	0	8
MODERATE	NONE	NA	NA	NONE	4
SEVERE	NONE	NA	NA	NONE	4
-NECROSIS, GRANULOSA CELL, BILATERAL	0	NA	NA	0	8
MODERATE	NONE	NA	NA	NONE	3
SEVERE	NONE	NA	NA	NONE	5
PARATHYROID					
TOTAL NUMBER EXAMINED	0	NA	NA	0	5
EXAMINED, UNREMARKABLE	0	NA	NA	0	4
NOT EXAMINED	0	NA	NA	0	3
-FIBROSIS, BILATERAL	0	NA	NA	0	1
MINIMAL	NONE	NA	NA	NONE	1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

NA = NOT APPLICABLE

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Modified: 5/4/2007

TABLE 10A (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	0	0	0	0	8
THYMUS					
TOTAL NUMBER EXAMINED	NA	NA	NA	NA	1
EXAMINED, UNREMARKABLE	NA	NA	NA	NA	0
-NECROSIS	NA	NA	NA	NA	1
MILD	NA	NA	NA	NA	1
THYROID GLANDS					
TOTAL NUMBER EXAMINED	0	NA	NA	0	7
EXAMINED, UNREMARKABLE	0	NA	NA	0	3
NOT EXAMINED	0	NA	NA	0	1
-CYST, ULTIMOBRANCHIAL, BILATERAL	0	NA	NA	0	2
PRESENT	NONE	NA	NA	NONE	2
-HYPERTROPHY, FOLLICULAR CELL	0	NA	NA	0	3
MILD	NONE	NA	NA	NONE	3
UTERUS					
TOTAL NUMBER EXAMINED	0	NA	NA	0	7
EXAMINED, UNREMARKABLE	0	NA	NA	0	0
NOT EXAMINED	0	NA	NA	0	1
-ATROPHY	0	NA	NA	0	7
MILD	NONE	NA	NA	NONE	4
SEVERE	NONE	NA	NA	NONE	3
-DILATATION, LUMEN	0	NA	NA	0	5
MILD	NONE	NA	NA	NONE	2
MODERATE	NONE	NA	NA	NONE	3

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 10A (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted]

SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	0	0	0	0	8

UTERUS - CONTINUED

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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05/03/2007
R:05/03/2007

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TABLE 11 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF MACROSCOPIC FINDINGS

SCHEDULED NECROPSY

	----- FEMALE -----				
GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	15	15	15	15	7
OVARIES					
-SMALL	0	0	0	1	2
OVIDUCTS					
-SMALL	0	0	0	0	1
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	15	15	15	14	5

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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04/25/2007
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Revised Audited Draft

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TABLE 11A (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	15	0	0	15	7
CERVIX					
TOTAL NUMBER EXAMINED	15	NA	NA	15	7
EXAMINED, UNREMARKABLE	15	NA	NA	13	7
-DILATATION, GLANDULAR	0	NA	NA	1	0
MILD	NONE	NA	NA	1	NONE
-NECROSIS, SINGLE CELL	0	NA	NA	1	0
MINIMAL	NONE	NA	NA	1	NONE
OVARIES					
TOTAL NUMBER EXAMINED	15	NA	NA	15	7
EXAMINED, UNREMARKABLE	15	NA	NA	0	0
-CORPORA LUTEA ABSENT, BILATERAL	0	NA	NA	9	6
-DEGENERATION, OOCYTE, BILATERAL	0	NA	NA	15	7
MILD	NONE	NA	NA	14	NONE
MODERATE	NONE	NA	NA	1	6
SEVERE	NONE	NA	NA	NONE	1
-HEMORRHAGE, FOLLICULAR	0	NA	NA	1	0
MINIMAL	NONE	NA	NA	1	NONE
-NECROSIS, GRANULOSA CELL, BILATERAL	0	NA	NA	15	7
MILD	NONE	NA	NA	14	NONE
MODERATE	NONE	NA	NA	1	6
SEVERE	NONE	NA	NA	NONE	1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

NA = NOT APPLICABLE

Revised Audited Draft

Modified: 5/4/2007

TABLE 11A (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	15	0	0	15	7
OVIDUCTS					
TOTAL NUMBER EXAMINED	NA	NA	NA	NA	1
EXAMINED, UNREMARKABLE	NA	NA	NA	NA	1
PARATHYROID					
TOTAL NUMBER EXAMINED	13	NA	NA	12	5
EXAMINED, UNREMARKABLE	13	NA	NA	12	5
NOT EXAMINED	2	NA	NA	3	2
THYROID GLANDS					
TOTAL NUMBER EXAMINED	15	NA	NA	15	7
EXAMINED, UNREMARKABLE	11	NA	NA	7	1
-CYST, ULTIMOBRANCHIAL	4	NA	NA	1	6
PRESENT	4	NA	NA	1	6
-CYST, ULTIMOBRANCHIAL, BILATERAL	0	NA	NA	7	0
PRESENT	NONE	NA	NA	7	NONE
-INFILTRATE, LYMPHOCYTE	0	NA	NA	0	1
MINIMAL	NONE	NA	NA	NONE	1
UTERUS					
TOTAL NUMBER EXAMINED	15	NA	NA	15	7
EXAMINED, UNREMARKABLE	14	NA	NA	12	7
-DILATATION, GLANDULAR	0	NA	NA	3	0
MINIMAL	NONE	NA	NA	1	NONE
MILD	NONE	NA	NA	2	NONE

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

NA = NOT APPLICABLE

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TABLE 11A (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] SUMMARY OF MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	15	0	0	15	7
UTERUS - CONTINUED					
-INFLAMMATION, SUBACUTE	1	NA	NA	0	0
MINIMAL	1	NA	NA	NONE	NONE

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

NA = NOT APPLICABLE

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05/03/2007
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TABLE 12

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
ADRENAL GLANDS (G)					
MEAN	0.0396	0.0437	0.0427	0.0435	0.0419
% DIFFERENCE		10.4	7.8	9.8	5.8
S.D.	0.00696	0.00530	0.00805	0.00656	0.00562
N	15	15	15	15	7
KIDNEYS (G)					
MEAN	1.6641	1.6510	1.6889	1.6067	1.4928
% DIFFERENCE		-0.8	1.5	-3.4	-10.3
S.D.	0.22415	0.20666	0.22170	0.20455	0.13653
N	15	15	15	15	7
LIVER (G)					
MEAN	8.2487	7.8837	7.9892	8.3159	12.1045**
% DIFFERENCE		-4.4	-3.1	0.8	46.7
S.D.	1.43299	1.29677	0.92902	1.20357	2.05268
N	15	15	15	15	7
OVARIES/OVIDUCTS (G)					
MEAN	0.0936	0.0855	0.0787*	0.0548**	0.0393**
% DIFFERENCE		-8.7	-15.9	-41.5	-58.0
S.D.	0.01945	0.01569	0.01240	0.01456	0.00589
N	15	15	15	15	7
PITUITARY (G)					
MEAN	0.0097	0.0096	0.0097	0.0089	0.0085
% DIFFERENCE		-1.0	0.0	-8.2	-12.4
S.D.	0.00139	0.00188	0.00176	0.00222	0.00208
N	15	15	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

Revised Audited Draft

Modified: 5/4/2007

TABLE 12

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
SPLEEN (G)					
MEAN	0.4681	0.4643	0.4877	0.4209	0.3611**
% DIFFERENCE		-0.8	4.2	-10.1	-22.9
S.D.	0.06130	0.07991	0.09111	0.06057	0.07612
N	15	15	15	15	7
THYMUS (G)					
MEAN	0.5948	0.5867	0.5768	0.4598**	0.3105**
% DIFFERENCE		-1.4	-3.0	-22.7	-47.8
S.D.	0.05361	0.08625	0.08373	0.06129	0.05382
N	15	15	15	15	7
THYROIDS/PARA (G)					
MEAN	0.0155	0.0142	0.0144	0.0149	0.0158
% DIFFERENCE		-8.4	-7.1	-3.9	1.9
S.D.	0.00484	0.00252	0.00397	0.00432	0.00371
N	15	15	15	15	7
UTERUS- BLOTTED (G)					
MEAN	0.3371	0.3277	0.3083	0.2022**	0.1992**
% DIFFERENCE		-2.8	-8.5	-40.0	-40.9
S.D.	0.07422	0.05425	0.06803	0.03612	0.01417
N	15	15	15	15	7
UTERUS- WET (G)					
MEAN	0.4201	0.3760	0.4013	0.2177**	0.2143**
% DIFFERENCE		-10.5	-4.5	-48.2	-49.0
S.D.	0.16366	0.10889	0.16927	0.03805	0.01544
N	15	15	15	15	7
UTERUS- LUMINAL FLUID (G)					
MEAN	0.0829	0.0482	0.0930	0.0155	0.0151
% DIFFERENCE		-41.9	12.2	-81.3	-81.8
S.D.	0.12438	0.06930	0.12503	0.00473	0.00442
N	15	15	15	15	7

** = Significantly different from the control group at 0.01 using Dunnett's test

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11/09/2006
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TABLE 13

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 1
SPONSOR: [redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-023

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
FINAL BODY WT (G)					
MEAN	160.	161.	159.	150.	145.
% DIFFERENCE		0.6	-0.6	-6.3	-9.4
S.D.	17.6	17.0	11.6	17.1	15.7
N	15	15	15	15	7
ADRENAL GLANDS (G/100 G FINAL BODY WEIGHT)					
MEAN	0.025	0.027	0.027	0.029	0.029
S.D.	0.0044	0.0047	0.0050	0.0042	0.0054
N	15	15	15	15	7
KIDNEYS (G/100 G FINAL BODY WEIGHT)					
MEAN	1.036	1.025	1.056	1.075	1.035
S.D.	0.0667	0.0761	0.0886	0.0782	0.0869
N	15	15	15	15	7
LIVER (G/100 G FINAL BODY WEIGHT)					
MEAN	5.117	4.872	5.001	5.547*	8.316**
S.D.	0.4415	0.3374	0.3416	0.3698	0.6277
N	15	15	15	15	7
OVARIES/OVIDUCTS (G/100 G FINAL BODY WEIGHT)					
MEAN	0.059	0.053	0.049*	0.037**	0.027**
S.D.	0.0124	0.0097	0.0072	0.0107	0.0043
N	15	15	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 13

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-023

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PITUITARY (G/100 G FINAL BODY WEIGHT)					
MEAN	0.006	0.006	0.006	0.006	0.006
S.D.	0.0008	0.0012	0.0011	0.0011	0.0016
N	15	15	15	15	7
SPLEEN (G/100 G FINAL BODY WEIGHT)					
MEAN	0.292	0.287	0.304	0.282	0.248*
S.D.	0.0265	0.0279	0.0432	0.0309	0.0368
N	15	15	15	15	7
THYMUS (G/100 G FINAL BODY WEIGHT)					
MEAN	0.374	0.366	0.362	0.308**	0.214**
S.D.	0.0401	0.0517	0.0488	0.0293	0.0244
N	15	15	15	15	7
THYROIDS/PARA (G/100 G FINAL BODY WEIGHT)					
MEAN	0.010	0.009	0.009	0.010	0.011
S.D.	0.0037	0.0022	0.0025	0.0034	0.0029
N	15	15	15	15	7
UTERUS- BLOTTED (G/100 G FINAL BODY WEIGHT)					
MEAN	0.212	0.204	0.194	0.135**	0.139**
S.D.	0.0474	0.0325	0.0409	0.0213	0.0149
N	15	15	15	15	7

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 13

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-023

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
UTERUS- WET (G/100 G FINAL BODY WEIGHT)					
MEAN	0.267	0.233	0.251	0.146**	0.149**
S.D.	0.1176	0.0595	0.0993	0.0227	0.0156
N	15	15	15	15	7

** = Significantly different from the control group at 0.01 using Dunnett's test

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11/09/2006

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 1

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38694-07	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38696-08	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38695-01	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38695-07	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38694-04	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38696-04	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38697-07	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38698-04	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38699-07	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38698-05	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38699-02	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38697-03	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38703-06	F	0 MG/KG/DAY	DISPOSITION	10-18-06	7:58	P	SCHEDULED EUTHANASIA
38700-06	F	0 MG/KG/DAY	DISPOSITION	10-18-06	7:58	P	SCHEDULED EUTHANASIA
38702-05	F	0 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38695-02	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38694-10	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38696-06	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38696-01	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38695-04	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38695-04	F	10 MG/KG/DAY	BODY/INTEGUMENT	10-15-06	6:20	P	SCABBING MEDIAL PORTION OF TAIL
				10-16-06	6:45	P	SCABBING MEDIAL PORTION OF TAIL
38694-02	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38698-07	F	10 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38697-04	F	10 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38699-08	F	10 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38699-06	F	10 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38698-06	F	10 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38697-05	F	10 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38702-09	F	10 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38703-01	F	10 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38701-03	F	10 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38694-06	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38695-10	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38696-07	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38696-09	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:53	P	SCHEDULED EUTHANASIA
38694-05	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:54	P	SCHEDULED EUTHANASIA
38695-05	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:54	P	SCHEDULED EUTHANASIA
38697-02	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38698-09	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38699-01	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38699-10	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38698-01	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38697-09	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:08	P	SCHEDULED EUTHANASIA
38703-04	F	50 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38700-01	F	50 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38701-06	F	50 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38696-02	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:54	P	SCHEDULED EUTHANASIA
38695-06	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:54	P	SCHEDULED EUTHANASIA
38694-08	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:54	P	SCHEDULED EUTHANASIA
38696-05	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:54	P	SCHEDULED EUTHANASIA
38695-09	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:55	P	SCHEDULED EUTHANASIA
38694-03	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:55	P	SCHEDULED EUTHANASIA
38697-06	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:09	P	SCHEDULED EUTHANASIA
38699-05	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:09	P	SCHEDULED EUTHANASIA
38698-10	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:09	P	SCHEDULED EUTHANASIA
38699-04	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:10	P	SCHEDULED EUTHANASIA
38698-02	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:09	P	SCHEDULED EUTHANASIA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38697-01	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:09	P	SCHEDULED EUTHANASIA
38703-05	F	200 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38702-02	F	200 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38701-10	F	200 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38695-08	F	800 MG/KG/DAY	DISPOSITION	10-16-06	7:56	P	SCHEDULED EUTHANASIA
38695-08	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	6:58	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38694-09	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:33	P	FOUND DEAD
38694-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-29-06	8:45	P	HUNCHED POSTURE
38694-09	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:45	1	WET BROWN MATERIAL UROGENITAL AREA
38696-03	F	800 MG/KG/DAY	DISPOSITION	09-29-06	14:41	P	FOUND DEAD
38696-03	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-29-06	8:47	P	HUNCHED POSTURE
				09-29-06	8:47	1	ROCKS, LURCHES, OR SWAYS AS IT WALKS
38696-03	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	7:04	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38696-10	F	800 MG/KG/DAY	DISPOSITION	10-16-06	7:55	P	SCHEDULED EUTHANASIA
38694-01	F	800 MG/KG/DAY	DISPOSITION	10-16-06	7:55	P	SCHEDULED EUTHANASIA
38694-01	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:50	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	8:51	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				09-30-06	8:13	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-30-06	8:13	1	WET BROWN MATERIAL UROGENITAL AREA
				10-01-06	7:40	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-01-06	7:40	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				10-01-06	7:40	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				10-02-06	7:44	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-02-06	7:44	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				10-02-06	7:44	1	WET BROWN MATERIAL UROGENITAL AREA
				10-03-06	7:42	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-10-06	7:12	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-11-06	7:12	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-14-06	6:29	1	DRIED BROWN MATERIAL ANOGENITAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38695-03	F	800 MG/KG/DAY	DISPOSITION	10-16-06	7:56	P	SCHEDULED EUTHANASIA
38695-03	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:15	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-12-06	7:45	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38697-10	F	800 MG/KG/DAY	DISPOSITION	10-17-06	7:09	P	SCHEDULED EUTHANASIA
38697-10	F	800 MG/KG/DAY	BODY/INTEGUMENT	10-01-06	7:42	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				10-03-06	7:44	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-04-06	7:53	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-11-06	7:13	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38698-08	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:33	P	FOUND DEAD
38698-08	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:52	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	8:52	1	WET BROWN MATERIAL UROGENITAL AREA
38699-09	F	800 MG/KG/DAY	DISPOSITION	10-17-06	7:10	P	SCHEDULED EUTHANASIA
38699-09	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:53	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-05-06	7:43	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38698-03	F	800 MG/KG/DAY	DISPOSITION	09-28-06	13:46	P	FOUND DEAD
38699-03	F	800 MG/KG/DAY	DISPOSITION	10-01-06	6:33	P	FOUND DEAD
38699-03	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	8:17	P	HUNCHED POSTURE
38699-03	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:54	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-30-06	8:16	1	WET BROWN MATERIAL ANOGENITAL AREA
38697-08	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:34	P	FOUND DEAD
38697-08	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:54	1	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	8:55	1	WET BROWN MATERIAL ANOGENITAL AREA
38703-07	F	800 MG/KG/DAY	DISPOSITION	10-02-06	14:05	P	FOUND DEAD
38703-07	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-02-06	7:48	P	HUNCHED POSTURE
38703-07	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:19	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-01-06	7:43	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-01-06	7:44	1	DRIED BROWN MATERIAL UROGENITAL AREA
				10-02-06	7:48	1	WET BROWN MATERIAL UROGENITAL AREA
				10-02-06	7:48	1	WET BROWN MATERIAL ANOGENITAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38701-01	F	800 MG/KG/DAY	DISPOSITION	10-01-06	6:33	P	FOUND DEAD
38701-01	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	8:20	P	HUNCHED POSTURE
38701-01	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:56	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	8:56	1	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	8:56	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				09-29-06	8:56	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				09-29-06	8:57	1	WET BROWN MATERIAL BASE OF TAIL
				09-30-06	8:19	1	WET BROWN MATERIAL BASE OF TAIL
				09-30-06	8:19	1	WET BROWN MATERIAL UROGENITAL AREA
				09-30-06	8:19	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				09-30-06	8:19	1	WET BROWN MATERIAL LEFT INGUINAL AREA
38700-07	F	800 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38700-07	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-03-06	7:46	P	HUNCHED POSTURE
38700-07	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:21	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-01-06	7:44	1	WET BROWN MATERIAL UROGENITAL AREA
				10-02-06	7:49	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-03-06	7:45	1	DRIED BROWN MATERIAL UROGENITAL AREA
				10-11-06	7:14	1	DRIED BROWN MATERIAL ANOGENITAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38696-06	F	10 MG/KG/DAY	ORAL/DENTAL	10-07-06	12:30	1	SALIVATION
38694-05	F	50 MG/KG/DAY	ORAL/DENTAL	10-15-06	12:24	1	SALIVATION PRIOR TO DOSING
38698-09	F	50 MG/KG/DAY	ORAL/DENTAL	10-15-06	12:26	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:21	1	SALIVATION PRIOR TO DOSING
38699-01	F	50 MG/KG/DAY	ORAL/DENTAL	10-14-06	12:28	1	SALIVATION PRIOR TO DOSING
				10-15-06	12:27	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:22	1	SALIVATION PRIOR TO DOSING
38703-04	F	50 MG/KG/DAY	ORAL/DENTAL	10-15-06	12:31	1	SALIVATION PRIOR TO DOSING
				10-17-06	12:09	1	SALIVATION PRIOR TO DOSING
38695-06	F	200 MG/KG/DAY	ORAL/DENTAL	10-09-06	13:01	1	SALIVATION PRIOR TO DOSING
				10-10-06	12:50	1	SALIVATION PRIOR TO DOSING
38694-08	F	200 MG/KG/DAY	ORAL/DENTAL	10-10-06	12:51	1	SALIVATION PRIOR TO DOSING
				10-11-06	12:38	1	SALIVATION PRIOR TO DOSING
38696-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-06-06	12:47	1	SALIVATION PRIOR TO DOSING
				10-09-06	13:03	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:36	1	SALIVATION PRIOR TO DOSING
38694-03	F	200 MG/KG/DAY	ORAL/DENTAL	10-05-06	13:08	1	SALIVATION PRIOR TO DOSING
38699-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-10-06	12:55	1	SALIVATION PRIOR TO DOSING
				10-12-06	12:50	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:37	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:28	1	SALIVATION PRIOR TO DOSING
38698-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-03-06	12:49	1	SALIVATION PRIOR TO DOSING
				10-04-06	12:59	1	SALIVATION PRIOR TO DOSING
				10-05-06	13:10	1	SALIVATION PRIOR TO DOSING
				10-06-06	12:50	1	SALIVATION PRIOR TO DOSING
				10-10-06	12:56	2	SALIVATION PRIOR TO DOSING
				10-11-06	12:41	1	SALIVATION PRIOR TO DOSING
				10-12-06	12:51	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:37	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38698-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-15-06	12:39	2	SALIVATION PRIOR TO DOSING
38698-02	F	200 MG/KG/DAY	ORAL/DENTAL	10-10-06	12:58	1	SALIVATION PRIOR TO DOSING
				10-11-06	12:43	1	SALIVATION PRIOR TO DOSING
				10-13-06	12:43	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:38	1	SALIVATION PRIOR TO DOSING
				10-15-06	12:40	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:31	1	SALIVATION PRIOR TO DOSING
38697-01	F	200 MG/KG/DAY	ORAL/DENTAL	10-13-06	12:44	1	SALIVATION PRIOR TO DOSING
38703-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-14-06	12:40	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:41	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:33	1	SALIVATION PRIOR TO DOSING
				10-17-06	12:11	2	SALIVATION PRIOR TO DOSING
38702-02	F	200 MG/KG/DAY	ORAL/DENTAL	10-04-06	13:03	1	SALIVATION PRIOR TO DOSING
				10-12-06	12:55	2	SALIVATION PRIOR TO DOSING
				10-14-06	12:41	1	SALIVATION PRIOR TO DOSING
				10-15-06	12:43	2	SALIVATION PRIOR TO DOSING
				10-16-06	12:34	1	SALIVATION PRIOR TO DOSING
38701-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-09-06	13:09	2	SALIVATION PRIOR TO DOSING
				10-11-06	12:45	1	SALIVATION PRIOR TO DOSING
				10-13-06	12:46	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:41	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:44	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:34	1	SALIVATION PRIOR TO DOSING
38695-08	F	800 MG/KG/DAY	ORAL/DENTAL	10-08-06	12:57	1	SALIVATION
				10-12-06	13:00	1	SALIVATION PRIOR TO DOSING
38696-10	F	800 MG/KG/DAY	ORAL/DENTAL	10-09-06	13:13	2	SALIVATION PRIOR TO DOSING
38694-01	F	800 MG/KG/DAY	ORAL/DENTAL	10-12-06	12:59	1	SALIVATION PRIOR TO DOSING
38695-03	F	800 MG/KG/DAY	ORAL/DENTAL	10-06-06	13:00	1	SALIVATION PRIOR TO DOSING
				10-10-06	13:07	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38695-03	F	800 MG/KG/DAY	ORAL/DENTAL	10-11-06	12:49	2	SALIVATION PRIOR TO DOSING
				10-13-06	12:50	2	SALIVATION PRIOR TO DOSING
				10-14-06	12:44	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:47	2	SALIVATION PRIOR TO DOSING
38697-10	F	800 MG/KG/DAY	ORAL/DENTAL	10-08-06	12:57	1	SALIVATION
				10-09-06	13:16	1	SALIVATION PRIOR TO DOSING
				10-10-06	13:08	2	SALIVATION PRIOR TO DOSING
				10-11-06	12:50	1	SALIVATION PRIOR TO DOSING
				10-12-06	13:02	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:37	1	SALIVATION PRIOR TO DOSING
38699-09	F	800 MG/KG/DAY	ORAL/DENTAL	10-03-06	12:59	1	SALIVATION PRIOR TO DOSING
				10-04-06	13:11	1	SALIVATION PRIOR TO DOSING
				10-05-06	13:22	1	SALIVATION PRIOR TO DOSING
				10-06-06	13:02	1	SALIVATION PRIOR TO DOSING
				10-07-06	12:58	2	SALIVATION
				10-08-06	12:58	1	SALIVATION
				10-10-06	13:09	2	SALIVATION PRIOR TO DOSING
				10-11-06	12:51	2	SALIVATION PRIOR TO DOSING
				10-12-06	13:02	2	SALIVATION PRIOR TO DOSING
				10-13-06	12:52	2	SALIVATION PRIOR TO DOSING
				10-14-06	12:46	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:49	2	SALIVATION PRIOR TO DOSING
				10-16-06	12:38	2	SALIVATION PRIOR TO DOSING
38700-07	F	800 MG/KG/DAY	ORAL/DENTAL	10-05-06	13:23	1	SALIVATION PRIOR TO DOSING
				10-06-06	13:02	1	SALIVATION PRIOR TO DOSING
				10-07-06	12:59	1	SALIVATION
				10-08-06	12:58	2	SALIVATION
				10-10-06	13:11	3	SALIVATION PRIOR TO DOSING
				10-11-06	12:52	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38700-07	F	800 MG/KG/DAY	ORAL/DENTAL	10-12-06	13:04	2	SALIVATION PRIOR TO DOSING
				10-13-06	12:52	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:47	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:50	2	SALIVATION PRIOR TO DOSING
				10-16-06	12:39	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38694-08	F	200 MG/KG/DAY	ORAL/DENTAL	10-05-06	14:10	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:48	2	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:55	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:35	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:42	1	WET CLEAR MATERIAL AROUND MOUTH
38696-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-10-06	13:55	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
38699-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-11-06	13:35	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:43	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:39	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:31	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:32	2	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:23	1	WET CLEAR MATERIAL AROUND MOUTH
38698-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-08-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:56	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:36	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:32	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:32	2	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:24	1	WET CLEAR MATERIAL AROUND MOUTH
38699-04	F	200 MG/KG/DAY	ORAL/DENTAL	10-15-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
38698-02	F	200 MG/KG/DAY	ORAL/DENTAL	10-04-06	13:59	2	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:46	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:49	2	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:45	2	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	14:05	2	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:56	2	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:37	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:44	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38698-02	F	200 MG/KG/DAY	ORAL/DENTAL	10-13-06	13:39	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:24	1	WET CLEAR MATERIAL AROUND MOUTH
38703-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-10-06	13:57	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:32	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:34	3	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:25	3	WET CLEAR MATERIAL AROUND MOUTH
				10-17-06	13:11	3	WET CLEAR MATERIAL AROUND MOUTH
38702-02	F	200 MG/KG/DAY	ORAL/DENTAL	10-16-06	13:25	1	WET RED MATERIAL AROUND MOUTH
				10-17-06	13:12	2	WET CLEAR MATERIAL AROUND MOUTH
38701-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-10-06	13:57	2	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:25	1	WET CLEAR MATERIAL AROUND MOUTH
38695-08	F	800 MG/KG/DAY	ORAL/DENTAL	10-05-06	14:12	1	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	14:07	1	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:59	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:55	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:43	1	WET CLEAR MATERIAL AROUND MOUTH
38694-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-29-06	13:42	P	HUNCHED POSTURE
38696-03	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-29-06	13:42	P	HUNCHED POSTURE
38696-10	F	800 MG/KG/DAY	ORAL/DENTAL	10-01-06	13:53	1	WET CLEAR MATERIAL AROUND MOUTH
				10-02-06	14:08	2	WET CLEAR MATERIAL AROUND MOUTH
				10-03-06	13:51	2	WET CLEAR MATERIAL AROUND MOUTH
				10-04-06	14:00	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted]

INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38696-10	F	800 MG/KG/DAY	ORAL/DENTAL	10-05-06	14:12	1	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:48	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:50	2	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:47	2	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	14:06	2	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:58	2	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:41	2	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:50	2	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:42	2	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:33	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:35	2	WET CLEAR MATERIAL AROUND MOUTH
38694-01	F	800 MG/KG/DAY	ORAL/DENTAL	10-02-06	14:08	1	WET CLEAR MATERIAL AROUND MOUTH
				10-04-06	14:01	1	WET CLEAR MATERIAL AROUND MOUTH
				10-05-06	14:12	1	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:48	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:46	2	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:43	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
38695-03	F	800 MG/KG/DAY	ORAL/DENTAL	10-02-06	14:09	2	WET CLEAR MATERIAL AROUND MOUTH
				10-04-06	14:01	1	WET CLEAR MATERIAL AROUND MOUTH
				10-05-06	14:12	1	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:48	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:50	2	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:46	3	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	14:06	1	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:58	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:41	2	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:54	2	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS

SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38695-03	F	800 MG/KG/DAY	ORAL/DENTAL	10-13-06	13:43	3	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:34	3	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:36	3	WET CLEAR MATERIAL AROUND MOUTH
38697-10	F	800 MG/KG/DAY	ORAL/DENTAL	10-05-06	14:13	1	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:51	1	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:47	2	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:59	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:41	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:55	2	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:44	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:34	1	WET CLEAR MATERIAL AROUND MOUTH
38699-09	F	800 MG/KG/DAY	BODY/INTEGUMENT	10-12-06	13:56	2	WET CLEAR MATERIAL VENTRAL NECK
				10-13-06	13:44	2	WET CLEAR MATERIAL VENTRAL NECK
38699-09	F	800 MG/KG/DAY	ORAL/DENTAL	10-03-06	13:52	2	WET CLEAR MATERIAL AROUND MOUTH
				10-05-06	14:13	2	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:49	2	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:51	3	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:47	3	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	14:08	3	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:59	3	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:42	3	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:55	3	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:44	3	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:34	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:37	3	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:26	3	WET CLEAR MATERIAL AROUND MOUTH
38699-03	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	13:53	P	BODY COOL TO TOUCH
				09-30-06	13:53	P	LIMBS COOL TO TOUCH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-023

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38703-07	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-01-06	13:55	P	HUNCHED POSTURE
38701-01	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	13:56	P	HUNCHED POSTURE
38700-07	F	800 MG/KG/DAY	BODY/INTEGUMENT	10-09-06	14:11	2	WET CLEAR MATERIAL FACIAL AREA
				10-09-06	14:11	2	WET CLEAR MATERIAL DORSAL HEAD
				10-10-06	14:02	1	WET CLEAR MATERIAL DORSAL ABDOMINAL AREA
				10-11-06	13:42	2	WET CLEAR MATERIAL DORSAL HEAD
				10-11-06	13:44	2	WET CLEAR MATERIAL DORSAL NECK
				10-11-06	13:44	1	WET CLEAR MATERIAL DORSAL THORACIC AREA
38700-07	F	800 MG/KG/DAY	ORAL/DENTAL	10-05-06	14:13	2	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:50	2	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:51	3	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:48	3	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	14:08	2	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	14:03	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:42	2	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:57	3	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:45	2	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:35	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:37	3	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
				10-17-06	13:13	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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11/09/2006

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Modified: 5/4/2007

TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: 0 MG/KG/DAY												
38694-07	59.0	63.3	67.9	74.3	80.5	88.9	93.5	101.0	107.9	115.9	127.4	133.1
38696-08	48.1	55.6	61.4	65.7	73.8	80.8	87.4	95.2	101.4	109.1	118.3	124.6
38695-01	51.5	58.1	62.3	65.9	73.3	78.7	84.8	90.2	96.6	101.5	111.2	115.8
38695-07	49.9	56.3	61.1	64.1	71.5	77.0	83.7	87.8	94.2	102.1	108.2	113.0
38694-04	49.2	53.1	58.9	63.5	68.2	73.3	79.1	83.7	89.2	94.3	101.7	105.9
38696-04	50.3	55.7	60.9	64.2	69.6	76.4	82.2	85.1	91.6	95.8	101.0	104.1
38697-07	45.5	47.4	52.2	56.9	61.8	65.9	71.7	75.8	82.1	88.0	92.6	97.8
38698-04	52.6	56.8	61.3	67.2	72.0	77.8	83.2	90.6	96.8	103.0	112.2	116.9
38699-07	63.7	69.0	73.4	77.6	85.6	91.7	97.5	104.1	111.5	114.7	124.5	133.2
38698-05	60.5	64.7	69.2	72.8	80.2	84.4	90.3	95.3	100.8	107.8	110.4	118.9
38699-02	50.6	55.4	59.4	64.5	69.3	73.2	79.1	84.7	91.0	94.9	102.3	107.5
38697-03	47.7	52.6	58.4	63.2	71.6	77.4	83.8	90.1	97.0	104.4	106.4	120.6
38703-06	56.2	61.0	67.0	72.0	79.3	83.0	89.1	93.6	100.9	108.5	114.3	122.1
38700-06	46.0	50.6	54.7	60.2	66.8	72.7	77.9	85.4	92.2	100.4	108.0	114.9
38702-05	44.4	49.1	54.2	59.1	65.1	68.6	74.7	78.6	84.9	89.2	93.3	100.1
MEAN	51.7	56.6	61.5	66.1	72.6	78.0	83.9	89.4	95.9	102.0	108.8	115.2
S.D.	5.74	5.94	5.86	5.82	6.46	7.03	6.95	7.71	7.95	8.44	9.98	10.79
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Audited Draft

Modified: 5/4/2007

TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: 0 MG/KG/DAY									
38694-07	141.4	150.3	157.6	165.8	172.9	179.2	185.3	185.4	184.2
38696-08	132.5	139.9	141.7	144.2	149.3	156.1	166.3	164.5	164.8
38695-01	122.9	128.1	134.3	142.1	141.6	145.3	149.9	153.1	156.5
38695-07	120.2	126.4	134.0	140.1	139.7	145.4	147.1	155.4	160.8
38694-04	111.9	120.8	125.6	129.4	130.0	133.9	137.6	138.1	139.8
38696-04	110.5	117.5	122.4	125.6	125.6	132.0	137.8	143.1	143.4
38697-07	105.4	109.7	115.8	119.5	128.5	134.3	141.8	144.7	149.6
38698-04	120.9	120.2	128.6	132.1	137.3	143.2	144.9	151.2	144.0
38699-07	140.9	148.0	152.9	160.2	170.1	176.6	183.6	188.3	180.9
38698-05	122.9	128.0	134.6	135.1	144.1	149.1	154.1	153.1	154.0
38699-02	112.7	113.6	124.9	126.2	133.2	131.7	141.8	143.8	146.8
38697-03	125.1	134.2	141.5	148.5	159.2	163.9	174.1	178.2	184.2
38703-06	130.4	136.6	140.5	153.4	157.6	163.9	173.0	179.4	189.8
38700-06	122.7	129.6	136.2	141.5	151.3	157.4	167.8	169.8	168.1
38702-05	106.9	113.6	115.9	117.5	128.5	134.0	139.3	139.9	138.2
MEAN	121.8	127.8	133.8	138.7	144.6	149.7	156.3	159.2	160.3
S.D.	11.19	12.33	12.11	14.27	15.14	15.92	17.06	17.15	17.58
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: 10 MG/KG/DAY												
38695-02	60.9	66.5	72.4	79.4	84.9	90.9	96.9	103.2	109.1	115.4	124.1	131.1
38694-10	51.7	57.0	62.5	66.7	73.0	79.9	84.9	91.7	97.3	102.3	110.7	115.0
38696-06	43.8	48.0	52.0	56.0	61.0	65.9	71.1	76.0	81.9	86.9	94.9	96.7
38696-01	44.8	49.8	55.0	57.6	63.6	68.3	73.6	78.2	82.1	87.4	94.3	98.6
38695-04	49.8	54.5	58.9	62.3	67.4	72.1	76.7	80.7	85.7	91.7	97.7	102.2
38694-02	55.2	61.7	69.1	73.8	79.6	86.4	93.9	100.3	110.5	115.6	126.1	131.1
38698-07	48.9	54.1	59.6	65.8	72.1	75.8	81.0	87.8	95.0	101.8	109.5	118.6
38697-04	49.1	54.2	60.0	64.2	70.8	77.9	80.5	89.4	95.9	99.9	105.0	114.9
38699-08	53.4	58.7	61.8	67.5	72.8	76.9	83.1	87.8	94.5	101.4	109.4	115.0
38699-06	58.2	62.3	66.6	71.4	76.9	81.6	85.9	94.0	98.7	105.2	111.9	120.9
38698-06	50.6	55.2	60.7	64.7	71.3	76.7	82.5	89.2	96.2	104.1	111.4	116.3
38697-05	46.9	49.5	56.4	59.7	66.7	73.5	78.4	85.1	90.3	99.3	107.2	115.2
38702-09	52.2	56.4	62.8	69.6	76.0	80.3	85.4	92.1	97.5	104.3	111.0	116.6
38703-01	48.9	53.5	57.2	63.0	66.9	70.9	75.9	80.6	86.5	93.1	99.9	100.5
38701-03	42.2	47.2	52.3	57.4	61.7	65.7	70.4	75.6	80.8	85.2	92.2	99.3
MEAN	50.4	55.2	60.5	65.3	71.0	76.2	81.3	87.4	93.5	99.6	107.0	112.8
S.D.	5.13	5.48	5.76	6.49	6.68	7.14	7.56	8.27	9.07	9.32	10.04	11.09
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Audited Draft

Modified: 5/4/2007

TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: 10 MG/KG/DAY									
38695-02	136.5	143.3	150.8	160.2	164.8	170.6	179.2	185.1	190.4
38694-10	126.4	131.1	138.2	144.6	150.7	153.1	159.4	164.2	166.1
38696-06	105.6	109.9	117.8	118.8	119.9	127.7	131.5	135.4	134.1
38696-01	102.3	108.3	115.2	120.2	123.2	123.6	129.9	136.2	139.5
38695-04	106.3	114.3	117.6	124.8	126.6	132.5	138.2	141.9	146.8
38694-02	139.5	146.0	153.1	159.8	158.5	167.9	172.5	177.2	178.3
38698-07	125.5	133.8	141.6	146.7	157.1	162.4	168.5	174.2	179.2
38697-04	118.6	128.6	130.7	136.8	143.6	152.8	157.7	162.9	156.8
38699-08	120.5	126.2	132.7	138.7	142.6	149.9	154.7	160.6	162.3
38699-06	124.8	131.6	136.4	139.4	147.6	151.8	157.9	158.0	163.9
38698-06	123.5	132.3	138.7	140.3	146.1	149.0	154.5	156.0	157.0
38697-05	122.7	130.8	139.6	147.3	155.6	162.5	172.2	177.4	187.7
38702-09	122.8	129.6	136.2	138.8	145.4	153.4	156.1	156.1	158.7
38703-01	107.6	114.2	117.5	122.2	123.9	128.9	132.7	138.7	142.9
38701-03	105.8	111.2	117.9	123.1	132.6	139.2	145.3	149.8	152.3
MEAN	119.2	126.1	132.3	137.4	142.5	148.4	154.0	158.2	161.1
S.D.	11.44	11.85	12.45	13.39	14.23	14.90	15.69	15.82	17.06
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: 50 MG/KG/DAY												
38694-06	57.2	62.0	67.7	73.1	78.7	85.4	91.5	97.2	104.3	112.5	121.8	127.2
38695-10	53.8	59.1	64.8	69.0	75.0	83.0	89.8	96.9	103.7	113.6	117.0	124.9
38696-07	46.7	51.1	56.0	60.3	65.3	71.2	75.9	80.8	85.8	91.2	95.4	99.8
38696-09	40.5	45.4	50.7	56.0	61.1	64.9	69.8	76.0	81.7	88.1	94.5	100.4
38694-05	52.3	58.7	63.2	69.9	74.4	83.6	90.8	96.3	102.6	109.2	117.9	119.2
38695-05	56.4	61.8	67.5	73.4	78.3	84.1	91.1	97.0	103.5	109.3	119.3	124.9
38697-02	46.1	51.2	56.1	59.3	66.9	72.4	76.1	82.2	86.2	93.7	99.1	106.8
38698-09	54.3	59.8	66.1	69.6	76.4	82.5	86.9	94.3	101.3	105.3	113.4	119.7
38699-01	56.6	62.0	67.2	71.9	78.7	83.7	89.7	95.4	100.3	109.7	114.2	121.7
38699-10	58.6	64.1	68.5	74.1	78.8	85.5	90.9	97.3	103.4	109.7	116.6	123.6
38698-01	59.1	65.2	69.1	75.2	80.3	86.8	93.4	100.0	106.3	112.9	120.4	126.0
38697-09	49.0	53.7	57.4	64.2	69.4	76.7	81.1	86.9	93.0	99.4	104.1	111.3
38703-04	50.2	56.4	62.7	69.5	73.3	78.1	84.8	89.9	95.1	100.4	108.1	116.1
38700-01	46.0	48.5	54.7	59.5	64.6	70.7	76.8	81.0	88.2	95.5	104.3	110.9
38701-06	45.0	48.6	53.3	57.2	61.8	66.2	71.1	76.0	81.5	86.6	93.4	99.8
MEAN	51.5	56.5	61.7	66.8	72.2	78.3	84.0	89.8	95.8	102.5	109.3	115.5
S.D.	5.72	6.32	6.30	6.71	6.74	7.45	8.11	8.52	8.95	9.50	10.10	9.98
N	15	15	15	15	15	15	15	15	15	15	15	15

Revised Audited Draft

Modified: 5/4/2007

TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: 50 MG/KG/DAY									
38694-06	135.6	141.7	149.0	153.4	156.3	160.0	166.0	169.8	169.4
38695-10	133.0	140.9	149.4	156.0	153.0	161.0	168.7	174.5	177.3
38696-07	104.6	110.3	114.7	115.8	119.4	124.6	127.9	131.1	131.1
38696-09	107.1	116.0	122.9	126.4	129.4	136.4	141.5	145.4	146.3
38694-05	127.5	135.5	142.1	140.1	150.9	155.1	159.6	156.8	166.8
38695-05	129.5	138.1	140.8	147.0	147.2	146.1	155.7	158.8	158.4
38697-02	114.5	118.5	125.8	129.8	137.5	140.8	147.2	153.5	156.6
38698-09	126.8	131.4	134.0	135.2	142.0	148.2	153.5	156.8	150.4
38699-01	126.3	132.5	137.8	137.5	143.6	151.8	154.8	153.8	158.4
38699-10	129.7	138.4	145.8	143.2	152.7	157.3	160.3	167.9	165.3
38698-01	135.3	141.2	150.7	152.9	154.7	166.2	170.8	174.4	173.5
38697-09	117.8	124.8	132.7	136.5	144.4	152.1	156.4	157.9	156.6
38703-04	124.6	130.5	132.0	141.9	147.8	153.2	156.6	157.2	167.9
38700-01	116.8	124.9	133.1	134.7	141.5	145.0	150.7	153.9	157.3
38701-06	104.4	112.9	120.4	128.7	136.7	141.7	144.2	153.0	158.4
MEAN	122.2	129.2	135.4	138.6	143.8	149.3	154.3	157.7	159.6
S.D.	10.73	10.72	11.12	11.04	10.07	10.69	11.08	11.16	11.52
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHTS [G]

FEMALES

PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: 200 MG/KG/DAY												
38696-02	53.9	58.4	64.4	68.4	75.2	80.7	86.1	91.4	96.1	101.0	105.7	110.7
38695-06	53.0	57.3	62.2	65.8	69.7	75.0	78.9	83.8	86.6	90.5	95.7	100.8
38694-08	49.5	53.9	60.0	64.0	69.0	76.5	80.7	86.1	91.6	98.0	102.7	108.5
38696-05	44.7	48.3	53.2	55.9	59.0	62.8	68.4	71.7	75.0	77.9	84.6	88.4
38695-09	50.1	52.2	57.0	60.7	64.8	70.2	73.8	77.2	82.5	86.2	93.5	97.9
38694-03	57.7	62.2	69.3	74.7	79.5	87.7	95.0	101.0	107.6	113.0	121.7	127.6
38697-06	47.7	52.0	58.1	62.7	70.3	75.5	81.4	86.8	92.3	98.2	104.9	109.2
38699-05	54.2	59.1	64.1	68.8	73.6	79.8	83.0	88.7	93.5	101.6	107.2	114.0
38698-10	57.4	64.1	68.2	72.7	78.6	83.8	88.4	94.2	99.7	104.7	109.3	115.5
38699-04	60.7	67.5	71.3	77.6	83.6	89.5	95.5	100.4	108.2	117.0	121.6	130.2
38698-02	58.8	65.8	69.2	74.5	82.1	88.3	95.0	98.4	105.5	113.0	119.9	124.4
38697-01	47.3	53.2	57.2	62.3	69.6	77.0	81.1	86.1	92.7	99.4	104.0	111.3
38703-05	52.7	57.5	61.5	68.2	74.0	79.4	86.1	89.6	99.0	106.8	112.3	116.6
38702-02	47.3	50.5	56.0	60.8	64.8	70.2	74.3	79.9	85.3	90.6	94.7	102.0
38701-10	44.9	48.4	53.3	59.5	64.9	68.8	73.5	77.4	83.8	87.9	93.2	100.9
MEAN	52.0	56.7	61.7	66.4	71.9	77.7	82.7	87.5	93.3	99.1	104.7	110.5
S.D.	5.14	6.18	5.95	6.39	7.07	7.71	8.38	8.73	9.68	11.01	11.15	11.53
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: 200 MG/KG/DAY									
38696-02	119.9	123.6	128.3	130.9	130.9	129.8	137.2	139.7	142.6
38695-06	101.6	105.3	109.3	111.6	113.5	117.6	119.0	123.8	128.6
38694-08	114.6	121.3	128.8	128.9	134.2	138.7	140.7	142.9	144.7
38696-05	92.5	98.1	97.8	102.7	103.0	107.3	110.8	113.6	114.9
38695-09	102.3	106.7	113.2	119.9	121.5	124.0	128.5	133.3	134.5
38694-03	134.2	136.7	143.7	143.9	146.6	150.4	152.1	160.1	163.2
38697-06	116.8	119.9	127.3	131.3	136.5	142.6	147.7	150.9	156.4
38699-05	117.4	121.6	131.6	128.5	133.5	137.2	140.1	144.4	143.9
38698-10	119.5	125.8	132.5	134.8	140.4	145.9	152.7	153.8	160.0
38699-04	135.6	142.7	147.5	153.9	157.9	162.7	168.1	175.9	174.0
38698-02	132.4	140.6	149.5	153.6	161.6	166.0	172.3	176.4	178.5
38697-01	116.3	120.6	126.3	131.5	133.2	141.6	143.7	146.9	146.0
38703-05	122.2	130.5	132.1	136.9	144.9	152.2	155.7	163.6	165.9
38702-02	105.7	106.0	112.6	118.2	122.5	127.8	131.9	136.3	139.7
38701-10	106.6	112.0	114.3	123.4	130.9	135.7	139.1	142.4	149.7
MEAN	115.8	120.8	126.3	130.0	134.1	138.6	142.6	146.9	149.5
S.D.	12.53	13.37	14.65	14.06	15.46	15.97	16.60	17.45	17.17
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

	FEMALES											
PND	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: 800 MG/KG/DAY												
38695-08	55.8	59.4	60.1	63.0	68.4	73.5	75.8	74.8	75.0	81.4	89.5	94.0
38694-09	52.5	54.9	52.8	48.0	NA							
38696-03	47.2	47.4	44.9	39.2								
38696-10	43.2	45.2	47.9	52.0	57.5	63.3	64.8	69.8	73.0	79.4	84.7	89.5
38694-01	54.0	59.3	63.1	63.3	62.4	67.9	68.4	76.8	85.5	93.7	101.9	106.2
38695-03	54.4	58.2	60.8	64.0	64.9	71.0	74.9	79.9	83.1	88.3	91.0	94.3
38697-10	50.1	52.8	56.5	58.4	57.4	62.4	68.8	73.7	79.1	84.7	91.7	97.0
38698-08	49.0	51.4	46.1	NA								
38699-09	60.6	64.6	66.0	70.8	76.6	81.5	88.3	92.8	99.5	106.3	113.4	118.3
38698-03	61.2	64.6										
38699-03	58.4	62.6	59.5	52.8	NA							
38697-08	44.9	45.8	40.2	NA								
38703-07	52.9	57.7	57.4	53.7	45.7							
38701-01	47.3	46.2	41.2	NA								
38700-07	44.5	48.9	48.5	48.7	54.0	60.3	65.9	74.2	81.4	90.1	95.4	95.6
MEAN	51.7	54.6	53.2	55.8	60.9	68.6	72.4	77.4	82.4	89.1	95.4	99.3
S.D.	5.77	6.90	8.40	9.07	9.44	7.44	8.16	7.44	8.73	9.05	9.56	9.80
N	15	15	14	11	8	7	7	7	7	7	7	7

NA = NOT APPLICABLE

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Modified: 5/4/2007

PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

TABLE 17
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
PND	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: 800 MG/KG/DAY									
38695-08	98.6	103.7	107.6	110.2	114.9	115.4	120.4	124.2	127.4
38696-10	93.0	100.4	105.5	111.4	110.9	116.4	122.5	128.2	129.5
38694-01	113.8	120.2	128.0	133.6	140.6	145.7	152.3	160.4	161.1
38695-03	98.0	105.8	105.4	107.1	113.2	121.3	123.2	129.4	132.7
38697-10	100.0	103.2	108.8	116.6	121.5	124.1	131.5	134.0	140.7
38699-09	122.6	129.2	134.1	142.5	145.7	152.5	161.0	164.5	163.2
38700-07	101.0	112.7	119.7	124.1	129.3	138.2	147.4	151.6	158.5
MEAN	103.9	110.7	115.6	120.8	125.2	130.5	136.9	141.8	144.7
S.D.	10.43	10.58	11.76	13.24	13.80	14.87	16.46	16.67	15.77
N	7	7	7	7	7	7	7	7	7

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: 0 MG/KG/DAY												
38694-07	4.3	4.6	6.4	6.2	8.4	4.6	7.5	6.9	8.0	11.5	5.7	8.3
38696-08	7.5	5.8	4.3	8.1	7.0	6.6	7.8	6.2	7.7	9.2	6.3	7.9
38695-01	6.6	4.2	3.6	7.4	5.4	6.1	5.4	6.4	4.9	9.7	4.6	7.1
38695-07	6.4	4.8	3.0	7.4	5.5	6.7	4.1	6.4	7.9	6.1	4.8	7.2
38694-04	3.9	5.8	4.6	4.7	5.1	5.8	4.6	5.5	5.1	7.4	4.2	6.0
38696-04	5.4	5.2	3.3	5.4	6.8	5.8	2.9	6.5	4.2	5.2	3.1	6.4
38697-07	1.9	4.8	4.7	4.9	4.1	5.8	4.1	6.3	5.9	4.6	5.2	7.6
38698-04	4.2	4.5	5.9	4.8	5.8	5.4	7.4	6.2	6.2	9.2	4.7	4.0
38699-07	5.3	4.4	4.2	8.0	6.1	5.8	6.6	7.4	3.2	9.8	8.7	7.7
38698-05	4.2	4.5	3.6	7.4	4.2	5.9	5.0	5.5	7.0	2.6	8.5	4.0
38699-02	4.8	4.0	5.1	4.8	3.9	5.9	5.6	6.3	3.9	7.4	5.2	5.2
38697-03	4.9	5.8	4.8	8.4	5.8	6.4	6.3	6.9	7.4	2.0	14.2	4.5
38703-06	4.8	6.0	5.0	7.3	3.7	6.1	4.5	7.3	7.6	5.8	7.8	8.3
38700-06	4.6	4.1	5.5	6.6	5.9	5.2	7.5	6.8	8.2	7.6	6.9	7.8
38702-05	4.7	5.1	4.9	6.0	3.5	6.1	3.9	6.3	4.3	4.1	6.8	6.8
MEAN	4.9	4.9	4.6	6.5	5.4	5.9	5.5	6.5	6.1	6.8	6.4	6.6
S.D.	1.30	0.68	0.96	1.33	1.38	0.53	1.56	0.54	1.71	2.79	2.68	1.51
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: 0 MG/KG/DAY									
38694-07	8.9	7.3	8.2	7.1	6.3	6.1	0.1	-1.2	125.2
38696-08	7.4	1.8	2.5	5.1	6.8	10.2	-1.8	0.3	116.7
38695-01	5.2	6.2	7.8	-0.5	3.7	4.6	3.2	3.4	105.0
38695-07	6.2	7.6	6.1	-0.4	5.7	1.7	8.3	5.4	110.9
38694-04	8.9	4.8	3.8	0.6	3.9	3.7	0.5	1.7	90.6
38696-04	7.0	4.9	3.2	0.0	6.4	5.8	5.3	0.3	93.1
38697-07	4.3	6.1	3.7	9.0	5.8	7.5	2.9	4.9	104.1
38698-04	-0.7	8.4	3.5	5.2	5.9	1.7	6.3	-7.2	91.4
38699-07	7.1	4.9	7.3	9.9	6.5	7.0	4.7	-7.4	117.2
38698-05	5.1	6.6	0.5	9.0	5.0	5.0	-1.0	0.9	93.5
38699-02	0.9	11.3	1.3	7.0	-1.5	10.1	2.0	3.0	96.2
38697-03	9.1	7.3	7.0	10.7	4.7	10.2	4.1	6.0	136.5
38703-06	6.2	3.9	12.9	4.2	6.3	9.1	6.4	10.4	133.6
38700-06	6.9	6.6	5.3	9.8	6.1	10.4	2.0	-1.7	122.1
38702-05	6.7	2.3	1.6	11.0	5.5	5.3	0.6	-1.7	93.8
MEAN	5.9	6.0	5.0	5.8	5.1	6.6	2.9	1.1	108.7
S.D.	2.77	2.39	3.29	4.22	2.06	2.99	2.94	4.75	15.81
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: 10 MG/KG/DAY												
38695-02	5.6	5.9	7.0	5.5	6.0	6.0	6.3	5.9	6.3	8.7	7.0	5.4
38694-10	5.3	5.5	4.2	6.3	6.9	5.0	6.8	5.6	5.0	8.4	4.3	11.4
38696-06	4.2	4.0	4.0	5.0	4.9	5.2	4.9	5.9	5.0	8.0	1.8	8.9
38696-01	5.0	5.2	2.6	6.0	4.7	5.3	4.6	3.9	5.3	6.9	4.3	3.7
38695-04	4.7	4.4	3.4	5.1	4.7	4.6	4.0	5.0	6.0	6.0	4.5	4.1
38694-02	6.5	7.4	4.7	5.8	6.8	7.5	6.4	10.2	5.1	10.5	5.0	8.4
38698-07	5.2	5.5	6.2	6.3	3.7	5.2	6.8	7.2	6.8	7.7	9.1	6.9
38697-04	5.1	5.8	4.2	6.6	7.1	2.6	8.9	6.5	4.0	5.1	9.9	3.7
38699-08	5.3	3.1	5.7	5.3	4.1	6.2	4.7	6.7	6.9	8.0	5.6	5.5
38699-06	4.1	4.3	4.8	5.5	4.7	4.3	8.1	4.7	6.5	6.7	9.0	3.9
38698-06	4.6	5.5	4.0	6.6	5.4	5.8	6.7	7.0	7.9	7.3	4.9	7.2
38697-05	2.6	6.9	3.3	7.0	6.8	4.9	6.7	5.2	9.0	7.9	8.0	7.5
38702-09	4.2	6.4	6.8	6.4	4.3	5.1	6.7	5.4	6.8	6.7	5.6	6.2
38703-01	4.6	3.7	5.8	3.9	4.0	5.0	4.7	5.9	6.6	6.8	0.6	7.1
38701-03	5.0	5.1	5.1	4.3	4.0	4.7	5.2	5.2	4.4	7.0	7.1	6.5
MEAN	4.8	5.2	4.8	5.7	5.2	5.2	6.1	6.0	6.1	7.4	5.8	6.4
S.D.	0.87	1.19	1.30	0.88	1.20	1.06	1.39	1.46	1.34	1.26	2.63	2.17
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: 10 MG/KG/DAY									
38695-02	6.8	7.5	9.4	4.6	5.8	8.6	5.9	5.3	129.5
38694-10	4.7	7.1	6.4	6.1	2.4	6.3	4.8	1.9	114.4
38696-06	4.3	7.9	1.0	1.1	7.8	3.8	3.9	-1.3	90.3
38696-01	6.0	6.9	5.0	3.0	0.4	6.3	6.3	3.3	94.7
38695-04	8.0	3.3	7.2	1.8	5.9	5.7	3.7	4.9	97.0
38694-02	6.5	7.1	6.7	-1.3	9.4	4.6	4.7	1.1	123.1
38698-07	8.3	7.8	5.1	10.4	5.3	6.1	5.7	5.0	130.3
38697-04	10.0	2.1	6.1	6.8	9.2	4.9	5.2	-6.1	107.7
38699-08	5.7	6.5	6.0	3.9	7.3	4.8	5.9	1.7	108.9
38699-06	6.8	4.8	3.0	8.2	4.2	6.1	0.1	5.9	105.7
38698-06	8.8	6.4	1.6	5.8	2.9	5.5	1.5	1.0	106.4
38697-05	8.1	8.8	7.7	8.3	6.9	9.7	5.2	10.3	140.8
38702-09	6.8	6.6	2.6	6.6	8.0	2.7	0.0	2.6	106.5
38703-01	6.6	3.3	4.7	1.7	5.0	3.8	6.0	4.2	94.0
38701-03	5.4	6.7	5.2	9.5	6.6	6.1	4.5	2.5	110.1
MEAN	6.9	6.2	5.2	5.1	5.8	5.7	4.2	2.8	110.6
S.D.	1.56	1.93	2.32	3.37	2.54	1.78	2.08	3.66	14.70
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

FEMALES

PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: 50 MG/KG/DAY												
38694-06	4.8	5.7	5.4	5.6	6.7	6.1	5.7	7.1	8.2	9.3	5.4	8.4
38695-10	5.3	5.7	4.2	6.0	8.0	6.8	7.1	6.8	9.9	3.4	7.9	8.1
38696-07	4.4	4.9	4.3	5.0	5.9	4.7	4.9	5.0	5.4	4.2	4.4	4.8
38696-09	4.9	5.3	5.3	5.1	3.8	4.9	6.2	5.7	6.4	6.4	5.9	6.7
38694-05	6.4	4.5	6.7	4.5	9.2	7.2	5.5	6.3	6.6	8.7	1.3	8.3
38695-05	5.4	5.7	5.9	4.9	5.8	7.0	5.9	6.5	5.8	10.0	5.6	4.6
38697-02	5.1	4.9	3.2	7.6	5.5	3.7	6.1	4.0	7.5	5.4	7.7	7.7
38698-09	5.5	6.3	3.5	6.8	6.1	4.4	7.4	7.0	4.0	8.1	6.3	7.1
38699-01	5.4	5.2	4.7	6.8	5.0	6.0	5.7	4.9	9.4	4.5	7.5	4.6
38699-10	5.5	4.4	5.6	4.7	6.7	5.4	6.4	6.1	6.3	6.9	7.0	6.1
38698-01	6.1	3.9	6.1	5.1	6.5	6.6	6.6	6.3	6.6	7.5	5.6	9.3
38697-09	4.7	3.7	6.8	5.2	7.3	4.4	5.8	6.1	6.4	4.7	7.2	6.5
38703-04	6.2	6.3	6.8	3.8	4.8	6.7	5.1	5.2	5.3	7.7	8.0	8.5
38700-01	2.5	6.2	4.8	5.1	6.1	6.1	4.2	7.2	7.3	8.8	6.6	5.9
38701-06	3.6	4.7	3.9	4.6	4.4	4.9	4.9	5.5	5.1	6.8	6.4	4.6
MEAN	5.1	5.2	5.1	5.4	6.1	5.7	5.8	6.0	6.7	6.8	6.2	6.7
S.D.	1.01	0.83	1.18	1.01	1.39	1.11	0.86	0.92	1.59	2.02	1.70	1.61
N	15	15	15	15	15	15	15	15	15	15	15	15

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Modified: 5/4/2007

TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: 50 MG/KG/DAY									
38694-06	6.1	7.3	4.4	2.9	3.7	6.0	3.8	-0.4	112.2
38695-10	7.9	8.5	6.6	-3.0	8.0	7.7	5.8	2.8	123.5
38696-07	5.7	4.4	1.1	3.6	5.2	3.3	3.2	0.0	84.4
38696-09	8.9	6.9	3.5	3.0	7.0	5.1	3.9	0.9	105.8
38694-05	8.0	6.6	-2.0	10.8	4.2	4.5	-2.8	10.0	114.5
38695-05	8.6	2.7	6.2	0.2	-1.1	9.6	3.1	-0.4	102.0
38697-02	4.0	7.3	4.0	7.7	3.3	6.4	6.3	3.1	110.5
38698-09	4.6	2.6	1.2	6.8	6.2	5.3	3.3	-6.4	96.1
38699-01	6.2	5.3	-0.3	6.1	8.2	3.0	-1.0	4.6	101.8
38699-10	8.7	7.4	-2.6	9.5	4.6	3.0	7.6	-2.6	106.7
38698-01	5.9	9.5	2.2	1.8	11.5	4.6	3.6	-0.9	114.4
38697-09	7.0	7.9	3.8	7.9	7.7	4.3	1.5	-1.3	107.6
38703-04	5.9	1.5	9.9	5.9	5.4	3.4	0.6	10.7	117.7
38700-01	8.1	8.2	1.6	6.8	3.5	5.7	3.2	3.4	111.3
38701-06	8.5	7.5	8.3	8.0	5.0	2.5	8.8	5.4	113.4
MEAN	6.9	6.2	3.2	5.2	5.5	5.0	3.4	1.9	108.1
S.D.	1.57	2.40	3.57	3.72	2.87	1.94	3.06	4.55	9.49
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: 200 MG/KG/DAY												
38696-02	4.5	6.0	4.0	6.8	5.5	5.4	5.3	4.7	4.9	4.7	5.0	9.2
38695-06	4.3	4.9	3.6	3.9	5.3	3.9	4.9	2.8	3.9	5.2	5.1	0.8
38694-08	4.4	6.1	4.0	5.0	7.5	4.2	5.4	5.5	6.4	4.7	5.8	6.1
38696-05	3.6	4.9	2.7	3.1	3.8	5.6	3.3	3.3	2.9	6.7	3.8	4.1
38695-09	2.1	4.8	3.7	4.1	5.4	3.6	3.4	5.3	3.7	7.3	4.4	4.4
38694-03	4.5	7.1	5.4	4.8	8.2	7.3	6.0	6.6	5.4	8.7	5.9	6.6
38697-06	4.3	6.1	4.6	7.6	5.2	5.9	5.4	5.5	5.9	6.7	4.3	7.6
38699-05	4.9	5.0	4.7	4.8	6.2	3.2	5.7	4.8	8.1	5.6	6.8	3.4
38698-10	6.7	4.1	4.5	5.9	5.2	4.6	5.8	5.5	5.0	4.6	6.2	4.0
38699-04	6.8	3.8	6.3	6.0	5.9	6.0	4.9	7.8	8.8	4.6	8.6	5.4
38698-02	7.0	3.4	5.3	7.6	6.2	6.7	3.4	7.1	7.5	6.9	4.5	8.0
38697-01	5.9	4.0	5.1	7.3	7.4	4.1	5.0	6.6	6.7	4.6	7.3	5.0
38703-05	4.8	4.0	6.7	5.8	5.4	6.7	3.5	9.4	7.8	5.5	4.3	5.6
38702-02	3.2	5.5	4.8	4.0	5.4	4.1	5.6	5.4	5.3	4.1	7.3	3.7
38701-10	3.5	4.9	6.2	5.4	3.9	4.7	3.9	6.4	4.1	5.3	7.7	5.7
MEAN	4.7	5.0	4.8	5.5	5.8	5.1	4.8	5.8	5.8	5.7	5.8	5.3
S.D.	1.40	1.03	1.10	1.41	1.22	1.26	0.98	1.66	1.76	1.30	1.47	2.08
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

	FEMALES								
PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: 200 MG/KG/DAY									
38696-02	3.7	4.7	2.6	0.0	-1.1	7.4	2.5	2.9	88.7
38695-06	3.7	4.0	2.3	1.9	4.1	1.4	4.8	4.8	75.6
38694-08	6.7	7.5	0.1	5.3	4.5	2.0	2.2	1.8	95.2
38696-05	5.6	-0.3	4.9	0.3	4.3	3.5	2.8	1.3	70.2
38695-09	4.4	6.5	6.7	1.6	2.5	4.5	4.8	1.2	84.4
38694-03	2.5	7.0	0.2	2.7	3.8	1.7	8.0	3.1	105.5
38697-06	3.1	7.4	4.0	5.2	6.1	5.1	3.2	5.5	108.7
38699-05	4.2	10.0	-3.1	5.0	3.7	2.9	4.3	-0.5	89.7
38698-10	6.3	6.7	2.3	5.6	5.5	6.8	1.1	6.2	102.6
38699-04	7.1	4.8	6.4	4.0	4.8	5.4	7.8	-1.9	113.3
38698-02	8.2	8.9	4.1	8.0	4.4	6.3	4.1	2.1	119.7
38697-01	4.3	5.7	5.2	1.7	8.4	2.1	3.2	-0.9	98.7
38703-05	8.3	1.6	4.8	8.0	7.3	3.5	7.9	2.3	113.2
38702-02	0.3	6.6	5.6	4.3	5.3	4.1	4.4	3.4	92.4
38701-10	5.4	2.3	9.1	7.5	4.8	3.4	3.3	7.3	104.8
MEAN	4.9	5.6	3.7	4.1	4.6	4.0	4.3	2.6	97.5
S.D.	2.19	2.77	3.06	2.64	2.14	1.89	2.12	2.62	14.21
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

	FEMALES											
PND	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: 800 MG/KG/DAY												
38695-08	3.6	0.7	2.9	5.4	5.1	2.3	-1.0	0.2	6.4	8.1	4.5	4.6
38694-09	2.4	-2.1	-4.8	NA								
38696-03	0.2	-2.5	-5.7									
38696-10	2.0	2.7	4.1	5.5	5.8	1.5	5.0	3.2	6.4	5.3	4.8	3.5
38694-01	5.3	3.8	0.2	-0.9	5.5	0.5	8.4	8.7	8.2	8.2	4.3	7.6
38695-03	3.8	2.6	3.2	0.9	6.1	3.9	5.0	3.2	5.2	2.7	3.3	3.7
38697-10	2.7	3.7	1.9	-1.0	5.0	6.4	4.9	5.4	5.6	7.0	5.3	3.0
38698-08	2.4	-5.3	NA									
38699-09	4.0	1.4	4.8	5.8	4.9	6.8	4.5	6.7	6.8	7.1	4.9	4.3
38698-03	3.4											
38699-03	4.2	-3.1	-6.7	NA								
38697-08	0.9	-5.6	NA									
38703-07	4.8	-0.3	-3.7	-8.0								
38701-01	-1.1	-5.0	NA									
38700-07	4.4	-0.4	0.2	5.3	6.3	5.6	8.3	7.2	8.7	5.3	0.2	5.4
MEAN	2.9	-0.7	-0.3	1.6	5.5	3.9	5.0	4.9	6.8	6.2	3.9	4.6
S.D.	1.79	3.32	4.18	4.88	0.56	2.50	3.13	2.92	1.28	1.95	1.75	1.54
N	15	14	11	8	7	7	7	7	7	7	7	7

NA = NOT APPLICABLE

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TABLE 18

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-023

FEMALES

PND	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: 800 MG/KG/DAY									
38695-08	5.1	3.9	2.6	4.7	0.5	5.0	3.8	3.2	71.6
38696-10	7.4	5.1	5.9	-0.5	5.5	6.1	5.7	1.3	86.3
38694-01	6.4	7.8	5.6	7.0	5.1	6.6	8.1	0.7	107.1
38695-03	7.8	-0.4	1.7	6.1	8.1	1.9	6.2	3.3	78.3
38697-10	3.2	5.6	7.8	4.9	2.6	7.4	2.5	6.7	90.6
38699-09	6.6	4.9	8.4	3.2	6.8	8.5	3.5	-1.3	102.6
38700-07	11.7	7.0	4.4	5.2	8.9	9.2	4.2	6.9	114.0
MEAN	6.9	4.8	5.2	4.4	5.4	6.4	4.9	3.0	92.9
S.D.	2.63	2.66	2.49	2.45	2.98	2.44	1.91	3.05	15.58
N	7	7	7	7	7	7	7	7	7

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TABLE 19

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-023

GROUP: 0 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37
38694-07	28	94.1	N	N	Y									
38696-08	32	117.9	N	N	N	N	N	N	Y					
38695-01	33	116.2	N	N	N	N	N	N	N	Y				
38695-07	34	119.2	N	N	N	N	N	N	N	N	Y			
38694-04	34	112.5	N	N	N	N	N	N	N	N	Y			
38696-04	34	111.4	N	N	N	N	N	N	N	N	Y			
38697-07	34	105.0	N	N	N	N	N	N	N	N	Y			
38698-04	30	97.1	N	N	N	N	Y							
38699-07	30	112.3	N	N	N	N	Y							
38698-05	34	124.3	N	N	N	N	N	N	N	N	Y			
38699-02	33	108.2	N	N	N	N	N	N	N	Y				
38697-03	33	119.4	N	N	N	N	N	N	N	Y				
38703-06	33	121.5	N	N	N	N	N	N	N	Y				
38700-06	33	118.2	N	N	N	N	N	N	N	Y				
38702-05	33	101.0	N	N	N	N	N	N	N	Y				
MEAN	32.5	111.9												
S.D.	1.81	9.13												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 19

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-023

GROUP: 10 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37
38695-02	30	108.7	N	N	N	N	Y							
38694-10	32	110.1	N	N	N	N	N	N	Y					
38696-06	34	104.7	N	N	N	N	N	N	N	N	Y			
38696-01	34	103.0	N	N	N	N	N	N	N	N	Y			
38695-04	35	113.7	N	N	N	N	N	N	N	N	N	Y		
38694-02	32	121.6	N	N	N	N	N	N	Y					
38698-07	34	124.9	N	N	N	N	N	N	N	N	Y			
38697-04	31	99.2	N	N	N	N	N	Y						
38699-08	33	113.4	N	N	N	N	N	N	N	Y				
38699-06	34	123.4	N	N	N	N	N	N	N	N	Y			
38698-06	34	123.8	N	N	N	N	N	N	N	N	Y			
38697-05	33	114.9	N	N	N	N	N	N	N	Y				
38702-09	33	116.9	N	N	N	N	N	N	N	Y				
38703-01	33	100.6	N	N	N	N	N	N	N	Y				
38701-03	37	124.3	N	N	N	N	N	N	N	N	N	N	N	Y
MEAN	33.3	113.5												
S.D.	1.67	8.96												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 19

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-023

GROUP: 50 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37
38694-06	28	91.5	N	N	Y									
38695-10	28	90.1	N	N	Y									
38696-07	28	75.7	N	N	Y									
38696-09	28	73.3	N	N	Y									
38694-05	30	100.6	N	N	N	N	Y							
38695-05	28	91.7	N	N	Y									
38697-02	28	74.4	N	N	Y									
38698-09	29	94.1	N	N	N	Y								
38699-01	28	89.1	N	N	Y									
38699-10	29	96.5	N	N	N	Y								
38698-01	28	93.5	N	N	Y									
38697-09	28	79.3	N	N	Y									
38703-04	28	83.5	N	N	Y									
38700-01	27	71.3	N	Y										
38701-06	29	75.7	N	N	N	Y								
MEAN	28.3	85.4												
S.D.	0.70	9.65												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

187060 RAD

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Modified: 5/4/2007

TABLE 19

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-023

GROUP: 200 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37
38696-02	29	90.5	N	N	N	Y								
38695-06	28	79.7	N	N	Y									
38694-08	29	84.7	N	N	N	Y								
38696-05	31	80.5	N	N	N	N	N	Y						
38695-09	29	77.0	N	N	N	Y								
38694-03	31	114.5	N	N	N	N	N	Y						
38697-06	27	75.2	N	Y										
38699-05	27	78.5	N	Y										
38698-10	30	98.2	N	N	N	N	Y							
38699-04	27	89.7	N	Y										
38698-02	27	86.4	N	Y										
38697-01	28	81.7	N	N	Y									
38703-05	27	79.4	N	Y										
38702-02	26	65.5	Y											
38701-10	27	68.8	N	Y										
MEAN	28.2	83.4												
S.D.	1.57	11.93												
N	15	15												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY

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TABLE 19

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-023

GROUP: 800 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 26	27	28	29	30	31	32	33	34	35	36	37
38695-08	35	103.8	N	N	N	N	N	N	N	N	N	Y		
38694-09	A	A												
38696-03	A	A												
38696-10	30	72.7	N	N	N	N	Y							
38694-01	29	78.4	N	N	N	Y								
38695-03	29	80.7	N	N	N	Y								
38697-10	28	68.7	N	N	Y									
38698-08	B	B												
38699-09	27	81.7	N	Y										
38698-03	C	C												
38699-03	A	A												
38697-08	B	B												
38703-07	26	44.3	Y											
38701-01	B	B												
38700-07	27	61.2	N	Y										
MEAN	28.9	73.9												
S.D.	2.80	17.27												
N	8	8												

N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
PND= POSTNATAL DAY
A = RESPONSE NOT EXHIBITED BY DAY 25, THE DAY OF OR DAY PRIOR TO DEATH
B = RESPONSE NOT EXHIBITED BY DAY 24, THE DAY PRIOR TO DEATH
C = RESPONSE NOT EXHIBITED BY DAY 23, THE DAY OF DEATH

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TABLE 20

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-023

FEMALES FROM GROUP 1: 0 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF ESTRUS	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38694-07	28	E D D D D D D D D D D D D E	28	A
38696-08	32	E D D D P E D D D D E	32	5.0
38695-01	33	E D D D D E D D D P	33	5.0
38695-07	34	E D D D P E M D D	34	5.0
38694-04	34	D D D P E D D D E	38	A
38696-04	34	D D D P E D D D E	38	A
38697-07	34	D D P E D D D D D	37	A
38698-04	30	E D D D P E M D D D D D E	30	5.0
38699-07	30	P E D D D D D D D D D D P	31	A
38698-05	34	D D P E D D D P E	37	A
38699-02	33	D D E D D D E D D P	35	4.0
38697-03	33	D D D D D D D D D D	NA	A
38703-06	33	D D D D D D D D D D	NA	A
38700-06	33	D D D P E D D D E E	37	A
38702-05	33	D D D P E D D D P E	37	A
	MEAN		34.4	4.8
	S.D.		33.3	0.45
	N		13	5

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
DET = DETERMINATION
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
NA = NOT APPLICABLE, NO OCCURRENCE OF E

Revised Audited Draft

Modified: 5/4/2007

TABLE 20

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-023

FEMALES FROM GROUP 2: 10 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38695-02	30	P D D D D D D D D D D D	NA	A
38694-10	32	E D D D D D E D D D E	32	6.0
38696-06	34	D D D P E D D D E	38	A
38696-01	34	E D D D P E D D D	34	5.0
38695-04	35	D D D E D D D D	38	A
38694-02	32	D D D D D P E D D D E	38	A
38698-07	34	E D D D P E D D D	34	5.0
38697-04	31	D E D D D P E D D D E E	32	5.0
38699-08	33	E D D D D E D D D P	33	5.0
38699-06	34	D D D E D D D E D	37	4.0
38698-06	34	D D P E D D D E D	37	4.0
38697-05	33	E D D D D D D D D D	33	A
38702-09	33	D D D P E D D D E E	37	A
38703-01	33	E D D D P E D D D D	33	5.0
38701-03	37	D D D D P E	42	A
		MEAN	35.6	4.9
		S.D.	2.98	0.64
		N	14	8

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
DET = DETERMINATION
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
NA = NOT APPLICABLE, NO OCCURRENCE OF E

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TABLE 20

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-023

FEMALES FROM GROUP 3: 50 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DET DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38694-06	28	D D D E D D D D D P E D D D E	31	7.0
38695-10	28	D D D E E D D D D D E D D D D	31	6.0
38696-07	28	D D D E E D D D P E D D D P E	31	5.0
38696-09	28	D D D D D D D D D D E D D D P	38	A
38694-05	30	D D P E D D D E D D D E D	33	4.0
38695-05	28	D D D D D P E D D D D E D D D	34	5.0
38697-02	28	D D D D P E D D D D E E D D D	33	6.0
38698-09	29	D D E D D D D E E D D D D E	31	6.0
38699-01	28	E D D E E D D D D E D D D D E	28	4.5
38699-10	29	D D E E D D D D E D D D P E	31	5.0
38698-01	28	D D D D P E D D D P E D D D E	33	5.0
38697-09	28	D D D D D D D D E E D D D P E	35	A
38703-04	28	D D D E E D D P E D D D P E D	31	4.5
38700-01	27	E E E E E E D D D D E D D D E E	27	5.0
38701-06	29	D D D D D P E D D D D E D D	35	5.0
		MEAN	32.1	5.2
		S.D.	2.77	0.81
		N	15	13

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
DET = DETERMINATION
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

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TABLE 20

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-023

FEMALES FROM GROUP 4: 200 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38696-02	29	E E D E E D D D D D E D D D	29	4.5
38695-06	28	D D D E E E E E E E E E E E	31	A
38694-08	29	D D D D E E E E E E E E E E	33	A
38696-05	31	D D D D E E E E D D D E	35	A
38695-09	29	D D D D D D D E E E D D D D	36	A
38694-03	31	D E E E D E E E D D D D	32	4.0
38697-06	27	E D D D D D E D D D D D E E E D	27	7.0
38699-05	27	E E D E E E E E I E E D D D D E	27	8.0
38698-10	30	D D D D E D E D E E E E E	34	2.0
38699-04	27	D E D D D D E E D E E E E E E E	28	6.0
38698-02	27	D D D E E E E E E D D E E E E E	30	A
38697-01	28	D D E D D D E E E E E E E E E	30	A
38703-05	27	E D D D D E E E E E E E E E E E	27	A
38702-02	26	D D D D D D D E D E D E D D D D D	33	2.0
38701-10	27	D D D D D D D D D E D D D D D D	36	A
		MEAN	31.2	4.8
		S.D.	3.23	2.34
		N	15	7

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
DET = DETERMINATION
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
I = INSUFFICIENT CELLS PRESENT

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TABLE 20

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-023

FEMALES FROM GROUP 5: 800 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38695-08	35	E E D E E E E	35	A
38694-09	B		B	B
38696-03	B		B	B
38696-10	30	E E E E E E E E E E E	30	A
38694-01	29	D D D D D D D D D D D D	NA	A
38695-03	29	E E E E E E E D E D D D D	29	2.0
38697-10	28	E E E E E E E E E E E E E	28	A
38698-08	B		B	B
38699-09	27	E E E D D E E E E E E E E E	27	A
38698-03	B		B	B
38699-03	B		B	B
38697-08	B		B	B
38703-07	26	E	26	B
38701-01	B		B	B
38700-07	27	E E E E E E E E E E E E E E	27	A
		MEAN	28.9	2.0
		S.D.	3.02	0.00
		N	7	1

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
DET = DETERMINATION
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
B = DIED PRIOR TO ATTAINMENT OF VAGINAL PATENCY
NA = NOT APPLICABLE, NO OCCURRENCE OF E

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TABLE 21

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-023

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 0 MG/KG/DAY FEMALES				
38694-07	6.20	105.00	5.20	0.4
38696-08	6.40	75.70	9.00	1.0
38695-01	7.10	145.00	15.20	1.3
38695-07	6.10	124.00	8.60	1.9
38694-04	8.00	138.00	10.30	25.9
38696-04	7.70	94.50	7.30	1.6
38697-07	4.80	105.00	7.60	0.8
38698-04	7.60	53.30	6.90	2.1
38699-07	8.00	87.60	12.60	2.0
38698-05	6.10	78.90	7.00	2.3
38699-02	6.60	99.50	5.00	1.1
38697-03	6.70	96.30	6.00	1.3
38703-06	6.00	102.00	10.00	1.6
38700-06	6.60	117.00	6.80	0.9
38702-05	5.80	105.00	4.90	1.7
MEAN	6.65	101.79	8.16	3.1
S.D.	0.898	23.573	2.903	6.34
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-023

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 10 MG/KG/DAY FEMALES				
38695-02	5.80	136.00	5.30	1.1
38694-10	7.80	143.00	5.80	0.8
38696-06	5.90	140.00	8.50	1.8
38696-01	5.70	150.00	11.90	3.5
38695-04	7.10	109.00	8.30	2.4
38694-02	7.60	94.10	7.80	1.3
38698-07	5.50	96.00	5.70	1.8
38697-04	6.70	98.50	4.70	1.4
38699-08	5.40	110.00	7.30	1.7
38699-06	4.70	75.80	6.70	2.8
38698-06	8.40	87.20	7.40	1.3
38697-05	6.70	137.00	8.70	1.3
38702-09	5.90	102.00	6.90	1.8
38703-01	7.00	113.00	10.10	2.0
38701-03	6.90	77.70	5.80	1.4
MEAN	6.47	111.29	7.39	1.8
S.D.	1.023	24.432	1.925	0.70
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-023

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 50 MG/KG/DAY FEMALES				
38694-06	7.30	101.00	5.10	1.0
38695-10	5.40	158.00	9.40	1.0
38696-07	5.50	117.00	12.90	1.6
38696-09	7.70	143.00	8.50	2.0
38694-05	7.30	93.80	4.90	1.7
38695-05	7.60	92.20	5.10	2.6
38697-02	4.90	133.00	8.50	1.8
38698-09	6.50	112.00	9.40	2.9
38699-01	6.70	97.00	6.40	2.1
38699-10	7.20	78.50	6.00	1.1
38698-01	6.70	82.70	5.50	1.7
38697-09	7.40	117.00	8.20	1.2
38703-04	4.70	91.00	8.00	0.8
38700-01	6.80	115.00	7.90	2.5
38701-06	6.60	62.10	4.70	1.5
MEAN	6.55	106.22	7.37	1.7
S.D.	0.978	25.435	2.277	0.63
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-023

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 200 MG/KG/DAY FEMALES				
38696-02	5.60	105.00	4.50	0.8
38695-06	4.40	105.00	8.40	1.8
38694-08	6.80	93.10	9.80	0.9
38696-05	7.00	99.90	6.90	2.6
38695-09	7.90	67.90	5.90	1.4
38694-03	8.40	104.00	5.60	1.8
38697-06	5.40	118.00	8.80	2.6
38699-05	7.00	77.50	14.30	2.0
38698-10	7.00	104.00	10.90	1.7
38699-04	7.30	98.50	9.20	1.7
38698-02	7.90	74.50	11.20	1.8
38697-01	6.20	88.10	11.50	1.5
38703-05	4.40	0.00	10.20	2.0
38702-02	5.80	46.50	9.70	1.3
38701-10	7.00	60.80	9.10	2.0
MEAN	6.54	82.85	9.07	1.7
S.D.	1.215	30.205	2.558	0.51
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-023

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 800 MG/KG/DAY FEMALES				
38695-08	4.30	124.00	7.30	1.4
38696-10	5.40	159.00	8.50	0.8
38694-01	5.70	89.80	8.90	0.9
38695-03	7.30	149.00	13.80	0.9
38697-10	4.30	118.00	16.20	RU
38699-09	5.90	133.00	14.50	1.4
38700-07	5.50	107.00	7.60	0.4
MEAN	5.49	125.69	10.97	1.0
S.D.	1.027	23.825	3.720	0.38
N	7	7	7	6

RU = RESULT UNOBTAINABLE

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted]

SPONSOR NO.:06-023

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38694-09 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

		GRADE
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	4
	NECROSIS, GRANULOSA CELL, BILATERAL	4
UTERUS	MICRO: ATROPHY	2
	DILATATION, LUMEN	2
PARATHYROID	MICRO: NOT EXAMINED	
	NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
CAUSE OF DEATH	MICRO: UNKNOWN	
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, BRAIN, LYMPH NODE, AXI, ESOPHAGUS	P
	EYES, HEART, INTESTINE, KIDNEYS	
	LIVER, LYMPH NODE, MES, LUNGS, MAMMARY GLAND	
	OVIDUCTS, OVARIES, PANCREAS, PITUITARY	
	SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN	
	STOMACH, THYMUS, THYROID GLANDS, TRACHEA	
	URINARY BLADDER, UTERUS, CERVIX, VAGINA	
	MICRO: THYROID GLANDS, CERVIX	
NOT EXAMINED	MICRO: PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38696-03 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/29/06 DATE OF DEATH: 09/29/06

		GRADE
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	4
	NECROSIS, GRANULOSA CELL, BILATERAL	4
THYMUS	MICRO: NECROSIS	(2)
	PRESENT IN THE SAME SECTION WITH THYROID GLAND	
UTERUS	MICRO: ATROPHY	2
	DILATATION, LUMEN	3
CERVIX	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	WITH MILD UTERINE BODY ATROPHY	
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
CAUSE OF DEATH	MICRO: UNKNOWN	
NO SIGNIFICANT CHANGES OBSERVED		P

GROSS:	ADRENAL GLANDS	BRAIN	LYMPH NODE, AXI	ESOPHAGUS
	EYES	HEART	INTESTINE	KIDNEYS
	LIVER	LYMPH NODE, MES	LUNGS	MAMMARY GLAND
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	SPINAL CORD	SAL. GLAND MAND	SKIN	SPLEEN
	STOMACH	THYMUS	THYROID GLANDS	TRACHEA
	URINARY BLADDER	UTERUS	CERVIX	VAGINA
MICRO:	THYROID GLANDS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT
( )-FOCAL, (( ))-MULTIFOCAL, NO PARENTHESES-DIFFUSE

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-08 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

			GRADE
GENERAL COMMENT	GROSS:	CANNIBALIZED VENTRAL ABDOMINAL; LIVER, ALL LOBES	P
OVARIES	MICRO:	DEGENERATION, OOCYTE, BILATERAL	4
		CORPORA LUTEA ABSENT, BILATERAL	4
		NECROSIS, GRANULOSA CELL, BILATERAL	4
THYROID GLANDS	MICRO:	HYPERTROPHY, FOLLICULAR CELL	2
UTERUS	MICRO:	ATROPHY	4
		DILATATION, LUMEN	2
CERVIX	MICRO:	NO SIGNIFICANT CHANGES OBSERVED WITH MILD UTERINE BODY ATROPHY	
PARATHYROID	MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
CAUSE OF DEATH	MICRO:	UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED			

GROSS:	ADRENAL GLANDS	BRAIN	LYMPH NODE, AXI	ESOPHAGUS
	EYES	HEART	INTESTINE	KIDNEYS
	LIVER	LYMPH NODE, MES	LUNGS	MAMMARY GLAND
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	SPINAL CORD	SAL. GLAND MAND	SKIN	SPLEEN
	STOMACH	THYMUS	THYROID GLANDS	TRACHEA
	URINARY BLADDER	UTERUS	CERVIX	VAGINA
MICRO:	CERVIX	PARATHYROID		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-03 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/28/06 DATE OF DEATH: 09/28/06

			GRADE
	OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
		DEGENERATION, OOCYTE, BILATERAL	3
		NECROSIS, GRANULOSA CELL, BILATERAL	3
	UTERUS	MICRO: ATROPHY	2
	CERVIX	MICRO: EDEMA, SUBMUCOSAL	2
	PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
	CAUSE OF DEATH	MICRO: UNKNOWN	P
	NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, BRAIN, LYMPH NODE, AXI, ESOPHAGUS; EYES, HEART, INTESTINE, KIDNEYS; LIVER, LYMPH NODE, MES, LUNGS, MAMMARY GLAND; OVIDUCTS, OVARIES, PANCREAS, PITUITARY; SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN; STOMACH, THYMUS, THYROID GLANDS, TRACHEA; URINARY BLADDER, UTERUS, CERVIX, VAGINA	
		MICRO: THYROID GLANDS, PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38699-03 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/01/06 DATE OF DEATH: 10/01/06

			GRADE
OVARIES	MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
		DEGENERATION, OOCYTE, BILATERAL	3
		NECROSIS, GRANULOSA CELL, BILATERAL	3
THYROID GLANDS	MICRO:	HYPERTROPHY, FOLLICULAR CELL	2
		CYST, ULTIMOBRANCHIAL, BILATERAL	P
UTERUS	GROSS:	CONTENTS, CLEAR FLUID	P
		BOTH HORNS	
UTERUS	MICRO:	ATROPHY	4
		DILATATION, LUMEN	3
		CORRELATES TO GROSS OBSERVATION(S)	
CERVIX	MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
		WITH MILD UTERINE BODY ATROPHY	
PARATHYROID	MICRO:	FIBROSIS, BILATERAL	1
CAUSE OF DEATH	MICRO:	UNKNOWN	P

NO SIGNIFICANT CHANGES OBSERVED

GROSS:	ADRENAL GLANDS	BRAIN	LYMPH NODE, AXI	ESOPHAGUS
	EYES	HEART	INTESTINE	KIDNEYS
	LIVER	LYMPH NODE, MES	LUNGS	MAMMARY GLAND
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	SPINAL CORD	SAL. GLAND MAND	SKIN	SPLEEN
	STOMACH	THYMUS	THYROID GLANDS	TRACHEA
	URINARY BLADDER	CERVIX	VAGINA	
MICRO:	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38697-08 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

			GRADE
OVARIES	MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
		DEGENERATION, OOCYTE, BILATERAL	3
		NECROSIS, GRANULOSA CELL, BILATERAL	4
THYROID GLANDS	MICRO:	NOT EXAMINED NOT PRESENT AT TRIMMING	
UTERUS	MICRO:	NOT EXAMINED NOT PRESENT AT TRIMMING	
CERVIX	MICRO:	NOT EXAMINED NOT PRESENT AT TRIMMING	
PARATHYROID	MICRO:	NOT EXAMINED NOT PRESENT AT TRIMMING	
CAUSE OF DEATH	MICRO:	UNKNOWN	P

NO SIGNIFICANT CHANGES OBSERVED

GROSS:	ADRENAL GLANDS	BRAIN	LYMPH NODE, AXI	ESOPHAGUS
	EYES	HEART	INTESTINE	KIDNEYS
	LIVER	LYMPH NODE, MES	LUNGS	MAMMARY GLAND
	OVIDUCTS	OVARIES	PANCREAS	PITUITARY
	SPINAL CORD	SAL. GLAND MAND	SKIN	SPLEEN
	STOMACH	THYMUS	THYROID GLANDS	TRACHEA
	URINARY BLADDER	UTERUS	CERVIX	VAGINA

NOT EXAMINED

MICRO:	THYROID GLANDS	UTERUS	CERVIX	PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38703-07 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/02/06 DATE OF DEATH: 10/02/06

			GRADE
LUNGS	GROSS:	DISCOLORATION, DARK RED ALL LOBES	P
OVARIES	MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
		DEGENERATION, OOCYTE, BILATERAL	3
		NECROSIS, GRANULOSA CELL, BILATERAL	3
THYROID GLANDS	MICRO:	CYST, ULTIMOBRANCHIAL, BILATERAL	P
UTERUS	MICRO:	ATROPHY	2
PARATHYROID	MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
CAUSE OF DEATH	MICRO:	UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS, BRAIN, LYMPH NODE, AXI, ESOPHAGUS EYES, HEART, INTESTINE, KIDNEYS LIVER, LYMPH NODE, MES, MAMMARY GLAND, OVIDUCTS OVARIES, PANCREAS, PITUITARY, SPINAL CORD SAL. GLAND MAND, SKIN, SPLEEN, STOMACH THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER UTERUS, CERVIX, VAGINA	
	MICRO:	CERVIX, PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

ANIMAL NO.38701-01 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/01/06 DATE OF DEATH: 10/01/06

			GRADE
	OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
		DEGENERATION, OOCYTE, BILATERAL	4
		NECROSIS, GRANULOSA CELL, BILATERAL	4
	THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	2
	UTERUS	MICRO: DILATATION, LUMEN	3
		ATROPHY	4
	CERVIX	MICRO: NO SIGNIFICANT CHANGES OBSERVED WITH MILD UTERINE BODY ATROPHY	
	PARATHYROID	MICRO: NOT EXAMINED NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
	CAUSE OF DEATH	MICRO: UNKNOWN	P
	NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, BRAIN, LYMPH NODE, AXI, ESOPHAGUS; EYES, HEART, INTESTINE, KIDNEYS; LIVER, LYMPH NODE, MES, LUNGS, MAMMARY GLAND; OVIDUCTS, OVARIES, PANCREAS, PITUITARY; SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN; STOMACH, THYMUS, THYROID GLANDS, TRACHEA; URINARY BLADDER, UTERUS, CERVIX, VAGINA	
		MICRO: CERVIX	
	NOT EXAMINED	MICRO: PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.55
05/03/2007

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38694-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4096	0.223
UTERUS- BLOTTED	0.3827	0.208
LIVER	10.3255	5.612
KIDNEYS	1.9066	1.036
SPLEEN	0.5160	0.280
THYMUS	0.5059	0.275
OVARIES/OVIDUCTS	0.1108	0.060
ADRENAL GLANDS	0.0462	0.025
PITUITARY	0.0107	0.006
THYROIDS/PARA	0.0166	0.009
FINAL BODY WT(G)	184.	

THYROID GLANDS NO SIGNIFICANT CHANGES OBSERVED

UTERUS NO SIGNIFICANT CHANGES OBSERVED

PARATHYROID NO SIGNIFICANT CHANGES OBSERVED

				GRADE
MICRO: CYST, ULTIMOBRANCHIAL				P
MICRO: INFLAMMATION, SUBACUTE				1
MICRO: NO SIGNIFICANT CHANGES OBSERVED				
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED				
GROSS:ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				
MICRO:OVARIES	CERVIX	PARATHYROID		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38696-08 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3765	0.228	
UTERUS- BLOTTED	0.3497	0.212	
LIVER	9.5224	5.771	
KIDNEYS	1.9762	1.198	
SPLEEN	0.4364	0.264	
THYMUS	0.6582	0.399	
OVARIES/OVIDUCTS	0.1194	0.072	
ADRENAL GLANDS	0.0494	0.030	
PITUITARY	0.0101	0.006	
THYROIDS/PARA	0.0183	0.011	
FINAL BODY WT(G)	165.		

PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED
NOT EXAMINED

MICRO: NOT EXAMINED
NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

MICRO: OVARIES, THYROID GLANDS, UTERUS, CERVIX

MICRO: PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38695-01 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6982	0.445
UTERUS- BLOTTED	0.4641	0.296
LIVER	7.2835	4.639
KIDNEYS	1.6109	1.026
SPLEEN	0.5048	0.322
THYMUS	0.6153	0.392
OVARIES/OVIDUCTS	0.0772	0.049
ADRENAL GLANDS	0.0411	0.026
PITUITARY	0.0087	0.006
THYROIDS/PARA	0.0187	0.012
FINAL BODY WT(G)	157.	

THYROID GLANDS
PARATHYROID
NO SIGNIFICANT
CHANGES OBSERVED

MICRO: CYST, ULTIMOBRANCHIAL				GRADE P
MICRO: NO SIGNIFICANT CHANGES OBSERVED				
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED				
GROSS:ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				
MICRO:OVARIES	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38695-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4985	0.310
UTERUS- BLOTTED	0.4342	0.270
LIVER	8.0222	4.983
KIDNEYS	1.5607	0.969
SPLEEN	0.4641	0.288
THYMUS	0.5436	0.338
OVARIES/OVIDUCTS	0.0799	0.050
ADRENAL GLANDS	0.0382	0.024
PITUITARY	0.0079	0.005
THYROIDS/PARA	0.0222	0.014
FINAL BODY WT(G)	161.	

PARATHYROID

NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

	GRADE			
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38694-04 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.7364	0.526
UTERUS- BLOTTED	0.3101	0.221
LIVER	6.3273	4.520
KIDNEYS	1.4132	1.009
SPLEEN	0.3951	0.282
THYMUS	0.5660	0.404
OVARIES/OVIDUCTS	0.0720	0.051
ADRENAL GLANDS	0.0417	0.030
PITUITARY	0.0087	0.006
THYROIDS/PARA	0.0164	0.012
FINAL BODY WT(G)	140.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE				
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38696-04 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2853	0.200	
UTERUS- BLOTTED	0.2699	0.189	
LIVER	6.4839	4.534	
KIDNEYS	1.3973	0.977	
SPLEEN	0.3812	0.267	
THYMUS	0.5184	0.363	
OVARIES/OVIDUCTS	0.0812	0.057	
ADRENAL GLANDS	0.0313	0.022	
PITUITARY	0.0097	0.007	
THYROIDS/PARA	0.0281	0.020	
FINAL BODY WT(G)	143.		

PARATHYROID
NO SIGNIFICANT
CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38697-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2601	0.173		GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
UTERUS- BLOTTED	0.2388	0.159			OVIDUCTS	OVARIES	PITUITARY	SPLEEN
LIVER	8.2656	5.510			THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.5263	1.018			VAGINA			
SPLEEN	0.5124	0.342		MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
THYMUS	0.6001	0.400			PARATHYROID			
OVARIES/OVIDUCTS	0.0824	0.055						
ADRENAL GLANDS	0.0317	0.021						
PITUITARY	0.0077	0.005						
THYROIDS/PARA	0.0112	0.007						
FINAL BODY WT(G)	150.							

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38698-04 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3536	0.246
UTERUS- BLOTTED	0.3328	0.231
LIVER	6.9727	4.842
KIDNEYS	1.5737	1.093
SPLEEN	0.4764	0.331
THYMUS	0.6105	0.424
OVARIES/OVIDUCTS	0.1148	0.080
ADRENAL GLANDS	0.0492	0.034
PITUITARY	0.0107	0.007
THYROIDS/PARA	0.0134	0.009
FINAL BODY WT(G)	144.	

PARATHYROID: NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GRADE				
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38699-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4452	0.246
UTERUS- BLOTTED	0.4138	0.229
LIVER	9.5810	5.293
KIDNEYS	1.8506	1.022
SPLEEN	0.4591	0.254
THYMUS	0.6633	0.366
OVARIES/OVIDUCTS	0.1160	0.064
ADRENAL GLANDS	0.0512	0.028
PITUITARY	0.0116	0.006
THYROIDS/PARA	0.0146	0.008
FINAL BODY WT(G)	181.	

PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GRADE			
GROSS: ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
OVIDUCTS	OVARIES	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA			
MICRO: OVARIES	THYROID GLANDS	UTERUS	CERVIX
PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-05 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2768	0.180		GROSS: ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
UTERUS- BLOTTED	0.2571	0.167		OVIDUCTS	OVARIES	PITUITARY	SPLEEN
LIVER	7.1187	4.623		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.6701	1.084		VAGINA			
SPLEEN	0.4346	0.282		MICRO: OVARIES	THYROID GLANDS	UTERUS	CERVIX
THYMUS	0.6528	0.424		PARATHYROID			
OVARIES/OVIDUCTS	0.0976	0.063					
ADRENAL GLANDS	0.0418	0.027					
PITUITARY	0.0113	0.007					
THYROIDS/PARA	0.0135	0.009					
FINAL BODY WT(G)	154.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38699-02 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6801	0.463
UTERUS- BLOTTED	0.4095	0.279
LIVER	7.1187	4.843
KIDNEYS	1.3740	0.935
SPLEEN	0.3868	0.263
THYMUS	0.5356	0.364
OVARIES/OVIDUCTS	0.0847	0.058
ADRENAL GLANDS	0.0331	0.023
PITUITARY	0.0077	0.005
THYROIDS/PARA	0.0121	0.008
FINAL BODY WT(G)	147.	

PARATHYROID

NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

				GRADE
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38697-03 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2826	0.154
UTERUS- BLOTTED	0.2618	0.142
LIVER	9.2621	5.034
KIDNEYS	1.7678	0.961
SPLEEN	0.5384	0.293
THYMUS	0.6155	0.335
OVARIES/OVIDUCTS	0.0721	0.039
ADRENAL GLANDS	0.0323	0.018
PITUITARY	0.0095	0.005
THYROIDS/PARA	0.0105	0.006
FINAL BODY WT(G)	184.	

THYROID GLANDS
PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED

MICRO: CYST, ULTIMOBRANCHIAL P
MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GRADE

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	UTERUS	CERVIX	PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38703-06 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2869	0.151		GROSS: ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
UTERUS- BLOTTED	0.2673	0.141		OVIDUCTS	OVARIES	PITUITARY	SPLEEN
LIVER	10.7276	5.646		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	2.0827	1.096		VAGINA			
SPLEEN	0.6022	0.317		MICRO: OVARIES	THYROID GLANDS	UTERUS	CERVIX
THYMUS	0.6689	0.352		PARATHYROID			
OVARIES/OVIDUCTS	0.0720	0.038					
ADRENAL GLANDS	0.0388	0.020					
PITUITARY	0.0087	0.005					
THYROIDS/PARA	0.0100	0.005					
FINAL BODY WT(G)	190.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38700-06 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4172	0.248
UTERUS- BLOTTED	0.3887	0.231
LIVER	9.3264	5.551
KIDNEYS	1.8054	1.075
SPLEEN	0.4890	0.291
THYMUS	0.6015	0.358
OVARIES/OVIDUCTS	0.1275	0.076
ADRENAL GLANDS	0.0343	0.020
PITUITARY	0.0118	0.007
THYROIDS/PARA	0.0136	0.008
FINAL BODY WT(G)	168.	

THYROID GLANDS PARATHYROID NO SIGNIFICANT CHANGES OBSERVED

GRADE

MICRO: CYST, ULTIMOBRANCHIAL P

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	OVARIES	UTERUS	CERVIX	PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38702-05 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2943	0.213	
UTERUS- BLOTTED	0.2766	0.200	
LIVER	7.3925	5.357	
KIDNEYS	1.4462	1.048	
SPLEEN	0.4249	0.308	
THYMUS	0.5665	0.411	
OVARIES/OVIDUCTS	0.0963	0.070	
ADRENAL GLANDS	0.0331	0.024	
PITUITARY	0.0100	0.007	
THYROIDS/PARA	0.0130	0.009	
FINAL BODY WT(G)	138.		

PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED
NOT EXAMINED

MICRO: NOT EXAMINED
BOTH NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

MICRO: OVARIES, THYROID GLANDS, UTERUS, CERVIX

MICRO: PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38695-02 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3383	0.178
UTERUS- BLOTTED	0.3153	0.166
LIVER	10.8304	5.700
KIDNEYS	1.9764	1.040
SPLEEN	0.5640	0.297
THYMUS	0.7215	0.380
OVARIES/OVIDUCTS	0.0727	0.038
ADRENAL GLANDS	0.0405	0.021
PITUITARY	0.0103	0.005
THYROIDS/PARA	0.0164	0.009
FINAL BODY WT(G)	190.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38694-10 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3852	0.232
UTERUS- BLOTTED	0.3654	0.220
LIVER	8.1668	4.920
KIDNEYS	1.7171	1.034
SPLEEN	0.4648	0.280
THYMUS	0.5173	0.312
OVARIES/OVIDUCTS	0.1127	0.068
ADRENAL GLANDS	0.0443	0.027
PITUITARY	0.0093	0.006
THYROIDS/PARA	0.0181	0.011
FINAL BODY WT(G)	166.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38696-06 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2916	0.218	
UTERUS- BLOTTED	0.2781	0.208	
LIVER	6.3626	4.748	
KIDNEYS	1.4305	1.068	
SPLEEN	0.3602	0.269	
THYMUS	0.5807	0.433	
OVARIES/OVIDUCTS	0.0896	0.067	
ADRENAL GLANDS	0.0547	0.041	
PITUITARY	0.0101	0.008	
THYROIDS/PARA	0.0195	0.015	
FINAL BODY WT(G)	134.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38696-01 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GENERAL COMMENT	GROSS: ORGAN DAMAGED AT NECROPSY				GRADE
UTERUS- WET	0.3452	0.247		PITUITARY				P
UTERUS- BLOTTED	0.2853	0.204	NO SIGNIFICANT					
LIVER	6.1267	4.376	CHANGES OBSERVED	GROSS:ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
KIDNEYS	1.2858	0.918		OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
SPLEEN	0.3382	0.242		THYMUS	THYROID GLANDS	UTERUS	CERVIX	
THYMUS	0.5096	0.364		VAGINA				
OVARIES/OVIDUCTS	0.0620	0.044						
ADRENAL GLANDS	0.0391	0.028						
PITUITARY	0.0046	0.003						
THYROIDS/PARA	0.0151	0.011						
FINAL BODY WT(G)	140.							

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38695-04 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3425	0.233
UTERUS- BLOTTED	0.3185	0.217
LIVER	6.6158	4.501
KIDNEYS	1.5631	1.063
SPLEEN	0.3961	0.269
THYMUS	0.5375	0.366
OVARIES/OVIDUCTS	0.0793	0.054
ADRENAL GLANDS	0.0428	0.029
PITUITARY	0.0080	0.005
THYROIDS/PARA	0.0145	0.010
FINAL BODY WT(G)	147.	

					GRADE
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
		OVIDUCTS	OVARIES	PITUITARY	SPLEEN
		THYMUS	THYROID GLANDS	UTERUS	CERVIX
		VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38694-02 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.6892	0.387	
UTERUS- BLOTTED	0.4019	0.226	
LIVER	8.3109	4.669	
KIDNEYS	2.0671	1.161	
SPLEEN	0.5115	0.287	
THYMUS	0.6372	0.358	
OVARIES/OVIDUCTS	0.1156	0.065	
ADRENAL GLANDS	0.0541	0.030	
PITUITARY	0.0121	0.007	
THYROIDS/PARA	0.0159	0.009	
FINAL BODY WT(G)	178.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38698-07 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4509	0.252	
UTERUS- BLOTTED	0.3849	0.215	
LIVER	9.3328	5.214	
KIDNEYS	1.6915	0.945	
SPLEEN	0.5595	0.313	
THYMUS	0.5506	0.308	
OVARIES/OVIDUCTS	0.0887	0.050	
ADRENAL GLANDS	0.0444	0.025	
PITUITARY	0.0113	0.006	
THYROIDS/PARA	0.0110	0.006	
FINAL BODY WT(G)	179.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38697-04 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3336	0.212
UTERUS- BLOTTED	0.3192	0.203
LIVER	7.6283	4.859
KIDNEYS	1.4744	0.939
SPLEEN	0.5211	0.332
THYMUS	0.7066	0.450
OVARIES/OVIDUCTS	0.0976	0.062
ADRENAL GLANDS	0.0455	0.029
PITUITARY	0.0113	0.007
THYROIDS/PARA	0.0130	0.008
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38699-08 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5190	0.320	NO SIGNIFICANT CHANGES OBSERVED
UTERUS- BLOTTED	0.4415	0.273	
LIVER	7.5913	4.686	
KIDNEYS	1.6927	1.045	
SPLEEN	0.4415	0.273	
THYMUS	0.6495	0.401	
OVARIES/OVIDUCTS	0.0700	0.043	
ADRENAL GLANDS	0.0426	0.026	
PITUITARY	0.0105	0.006	
THYROIDS/PARA	0.0135	0.008	
FINAL BODY WT(G)	162.		

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38699-06 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2740	0.167	GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
UTERUS- BLOTTED	0.2560	0.156		OVIDUCTS	OVARIES	PITUITARY	SPLEEN
LIVER	7.8568	4.791		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.6059	0.979		VAGINA			
SPLEEN	0.4522	0.276					
THYMUS	0.4649	0.283					
OVARIES/OVIDUCTS	0.0844	0.051					
ADRENAL GLANDS	0.0418	0.025					
PITUITARY	0.0096	0.006					
THYROIDS/PARA	0.0128	0.008					
FINAL BODY WT(G)	164.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38698-06 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2937	0.187		
UTERUS- BLOTTED	0.2787	0.178		
LIVER	7.6285	4.859		
KIDNEYS	1.8106	1.153		
SPLEEN	0.4991	0.318		
THYMUS	0.4544	0.289		
OVARIES/OVIDUCTS	0.0907	0.058		
ADRENAL GLANDS	0.0396	0.025		
PITUITARY	0.0092	0.006		
THYROIDS/PARA	0.0120	0.008		
FINAL BODY WT(G)	157.			

GRADE

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187060 RAD

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38697-05 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3447	0.183	NO SIGNIFICANT CHANGES OBSERVED
UTERUS- BLOTTED	0.3183	0.169	
LIVER	9.7000	5.160	
KIDNEYS	1.7381	0.925	
SPLEEN	0.6028	0.321	
THYMUS	0.7137	0.380	
OVARIES/OVIDUCTS	0.0790	0.042	
ADRENAL GLANDS	0.0386	0.021	
PITUITARY	0.0111	0.006	
THYROIDS/PARA	0.0116	0.006	
FINAL BODY WT(G)	188.		

GRADE			
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187060 RAD

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS PAGE 28

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38702-09 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3584	0.225		
UTERUS- BLOTTED	0.3398	0.214		
LIVER	8.2519	5.190		
KIDNEYS	1.6479	1.036		
SPLEEN	0.3917	0.246		
THYMUS	0.5662	0.356		
OVARIES/OVIDUCTS	0.0958	0.060		
ADRENAL GLANDS	0.0469	0.029		
PITUITARY	0.0106	0.007		
THYROIDS/PARA	0.0153	0.010		
FINAL BODY WT(G)	159.			

GRADE				
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

ANIMAL NO.38703-01 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

GRADE

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3988	0.279
UTERUS- BLOTTED	0.3556	0.249
LIVER	6.9814	4.882
KIDNEYS	1.4162	0.990
SPLEEN	0.3810	0.266
THYMUS	0.6232	0.436
OVARIES/OVIDUCTS	0.0653	0.046
ADRENAL GLANDS	0.0356	0.025
PITUITARY	0.0075	0.005
THYROIDS/PARA	0.0112	0.008
FINAL BODY WT(G)	143.	

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, LYMPH NODE, AXI, OVARIES, OVIDUCTS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38701-03 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2742	0.180	GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
UTERUS- BLOTTED	0.2575	0.169		OVIDUCTS	OVARIES	PITUITARY	SPLEEN
LIVER	6.8720	4.521		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.6474	1.084		VAGINA			
SPLEEN	0.4808	0.316					
THYMUS	0.5673	0.373					
OVARIES/OVIDUCTS	0.0787	0.052					
ADRENAL GLANDS	0.0457	0.030					
PITUITARY	0.0089	0.006					
THYROIDS/PARA	0.0131	0.009					
FINAL BODY WT(G)	152.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38694-06 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.7430	0.440	
UTERUS- BLOTTED	0.3571	0.211	
LIVER	8.7959	5.205	
KIDNEYS	1.9724	1.167	
SPLEEN	0.5056	0.299	
THYMUS	0.5519	0.327	
OVARIES/OVIDUCTS	0.0752	0.044	
ADRENAL GLANDS	0.0463	0.027	
PITUITARY	0.0106	0.006	
THYROIDS/PARA	0.0224	0.013	
FINAL BODY WT(G)	169.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, LYMPH NODE, AXI, OVARIES, OVIDUCTS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38695-10 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5288	0.299	
UTERUS- BLOTTED	0.4347	0.246	
LIVER	9.6296	5.440	
KIDNEYS	2.0262	1.145	
SPLEEN	0.5666	0.320	
THYMUS	0.6430	0.363	
OVARIES/OVIDUCTS	0.0942	0.053	
ADRENAL GLANDS	0.0545	0.031	
PITUITARY	0.0103	0.006	
THYROIDS/PARA	0.0199	0.011	
FINAL BODY WT(G)	177.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, LYMPH NODE, AXI, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

ANIMAL NO.38696-07 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2979	0.227
UTERUS- BLOTTED	0.2834	0.216
LIVER	6.0643	4.629
KIDNEYS	1.2695	0.969
SPLEEN	0.3648	0.278
THYMUS	0.4781	0.365
OVARIES/OVIDUCTS	0.0690	0.053
ADRENAL GLANDS	0.0371	0.028
PITUITARY	0.0068	0.005
THYROIDS/PARA	0.0180	0.014
FINAL BODY WT(G)	131.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER
OVIDUCTS, OVARIES, PITUITARY, SPLEEN
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38696-09 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5714	0.391	
UTERUS- BLOTTED	0.3374	0.231	
LIVER	7.5737	5.187	
KIDNEYS	1.3283	0.910	
SPLEEN	0.4320	0.296	
THYMUS	0.5905	0.404	
OVARIES/OVIDUCTS	0.0587	0.040	
ADRENAL GLANDS	0.0391	0.027	
PITUITARY	0.0076	0.005	
THYROIDS/PARA	0.0119	0.008	
FINAL BODY WT(G)	146.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
OVIDUCTS	OVARIES	PITUITARY	SPLEEN
THYMUS	THYROID GLANDS	UTERUS	CERVIX
VAGINA			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38694-05 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2306	0.138	NO SIGNIFICANT
UTERUS- BLOTTED	0.2129	0.127	CHANGES OBSERVED
LIVER	8.2872	4.962	
KIDNEYS	1.7295	1.036	
SPLEEN	0.6872	0.411	
THYMUS	0.4999	0.299	
OVARIES/OVIDUCTS	0.0854	0.051	
ADRENAL GLANDS	0.0382	0.023	
PITUITARY	0.0095	0.006	
THYROIDS/PARA	0.0163	0.010	
FINAL BODY WT(G)	167.		

GROSS:ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38695-05 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4493	0.284	GROSS:ADRENAL GLANDS	LYMPH NODE, AXI
UTERUS- BLOTTED	0.3714	0.235	OVIDUCTS	OVARIES
LIVER	7.1750	4.541	THYMUS	THYROID GLANDS
KIDNEYS	1.9514	1.235	VAGINA	
SPLEEN	0.4327	0.274		
THYMUS	0.5251	0.332		
OVARIES/OVIDUCTS	0.0707	0.045		
ADRENAL GLANDS	0.0582	0.037		
PITUITARY	0.0093	0.006		
THYROIDS/PARA	0.0196	0.012		
FINAL BODY WT(G)	158.			

KIDNEYS	LIVER
PITUITARY	SPLEEN
UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 5/4/2007

PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

ANIMAL NO.38697-02 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2295	0.146
UTERUS- BLOTTED	0.2133	0.136
LIVER	8.2300	5.242
KIDNEYS	1.6268	1.036
SPLEEN	0.4668	0.297
THYMUS	0.5401	0.344
OVARIES/OVIDUCTS	0.0602	0.038
ADRENAL GLANDS	0.0326	0.021
PITUITARY	0.0068	0.004
THYROIDS/PARA	0.0105	0.007
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER
OVIDUCTS, OVARIES, PITUITARY, SPLEEN
THYMUS, THYROID GLANDS, UTERUS, CERVIX
VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-09 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4317	0.288	GROSS:	
UTERUS- BLOTTED	0.3205	0.214		
LIVER	7.5269	5.018		
KIDNEYS	1.7126	1.142		
SPLEEN	0.3965	0.264		
THYMUS	0.6018	0.401		
OVARIES/OVIDUCTS	0.0945	0.063		
ADRENAL GLANDS	0.0477	0.032		
PITUITARY	0.0122	0.008		
THYROIDS/PARA	0.0109	0.007		
FINAL BODY WT(G)	150.			

ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38699-01 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3149	0.199		
UTERUS- BLOTTED	0.2999	0.190		
LIVER	8.0304	5.083		
KIDNEYS	1.5727	0.995		
SPLEEN	0.4381	0.277		
THYMUS	0.4267	0.270		
OVARIES/OVIDUCTS	0.0846	0.054		
ADRENAL GLANDS	0.0417	0.026		
PITUITARY	0.0111	0.007		
THYROIDS/PARA	0.0123	0.008		
FINAL BODY WT(G)	158.			

GROSS:

ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS		LIVER
OVIDUCTS	OVARIES	PITUITARY		SPLEEN
THYMUS	THYROID GLANDS	UTERUS		CERVIX
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

ANIMAL NO.38699-10 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3490	0.212	
UTERUS- BLOTTED	0.3314	0.201	
LIVER	8.5814	5.201	
KIDNEYS	1.7429	1.056	
SPLEEN	0.4263	0.258	
THYMUS	0.5700	0.345	
OVARIES/OVIDUCTS	0.0828	0.050	
ADRENAL GLANDS	0.0409	0.025	
PITUITARY	0.0110	0.007	
THYROIDS/PARA	0.0112	0.007	
FINAL BODY WT(G)	165.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-01 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.7083	0.407		ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
UTERUS- BLOTTED	0.3693	0.212		OVIDUCTS	OVARIES	PITUITARY	SPLEEN
LIVER	8.1739	4.698		THYMUS	THYROID GLANDS	UTERUS	CERVIX
KIDNEYS	1.8161	1.044		VAGINA			
SPLEEN	0.5731	0.329					
THYMUS	0.7070	0.406					
OVARIES/OVIDUCTS	0.0792	0.046					
ADRENAL GLANDS	0.0479	0.028					
PITUITARY	0.0097	0.006					
THYROIDS/PARA	0.0110	0.006					
FINAL BODY WT(G)	174.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38697-09 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3180	0.203
UTERUS- BLOTTED	0.2991	0.191
LIVER	7.2068	4.590
KIDNEYS	1.6369	1.043
SPLEEN	0.4142	0.264
THYMUS	0.7164	0.456
OVARIES/OVIDUCTS	0.0772	0.049
ADRENAL GLANDS	0.0513	0.033
PITUITARY	0.0106	0.007
THYROIDS/PARA	0.0143	0.009
FINAL BODY WT(G)	157.	

NO SIGNIFICANT CHANGES OBSERVED	GRADE
GROSS:ADRENAL GLANDS	LYMPH NODE, AXI
OVIDUCTS	OVARIES
THYMUS	THYROID GLANDS
VAGINA	
KIDNEYS	LIVER
PITUITARY	SPLEEN
UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38703-04 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2335	0.139	GROSS:ADRENAL GLANDS	LYMPH NODE, AXI
UTERUS- BLOTTED	0.2170	0.129	OVIDUCTS	OVARIES
LIVER	9.4065	5.599	THYMUS	THYROID GLANDS
KIDNEYS	1.8652	1.110	VAGINA	
SPLEEN	0.6112	0.364		
THYMUS	0.6404	0.381		
OVARIES/OVIDUCTS	0.0948	0.056		
ADRENAL GLANDS	0.0361	0.021		
PITUITARY	0.0117	0.007		
THYROIDS/PARA	0.0112	0.007		
FINAL BODY WT(G)	168.			

KIDNEYS	LIVER
PITUITARY	SPLEEN
UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38700-01 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3741	0.238	
UTERUS- BLOTTED	0.3563	0.227	
LIVER	8.0758	5.144	
KIDNEYS	1.5813	1.007	
SPLEEN	0.4480	0.285	
THYMUS	0.5110	0.325	
OVARIES/OVIDUCTS	0.0912	0.058	
ADRENAL GLANDS	0.0305	0.019	
PITUITARY	0.0111	0.007	
THYROIDS/PARA	0.0109	0.007	
FINAL BODY WT(G)	157.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187060 RAD

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38701-06 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2390	0.151	
UTERUS- BLOTTED	0.2208	0.140	
LIVER	7.0808	4.482	
KIDNEYS	1.5015	0.950	
SPLEEN	0.5519	0.349	
THYMUS	0.6494	0.411	
OVARIES/OVIDUCTS	0.0634	0.040	
ADRENAL GLANDS	0.0377	0.024	
PITUITARY	0.0077	0.005	
THYROIDS/PARA	0.0149	0.009	
FINAL BODY WT(G)	158.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:				
ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

ANIMAL NO.38696-02 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2101	0.147
UTERUS- BLOTTED	0.1855	0.130
LIVER	8.1365	5.690
KIDNEYS	1.6843	1.178
SPLEEN	0.4015	0.281
THYMUS	0.4088	0.286
OVARIES/OVIDUCTS	0.0856	0.060
ADRENAL GLANDS	0.0469	0.033
PITUITARY	0.0111	0.008
THYROIDS/PARA	0.0210	0.015
FINAL BODY WT(G)	143.	

NO SIGNIFICANT CHANGES OBSERVED

				GRADE
OVARIES	MICRO: NECROSIS, GRANULOSA CELL, BILATERAL			3
	DEGENERATION, OOCYTE, BILATERAL			3
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL, BILATERAL			P
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED			
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED			
	GROSS:ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
	MICRO:UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PROJECT NO.:WIL-187060
SPONSOR:[redacted]
SPONSOR NO.:06-023

ANIMAL NO.38695-06 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1969	0.153
UTERUS- BLOTTED	0.1821	0.141
LIVER	7.2083	5.588
KIDNEYS	1.4016	1.087
SPLEEN	0.3685	0.286
THYMUS	0.3773	0.292
OVARIES/OVIDUCTS	0.0459	0.036
ADRENAL GLANDS	0.0323	0.025
PITUITARY	0.0067	0.005
THYROIDS/PARA	0.0155	0.012
FINAL BODY WT(G)	129.	

OVARIES

NO SIGNIFICANT CHANGES OBSERVED

THYROID GLANDS
UTERUS
CERVIX
PARATHYROID

NOT EXAMINED

		GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	2
	NECROSIS, GRANULOSA CELL, BILATERAL	2
MICRO:	CYST, ULTIMOBRANCHIAL, BILATERAL	P
MICRO:	DILATATION, GLANDULAR	2
MICRO:	DILATATION, GLANDULAR	2
MICRO:	NOT EXAMINED	
	NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

MICRO:PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38694-08 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2101	0.145
UTERUS- BLOTTED	0.1956	0.135
LIVER	7.9020	5.450
KIDNEYS	1.6196	1.117
SPLEEN	0.3521	0.243
THYMUS	0.4501	0.310
OVARIES/OVIDUCTS	0.0551	0.038
ADRENAL GLANDS	0.0452	0.031
PITUITARY	0.0087	0.006
THYROIDS/PARA	0.0225	0.016
FINAL BODY WT(G)	145.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	2
	NECROSIS, GRANULOSA CELL, BILATERAL	2
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL, BILATERAL	P
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38696-05 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1801	0.157
UTERUS- BLOTTED	0.1643	0.143
LIVER	5.8648	5.100
KIDNEYS	1.2490	1.086
SPLEEN	0.3122	0.271
THYMUS	0.3755	0.327
OVARIES/OVIDUCTS	0.0477	0.041
ADRENAL GLANDS	0.0346	0.030
PITUITARY	0.0057	0.005
THYROIDS/PARA	0.0130	0.011
FINAL BODY WT(G)	115.	

OVARIES
THYROID GLANDS
PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED
NOT EXAMINED

		GRADE
MICRO:	NECROSIS, GRANULOSA CELL, BILATERAL	2
	DEGENERATION, OOCYTE, BILATERAL	2
MICRO:	CYST, ULTIMOBRANCHIAL, BILATERAL	P
MICRO:	NOT EXAMINED	
	NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX		
MICRO:	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
SPONSOR NO.:06-023
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38695-09 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2083	0.154
UTERUS- BLOTTED	0.1935	0.143
LIVER	7.2470	5.368
KIDNEYS	1.5073	1.117
SPLEEN	0.4138	0.307
THYMUS	0.4215	0.312
OVARIES/OVIDUCTS	0.0583	0.043
ADRENAL GLANDS	0.0480	0.036
PITUITARY	0.0071	0.005
THYROIDS/PARA	0.0190	0.014
FINAL BODY WT(G)	135.	

OVARIES: NO SIGNIFICANT CHANGES OBSERVED

					GRADE
MICRO:	DEGENERATION, OOCYTE, BILATERAL				2
	NECROSIS, GRANULOSA CELL, BILATERAL				2
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
	THYMUS	THYROID GLANDS	UTERUS	CERVIX	
	VAGINA				
MICRO:	THYROID GLANDS	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38694-03 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2808	0.172
UTERUS- BLOTTED	0.2542	0.156
LIVER	8.3207	5.105
KIDNEYS	1.8366	1.127
SPLEEN	0.4938	0.303
THYMUS	0.4812	0.295
OVARIES/OVIDUCTS	0.0744	0.046
ADRENAL GLANDS	0.0509	0.031
PITUITARY	0.0110	0.007
THYROIDS/PARA	0.0225	0.014
FINAL BODY WT(G)	163.	

OVARIES

NO SIGNIFICANT CHANGES OBSERVED

					GRADE
MICRO:	HEMORRHAGE, FOLLICULAR				1
	DEGENERATION, OOCYTE, BILATERAL				2
	NECROSIS, GRANULOSA CELL, BILATERAL				2
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
	THYMUS	THYROID GLANDS	UTERUS	CERVIX	
	VAGINA				
MICRO:	THYROID GLANDS	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

SPONSOR NO.:06-023

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38697-06 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2178	0.140
UTERUS- BLOTTED	0.2043	0.131
LIVER	9.0136	5.778
KIDNEYS	1.6093	1.032
SPLEEN	0.3692	0.237
THYMUS	0.4985	0.320
OVARIES/OVIDUCTS	0.0441	0.028
ADRENAL GLANDS	0.0417	0.027
PITUITARY	0.0077	0.005
THYROIDS/PARA	0.0098	0.006
FINAL BODY WT(G)	156.	

OVARIES NO SIGNIFICANT CHANGES OBSERVED

THYROID GLANDS NO SIGNIFICANT CHANGES OBSERVED

PARATHYROID NO SIGNIFICANT CHANGES OBSERVED

				GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL			4
	DEGENERATION, OOCYTE, BILATERAL			2
	NECROSIS, GRANULOSA CELL, BILATERAL			2
MICRO:	CYST, ULTIMOBRANCHIAL			P
MICRO:	NO SIGNIFICANT CHANGES OBSERVED			
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED			
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38699-05 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2872	0.199
UTERUS- BLOTTED	0.2745	0.191
LIVER	8.4092	5.840
KIDNEYS	1.5575	1.082
SPLEEN	0.3819	0.265
THYMUS	0.4544	0.316
OVARIES/OVIDUCTS	0.0823	0.057
ADRENAL GLANDS	0.0558	0.039
PITUITARY	0.0100	0.007
THYROIDS/PARA	0.0147	0.010
FINAL BODY WT(G)	144.	

OVARIES
THYROID GLANDS
PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED

NOT EXAMINED

		GRADE
MICRO:	NECROSIS, GRANULOSA CELL, BILATERAL	2
	DEGENERATION, OOCYTE, BILATERAL	2
MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	
MICRO:	NOT EXAMINED	
	NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	THYROID GLANDS	UTERUS	CERVIX	
MICRO:	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-10 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2055	0.128
UTERUS- BLOTTED	0.1943	0.121
LIVER	8.2443	5.153
KIDNEYS	1.4773	0.923
SPLEEN	0.4694	0.293
THYMUS	0.3970	0.248
OVARIES/OVIDUCTS	0.0401	0.025
ADRENAL GLANDS	0.0390	0.024
PITUITARY	0.0077	0.005
THYROIDS/PARA	0.0116	0.007
FINAL BODY WT(G)	160.	

OVARIES: NO SIGNIFICANT CHANGES OBSERVED

					GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL				4
	NECROSIS, GRANULOSA CELL, BILATERAL				2
	DEGENERATION, OOCYTE, BILATERAL				2
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
	THYMUS	THYROID GLANDS	UTERUS	CERVIX	
	VAGINA				
MICRO:	THYROID GLANDS	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38699-04 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2582	0.148
UTERUS- BLOTTED	0.2390	0.137
LIVER	9.4987	5.459
KIDNEYS	2.0695	1.189
SPLEEN	0.4502	0.259
THYMUS	0.5772	0.332
OVARIES/OVIDUCTS	0.0519	0.030
ADRENAL GLANDS	0.0463	0.027
PITUITARY	0.0140	0.008
THYROIDS/PARA	0.0133	0.008
FINAL BODY WT(G)	174.	

NO SIGNIFICANT CHANGES OBSERVED: OVARIES; THYROID GLANDS; UTERUS; CERVIX; PARATHYROID

		GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	2
	NECROSIS, GRANULOSA CELL, BILATERAL	2
MICRO:	CYST, ULTIMOBRANCHIAL, BILATERAL	P
MICRO:	DILATATION, GLANDULAR	2
MICRO:	NECROSIS, SINGLE CELL	1
MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

MICRO: PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38698-02 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2493	0.139
UTERUS- BLOTTED	0.2352	0.131
LIVER	10.0117	5.593
KIDNEYS	1.7484	0.977
SPLEEN	0.5138	0.287
THYMUS	0.4560	0.255
OVARIES/OVIDUCTS	0.0489	0.027
ADRENAL GLANDS	0.0514	0.029
PITUITARY	0.0115	0.006
THYROIDS/PARA	0.0127	0.007
FINAL BODY WT(G)	179.	

OVARIES
NO SIGNIFICANT
CHANGES OBSERVED

					GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL				4
	DEGENERATION, OOCYTE, BILATERAL				2
	NECROSIS, GRANULOSA CELL, BILATERAL				2
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
	THYMUS	THYROID GLANDS	UTERUS	CERVIX	
	VAGINA				
MICRO:	THYROID GLANDS	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38697-01 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2198	0.151
UTERUS- BLOTTED	0.2028	0.139
LIVER	7.5772	5.190
KIDNEYS	1.6842	1.154
SPLEEN	0.4183	0.287
THYMUS	0.4753	0.326
OVARIES/OVIDUCTS	0.0462	0.032
ADRENAL GLANDS	0.0389	0.027
PITUITARY	0.0083	0.006
THYROIDS/PARA	0.0130	0.009
FINAL BODY WT(G)	146.	

NO SIGNIFICANT CHANGES OBSERVED

OVARIES

THYROID GLANDS

PARATHYROID

		GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	2
	NECROSIS, GRANULOSA CELL, BILATERAL	2
MICRO:	CYST, ULTIMOBRANCHIAL, BILATERAL	P
MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

ANIMAL NO.38703-05 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2145	0.129
UTERUS- BLOTTED	0.2028	0.122
LIVER	10.8338	6.526
KIDNEYS	1.7384	1.047
SPLEEN	0.3957	0.238
THYMUS	0.5768	0.347
OVARIES/OVIDUCTS	0.0541	0.033
ADRENAL GLANDS	0.0423	0.025
PITUITARY	0.0096	0.006
THYROIDS/PARA	0.0099	0.006
FINAL BODY WT(G)	166.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	2
	NECROSIS, GRANULOSA CELL, BILATERAL	2
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL, BILATERAL	P
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38702-02 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1822	0.130
UTERUS- BLOTTED	0.1701	0.122
LIVER	8.1221	5.802
KIDNEYS	1.3441	0.960
SPLEEN	0.4639	0.331
THYMUS	0.4891	0.349
OVARIES/OVIDUCTS	0.0490	0.035
ADRENAL GLANDS	0.0376	0.027
PITUITARY	0.0075	0.005
THYROIDS/PARA	0.0129	0.009
FINAL BODY WT(G)	140.	

OVARIES: NO SIGNIFICANT CHANGES OBSERVED

				GRADE
MICRO: NECROSIS, GRANULOSA CELL, BILATERAL				2
DEGENERATION, OOCYTE, BILATERAL				2
GROSS: ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
OVIDUCTS	OVARIES	PITUITARY	SPLEEN	
THYMUS	THYROID GLANDS	UTERUS	CERVIX	
VAGINA				
MICRO: THYROID GLANDS	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

ANIMAL NO.38701-10 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1446	0.096
UTERUS- BLOTTED	0.1347	0.090
LIVER	8.3480	5.565
KIDNEYS	1.5733	1.049
SPLEEN	0.5092	0.339
THYMUS	0.4584	0.306
OVARIES/OVIDUCTS	0.0388	0.026
ADRENAL GLANDS	0.0409	0.027
PITUITARY	0.0075	0.005
THYROIDS/PARA	0.0116	0.008
FINAL BODY WT(G)	150.	

OVARIES NO SIGNIFICANT CHANGES OBSERVED

					GRADE
GROSS:	SMALL				P
	BILATERAL				
MICRO:	CORPORA LUTEA ABSENT, BILATERAL				4
	CORRELATES TO GROSS OBSERVATION(S)				
	DEGENERATION, OOCYTE, BILATERAL				2
	NECROSIS, GRANULOSA CELL, BILATERAL				2
MICRO:	DILATATION, GLANDULAR				1
GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER	
	OVIDUCTS	PITUITARY	SPLEEN	THYMUS	
	THYROID GLANDS	UTERUS	CERVIX	VAGINA	
MICRO:	THYROID GLANDS	CERVIX	PARATHYROID		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38695-08 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1900	0.150
UTERUS- BLOTTED	0.1804	0.142
LIVER	9.9889	7.865
KIDNEYS	1.5538	1.223
SPLEEN	0.2633	0.207
THYMUS	0.2279	0.179
OVARIES/OVIDUCTS	0.0388	0.031
ADRENAL GLANDS	0.0448	0.035
PITUITARY	0.0080	0.006
THYROIDS/PARA	0.0204	0.016
FINAL BODY WT(G)	127.	

OVARIES
THYROID GLANDS
PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED

NOT EXAMINED

		GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	4
	NECROSIS, GRANULOSA CELL, BILATERAL	4
MICRO:	CYST, ULTIMOBRANCHIAL	P
MICRO:	NOT EXAMINED	
	NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX		

MICRO:PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-023

ANIMAL NO.38696-10 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2082	0.160
UTERUS- BLOTTED	0.1917	0.147
LIVER	10.6901	8.223
KIDNEYS	1.3437	1.034
SPLEEN	0.2851	0.219
THYMUS	0.3077	0.237
OVARIES/OVIDUCTS	0.0318	0.024
ADRENAL GLANDS	0.0452	0.035
PITUITARY	0.0064	0.005
THYROIDS/PARA	0.0152	0.012
FINAL BODY WT(G)	130.	

		GRADE
OVIDUCTS	GROSS: SMALL	P
	BILATERAL	
OVIDUCTS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	NOT CORRELATES TO GROSS OBSERVATION(S)	
OVARIES	GROSS: SMALL	P
	BILATERAL	
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	CORRELATES TO GROSS OBSERVATION(S)	
	DEGENERATION, OOCYTE, BILATERAL	3
	NECROSIS, GRANULOSA CELL, BILATERAL	3
NO SIGNIFICANT CHANGES OBSERVED		

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

MICRO: OVIDUCTS, THYROID GLANDS, UTERUS, CERVIX, PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38694-01 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2244	0.139
UTERUS- BLOTTED	0.2021	0.126
LIVER	13.5600	8.422
KIDNEYS	1.6470	1.023
SPLEEN	0.4058	0.252
THYMUS	0.3781	0.235
OVARIES/OVIDUCTS	0.0389	0.024
ADRENAL GLANDS	0.0467	0.029
PITUITARY	0.0080	0.005
THYROIDS/PARA	0.0217	0.013
FINAL BODY WT(G)	161.	

OVARIES — NO SIGNIFICANT CHANGES OBSERVED

THYROID GLANDS — NO SIGNIFICANT CHANGES OBSERVED

PARATHYROID — NO SIGNIFICANT CHANGES OBSERVED

		GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	3
	NECROSIS, GRANULOSA CELL, BILATERAL	3
MICRO:	INFILTRATE, LYMPHOCYTE	(1)
	CYST, ULTIMOBRANCHIAL	P

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT
( )-FOCAL, (( ))-MULTIFOCAL, NO PARENTHESES-DIFFUSE

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Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38695-03 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2146	0.161
UTERUS- BLOTTED	0.1970	0.148
LIVER	9.9073	7.449
KIDNEYS	1.2913	0.971
SPLEEN	0.3429	0.258
THYMUS	0.2516	0.189
OVARIES/OVIDUCTS	0.0359	0.027
ADRENAL GLANDS	0.0360	0.027
PITUITARY	0.0074	0.006
THYROIDS/PARA	0.0141	0.011
FINAL BODY WT(G)	133.	

OVARIES
THYROID GLANDS
PARATHYROID
NO SIGNIFICANT CHANGES OBSERVED

		GRADE
MICRO:	NECROSIS, GRANULOSA CELL, BILATERAL	3
	DEGENERATION, OOCYTE, BILATERAL	3
MICRO:	CYST, ULTIMOBRANCHIAL	P
MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Modified: 5/4/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38697-10 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2402	0.170
UTERUS- BLOTTED	0.2271	0.161
LIVER	11.7143	8.308
KIDNEYS	1.4479	1.027
SPLEEN	0.3918	0.278
THYMUS	0.3362	0.238
OVARIES/OVIDUCTS	0.0485	0.034
ADRENAL GLANDS	0.0456	0.032
PITUITARY	0.0121	0.009
THYROIDS/PARA	0.0124	0.009
FINAL BODY WT(G)	141.	

NO SIGNIFICANT CHANGES OBSERVED

NOT EXAMINED

		GRADE
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	3
	NECROSIS, GRANULOSA CELL, BILATERAL	3
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
PARATHYROID	MICRO: NOT EXAMINED	
	NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS: ADRENAL GLANDS, LYMPH NODE, AXI, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA

MICRO: UTERUS, CERVIX

MICRO: PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

ANIMAL NO.38699-09 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2138	0.131
UTERUS- BLOTTED	0.1974	0.121
LIVER	13.7878	8.459
KIDNEYS	1.6230	0.996
SPLEEN	0.3511	0.215
THYMUS	0.3526	0.216
OVARIES/OVIDUCTS	0.0355	0.022
ADRENAL GLANDS	0.0427	0.026
PITUITARY	0.0106	0.007
THYROIDS/PARA	0.0138	0.008
FINAL BODY WT(G)	163.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
OVARIES	GROSS: SMALL	P
	BILATERAL	
OVARIES	MICRO: CORPORA LUTEA ABSENT, BILATERAL	4
	CORRELATES TO GROSS OBSERVATION(S)	
	DEGENERATION, OOCYTE, BILATERAL	3
	NECROSIS, GRANULOSA CELL, BILATERAL	3
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
CERVIX	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	WITH MILD UTERINE BODY ATROPHY	
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-023

ANIMAL NO.38700-07 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2089	0.131
UTERUS- BLOTTED	0.1984	0.125
LIVER	15.0832	9.486
KIDNEYS	1.5432	0.971
SPLEEN	0.4878	0.307
THYMUS	0.3191	0.201
OVARIES/OVIDUCTS	0.0457	0.029
ADRENAL GLANDS	0.0320	0.020
PITUITARY	0.0069	0.004
THYROIDS/PARA	0.0130	0.008
FINAL BODY WT(G)	159.	

OVARIES NO SIGNIFICANT CHANGES OBSERVED

THYROID GLANDS NO SIGNIFICANT CHANGES OBSERVED

PARATHYROID NO SIGNIFICANT CHANGES OBSERVED

		GRADE
MICRO:	CORPORA LUTEA ABSENT, BILATERAL	4
	DEGENERATION, OOCYTE, BILATERAL	3
	NECROSIS, GRANULOSA CELL, BILATERAL	3
MICRO:	CYST, ULTIMOBRANCHIAL	P
MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION, RECUT REQUESTED AND EXAMINED	

GROSS:	ADRENAL GLANDS	LYMPH NODE, AXI	KIDNEYS	LIVER
	OVIDUCTS	OVARIES	PITUITARY	SPLEEN
	THYMUS	THYROID GLANDS	UTERUS	CERVIX
	VAGINA			
MICRO:	UTERUS	CERVIX	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.55
05/03/2007

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38694-07	0.4096	0.3827	0.0269	10.3255	1.9066	0.5160	0.5059	0.1108	0.0462	0.0107	0.0166
38696-08	0.3765	0.3497	0.0268	9.5224	1.9762	0.4364	0.6582	0.1194	0.0494	0.0101	0.0183
38695-01	0.6982	0.4641	0.2341	7.2835	1.6109	0.5048	0.6153	0.0772	0.0411	0.0087	0.0187
38695-07	0.4985	0.4342	0.0643	8.0222	1.5607	0.4641	0.5436	0.0799	0.0382	0.0079	0.0222
38694-04	0.7364	0.3101	0.4263	6.3273	1.4132	0.3951	0.5660	0.0720	0.0417	0.0087	0.0164
38696-04	0.2853	0.2699	0.0154	6.4839	1.3973	0.3812	0.5184	0.0812	0.0313	0.0097	0.0281
38697-07	0.2601	0.2388	0.0213	8.2656	1.5263	0.5124	0.6001	0.0824	0.0317	0.0077	0.0112
38698-04	0.3536	0.3328	0.0208	6.9727	1.5737	0.4764	0.6105	0.1148	0.0492	0.0107	0.0134
38699-07	0.4452	0.4138	0.0314	9.5810	1.8506	0.4591	0.6633	0.1160	0.0512	0.0116	0.0146
38698-05	0.2768	0.2571	0.0197	7.1187	1.6701	0.4346	0.6528	0.0976	0.0418	0.0113	0.0135
38699-02	0.6801	0.4095	0.2706	7.1187	1.3740	0.3868	0.5356	0.0847	0.0331	0.0077	0.0121
38697-03	0.2826	0.2618	0.0208	9.2621	1.7678	0.5384	0.6155	0.0721	0.0323	0.0095	0.0105
38703-06	0.2869	0.2673	0.0196	10.7276	2.0827	0.6022	0.6689	0.0720	0.0388	0.0087	0.0100
38700-06	0.4172	0.3887	0.0285	9.3264	1.8054	0.4890	0.6015	0.1275	0.0343	0.0118	0.0136
38702-05	0.2943	0.2766	0.0177	7.3925	1.4462	0.4249	0.5665	0.0963	0.0331	0.0100	0.0130
MEAN	0.4201	0.3371	0.0829	8.2487	1.6641	0.4681	0.5948	0.0936	0.0396	0.0097	0.0155
S.D.	0.16366	0.07422	0.12438	1.43299	0.22415	0.06130	0.05361	0.01945	0.00696	0.00139	0.00484
N	15	15	15	15	15	15	15	15	15	15	15

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)
38694-07	184.
38696-08	165.
38695-01	157.
38695-07	161.
38694-04	140.
38696-04	143.
38697-07	150.
38698-04	144.
38699-07	181.
38698-05	154.
38699-02	147.
38697-03	184.
38703-06	190.
38700-06	168.
38702-05	138.
MEAN	160.
S.D.	17.6
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR: [redacted]
SPONSOR NO.:06-023 INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: 10 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38695-02	0.3383	0.3153	0.0230	10.8304	1.9764	0.5640	0.7215	0.0727	0.0405	0.0103	0.0164
38694-10	0.3852	0.3654	0.0198	8.1668	1.7171	0.4648	0.5173	0.1127	0.0443	0.0093	0.0181
38696-06	0.2916	0.2781	0.0135	6.3626	1.4305	0.3602	0.5807	0.0896	0.0547	0.0101	0.0195
38696-01	0.3452	0.2853	0.0599	6.1267	1.2858	0.3382	0.5096	0.0620	0.0391	0.0046	0.0151
38695-04	0.3425	0.3185	0.0240	6.6158	1.5631	0.3961	0.5375	0.0793	0.0428	0.0080	0.0145
38694-02	0.6892	0.4019	0.2873	8.3109	2.0671	0.5115	0.6372	0.1156	0.0541	0.0121	0.0159
38698-07	0.4509	0.3849	0.0660	9.3328	1.6915	0.5595	0.5506	0.0887	0.0444	0.0113	0.0110
38697-04	0.3336	0.3192	0.0144	7.6283	1.4744	0.5211	0.7066	0.0976	0.0455	0.0113	0.0130
38699-08	0.5190	0.4415	0.0775	7.5913	1.6927	0.4415	0.6495	0.0700	0.0426	0.0105	0.0135
38699-06	0.2740	0.2560	0.0180	7.8568	1.6059	0.4522	0.4649	0.0844	0.0418	0.0096	0.0128
38698-06	0.2937	0.2787	0.0150	7.6285	1.8106	0.4991	0.4544	0.0907	0.0396	0.0092	0.0120
38697-05	0.3447	0.3183	0.0264	9.7000	1.7381	0.6028	0.7137	0.0790	0.0386	0.0111	0.0116
38702-09	0.3584	0.3398	0.0186	8.2519	1.6479	0.3917	0.5662	0.0958	0.0469	0.0106	0.0153
38703-01	0.3988	0.3556	0.0432	6.9814	1.4162	0.3810	0.6232	0.0653	0.0356	0.0075	0.0112
38701-03	0.2742	0.2575	0.0167	6.8720	1.6474	0.4808	0.5673	0.0787	0.0457	0.0089	0.0131
MEAN	0.3760	0.3277	0.0482	7.8837	1.6510	0.4643	0.5867	0.0855	0.0437	0.0096	0.0142
S.D.	0.10889	0.05425	0.06930	1.29677	0.20666	0.07991	0.08625	0.01569	0.00530	0.00188	0.00252
N	15	15	15	15	15	15	15	15	15	15	15

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 10 MG/KG/DAY

ANIMAL	FBW(G)
38695-02	190.
38694-10	166.
38696-06	134.
38696-01	140.
38695-04	147.
38694-02	178.
38698-07	179.
38697-04	157.
38699-08	162.
38699-06	164.
38698-06	157.
38697-05	188.
38702-09	159.
38703-01	143.
38701-03	152.
MEAN	161.
S.D.	17.0
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 50 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38694-06	0.7430	0.3571	0.3859	8.7959	1.9724	0.5056	0.5519	0.0752	0.0463	0.0106	0.0224
38695-10	0.5288	0.4347	0.0941	9.6296	2.0262	0.5666	0.6430	0.0942	0.0545	0.0103	0.0199
38696-07	0.2979	0.2834	0.0145	6.0643	1.2695	0.3648	0.4781	0.0690	0.0371	0.0068	0.0180
38696-09	0.5714	0.3374	0.2340	7.5737	1.3283	0.4320	0.5905	0.0587	0.0391	0.0076	0.0119
38694-05	0.2306	0.2129	0.0177	8.2872	1.7295	0.6872	0.4999	0.0854	0.0382	0.0095	0.0163
38695-05	0.4493	0.3714	0.0779	7.1750	1.9514	0.4327	0.5251	0.0707	0.0582	0.0093	0.0196
38697-02	0.2295	0.2133	0.0162	8.2300	1.6268	0.4668	0.5401	0.0602	0.0326	0.0068	0.0105
38698-09	0.4317	0.3205	0.1112	7.5269	1.7126	0.3965	0.6018	0.0945	0.0477	0.0122	0.0109
38699-01	0.3149	0.2999	0.0150	8.0304	1.5727	0.4381	0.4267	0.0846	0.0417	0.0111	0.0123
38699-10	0.3490	0.3314	0.0176	8.5814	1.7429	0.4263	0.5700	0.0828	0.0409	0.0110	0.0112
38698-01	0.7083	0.3693	0.3390	8.1739	1.8161	0.5731	0.7070	0.0792	0.0479	0.0097	0.0110
38697-09	0.3180	0.2991	0.0189	7.2068	1.6369	0.4142	0.7164	0.0772	0.0513	0.0106	0.0143
38703-04	0.2335	0.2170	0.0165	9.4065	1.8652	0.6112	0.6404	0.0948	0.0361	0.0117	0.0112
38700-01	0.3741	0.3563	0.0178	8.0758	1.5813	0.4480	0.5110	0.0912	0.0305	0.0111	0.0109
38701-06	0.2390	0.2208	0.0182	7.0808	1.5015	0.5519	0.6494	0.0634	0.0377	0.0077	0.0149
MEAN	0.4013	0.3083	0.0930	7.9892	1.6889	0.4877	0.5768	0.0787	0.0427	0.0097	0.0144
S.D.	0.16927	0.06803	0.12503	0.92902	0.22170	0.09111	0.08373	0.01240	0.00805	0.00176	0.00397
N	15	15	15	15	15	15	15	15	15	15	15

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 50 MG/KG/DAY

ANIMAL	FBW(G)
38694-06	169.
38695-10	177.
38696-07	131.
38696-09	146.
38694-05	167.
38695-05	158.
38697-02	157.
38698-09	150.
38699-01	158.
38699-10	165.
38698-01	174.
38697-09	157.
38703-04	168.
38700-01	157.
38701-06	158.
MEAN	159.
S.D.	11.6
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 200 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38696-02	0.2101	0.1855	0.0246	8.1365	1.6843	0.4015	0.4088	0.0856	0.0469	0.0111	0.0210
38695-06	0.1969	0.1821	0.0148	7.2083	1.4016	0.3685	0.3773	0.0459	0.0323	0.0067	0.0155
38694-08	0.2101	0.1956	0.0145	7.9020	1.6196	0.3521	0.4501	0.0551	0.0452	0.0087	0.0225
38696-05	0.1801	0.1643	0.0158	5.8648	1.2490	0.3122	0.3755	0.0477	0.0346	0.0057	0.0130
38695-09	0.2083	0.1935	0.0148	7.2470	1.5073	0.4138	0.4215	0.0583	0.0480	0.0071	0.0190
38694-03	0.2808	0.2542	0.0266	8.3207	1.8366	0.4938	0.4812	0.0744	0.0509	0.0110	0.0225
38697-06	0.2178	0.2043	0.0135	9.0136	1.6093	0.3692	0.4985	0.0441	0.0417	0.0077	0.0098
38699-05	0.2872	0.2745	0.0127	8.4092	1.5575	0.3819	0.4544	0.0823	0.0558	0.0100	0.0147
38698-10	0.2055	0.1943	0.0112	8.2443	1.4773	0.4694	0.3970	0.0401	0.0390	0.0077	0.0116
38699-04	0.2582	0.2390	0.0192	9.4987	2.0695	0.4502	0.5772	0.0519	0.0463	0.0140	0.0133
38698-02	0.2493	0.2352	0.0141	10.0117	1.7484	0.5138	0.4560	0.0489	0.0514	0.0115	0.0127
38697-01	0.2198	0.2028	0.0170	7.5772	1.6842	0.4183	0.4753	0.0462	0.0389	0.0083	0.0130
38703-05	0.2145	0.2028	0.0117	10.8338	1.7384	0.3957	0.5768	0.0541	0.0423	0.0096	0.0099
38702-02	0.1822	0.1701	0.0121	8.1221	1.3441	0.4639	0.4891	0.0490	0.0376	0.0075	0.0129
38701-10	0.1446	0.1347	0.0099	8.3480	1.5733	0.5092	0.4584	0.0388	0.0409	0.0075	0.0116
MEAN	0.2177	0.2022	0.0155	8.3159	1.6067	0.4209	0.4598	0.0548	0.0435	0.0089	0.0149
S.D.	0.03805	0.03612	0.00473	1.20357	0.20455	0.06057	0.06129	0.01456	0.00656	0.00222	0.00432
N	15	15	15	15	15	15	15	15	15	15	15

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 200 MG/KG/DAY

ANIMAL	FBW(G)
38696-02	143.
38695-06	129.
38694-08	145.
38696-05	115.
38695-09	135.
38694-03	163.
38697-06	156.
38699-05	144.
38698-10	160.
38699-04	174.
38698-02	179.
38697-01	146.
38703-05	166.
38702-02	140.
38701-10	150.
MEAN	150.
S.D.	17.1
N	15

FBW = FINAL BODY WEIGHT

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PROJECT NO.:WIL-187060
SPONSOR: [redacted]
SPONSOR NO.:06-023

TABLE 24
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: 800 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38695-08	0.1900	0.1804	0.0096	9.9889	1.5538	0.2633	0.2279	0.0388	0.0448	0.0080	0.0204
38696-10	0.2082	0.1917	0.0165	10.6901	1.3437	0.2851	0.3077	0.0318	0.0452	0.0064	0.0152
38694-01	0.2244	0.2021	0.0223	13.5600	1.6470	0.4058	0.3781	0.0389	0.0467	0.0080	0.0217
38695-03	0.2146	0.1970	0.0176	9.9073	1.2913	0.3429	0.2516	0.0359	0.0360	0.0074	0.0141
38697-10	0.2402	0.2271	0.0131	11.7143	1.4479	0.3918	0.3362	0.0485	0.0456	0.0121	0.0124
38699-09	0.2138	0.1974	0.0164	13.7878	1.6230	0.3511	0.3526	0.0355	0.0427	0.0106	0.0138
38700-07	0.2089	0.1984	0.0105	15.0832	1.5432	0.4878	0.3191	0.0457	0.0320	0.0069	0.0130
MEAN	0.2143	0.1992	0.0151	12.1045	1.4928	0.3611	0.3105	0.0393	0.0419	0.0085	0.0158
S.D.	0.01544	0.01417	0.00442	2.05268	0.13653	0.07612	0.05382	0.00589	0.00562	0.00208	0.00371
N	7	7	7	7	7	7	7	7	7	7	7

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TABLE 24

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-023

FEMALE GROUP: 800 MG/KG/DAY

ANIMAL	FBW(G)
38695-08	127.
38696-10	130.
38694-01	161.
38695-03	133.
38697-10	141.
38699-09	163.
38700-07	159.
MEAN	145.
S.D.	15.7
N	7

FBW = FINAL BODY WEIGHT

POFBWv4.14
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TABLE 25

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-023

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38694-07	184.	0.223	0.208	5.612	1.036	0.280	0.275	0.060	0.025	0.006	0.009
38696-08	165.	0.228	0.212	5.771	1.198	0.264	0.399	0.072	0.030	0.006	0.011
38695-01	157.	0.445	0.296	4.639	1.026	0.322	0.392	0.049	0.026	0.006	0.012
38695-07	161.	0.310	0.270	4.983	0.969	0.288	0.338	0.050	0.024	0.005	0.014
38694-04	140.	0.526	0.222	4.520	1.009	0.282	0.404	0.051	0.030	0.006	0.012
38696-04	143.	0.200	0.189	4.534	0.977	0.267	0.363	0.057	0.022	0.007	0.020
38697-07	150.	0.173	0.159	5.510	1.018	0.342	0.400	0.055	0.021	0.005	0.007
38698-04	144.	0.246	0.231	4.842	1.093	0.331	0.424	0.080	0.034	0.007	0.009
38699-07	181.	0.246	0.229	5.293	1.022	0.254	0.366	0.064	0.028	0.006	0.008
38698-05	154.	0.180	0.167	4.623	1.084	0.282	0.424	0.063	0.027	0.007	0.009
38699-02	147.	0.463	0.279	4.843	0.935	0.263	0.364	0.058	0.023	0.005	0.008
38697-03	184.	0.154	0.142	5.034	0.961	0.293	0.335	0.039	0.018	0.005	0.006
38703-06	190.	0.151	0.141	5.646	1.096	0.317	0.352	0.038	0.020	0.005	0.005
38700-06	168.	0.248	0.231	5.551	1.075	0.291	0.358	0.076	0.020	0.007	0.008
38702-05	138.	0.213	0.200	5.357	1.048	0.308	0.411	0.070	0.024	0.007	0.009
MEAN	160.	0.267	0.212	5.117	1.036	0.292	0.374	0.059	0.025	0.006	0.010
S.D.	17.6	0.1176	0.0474	0.4415	0.0667	0.0265	0.0401	0.0124	0.0044	0.0008	0.0037
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 25

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-023

FEMALE GROUP: 10 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38695-02	190.	0.178	0.166	5.700	1.040	0.297	0.380	0.038	0.021	0.005	0.009
38694-10	166.	0.232	0.220	4.920	1.034	0.280	0.312	0.068	0.027	0.006	0.011
38696-06	134.	0.218	0.208	4.748	1.068	0.269	0.433	0.067	0.041	0.008	0.015
38696-01	140.	0.247	0.204	4.376	0.918	0.242	0.364	0.044	0.028	0.003	0.011
38695-04	147.	0.233	0.217	4.501	1.063	0.269	0.366	0.054	0.029	0.005	0.010
38694-02	178.	0.387	0.226	4.669	1.161	0.287	0.358	0.065	0.030	0.007	0.009
38698-07	179.	0.252	0.215	5.214	0.945	0.313	0.308	0.050	0.025	0.006	0.006
38697-04	157.	0.212	0.203	4.859	0.939	0.332	0.450	0.062	0.029	0.007	0.008
38699-08	162.	0.320	0.273	4.686	1.045	0.273	0.401	0.043	0.026	0.006	0.008
38699-06	164.	0.167	0.156	4.791	0.979	0.276	0.283	0.051	0.025	0.006	0.008
38698-06	157.	0.187	0.178	4.859	1.153	0.318	0.289	0.058	0.025	0.006	0.008
38697-05	188.	0.183	0.169	5.160	0.925	0.321	0.380	0.042	0.021	0.006	0.006
38702-09	159.	0.225	0.214	5.190	1.036	0.246	0.356	0.060	0.029	0.007	0.010
38703-01	143.	0.279	0.249	4.882	0.990	0.266	0.436	0.046	0.025	0.005	0.008
38701-03	152.	0.180	0.169	4.521	1.084	0.316	0.373	0.052	0.030	0.006	0.009
MEAN	161.	0.233	0.204	4.872	1.025	0.287	0.366	0.053	0.027	0.006	0.009
S.D.	17.0	0.0595	0.0325	0.3374	0.0761	0.0279	0.0517	0.0097	0.0047	0.0012	0.0022
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 5/4/2007

TABLE 25

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-023

FEMALE GROUP: 50 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38694-06	169.	0.440	0.211	5.205	1.167	0.299	0.327	0.044	0.027	0.006	0.013
38695-10	177.	0.299	0.246	5.440	1.145	0.320	0.363	0.053	0.031	0.006	0.011
38696-07	131.	0.227	0.216	4.629	0.969	0.278	0.365	0.053	0.028	0.005	0.014
38696-09	146.	0.391	0.231	5.187	0.910	0.296	0.404	0.040	0.027	0.005	0.008
38694-05	167.	0.138	0.127	4.962	1.036	0.411	0.299	0.051	0.023	0.006	0.010
38695-05	158.	0.284	0.235	4.541	1.235	0.274	0.332	0.045	0.037	0.006	0.012
38697-02	157.	0.146	0.136	5.242	1.036	0.297	0.344	0.038	0.021	0.004	0.007
38698-09	150.	0.288	0.214	5.018	1.142	0.264	0.401	0.063	0.032	0.008	0.007
38699-01	158.	0.199	0.190	5.083	0.995	0.277	0.270	0.054	0.026	0.007	0.008
38699-10	165.	0.212	0.201	5.201	1.056	0.258	0.345	0.050	0.025	0.007	0.007
38698-01	174.	0.407	0.212	4.698	1.044	0.329	0.406	0.046	0.028	0.006	0.006
38697-09	157.	0.203	0.191	4.590	1.043	0.264	0.456	0.049	0.033	0.007	0.009
38703-04	168.	0.139	0.129	5.599	1.110	0.364	0.381	0.056	0.021	0.007	0.007
38700-01	157.	0.238	0.227	5.144	1.007	0.285	0.325	0.058	0.019	0.007	0.007
38701-06	158.	0.151	0.140	4.482	0.950	0.349	0.411	0.040	0.024	0.005	0.009
MEAN	159.	0.251	0.194	5.001	1.056	0.304	0.362	0.049	0.027	0.006	0.009
S.D.	11.6	0.0993	0.0409	0.3416	0.0886	0.0432	0.0488	0.0072	0.0050	0.0011	0.0025
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 25

PROJECT NO.:WIL-187060 FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-023

FEMALE GROUP: 200 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38696-02	143.	0.147	0.130	5.690	1.178	0.281	0.286	0.060	0.033	0.008	0.015
38695-06	129.	0.153	0.141	5.588	1.087	0.286	0.292	0.036	0.025	0.005	0.012
38694-08	145.	0.145	0.135	5.450	1.117	0.243	0.310	0.038	0.031	0.006	0.016
38696-05	115.	0.157	0.143	5.100	1.086	0.271	0.327	0.041	0.030	0.005	0.011
38695-09	135.	0.154	0.143	5.368	1.117	0.307	0.312	0.043	0.036	0.005	0.014
38694-03	163.	0.172	0.156	5.105	1.127	0.303	0.295	0.046	0.031	0.007	0.014
38697-06	156.	0.140	0.131	5.778	1.032	0.237	0.320	0.028	0.027	0.005	0.006
38699-05	144.	0.199	0.191	5.840	1.082	0.265	0.316	0.057	0.039	0.007	0.010
38698-10	160.	0.128	0.121	5.153	0.923	0.293	0.248	0.025	0.024	0.005	0.007
38699-04	174.	0.148	0.137	5.459	1.189	0.259	0.332	0.030	0.027	0.008	0.008
38698-02	179.	0.139	0.131	5.593	0.977	0.287	0.255	0.027	0.029	0.006	0.007
38697-01	146.	0.151	0.139	5.190	1.154	0.287	0.326	0.032	0.027	0.006	0.009
38703-05	166.	0.129	0.122	6.526	1.047	0.238	0.347	0.033	0.025	0.006	0.006
38702-02	140.	0.130	0.122	5.802	0.960	0.331	0.349	0.035	0.027	0.005	0.009
38701-10	150.	0.096	0.090	5.565	1.049	0.339	0.306	0.026	0.027	0.005	0.008
MEAN	150.	0.146	0.135	5.547	1.075	0.282	0.308	0.037	0.029	0.006	0.010
S.D.	17.1	0.0227	0.0213	0.3698	0.0782	0.0309	0.0293	0.0107	0.0042	0.0011	0.0034
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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Modified: 5/4/2007

PROJECT NO.:WIL-187060
SPONSOR: [redacted]
SPONSOR NO.:06-023

TABLE 25
FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: 800 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38695-08	127.	0.150	0.142	7.865	1.223	0.207	0.179	0.031	0.035	0.006	0.016
38696-10	130.	0.160	0.147	8.223	1.034	0.219	0.237	0.024	0.035	0.005	0.012
38694-01	161.	0.139	0.126	8.422	1.023	0.252	0.235	0.024	0.029	0.005	0.013
38695-03	133.	0.161	0.148	7.449	0.971	0.258	0.189	0.027	0.027	0.006	0.011
38697-10	141.	0.170	0.161	8.308	1.027	0.278	0.238	0.034	0.032	0.009	0.009
38699-09	163.	0.131	0.121	8.459	0.996	0.215	0.216	0.022	0.026	0.007	0.008
38700-07	159.	0.131	0.125	9.486	0.971	0.307	0.201	0.029	0.020	0.004	0.008
MEAN	145.	0.149	0.139	8.316	1.035	0.248	0.214	0.027	0.029	0.006	0.011
S.D.	15.7	0.0156	0.0149	0.6277	0.0869	0.0368	0.0244	0.0043	0.0054	0.0016	0.0029
N	7	7	7	7	7	7	7	7	7	7	7

FBW = FINAL BODY WEIGHT

POFBWv4.14
11/09/2006
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APPENDIX A

Certificate Of Analysis (Sponsor-Provided Data)

Revised Audited Draft

[redacted]

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Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Amber viscous liquid

Storage Conditions
Ambient

Expiration Date
1 January 2007

Additional Comments
None

[redacted]

13 September 2006
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

Revised Audited Draft

APPENDIX C

Animal Room Environmental Conditions

Revised Audited Draft

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Modified: 11/15/2006

FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
TEMPERATURE/HUMIDITY REPORT BY STUDY

PROJECT NO [redacted] 187060
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187060

DATE IN: 09/12/06 TIME IN: 11:00
DATE OUT: 10/18/06 TIME OUT: 9:00

ROOM SPECIFICATIONS: B ROOM 32
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
12-Sep-06	70.9	21.6	46.6
13-Sep-06	70.8	21.5	46.7
14-Sep-06	71.0	21.7	46.4
15-Sep-06	71.0	21.6	45.6
16-Sep-06	70.7	21.5	45.3
17-Sep-06	71.0	21.7	45.9
18-Sep-06	70.9	21.6	46.3
19-Sep-06	70.9	21.6	43.5
20-Sep-06	70.9	21.6	39.7
21-Sep-06	70.5	21.4	37.7
22-Sep-06	70.8	21.6	43.1
23-Sep-06	70.7	21.5	46.4
24-Sep-06	70.8	21.6	44.9
25-Sep-06	70.3	21.3	40.3
26-Sep-06	71.0	21.7	42.5
27-Sep-06	70.4	21.3	45.6
28-Sep-06	70.8	21.5	42.9
29-Sep-06	71.0	21.7	36.9
30-Sep-06	70.7	21.5	41.6
01-Oct-06	70.7	21.5	41.8
02-Oct-06	70.7	21.5	42.8
03-Oct-06	70.8	21.5	45.3
04-Oct-06	70.5	21.4	47.7

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

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Modified: 11/15/2006

FEMALE PUBERTAL ASSAY OF [redacted] IN JUVENILE RATS
TEMPERATURE/HUMIDITY REPORT BY STUDY

PROJECT NO [redacted] 187060
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187060

DATE IN: 09/12/06 TIME IN: 11:00
DATE OUT: 10/18/06 TIME OUT: 9:00

ROOM SPECIFICATIONS: B ROOM 32
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
05-Oct-06	70.7	21.5	41.0
06-Oct-06	70.6	21.4	39.1
07-Oct-06	70.9	21.6	40.0
08-Oct-06	70.8	21.5	42.4
09-Oct-06	70.6	21.4	46.5
10-Oct-06	70.5	21.4	45.3
11-Oct-06	70.9	21.6	46.8
12-Oct-06	70.6	21.4	39.0
13-Oct-06	70.7	21.5	39.3
14-Oct-06	70.9	21.6	38.8
15-Oct-06	70.5	21.4	38.9
16-Oct-06	70.4	21.3	39.3
17-Oct-06	70.8	21.6	44.8
18-Oct-06	71.0	21.7	45.0

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.7	70.3	71.0
TEMPERATURE °C	21.5	21.3	21.7
HUMIDITY (%RH)	43.0	36.9	47.7
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

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Modified: 11/15/2006

ROOM SPECIFICATIONS:	B ROOM 32		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	09/12/06
HIGH TEMPERATURE:	76.0	TIME IN:	11:00
LOW HUMIDITY:	30.0	DATE OUT:	10/18/06
HIGH HUMIDITY:	70.0	TIME OUT:	9:00

ROOM B ROOM 32 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.7	42.9
MIN	69.0	34.2
MAX	73.0	62.1
SD	1.06	3.85
N SAMPLES	862	862
FIRST DAY	09/12/06	
LAST DAY	10/18/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

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STUDY 187060 SUMMARY

MEAN	70.7	42.9
MIN	69.0	34.2
MAX	73.0	62.1
SD	1.06	3.85
N SAMPLES	862	862
FIRST DAY	09/12/06	
LAST DAY	10/18/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

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APPENDIX D

Clinical Pathology, Methods, Procedures And References

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CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Immunoassay- DPC Immulite®

Estradiol (estradiol-17β) - Competitive Immunoassay for the quantitative measurement of estradiol in serum. Default unit: pg/mL.

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

Immunoassay-GAMMA-C12 Gamma Counter (continued)

Rat Luteinizing Hormone (rLH) - ^{125}I radioimmunoassay system for the quantitative determination of (rLH) DPC GAMMA C-12 gamma counter. Default unit: mIU/mL. Biotrak™ rat luteinizing hormone [^{125}I] assay system©. Amersham Life Science Ltd. Package Insert.

Rat Thyroid Stimulating Hormone (rTSH) - ^{125}I assay system with magnetic separation for the quantitative measurement of (rTSH). DPC GAMMA C-12 gamma counter. Biotrak™ rat thyroid stimulating hormone ^{125}I assay system. Amersham Pharmacia Biotech. Package insert.

References:

Immulite®. Diagnostics Products Corporation. Package Insert.

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APPENDIX E

Pathology Report (WIL Research Laboratories, LLC)

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A FEMALE PUBERTAL ASSAY OF [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

PATHOLOGY REPORT

Pathology Department

WIL Research Laboratories, LLC

Revised Audited Draft

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1. INTRODUCTION

The objective of this study was to evaluate the ability of the test article to induce effects on pubertal development in the intact juvenile female rat.

2. STUDY DESIGN

Female Crl:CD(SD) rats were administered [redacted] via oral gavage as single daily doses beginning on postnatal day (PND) 22 and continuing through PND 41. All animals were dosed at approximately the same time each day (after 12:00 pm). The dosage volume was 5 mL/kg for all groups.

Group Number	Test Article	Dosage Level (mg/kg/day)	Number of Females
1	Corn Oil	0	15
2	[redacted]	10	15
3		50	15
4		200	15
5		800	15

All surviving animals were euthanized by carbon dioxide inhalation on PND 42.

3. METHODS

3.1. HORMONE ANALYSES

Following euthanasia on PND 42, blood was collected from the vena cava of from all animals that survived until scheduled euthanasia. All blood samples were allowed to clot, processed to generate serum and then placed in an ice bath. The following hormone concentrations were determined from all serum samples:

Thyroid Stimulating Hormone (TSH)
Estradiol
Thyroxine (Total T4)
Luteinizing Hormone (Lutein' Hormone)

( ) - Designates tabular abbreviation

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3.2. ANATOMIC PATHOLOGY

3.2.1. MACROSCOPIC EXAMINATION

Complete postmortem examinations were performed on all animals found dead, or at the scheduled necropsies. At the scheduled necropsy, animals were euthanized by carbon dioxide inhalation. At the time of necropsy, the following tissues and organs were collected and placed in 10% neutral-buffered formalin fixative unless otherwise noted:

- Axillary Lymph Node
- Cervix and Uterine Body (1 longitudinal section)
- Ovaries
- Pituitary
- Spleen
- Thymus
- Thyroid with parathyroids
- Uterine horns (4 sections per horn)
- Vagina
- All gross (internal) lesions (when possible)

3.2.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsy:

- Adrenal glands
- Kidneys
- Liver
- Ovaries and oviducts
- Pituitary gland
- Spleen
- Thymus
- Thyroid with parathyroids *

Paired organs were weighed together. Designated (*) organs were weighed after fixation. Organ-to-final-body-weights were calculated.

In addition, wet and blotted uterine weights were measured for all animals that survived to the scheduled necropsy. The uterus harvesting and weighing procedure was performed as described below.

1) Animal was euthanized and uterus harvested.
2) Uterus (with luminal fluid) was immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3) The uterus' wet weight was recorded to the nearest 0.1 mg.

4) The uterus was opened and blotted.
5) The uterus was placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6) The uterus' blotted weight was recorded to the nearest 0.1 mg.

3.2.3. MICROSCOPIC EXAMINATION

Microscopic examination of routinely prepared hematoxylin-eosin stained paraffin sections was performed on the cervix and uterine body (1 longitudinal section), ovaries, thyroids with parathyroids and uterine horns (4 sections per horn) collected at necropsy from all animals in the 0, 200 and 800 mg/kg/day groups.

The stained histologic sections were examined by routine light microscopy and histologic observations were entered in the WIL Toxicology Data Management System (WTDMS™) by the pathologist at the time of examination. At the time of histologic examination, all gross necropsy observations were addressed. Due to sectioning difficulties or minor laboratory errors, the number of tissues examined from each dosage group does not necessarily correlate with the number of animals included in the group. The number of missing tissues was small and did not interfere with detection of test article-related histologic alterations in the study. The histologic sections were of adequate size and quality for detailed histologic evaluation. The WTDMS™ histopathology tables contain a record of tissues examined and histologic findings, and serve as the basis for this narrative report. Histopathologic lesions were classified using standard published terminology to the extent possible.

3.3. ABBREVIATIONS

The following abbreviations may apply to this report:

Interval - point in the study at which an animal died or was euthanized
FD - found dead
SN - scheduled necropsy

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3.4. DATA INTERPRETATION

In the discussion of hormones, values derived from the control group animals were considered as concurrent control values for purposes of constructing a 'normal' range for the present study. Unless otherwise stated in this report, the 'normal' historical control range was considered to be the mean value ± 2 standard deviations. This narrative report addresses all clinical pathology values that were identified as statistically significantly different from control group values on the clinical pathology data tables.

In the discussion of organ weight changes, the indication of higher or lower mean organ weights refers to a statistically significant ($p<0.05$ or $p<0.01$ using Dunnett's test) difference between test article-treated versus control group animals in the present study. In addition, historical control values for this laboratory were consulted to refine data interpretation. This narrative report addresses all organ weight values that were identified as statistically significantly different from control group values on the organ weight data tables.

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4. RESULTS

4.1. SURVIVAL

Eight 800 mg/kg/day females were found dead prior to the scheduled necropsy. The causes of death were undetermined because only reproductive organs, thyroids and parathyroids were provided for microscopic examination. All other rats survived until the scheduled necropsy without clinical signs of distress or physiologic impairment.

4.2. HORMONE ANALYSES

There were no test article-related effects or statistically significant differences on analyzed hormone levels.

4.3. GROSS OBSERVATIONS

Review of the gross necropsy observations revealed the following test article-related alterations:

Text Table 1. Toxicologically Relevant Gross Necropsy Observations

Organ	Observation	Dosage Level(s) (mg/kg/day)	Sex	Interval(s)
Ovaries	(A) small	800	F	SN
		200	F	SN
Uterus	(B) contents, clear fluid	800	F	FD
Histologic correlates	(A) Corpora lutea absence (B) Dilatation			

Descriptions of test article-related histologic alterations are discussed in Section 4.5. (Histologic Changes).

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4.4. ORGAN WEIGHTS

The following organ weight changes were considered to be test article-related:

Text Table 2. Toxicologically Relevant Organ WeightS

Organ	Direction and magnitude of change	Dosage Level(s) (mg/kg/day)	Sex	Interval	Histologic Correlate
Ovaries/Oviducts					
absolute relative to FBW	↓15.9%* ↓16.9%*	50	F	SN	No correlate
absolute relative to FBW	↓41.5%** ↓37.3%**	200	F	SN	Corpora lutea absence
absolute relative to FBW	↓58.0%** ↓54.2%**	800	F	SN	Corpora lutea absence
Uterus-Blotted					
absolute relative to FBW	↓40.0%** ↓36.3%**	200	F	SN	No correlate
absolute relative to FBW	↓40.9%** ↓34.4%**	800	F	SN	Atrophy[a]
Uterus-Wet					
absolute relative to FBW	↓48.2%** ↓45.3%**	200	F	SN	No correlate
absolute relative to FBW	↓49.0%** ↓44.2%**	800	F	SN	Atrophy[a]
Liver					
relative to FBW	↑8.4%*	200	F	SN	NA (Not examined)
absolute relative to FBW	↑46.7%** ↑62.5%**	800	F	SN	NA (Not examined)
Spleen					
absolute relative to FBW	↓22.9%** ↓15.1%*	800	F	SN	NA (Not examined)
Thymus					
absolute relative to FBW	↓22.7%** ↓17.6%**	200	F	SN	NA (Not examined)
absolute relative to FBW	↓47.8%** ↓42.8%**	800	F	SN	NA (Not examined)

* = Significantly ($p<0.05$) different from the control group using Dunnett's test.
** = Significantly ($p<0.01$) different from the control group using Dunnett's test.
FBW = Final body weight. NA = Not available.
[a] = One rat from scheduled necropsy in this group had uterine atrophy.

There were no other test article-related effects on organ weights.

4.5. HISTOLOGIC CHANGES

4.5.1. CHANGES ASSOCIATED WITH TEST ARTICLE ADMINISTRATION

Histopathologic effects attributable to test article administration are tabulated in Text Table 3. Fourteen of 15 rats from 800 mg/kg/day group had absent corpora lutea. This effect was accompanied by moderate (9 of 15 rats) and severe (6 of 15 rats) granulosa cell necrosis, and moderate (10 of 15 rats) to severe (5 of 15 rats) oocyte degeneration. In the 200 mg/kg/day group, there were 9 rats with absent corpora. Fourteen rats from this group had mild granulosa cell necrosis, and 1 rat had moderate granulosa cell necrosis.

The uterus of 7 rats from the 800 mg/kg/day group that were found dead had mild (4 of 14 rats) to severe (3 of 14 rats) atrophy, consisting of decreased endometrial and myometrial thickness as well as a reduced number of endometrial glands. The atrophic glandular epithelial cells had an inactive appearance with a reduced amount of cytoplasm. All the examined tissues from the control group were microscopically normal.

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Text Table 3. Incidence Of Selected Histopathologic Findings

Dosage (mg/kg/day)	0	200	800
Ovaries [a]	15	15	15
Corpora lutea absent, bilateral	0	9	14
Necrosis, granulosa cell, bilateral	0	15	15
Mild	0	14	0
Moderate	0	1	9
Severe	0	0	6
Degeneration, oocyte, bilateral	0	15	15
Mild	0	14	0
Moderate	0	1	10
Severe	0	0	5
Uterus [a]	15	15	14 [b,c]
Atrophy	0	0	7
Mild	0	0	4
Severe	0	0	3

[a] = Number of tissues examined from each group.
[b] = Missing 1 uterus and cervix at the tissue trim.
[c] = Only noted for females that were found dead

4.5.2. CHANGES OF UNCERTAIN RELATIONSHIP TO TEST ARTICLE ADMINISTRATION

Mild follicular cell hypertrophy was noted in the thyroid glands of 3 rats from the 800 mg/kg/day group that were found dead.

4.5.3. CHANGES UNRELATED TO TEST ARTICLE ADMINISTRATION

In the 800 mg/kg/day group, there was mild focal necrosis in ectopic thymic tissue that was present in the thryoid gland section of 1 rat that was found dead, and minimal focal lymphocytic infiltration was present in the thyroid gland of 1 rat that was euthanized at the scheduled termination. Remaining histologic changes were considered to be incidental findings, manifestations of spontaneous diseases, or related to some aspect of

experimental manipulation other than administration of the test article. There was no test article-related alteration in the incidence, severity or histologic character of those incidental and spontaneous tissue alterations.

5. DISCUSSION

Chemicals can cause type I toxicity characterized by an absence of corpora lutea and impairment of follicular development (Yuan and Foley, 2002). In those cases, atrophy of uterus is secondary to deficiency of ovarian steroid hormone (Yuan and Foley, 2002). The histologic changes present in this study indicated the test article had effects on reproductive organs. The mild hypertrophy of thyroids that was seen in 3 rats from the 800 mg/kg/day group was of concern, but the low incidence and mild degree of histologic alteration and no statistically significant differences on analyzed hormone levels prohibited a conclusion with regard to the etiology of the alteration. Lymphocytic infiltration in the thyroid gland of 1 rat was incidental finding. The lesion was minimal focal and the adjacent thyroid parenchyma were normal. The mild focal necrosis of thymus of 1 rat was also incidental finding. Individual necrotic cells in thymus are common (Stefanski, et al., 1990). The organ weight changes of liver, spleen and thymus may be test article related, but this interpretation can not be confirmed without histopathological evaluations.

6. CONCLUSIONS

Female Crl:CD(SD) rats were administered [redacted] via oral gavage as single daily doses beginning on post-natal day (PND) 22 and continuing through PND 41. Groups 1-5 were administered the test article at dosages of 0, 10, 50, 200 and 800 mg/kg/day, respectively. Thyroid stimulating hormone (TSH), thyroxine (T_4), estradiol (E_2) and luteinizing hormone (LH) were determined on PND 42. There were no test article-related effects or statistically significant differences on analyzed hormone levels.

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The reproductive organs (ovaries, uterus, and cervix), thyroids and parathyroids were examined grossly and histopathologically. The 800 mg/kg/day dosage level resulted in complete absence of corpora lutea in 14 of 15 rats. All ovaries in this group had moderate to severe granulosa cell necrosis and moderate to severe oocyte degeneration. Mild to severe atrophy of the uterus was present in 7 rats in the 800 mg/kg/day group. In the 200 mg/kg/day group, similar but milder morphologic changes in ovaries were present. Both absolute and relative to final body weight organ weights of ovary and uterus from both the 200 and 800 mg/kg/day groups were significantly lower than control group ($p<0.01$or $p<0.05$). Collectively, histopathologic evaluations and organ weight data indicated that test article when given orally at dosages of 200 and 800mg/kg/day had mild to severe effects on the reproductive tract of intact juvenile female rats.

7. REFERENCES

Yuan YD. and Foley GL. Female Reproductive System. In: *Handbook of Toxicologic Pathology.* 2nd ed. Academic Press. **2002;** P 847-889.

Stefanski SA, Elwell MR and Stromberg PC. Spleen, Lymph nodes, and Thymus. In: *Pathology of the Fisher Rat.* Academic Press. **1990**; P 369-393.

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8. REPORT SUBMISSION

Report Submitted By:

[redacted]
Study Clinical Pathologist

Date

[redacted]
Study Pathologist

Date

Report Reviewed By:

[redacted]
Reviewing Pathologist

Date

Revised Audited Draft

APPENDIX F

Pathology Peer Review Statement (WIL Research Laboratories, LLC)

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WIL Study No. 187060

Peer Review Statement

A peer review of histopathology data was performed as follows for this study:

1. All processed tissues and diagnoses were reviewed from five numbered female rats selected randomly from the control and high dose groups. Identification numbers for the control animals evaluated were 38694-07, 38695-01, 38694-04, 38697-03 and 38702-05 and for the high-dose animals were 38695-08, 38694-01, 38695-03, 38699-09 and 38700-07.

2. Potential target organs for which all diagnoses were verified from all animals in all treatment groups were as follows: ovary, uterus, cervix and vagina.

Following review of the microscopic findings reported by the study pathologist, the results were discussed and appropriate terminology and diagnoses were mutually agreed upon. Differences of opinion between the study and reviewing pathologists were resolved with agreement on the final diagnoses. The tables contained in the final report reflect the mutually agreed-upon diagnoses.

[redacted]

Reviewing Pathologist

13 April 2007

Date

APPENDIX G

WIL Female Pubertal Assay Historical Control Data Version 1.1 [Crl:CD(SD) Rats]

Revised Audited Draft

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WIL Research Laboratories, LLC Historical Control

FEMALE PUBERTAL ASSAYS - Crl:CD(SD) RATS

	Grand Mean	SD	N	Min	Max	25th Quartile	75th Quartile
Vaginal Patency (PND)	33.7	1.3	11	31.8	36.5	33.0	34.4
Body Weight At Patency (g)	110.9	4.4	11	102.1	116.4	108.5	114.1
Estrous Cycle Length (days)	5.1	0.4	10	4.8	6.1	4.9	5.2
Age At First Estrus (PND)	35.6	1.4	11	34.1	38	34.5	36.4
T4 (µg/dL)	4.6	0.5	7	3.89	5.23	4.3	5.0
TSH (ng/mL)	9.0	1.7	7	7.3	11.4	7.8	10.4
Estradiol (pg/mL)	138	24	2	121	155	130	147
Luteinizing Hormone (ng/mL)	3.5	0.3	2	3.3	3.7	3.4	3.6
Uterus - Wet (g)	0.3542	0.0528	11	0.2932	0.4400	0.3149	0.4026
Uterus - Blotted (g)	0.2930	0.0296	11	0.2621	0.3610	0.2764	0.3079
Luminal Fluid (g)	0.0619	0.0272	11	0.0306	0.1001	0.0383	0.0894
Liver (g)	7.6484	0.6662	11	6.6900	8.9920	7.2418	7.9729
Kidney (g)	1.6135	0.0358	7	1.5682	1.6573	1.5874	1.6389
Ovaries/Oviducts (g)	0.0835	0.0048	10	0.0769	0.0940	0.0804	0.0855
Adrenal Glands (g)	0.0381	0.0035	11	0.0321	0.0428	0.0365	0.0405
Pituitary (g)	0.0086	0.0008	11	0.0074	0.0101	0.0080	0.0092
Thyroid Glands (g)	0.0163	0.0029	7	0.0129	0.0213	0.0143	0.0178
Spleen (g)	0.4386	0.0062	2	0.4342	0.4430	0.4364	0.4408
Thymus Glands (g)	0.6013	0.0170	2	0.5892	0.6133	0.5952	0.6073

Version 1.1 - 16 November 2006

APPENDIX H

WIL Reproductive Historical Control Data Version 2.4 [Crl:CD(SD) Rats]

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Reproductive Performance

Sex: Male/Female | Species: Rat | Number of Studies/Data Sets: 62 / 96
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Total	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Number of Males in Control Group	1600						
Male Mating Index (%)		96.8	3.69	61	89.42 / 100.00	85.73 / 100.00	86.7 / 100.0
Male Fertility Index (%)		89.8	6.89	61	76.02 / 100.00	69.13 / 100.00	72.0 / 100.0
Male Copulation Index (%)		92.7	6.08	61	80.54 / 100.00	74.46 / 100.00	75.0 / 100.0
Number of Females in Control Group	2248						
Female Mating Index (%)		97.8	3.26	73	91.28 / 100.00	88.02 / 100.00	86.7 / 100.0
Female Fertility Index (%)		91.3	7.17	82	76.96 / 100.00	69.79 / 100.00	72.0 / 100.0
Female Conception Index (%)		92.9	5.82	73	81.26 / 100.00	75.44 / 100.00	75.0 / 100.0
Number of Females Selected to Deliver	1301						
Number that Delivered	1151						
Number that did not Deliver	145						
Number with Total Litter Loss	11						
Number with Dystocia	3						

Version 2.4
23-Aug-06

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WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Reproductive Performance

Sex: Female | Species: Rat | Number of Studies/Control Groups: 62 / 96

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Mean Estrous Cycle Length (days)	4.5	0.41	63	3.68 / 5.32	3.27 / 5.73	4.0 / 5.8
Mean Pre-Coital Interval (days)	3.0	0.52	74	1.96 / 4.04	1.44 / 4.56	1.8 / 4.7
Mean Gestation Length (days)	21.9	0.20	46	21.50 / 22.30	21.30 / 22.50	21.5 / 22.3
Mean Number of Pups Born	14.3	0.91	46	12.48 / 16.12	11.57 / 17.03	12.2 / 16.0
Mean Viable Litter Size (PND 0)	14.1	0.94	46	12.22 / 15.98	11.28 / 16.92	12.0 / 16.0
Mean % Males/ Litter	50.08	2.78	58	44.52 / 55.64	41.74 / 58.42	42.7 / 58.5
Mean % Females/ Litter	49.92	2.78	58	44.36 / 55.48	41.58 / 58.26	41.5 / 57.3
Mean No. of Former Implantation Sites at Weaning	15.2	0.87	44	13.46 / 16.94	12.59 / 17.81	13.2 / 17.1
Mean No. of Sites Unaccounted for at Weaning	0.9	0.24	44	0.00 / 1.38	0.18 / 1.62	0.4 / 1.4
Mean Viable Embryos/Dam (GD 15)	14.9	0.79	25	13.32 / 16.48	12.53 / 17.27	13.5 / 16.3
Mean Viable Embryos (%/Litter)	95.0	1.84	25	91.32 / 98.68	89.48 / 100.00	90.0 / 97.1
Mean Viable Fetuses/Dam (GD 20)	14.3	0.79	16	12.72 / 15.88	11.93 / 16.67	13.0 / 15.6
Mean Viable Fetuses (%/Litter)	94.6	1.34	16	91.92 / 97.28	90.58 / 98.62	91.9 / 96.8
Mean Post-Implantation Loss/Dam	0.8	0.24	41	0.32 / 1.28	0.08 / 1.52	0.4 / 1.5
Mean Post-Implantation Loss (%/Litter)	5.1	1.65	41	1.80 / 8.40	0.15 / 10.05	2.9 / 10.0
Mean No. of Corpora Lutea/Dam	16.7	0.88	41	14.94 / 18.46	14.06 / 19.34	15.3 / 18.8
Mean No. of Implantation Sites/Dam	15.3	0.81	41	13.68 / 16.92	12.87 / 17.73	13.9 / 16.8
Mean Pre-Implantation Loss/Dam	1.4	0.41	41	0.58 / 2.22	0.17 / 2.63	0.5 / 2.1
Mean Pre-Implantation Loss (%/Litter)	8.2	2.42	41	3.36 / 13.04	0.94 / 15.46	2.7 / 13.8
Mean Fetal Body Weight (GD 20) (g)	3.6	0.16	16	3.28 / 3.92	3.12 / 4.08	3.3 / 3.8
Mean Primordial Follical Count of 10 Sections/Dam	115.2	31.74	11	51.72 / 178.68	19.98 / 210.42	50.4 / 148.8

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Survival Indices (%)

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Age Range: 0 - 21 Days
Number of Studies/Data Sets: 62 / 96
Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Number of Pups Born	14.3	0.91	46	12.48 / 16.12	11.57 / 17.03	12.2 / 16.0
Survival (%)						
PND 0 (Relative to No. Born)	98.0	1.53	46	94.94 / 100.00	93.41 / 100.00	93.3 / 100.0
PND 0 to PND 1	99.1	0.89	46	97.32 / 100.00	96.43 / 100.00	95.8 / 100.0
PND 1 to PND 4 (Before Selection)	98.6	1.33	45	95.94 / 100.00	94.61 / 100.00	94.1 / 100.0
PND 4 (After Selection) to PND 7	98.9	1.76	44	95.38 / 100.00	93.62 / 100.00	91.7 / 100.0
PND 7 to PND 14	99.3	1.46	41	96.38 / 100.00	94.92 / 100.00	93.5 / 100.0
PND 14 to PND 21	99.5	1.11	41	97.28 / 100.00	96.17 / 100.00	94.7 / 100.0
Birth to PND 4 (Before Selection)	95.8	2.26	43	91.28 / 100.00	89.02 / 100.00	86.6 / 98.7
PND 4 (After Selection) to PND 21	97.8	2.50	40	92.80 / 100.00	90.30 / 100.00	91.1 / 100.0

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Body Weights (g)

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Age Range: 1 - 28 Days
Number of Studies/Data Sets: 62 / 96
Range of Study Dates: 08/00 - 09/05

Males (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	7.1	0.25	46	6.60 / 7.60	6.35 / 7.85	6.7 / 7.6
PND 4	10.0	0.58	45	8.84 / 11.16	8.26 / 11.74	9.0 / 11.4
PND 7	15.3	1.22	44	12.86 / 17.74	11.64 / 18.96	11.9 / 17.5
PND 14	30.4	3.70	36	23.00 / 37.80	19.30 / 41.50	20.2 / 35.3
PND 21	47.5	5.18	41	37.14 / 57.86	31.96 / 63.04	32.8 / 56.7
PND 28 (weaned PND 28)	82.0	6.86	15	68.28 / 95.72	61.42 / 102.58	69.8 / 94.0

Females (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	6.7	0.25	46	6.20 / 7.20	5.95 / 7.45	6.3 / 7.3
PND 4	9.5	0.56	45	8.38 / 10.62	7.82 / 11.18	8.6 / 10.9
PND 7	14.5	1.17	44	12.16 / 16.84	10.99 / 18.01	11.3 / 16.7
PND 14	29.2	3.46	36	22.28 / 36.12	18.82 / 39.58	20.3 / 33.9
PND 21	45.6	4.76	41	36.08 / 55.12	31.32 / 59.88	32.8 / 53.5
PND 28 (weaned PND 28)	75.8	6.11	15	63.58 / 88.02	57.47 / 94.13	66.7 / 86.2

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Organ Weights (PND 21)

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Age: 21 Days
Number of Studies/Number Data Sets: 62 / 96
Range of Study Dates: 08/00 - 09/05

Males

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Brain (g)	1.4397	0.04072	21	1.35826 / 1.52114	1.31754 / 1.56186	1.3451 / 1.4899
Spleen (g)	0.2058	0.03054	21	0.14472 / 0.26688	0.11418 / 0.29742	0.1471 / 0.2480
Thymus (g)	0.1963	0.02035	21	0.15560 / 0.23700	0.13525 / 0.25735	0.1617 / 0.2330

Females

Brain (g)	1.3931	0.03322	21	1.32666 / 1.45954	1.29344 / 1.49276	1.3142 / 1.4378
Spleen (g)	0.2020	0.03048	21	0.14104 / 0.26296	0.11056 / 0.29344	0.1471 / 0.2448
Thymus (g)	0.1987	0.02387	21	0.15096 / 0.24644	0.12709 / 0.27031	0.1669 / 0.2547

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WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Developmental Landmarks

Sex: Male/Female | Species: Rat | Number of Studies/Control Groups: 62 / 96

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Male Anogenital Distance (PND1) (mm)	4.37	0.171	6	4.028 / 4.712	3.857 / 4.883	4.1 / 4.7
Mean Female Anogenital Distance (PND1) (mm)	2.38	0.175	6	2.030 / 2.730	1.855 / 2.905	2.1 / 2.6
Mean Day of Balanopreputial Separation	44.8	1.30	31	42.20 / 47.40	40.90 / 48.70	42.0 / 49.0
Mean Body Weight at Aquisition (g)	225.9	9.72	31	206.46 / 245.34	196.74 / 255.06	203.7 / 246.8
Mean Day of Vaginal Patency	33.6	1.05	31	31.50 / 35.70	30.45 / 36.75	31.7 / 37.0
Mean Body Weight at Aquisition (g)	111.9	6.42	31	99.06 / 124.74	92.64 / 131.16	99.5 / 127.4
Mean Day of Surface Righting Response						
Males	5.0	0.06	3	4.88 / 5.12	4.82 / 5.18	5.0 / 5.1
Females	5.2	0.10	3	5.00 / 5.40	4.90 / 5.50	5.1 / 5.3
Mean Day of Pinnal Detachment						
Males	4.1	0.15	4	3.80 / 4.40	3.65 / 4.55	4.0 / 4.3
Females	4.1	0.10	4	3.90 / 4.30	3.80 / 4.40	4.0 / 4.2
Mean Day of Eye Opening						
Males	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Females	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Mean Day of Air Drop Righting Reflex						
Males	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Females	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Mean Day of Hair Growth						
Males	13.5	1.43	4	10.64 / 16.36	9.21 / 17.79	11.7 / 15.0
Females	13.6	1.51	4	10.58 / 16.62	9.07 / 18.13	11.8 / 15.2
Mean Day of Incisor Eruption						
Males	9.9	0.41	5	9.08 / 10.72	8.67 / 11.13	9.3 / 10.4
Females	9.9	0.34	5	9.22 / 10.58	8.88 / 10.92	9.3 / 10.2

Version 2.4

23-Aug-06

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Male and Female Organ Weights (Necropsy)

Sex: Male/Female | Species: Rat | Number of Studies/Number Data Sets: 62 / 96
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

Males	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Age of Males at Necropsy (weeks)	22.2	4.20	27	13.80 / 30.60	9.60 / 34.80	16.4 / 30.6
Mean Seminal Vesicle/Coagulating Gland Weight (g)	2.21	0.169	36	1.872 / 2.548	1.703 / 2.717	1.82 / 2.57
Mean Prostate Weight (g)	1.07	0.102	22	0.866 / 1.274	0.764 / 1.376	0.76 / 1.27
Mean Right Testis Weight (g)	1.79	0.069	48	1.652 / 1.928	1.583 / 1.997	1.66 / 1.93
Mean Left Testis Weight (g)	1.80	0.077	48	1.646 / 1.954	1.569 / 2.031	1.67 / 2.09
Mean Right Epididymis Weight (g)	0.72	0.041	48	0.638 / 0.802	0.597 / 0.843	0.63 / 0.80
Mean Left Epididymis Weight (g)	0.72	0.041	48	0.638 / 0.802	0.597 / 0.843	0.62 / 0.78
Mean Right Cauda Epididymis Weight (g)	0.3275	0.02230	48	0.28290 / 0.37210	0.26060 / 0.39440	0.2629 / 0.3693
Mean Left Cauda Epididymis Weight (g)	0.3309	0.02064	48	0.28962 / 0.37218	0.26898 / 0.39282	0.2714 / 0.3706
Females						
Mean Age of Females at Necropsy (weeks)	23.2	5.03	19	13.14 / 33.26	8.11 / 38.29	16.0 / 32.0
Mean Combined Ovary Weight (g)	0.1448	0.03004	19	0.08472 / 0.20488	0.05468 / 0.23492	0.0926 / 0.1779

Version 2.4
23-Aug-06

Revised Audited Draft

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Sperm Concentration and Morphology

Sex: Male/Female | Species: Rat | Number of Studies/Control Groups: 62 / 96
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

Mean Sperm Concentration (millions/ gram of tissue)	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Left Testis	80.9	7.33	43	66.24 / 95.56	58.91 / 102.89	68.2 / 96.6
Left Epididymis	454.5	49.37	37	355.76 / 553.24	306.39 / 602.61	339.1 / 619.2
Left Cauda Epididymis	666.2	57.99	7	550.22 / 782.18	492.23 / 840.17	568.0 / 738.9
Mean Sperm Production Rate (millions/ gram of tissue/ day)	13.4	1.21	23	10.98 / 15.82	9.77 / 17.03	11.4 / 15.8
Mean Sperm Motility (%)	85.4	3.01	44	79.38 / 91.42	76.37 / 94.43	78.9 / 91.0
Mean Progressive Sperm Motility (%)	72.5	3.70	15	65.10 / 79.90	61.40 / 83.60	67.0 / 80.0
Sperm Morphology Differential Count (%)						
Normal	99.1	0.81	43	97.48 / 100.00	96.67 / 100.00	96.1 / 99.9
Normal Head Separated from Flagellum	0.4	0.40	43	0.00 / 1.20	0.00 / 1.60	0.1 / 1.8
Head Absent w/ Normal Flagellum	0.3	0.39	43	0.00 / 1.08	0.00 / 1.47	0.0 / 2.3
Head Absent w/ Abnormal Flagellum	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Misshapen Head w/ Normal Flagellum	0.0	0.17	43	0.00 / 0.34	0.00 / 0.51	0.0 / 1.1
Misshapen Head w/ Abnormal Flagellum	0.0	0.06	43	0.00 / 0.12	0.00 / 0.18	0.0 / 0.4
Degenerative Flagellar Defects w/ Normal Head	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Other Flagellar Defects w/ Normal Head	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0

Version 2.4
23-Aug-06

APPENDIX I

Study Protocol

Revised Audited Draft

Revised Audited Draft

Study Number: WIL-187060

PROTOCOL AMENDMENT II

Sponsor: [redacted]

Sponsor No.: 06-023

A. Title:

A Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **9.3 Microscopic Examination:**

The second paragraph is changed to read:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the following tissues from the 0, 200 and 800 mg/kg/day animals.

C. Reason for Protocol Modifications:

1) The client has authorized microscopic examination of the preserved tissues.

Approved By:

[redacted]

19 Jan 07
Date

WIL Research Laboratories, LLC

[redacted]

18 Jan 2007
Date

[redacted]

18 Jan 2007
Date

Reproductive Toxicology

Study Number: WIL-187060

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor No.: 06-023

A. Title:

A Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **3** **STUDY SCHEDULE:**

Proposed Audited Report Date: January 4, 2007

2) **7.6.3** **Vaginal Perforation:**

The first sentence is changed to the following:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 23 (Adams, 1985).

C. Reason for Protocol Modifications:

1) The proposed audited report date has been determined.

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2) To correct the postnatal day on which to begin observation for vaginal perforation to PND 23.

Approved By:

[redacted]

22 Sept 2006
Date

WIL Research Laboratories, LLC

[redacted]

20 Sept. 2006
Date

[redacted]

20 Sept. 2006
Date

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PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 06-023

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

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1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test article to induce effects on pubertal development in the intact juvenile female rat.

This study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF), Law No. 82, 1984, Good Laboratory Practice (GLP) Standards. The study will be performed according to the protocol and WIL Standard Operating Procedures.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representatives:

[redacted]

2.2 Principal Invesitgator-Dose Formulation Analysis:

[redacted]

2.3 WIL Study Director:

[redacted]

2.4 WIL Deputy Director:

2.5 WIL Departmental Responsibilities:

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3 STUDY SCHEDULE:

Proposed Animal Receipt Date: (Experimental Starting Date)	September 12, 2006
Proposed Experimental Start Date:	September 26, 2006
Proposed Experimental Termination/Completion Date:	October 18, 2006
Proposed Audited Report Date:	To be determined.

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

4.2 Lot Number:

To be determined.

4.3 Purity:

100%

4.4 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.5 Physical Description:

To be determined.

4.6 Storage Conditions:

Store at ambient conditions.

4.7 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

4.8 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Crl:CD(SD)

5.3 Source:

Charles River Laboratories
Raleigh, NC

5.4 Number on Study:

Seventy-five females (maximum of 100 females and 10 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 6-8 days old upon receipt. Pups not expected to survive to the next observation period (moribund) will be euthanized by intraperitoneal injection of sodium pentobarbital (prior to PND11) or by carbon dioxide inhalation (after PND11) and the carcass discarded. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and the carcasses discarded.

5.5 Body Weight Range:

At randomization: 30-50 g for immature females. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal ear tag displaying the animal number. The pups will be identified by tail tattoo.

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Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal. Following randomization the pups will be individually identified by an ear tag.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed O'Cobs®). Following randomization, the juvenile female animals will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. Control animals (Group 1) will be housed on a separate rack from exposed animals. Exposed animals from a companion study, housed concurrently in the same animal room, will also be housed on a separate rack. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL standard operating procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12 hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL

Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Each lot utilized will be identified and recorded. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean. Each of 5 groups will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

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7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel, ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses, or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1	Corn Oil	0	0	5	15
2	[redacted]	10	2	5	15
3	[redacted]	50	10	5	15
4	[redacted]	200	40	5	15
5	[redacted]	800	160	5	15

7.4.2 Vehicle Control Article:

Corn oil.

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 and continuing through 41 days of age. All animals will be dosed at approximately the same time each day, after 12:00 p.m., and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

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7.5 Preparation and Analysis of Test Article Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly and stored at room temperature. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration, if possible. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] c/o [redacted], for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed

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by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The method employed will be listed in the analytical report.

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

7.6 General Observations During the Experimental Period:

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will also be observed at the time of dosing and again approximately one hour after administration. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded. Findings noted outside of the scheduled observation time periods will be recorded at the time they are observed.

7.6.2 Body Weights:

Body weights will be recorded individually (to the nearest 0.1 gram PND 22-42) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will be performed at approximately the same time each day and will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will be performed at approximately the same time each day (with the exception

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that the lavage performed on the day of necropsy will be collected immediately prior to euthanasia) and will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized by carbon dioxide inhalation and necropsied as described in section 9.

8 HORMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples (target volume of 2mL) will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH)	Thyroxine (T_4)
Estradiol (E_2)	Lutenizing Hormone (LH)

9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized *in extremis*. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete necropsy will not be conducted on animals surviving to study termination. Gross lesions (i.e., masses) will be collected and placed in 10% neutral-buffered formalin. The following tissues will be collected and placed in 10% neutral-buffered formalin:

Axillary Lymph Node	Spleen
Cervix and Uterine Body (one longitudinal section)	Thymus
	Thyroid with parathyroids
Ovaries	Uterine Horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

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9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized *in extremis*.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in a round-robin order. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).
5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex.

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Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

9.2.2 Ovary, Liver, Pituitary, Kidney, Spleen, Thymus, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Pituitary gland
Kidneys	Spleen
Liver	Thymus
Ovaries and oviducts	Thyroid with parathyroids (following fixation)

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 <u>Microscopic Examination:</u>

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination. The vagina, ovaries, and thyroids with parathyroids from each animal will be similarly preserved.

Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

Cervix and Uterine Body (one longitudinal section)	Thyroids with parathyroids
Ovaries	Uterine Horns (four sections per horn)

10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

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11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, organ weights relative to body weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age at first estrous, estrous cycle length, and serum hormone concentrations will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol, protocol amendments and WIL Standard Operating Procedures. The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF) Law No. 82, 1984, Good Laboratory Practices (GLP) Standards. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

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15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories, LLC will provide one copy of an audited draft report, submitted in a timely manner upon completion of the study prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R and one paper copy will be provided. Requests for additional paper copies of the final report may result in additional charges.

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has

provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via e-mail on September 5, 2006.

[redacted]

11Sept06
Date

WIL Research Laboratories, LLC

[redacted]

7 Sept. 2006
Date

Study Director

[redacted]

7Sept. 2006
Date

Reproductive Toxicology

Revised Audited Draft

COMPANY SANITIZED

REVISED ABBREVIATED AUDITED DRAFT

STUDY TITLE

A FEMALE PUBERTAL ASSAY OF [ ]
ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

STUDY NUMBER

WIL-187061

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

7 September 2006

STUDY COMPLETION DATE

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

SPONSOR STUDY NUMBER

06-025

SPONSOR

[ ]
[ ]
[ ]
[ ]

COMPLIANCE STATEMENT

This study, designated WIL-187061, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) Good Laboratory Practice Standards Law No. 82, 1984; the standard operating procedures of WIL Research Laboratories, LLC, and the protocol as approved by the sponsor. **A Certificate of Analysis was provided by the sponsor (presented in Appendix A); the characterization analyses were conducted according to Good Laboratory Practices (GLP) [sponsor-supplied documentation required]. Stability of the test article to be addressed by the sponsor.**

_____ _____

[ ]
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Date

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the ability of the test article to induce effects on pubertal development in the intact juvenile female rat.

1.2. STUDY DESIGN

[,] in the vehicle, Mazola® corn oil, was administered orally by gavage once daily for 20 consecutive days to 4 groups each of 15 Crl:CD(SD) immature female rats. Dosage levels were 10, 50, 200 and 800 mg/kg/day, and the dosage volume was 5 mL/kg. A concurrent control group received the vehicle on a comparable regimen. These dosage levels were determined from the results of previous studies and were provided by the sponsor representative after consultation with the WIL study director. **Stability of the test article to be addressed by the sponsor.**

Dosing procedures were performed from 26 September 2006 through 17 October 2006, when the animals were 22 to 41 days of age; the start of dose administration was staggered, based on age. At the initiation of dose administration, individual body weights ranged from 40.7 g to 63.7 g. The following table presents the study group assignment:

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Females
1*	Corn Oil	0	0	5	15
2		10	2	5	15
3		50	10	5	15
4		200	40	5	15
5		800	160	5	15

*The control group data was collected under a companion study (WIL-187060). Record of dose administration was collected under WIL-187060 and transferred to the computer protocol for this study.

Dose administration and sampling procedures for the vehicle control group were conducted under a companion study Preparation, storage and sampling of the test article formulations were conducted as follows. The appropriate amount of test article for each group was weighed into a tared, calibrated glass container. A stir bar and approximately 80% of the vehicle were added to each container, and the mixtures were stirred until uniform. The appropriate volume of vehicle was added to bring each formulation to the calibration mark, and the preparations were stirred until uniform and throughout use. The test article formulations were prepared approximately weekly, divided into aliquots for daily dispensation and stored at room temperature. Three sets of samples from the top, middle and bottom strata of the test article formulations were collected prior to the initiation of dose administration. Additional samples (3 sets) were collected for resuspension homogeneity from the same formulations following 10 days of room temperature storage. Two sets of samples for concentration verification were collected on each day of preparation and 2 sets were collected on the last day of use of each preparation. Two sets of homogeneity/stability samples and 6 sets of concentration samples were shipped under ambient conditions to the sponsor for homogeneity, stability and concentration analyses; the remaining samples were stored under normal laboratory conditions at WIL Research Laboratories, LLC for possible future analysis.

Eight dams with 10 female pups each (80 pups total) were received from Charles River Laboratories, Inc., Raleigh, North Carolina, on 12 September 2006. The pups were 6 to 8 days old upon receipt. Pups were initially identified by tail tattoo, housed in plastic maternity cages (by litter with their own or a fostering dam for 14 to 16 days) during the acclimation period until randomization of the pups on postnatal day (PND) 21. Following randomization, the female pups were weaned, identified by metal eartag and housed 3 per cage in plastic maternity cages. Environmental controls were set to maintain an average daily temperature of 71°F ± 5°F and an average daily relative humidity of 50% ± 20%. Actual mean daily temperatures ranged from 70.3°F to 71.0°F

(21.3°C to 21.7°C) and mean daily relative humidity ranged from 36.9% to 47.7%. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide approximately 10 fresh air changes per hour. PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002 and reverse osmosis-purified water were offered ad libitum.

All animals were observed twice daily for appearance, behavior, mortality and moribundity. A detailed physical examination was performed at the time of randomization. The rats were also observed daily (prior to dosing). Clinical findings at the time of dose administration and approximately 1 hour following dose administration were recorded when observed. Individual body weights were recorded daily. Each female pup was observed daily for vaginal patency beginning on PND 23 (Adams et al., 1985). Examination continued daily until vaginal patency was observed. Body weights were recorded on the day that vaginal patency was noted. Beginning on the day that vaginal patency was observed, vaginal lavages were performed daily, through the day of euthanasia, and the slides were examined to determine the stage of estrus. The mean estrous cycle length was calculated and reported for complete estrous cycles (i.e., the total number of returns to metestrus [M] or diestrus [D] from estrus [E] or proestrus [P] until the day of euthanasia). Estrous cycle length was determined by counting the number of days from the first M or D in a cycle to the first M or D in a subsequent cycle. In addition, the mean age at the onset of the first estrous cycle was calculated using the first day each animal was observed to be in estrus. A complete gross necropsy was performed only on animals that were found dead. All surviving animals were euthanized on PND 42 by carbon dioxide inhalation; blood was collected via the vena cava for evaluation of serum estradiol (E_2), luteinizing hormone (LH), thyroxine (T_4) and thyroid stimulating hormone (TSH) levels. The uterus (wet and blotted), kidneys, liver, ovaries and oviducts, pituitary gland, spleen, adrenal glands, thymus gland and thyroid glands (with parathyroid glands) were weighed at the scheduled euthanasia. Luminal fluid weight was calculated by subtracting the blotted uterus weight from the wet uterus

weight. The adrenal glands, axillary lymph nodes, ovaries, oviducts, uterus (horns and body), cervix, vagina, kidneys, liver, spleen, thymus gland, pituitary gland, thyroid glands (with parathyroid glands) and internal gross lesions were examined from all females, including those found dead; all of these tissues were retained with the exception of the adrenal glands, kidneys and liver. Microscopic examination was performed on the cervix and uterine body, ovaries, thyroids with parathyroids and uterine horns from all animals in the control, 200 and 800 mg/kg/day groups.

Statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. In addition, percent difference from control is presented for body weights, clinical pathology parameters and organ weights. Statistical analyses were not conducted if the number of animals was 2 or less. Due to the different rounding conventions inherent in the types of software used, the means and standard deviations on the summary and individual tables may differ by ±1 in the last significant figure. Mean body weights, body weight changes, days of acquisition of vaginal patency, estrous cycle lengths, ages at the first occurrence of estrus, serum hormone levels, luminal fluid weights and absolute and relative organ weights were subjected to a parametric one-way analysis of variance (ANOVA; Snedecor and Cochran, 1980) to determine intergroup differences. If the ANOVA revealed statistically significant ($p<0.05$) intergroup variance, Dunnett's test (Dunnett, 1964) was used to compare the test article-treated groups to the control group.

1.3. KEY STUDY DATES

Date(s)	Event(s)
12 September 2006	Experimental starting date (animal receipt)
26 September 2006	Experimental start date (first day of dose administration)
26 September – 17 October 2006	Test article administration
12 April 2007	Experimental termination/completion date (last microscopic examination)

1.4. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC, as specified in the study protocol. Data generated by the sponsor will be archived by the sponsor or the sponsor's designee.

Reserve samples of the test article, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

1.5. RESULTS

Brown material on various body surfaces (primarily urogenital and anogenital areas) and hunched posture were noted in the 800 mg/kg/day group at the daily examinations beginning as early as PND 23; hunched posture was also observed at the time of and 1 hour following dose administration. These findings were attributed to the test article. Clear material around the mouth was noted in the 200 and 800 mg/kg/day groups 1 hour following dose administration beginning as early as PND 31 and 27, respectively. This finding was attributed to the test article, but was not considered adverse because it was not observed prior to administration of the daily dose on the following day. Salivation prior to dose administration was also observed in the 200 and 800 mg/kg/day groups beginning as early as PND 27 and 28, respectively; however, this finding was not

considered adverse because it was not observed prior to administration of the daily dose on the following day.

Eleven females in the 800 mg/kg/day group were found dead at 24-28 days of age as a result of test article administration. All females were found dead on the morning after the previous daily dose. Findings noted in the 800 mg/kg/day group animals that died (in addition to those noted above) included eyelids that were half-closed and rocking, lurching or swaying while ambulating for a single animal on PND 23; 2 females had red material around the nose on PND 24. At necropsy, 1 female each in this group had a small spleen and clear fluid contents in the uterus. All other females survived to the scheduled necropsy.

Lower mean body weight gains (PND 22-23 and 25-26) and mean body weight losses (PND 23-24 and 24-25) were noted in the 800 mg/kg/day group during the first 4 days of dose administration. The differences from the control group values were statistically significant ($p<0.01$). Throughout the remainder of the dosing period (following the deaths of the most sensitive females), sporadically lower mean body weight gains were observed in this group; the difference was statistically significant ($p<0.01$) during PND 29-30. When the entire treatment period (PND 22-42) was evaluated, a lower ($p<0.05$) mean body weight gain was observed in the 800 mg/kg/day group compared to the control group value. As a result of the decrements in mean body weight gain, mean body weights in this group were 9.7% to 24.5% lower than the control group values from PND 23-42. The differences were statistically significant ($p<0.05$ or $p<0.01$) from PND 24-41. Mean body weight gains in the 200 mg/kg/day group were similar to those in the control group during PND 22-23 through 26-27. Slightly lower (not statistically significant) mean body weight gains were noted in this group compared to the control group generally throughout the remainder of the study; however, there were often no dose-related trends in comparison to the 800 mg/kg/day group (N=4), as the most sensitive animals in that group had died prior to the onset of lower body weight gains in the 200 mg/kg/day group. The lower mean body weight gains (not statistically

significant) in the 200 mg/kg/day resulted in a slightly lower mean body weight gain when the entire treatment period (PND 22-42) was evaluated and mean body weights that were 5.0% to 9.8% lower than the control group values during PND 30-42. The differences in mean body weight were statistically significant ($p<0.05$ or $p<0.01$) during PND 34-41. Mean body weights and body weight gains in the 10 and 50 mg/kg/day groups were generally similar to those in the control group throughout the study. The only statistically significant ($p<0.01$) difference from the control group was a higher mean body weight gain in the 10 mg/kg/day group observed during PND 41-42.

The mean age of attainment of vaginal patency in the 50, 200 and 800 mg/kg/day groups was earlier than in the control group; this change was attributed to the test article. The differences from the concurrent control group were statistically significant ($p<0.05$ or $p<0.01$). Mean ages of attainment were 32.5, 32.3, 29.3, 29.2 and 29.4 days in the control, 10, 50, 200 and 800 mg/kg/day groups, respectively. The values in the 50, 200 and 800 mg/kg/day groups were also lower than the mean minimum value in the WIL historical control data for female pubertal studies (31.8 days of age). Mean body weights at the age of attainment (87.3 g, 86.1 g and 71.6 g) in the 50, 200 and 800 mg/kg/day groups, respectively, were statistically significantly ($p<0.01$) lower than the concurrent control group value (111.9 g); the values were also below the minimum mean value in the WIL historical control data (102.1 g).

Consistent with an earlier age of attainment of vaginal patency, the ages of the first occurrence of estrus in the 50, 200 and 800 mg/kg/day groups (31.6, 32.1 and 29.4 days of age, respectively) were earlier than in the concurrent control group (34.4 days of age); the difference in the 800 mg/kg/day group was statistically significant ($p<0.05$). These values were also lower than the minimum mean value in the WIL historical control data (34.1 days of age). Estrous cycle lengths could only be determined for 5/15, 9/15, 12/15, 10/15 and 2/4 females in the control, 10, 50, 200 and 800 mg/kg/day groups, respectively, due to a high number of females with incomplete cycles. No differences in estrous cycle lengths were noted in the 10, 50 and 200 mg/kg/day groups with the number of cycling

animals available for evaluation. Estrous cycle lengths in females of this age are highly variable. Abnormal estrous cycles (≥5 consecutive days of diestrus [D] or ≥3 consecutive days estrus [E]) were noted in 6/15, 6/15, 8/15, 14/15 and 3/4 females in the control, 10, 50, 200 and 800 mg/kg/day groups, respectively, as presented in the following table.

Text Table 1: Number of Females with Abnormal Estrous Cycles

Group (mg/kg/day)	Number with Extended D	Number with Extended E	Number with Both Extended E and D
0	6/15	0/15	0/15
10	6/15	0/15	0/15
50	6/15	2/15	0/15
200	10/15	6/15	2/15
800	0/4	3/4	0/4

All females in the control and 10 mg/kg/day groups with abnormal estrous cycles had extended diestrus, whereas a shift toward extended estrus was noted in the 200 and 800 mg/kg/day groups. The persistent estrus in the 50, 200 and 800 mg/kg/day groups was consistent with elevated estradiol levels and earlier attainment of vaginal patency in these groups.

Test article-related higher mean TSH and E_2 levels were observed in the 800 mg/kg/day group; the differences from the control group were statistically significant ($p<0.01$). Mean T_4 and LH levels in this group were not statistically significantly different compared to the control group values. No test article-related effects on serum hormones were noted in the 10, 50 and 200 mg/kg/day groups; differences from the control group were not statistically significant.

Test article-related, generally statistically significant ($p<0.05$ or $p<0.01$) increases in mean absolute and relative (to final body weight) liver weights (800 mg/kg/day group) and decreases in mean absolute pituitary gland weight (800 mg/kg/day group), absolute and/or relative spleen, luminal fluid, wet and blotted uterus and thymus gland (200 and 800 mg/kg/day groups) and absolute and relative ovary/oviduct weights (200 and

800 mg/kg/day groups) were observed compared to the control group values. In addition, lower, generally statistically significant ($p<0.05$) mean absolute and relative ovary/oviduct weights were observed in the 10 and 50 mg/kg/day groups; however, there was no dose-response relationship. The following table presents these changes.

Text Table 2: Summary of Test Article-Related Effects on Absolute Organ Weight [G] with Percent Difference from the Control Group

Organ	0 mg/kg/day	10 mg/kg/day	50 mg/kg/day	200 mg/kg/day	800 mg/kg/day
Liver	8.2487	7.9599 (-3.5%)	7.7336 (-6.2%)	7.6668 (-7.1%)	12.1067** (+46.8%)
Spleen	0.4681	0.4814 (+2.8%)	0.4170 (-10.9%)	0.3917* (-16.3%)	0.3555* (-24.1%)
Wet Uterus	0.4201	0.3166 (-24.6%)	0.3398 (-19.1%)	0.2170** (-48.3%)	0.2229* (-46.9%)
Blot. Uterus	0.3371	0.2761* (-18.1%)	0.2863 (-15.1%)	0.1988** (-41.0%)	0.2071** (-38.6%)
Luminal Fluid	0.0829	0.0405 (-51.1%)	0.0535 (-35.5%)	0.0182 (-78.0%)	0.0158 (-80.9%)
Thymus	0.5948	0.5931 (-0.3%)	0.5735 (-3.6%)	0.5127* (-13.8%)	0.2482** (-58.3%)
Ovary	0.0936	0.0796* (-15.0%)	0.0793* (-15.3%)	0.0603** (-35.6%)	0.0441** (52.9%)
Pituitary	0.0097	0.0093 (-4.1%)	0.0094 (-3.1%)	0.0085 (-12.4%)	0.0074* (-23.7%)

Blot. = Blotted, Ovary = Ovaries/Oviducts
* = $p<0.05$ ** = $p<0.01$

One female each in the 800 mg/kg/day group had small ovaries/oviducts and a small thymus gland at necropsy, corresponding to the lower ovary and thymus gland weights noted in this group. Mean absolute and relative blotted uterus weight in the 10 mg/kg/day group and mean relative wet uterus weight in the 10 mg/kg/day group were statistically significantly ($p<0.05$) lower than the control group values; however, no dose-related trend was evident. Therefore, the decreases in the wet and blotted uterus weights in this group were not considered test article-related.

Degeneration of oocytes, necrosis of granulosa cells in the ovarian follicles and complete absence or decrease in the number of corpora lutea were noted in the ovaries of rats

administered the test article at dosage levels 200 and 800 mg/kg/day, corresponding to the lower mean ovary weights observed in these groups..

In all of the female rats (15/15) administered the test article at the highest dosage level (800 mg/kg/day), all of the ovaries were completely devoid of corpora lutea. Corpora lutea were occasionally completely absent (1/15) or reduced in number (3/15) in rats from the 200 mg/kg/day group.

An increase in severity of microscopic alterations (as mentioned above) was observed in the ovaries of rats in the 800 mg/kg/day group, relative to rats administered the test article at 200 mg/kg/day. Because the severity of the microscopic alterations correlated with increasing dosage level, these microscopic alterations were considered to be test article-related.

Microscopic alterations present in the uterus of rats administered the test article were most consistent with atrophy affecting primarily the muscular and mucosal tunics characterized by reduced thickness of the tunica muscularis and/or tunica mucosa or generalized reduction in size of the organ due to symmetric atrophy of all of the tunics. The uterine atrophy was more severe in rats administered the test article at 800 mg/kg/day versus 200 mg/kg/day. Additionally, mild (4/15) to moderate (4/15) atrophy of the cervix was present in rats from the 800 mg/kg/day group. This alteration was also attributed to administration of the test article.

Microscopic alterations in ovaries, uterus and cervix considered to be related to administration of the test article are summarized in the following table.

Text Table 3. Summary Of Microscopic Findings

Tissue	0 mg/kg/day	200 mg/kg/day	800 mg/kg/day
Ovaries [a]	15	15	15
Corpora Lutea Absent	0	1	15
Decreased corpora lutea	0	3	0
Mild	0	1	0
Severe	0	2	0
Granulosa cell necrosis	0	14	15
Minimal	0	5	0
Mild	0	8	2
Moderate	0	1	13
Oocyte degeneration	0	14	15
Mild	0	1	2
Moderate	0	13	9
Severe	0	0	4
Uterus [a]	15	15	15
Atrophy	0	8	15
Minimal	0	5	0
Mild	0	3	4
Moderate	0	0	11
Cervix [a]	15	15	15
Atrophy	0	0	8
Mild	0	0	4
Moderate	0	0	4

[a] = Number of tissues examined from each group.

Minimal to mild depletion of colloid in the thyroid glands was present in 11/15 rats administered the test article at 800 mg/kg/day. Occasionally, colloid depletion occurred in conjunction with hypertrophy of the follicular epithelial cells, possibly due to enhanced stimulation to the thyroid glands from elevated TSH. Similar microscopic alterations were also present in rats administered the test article at 200 mg/kg/day, albeit at a much reduced frequency (colloid depletion was present in 2/15 rats in this groups). Microscopic alterations in the thyroid gland were also considered related to test article

administration because of the higher frequency and severity of colloid depletion in rats administered the test article at 800 mg/kg/day. Microscopic alterations in thyroid gland considered to be related to administration of the test article are summarized in the following table.

Text Table 4. Summary Of Microscopic Findings In The Thyroid Gland

	0 mg/kg/day	200 mg/kg/day	800 mg/kg/day
Thyroid [a]	15	15	15
Colloid depletion	0	2	11
Minimal	0	2	4
Mild	0	0	7
Follicular cell hypertrophy	0	4	2
Minimal	0	2	0
Mild	0	2	2
Ectopic thymus	0	1	2

[a] = Number of tissues examined from each group.

There were no other test article-related histologic changes. Remaining histologic changes were considered to be incidental findings, manifestations of spontaneous diseases, or related to some aspect of experimental manipulation other than administration of the test article. There was no test article-related alteration in the incidence, severity or histologic character of those incidental and spontaneous tissue alterations.

1.6. CONCLUSIONS

Based on the results of this study, [ ] administered orally to juvenile female rats resulted in estrogenic effects for females at 50, 200 and 800 mg/kg/day as evidenced by earlier attainment of vaginal patency (with corresponding lower mean body weight on the day of attainment) and by earlier age at the first occurrence of estrus. In addition, estrous cycle disturbances were noted in the 50, 200 and 800 mg/kg/day groups with 2/15, 6/15 and 3/4 females, respectively, exhibiting persistent estrus (≥3 consecutive days of estrus). Test article-related increases in mean E_2 and TSH levels were noted in the 800 mg/kg/day group. No test article-related effects on mean serum E_2, LH, T_4 or TSH levels were observed at 10, 50 and 200 mg/kg/day. Mean absolute and relative (to final body weight) wet and blotted uterus weights (and thus,

luminal fluid weight), ovary/oviduct, spleen weights and thymus gland weights in the 200 and 800 mg/kg/day groups were lower than the control group values. Microscopic correlates in the ovary included absence or reduction in the number of corpora lutea, degeneration of oocytes and necrosis of granulosa cells in ovarian follicles in the 200 and 800 mg/kg/day groups. Severity of the ovarian and uterine changes was generally dose-related. Although lower mean absolute and relative ovary/oviduct weights were also noted in the 10 and 50 mg/kg/day groups, no clear indication of an effect was apparent based on the lack of a dose response. Mean absolute and relative liver weights in the 800 mg/kg/day groups were higher than the control group values, and mean absolute pituitary gland weight in this group was lower than the control group value.

2. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

_____ _____
[ ] Date
Staff Toxicologist, Developmental,
Reproductive and Neurotoxicology
Study Director

Report Prepared By:

_____ _____
[ ] Date
Senior Study Analyst

Report Reviewed By:

_____ _____
[ ] Date
Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Associate Director, Developmental and
Reproductive Toxicology

_____ _____
[ ] Date
Senior Study Analyst

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Key Personnel:

Manager, Clinical Pathology
Senior Operations Manager, Vivarium
Manager, Gross Pathology and Developmental Toxicology Laboratory
Group Manager, Formulations Laboratory
Director, Metabolism and Analytical Chemistry
Operations Manager, Developmental and Reproductive Toxicology and the Formulations Laboratory
Manager, Reporting and Regulatory Technical Services

3. QUALITY ASSURANCE UNIT STATEMENT

3.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
06-Oct-2006	Estrous Lavage	06-Oct-2006	27-Nov-2006	
17-Nov-2006, 20-Nov-2006, 21-Nov-2006	Study Records (I-1)	22-Nov-2006	20-Dec-2006	
22-Nov-2006	Study Records (I-2)	22-Nov-2006	20-Dec-2006	
30-Nov-2006, 01-Dec-2006	Study Records (C-1, C-2)	01-Dec-2006	30-Jan-2007	
01-Dec-2006	Study Records (N-1)	01-Dec-2006	30-Jan-2007	
01-Dec-2006	Study Records (RX-1)	01-Dec-2006	30-Jan-2007	
27-Dec-2006, 28-Dec-2006, 29-Dec-2006	Draft Report (without Clinical Pathology Report)	29-Dec-2006	30-Jan-2007	
29-Dec-2006	Draft Report (Clinical Pathology Report)	29-Dec-2006	30-Jan-2007	
08-Feb-2007	Trimming of Tissues	08-Feb-2007	21-Mar-2007	
17, 21-Mar-2007	Study Records (H-1)	21-Mar-2007	23-Apr-2007	
21-Apr-2007	Revised Pathology Report	21-Apr-2007	__-May-2007	
21-Apr-2007	Study Records (P-1)	21-Apr-2007	__-May-2007	
27, 30-Apr-2007	Revised Draft Report	30-Apr-2007	__-May-2007	
30-Apr-2007	Study Records (P-1, supplemental)	30-Apr-2007	__-May-2007	
01-May-2007	Study Records (P-1, supplemental 2)	01-May-2007	__-May-2007	

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice Standards (40 CFR Part 792), the OECD Principles of Good Laboratory Practice, the Japanese MAFF Good Laboratory Practice Standards, the standard operating procedures of WIL Research Laboratories, LLC and the sponsor's protocol and protocol amendment with the following exceptions. The data located in Appendices A (Certificate of Analysis) and B (Analytical Chemistry Report) were the responsibility of the sponsor. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, LLC.

The raw data, the retention sample(s), and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the sponsor.

3.2. APPROVAL

This study was inspected according to the criteria discussed in Section 3.1.

Report Audited By:

_____ _____
[ ] Date
Senior Compliance Specialist

Report Released By:

_____ _____
[ ] Date
Manager, Quality Assurance

4. REFERENCES

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Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

5. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 5.5** states that the females would weigh 30 g to 50 g at the time of randomization, and that body weights for all animals assigned to the study would be within approximately ± 5 g of the mean. The upper limit was extended to 60 g in order to obtain a sufficient number of females for the study. The animals assigned to study were -8.9 g to +11.4 g of the mean.
- **Protocol Section 6.1** states that animals would be housed 3 per cage in plastic maternity cages following weaning. Although PND 21 females were randomized into treatment groups and placed into plastic maternity cages, there is no documentation that females were housed 3 per cage.
- **Protocol Section 7.6.4** states that vaginal lavages would be performed daily to determine the stage of estrous cycle. No estrous slide could be located for female no. 38705-03 in the 10 mg/kg/day group for the day that vaginal patency was observed (PND 33). Therefore, estrous cycle data was not recorded for that female on PND 33.
- **Protocol Section 9.1** states that the ovaries from each animal would be preserved. The oviducts were also retained.
- **Protocol Section 9.3** states that microscopic examinations would be performed on specified tissues. Although not specified by protocol, a peer review of the study pathologist's findings was also conducted.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

FIGURES 1-9

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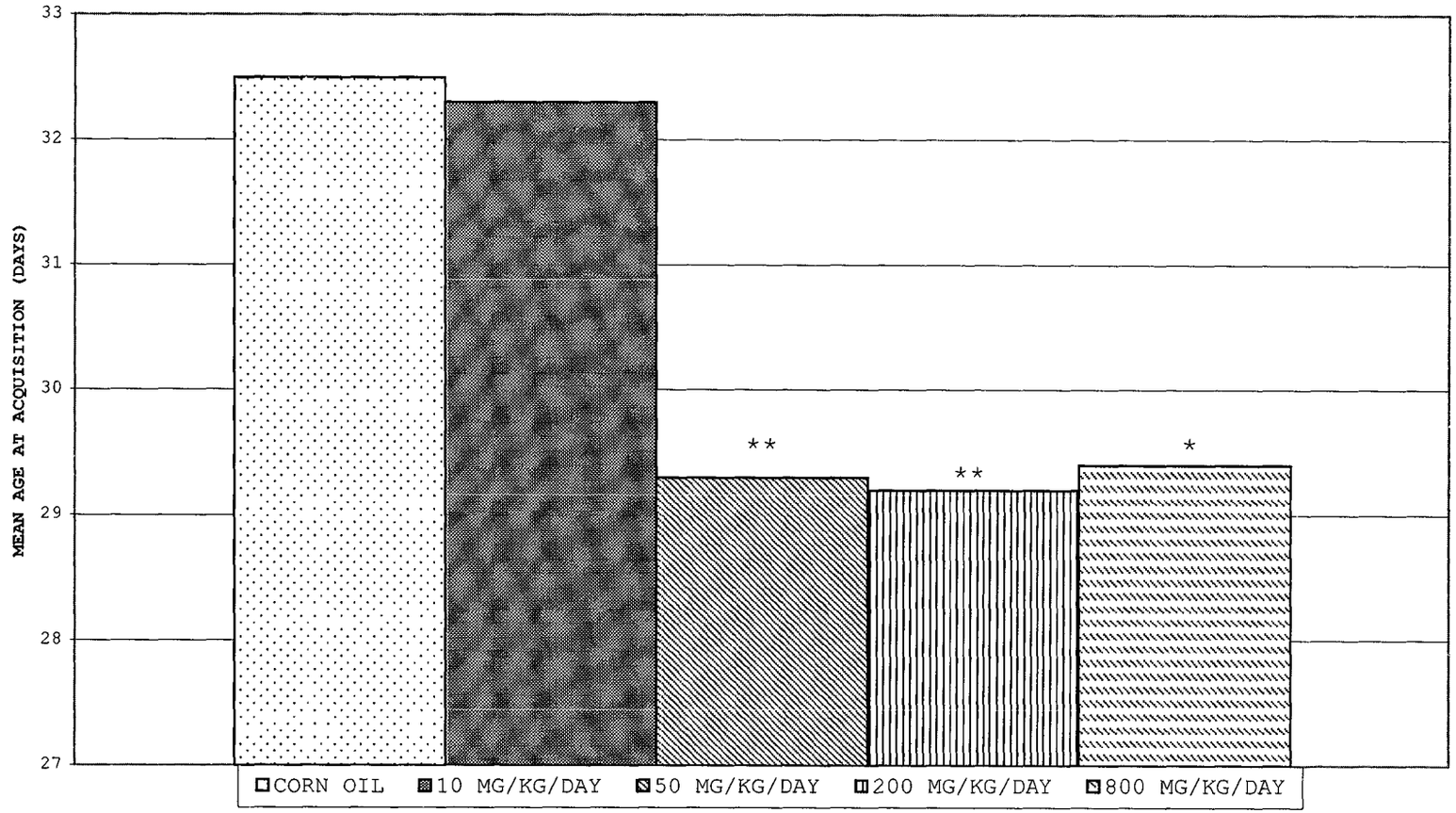
PROJECT [redacted]-187061
SPONSOR: [redacted]
SPONSOR [redacted]025

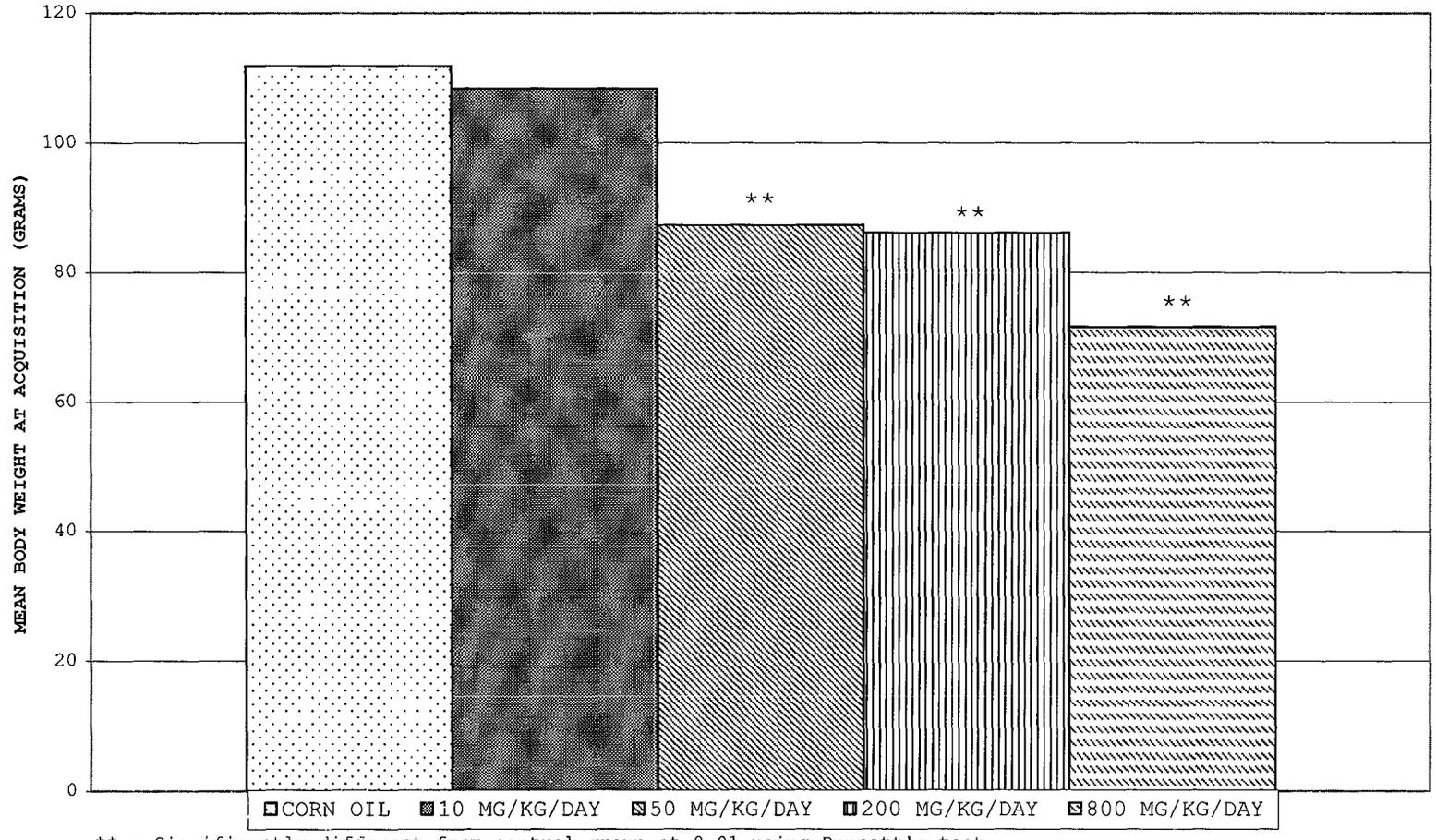
FIGURE 1
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
MEAN AGE (DAYS) AT [redacted]CY



* = Significantly different from control group at 0.05 using Dunnett's test
** = Significantly different from control group at 0.01 using Dunnett's test

PROJECT [redacted]-187061
SPONSOR [redacted]
SPONSOR 025

FIGURE 2
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
MEAN BODY WEIGHT (GRAMS PATENCY



** = Significantly different from control group at 0.01 using Dunnett's test

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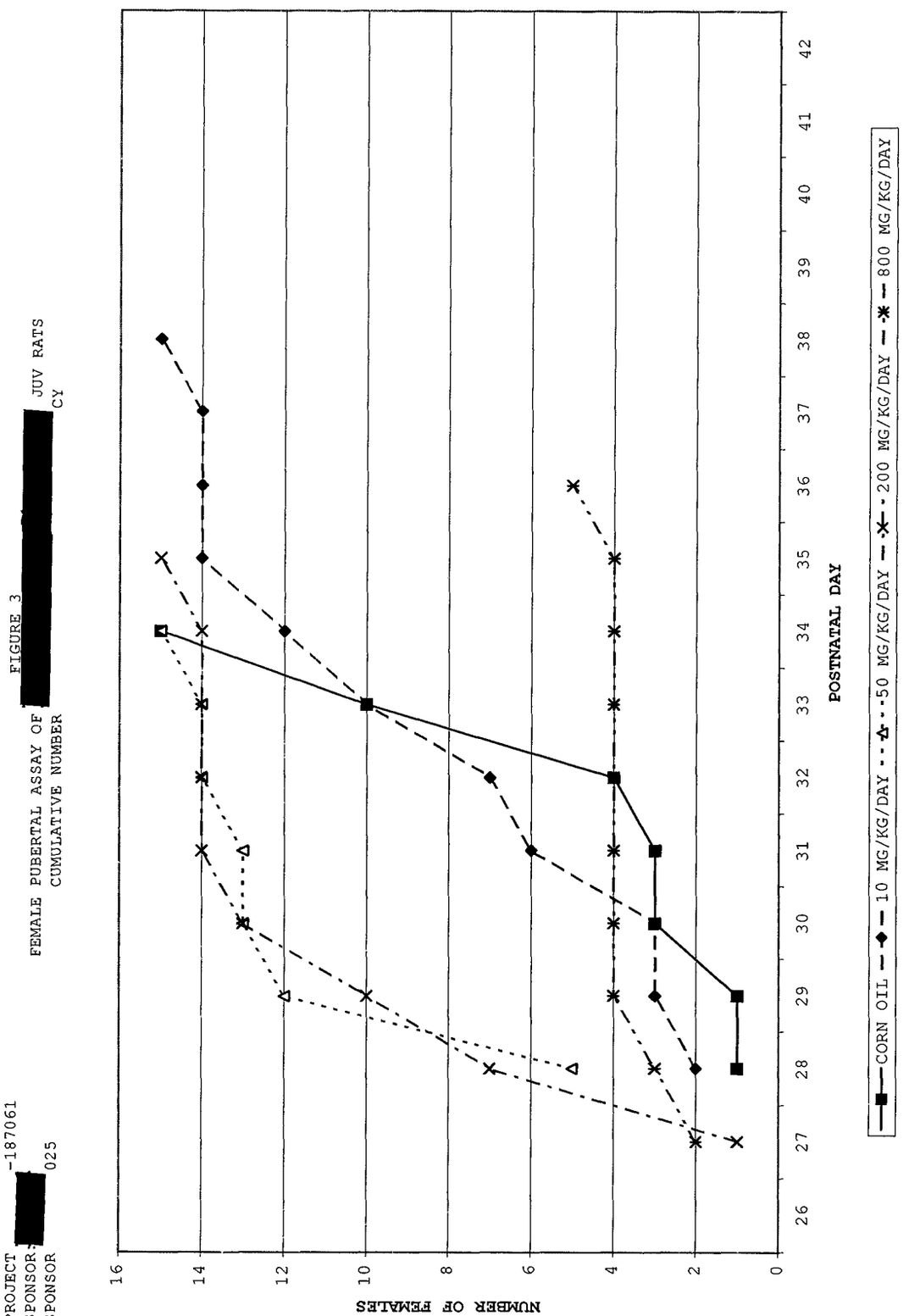

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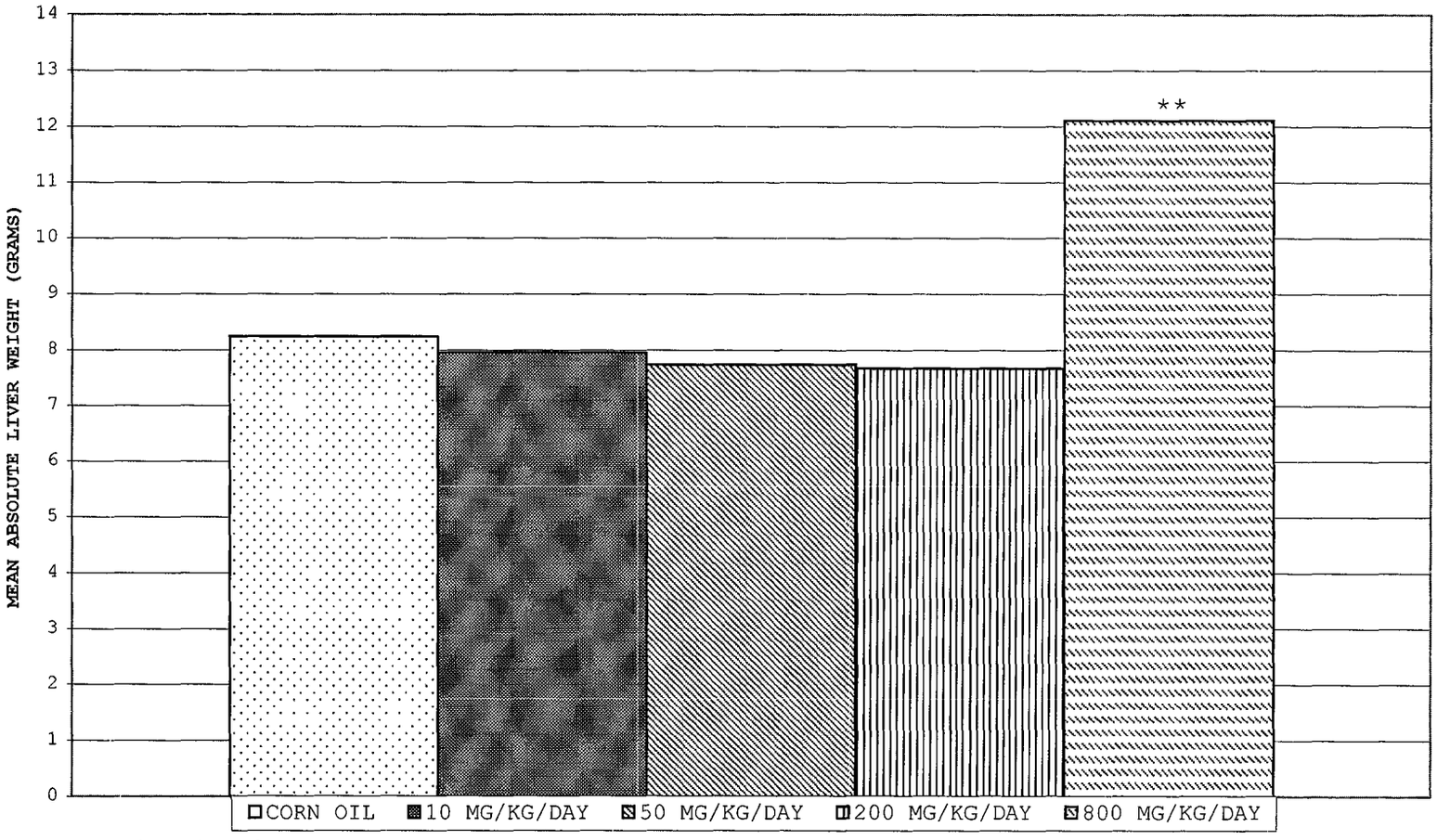
PROJECT [redacted]-187061
SPONSOR [redacted]
SPONSOR [redacted]025

FIGURE 4

FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
MEAN ABSOLU



** = Significantly different from control group at 0.01 using Dunnett's test

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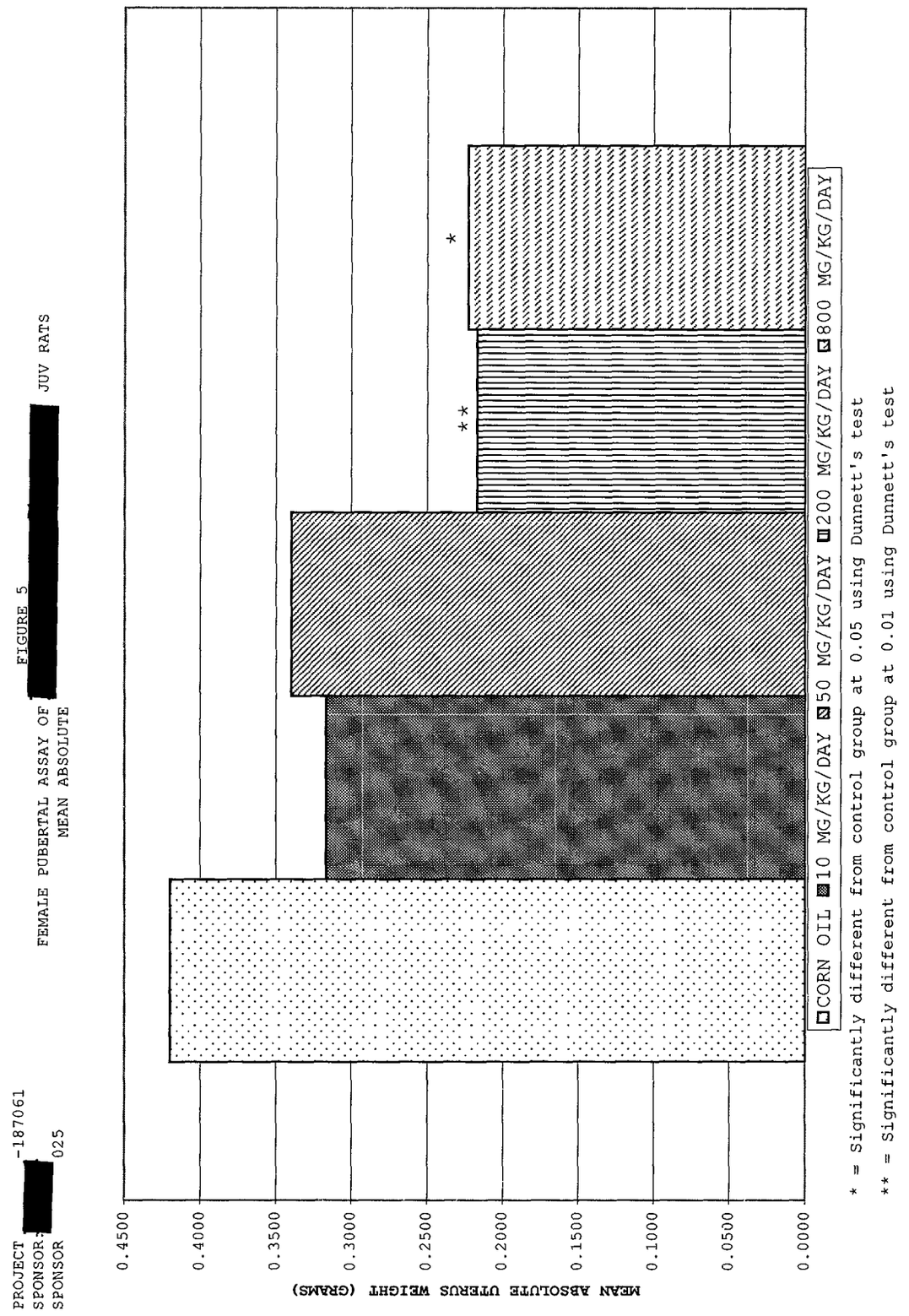

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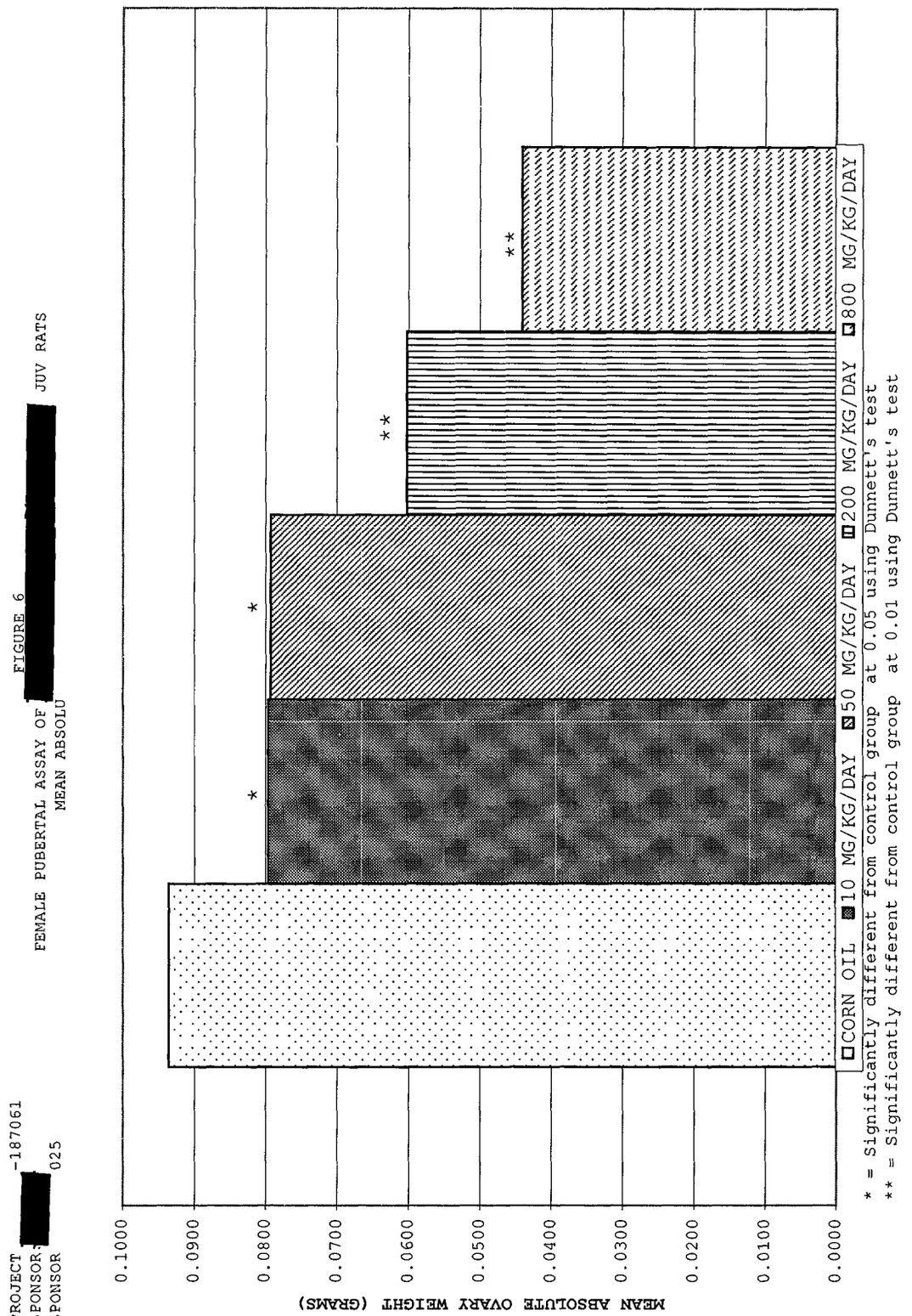

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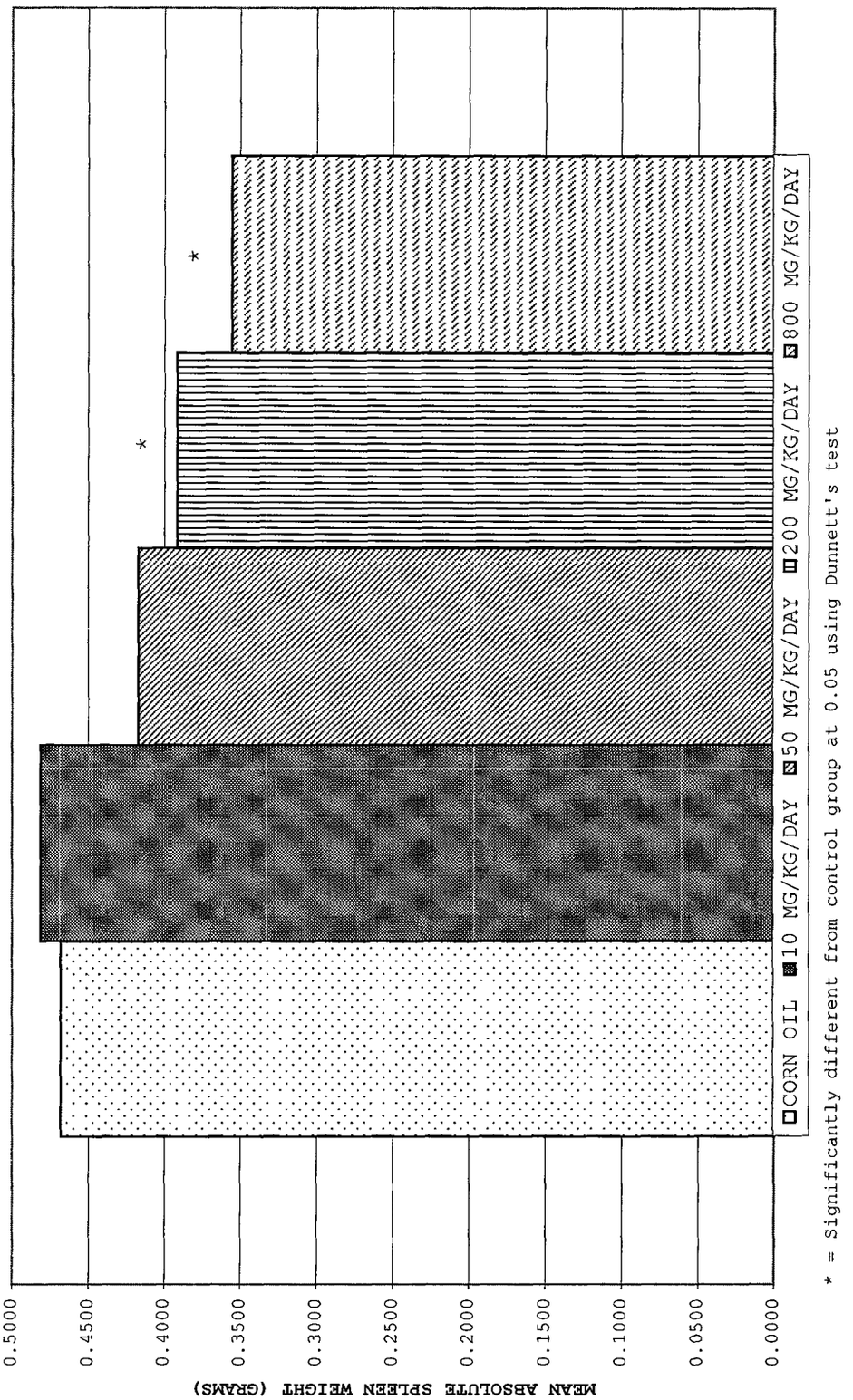
FIGURE 7

FEMALE PUBERTAL ASSAY OF JUV RATS
MEAN ABSOLU

PROJECT -187061
SPONSOR:
SPONSOR 025



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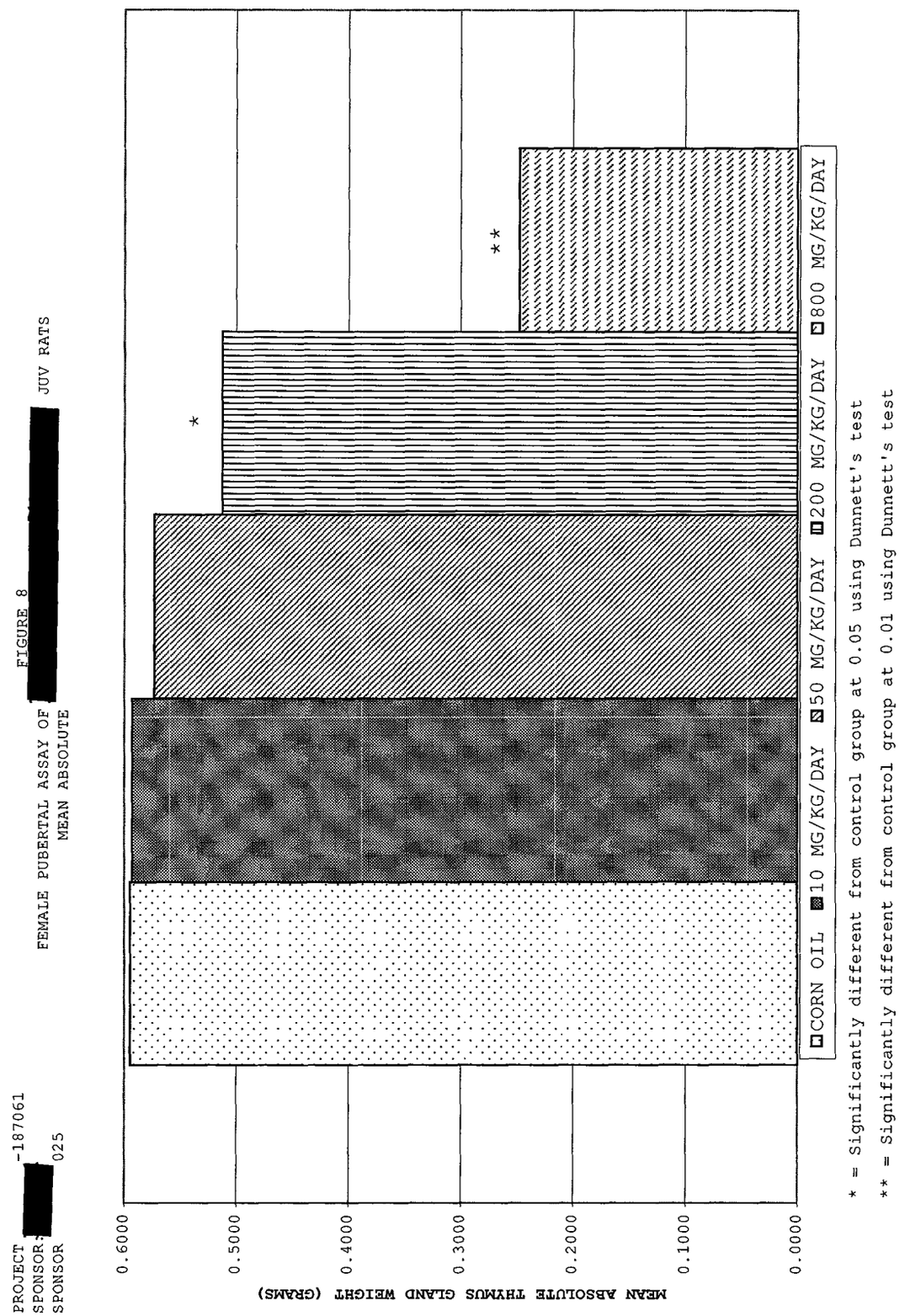

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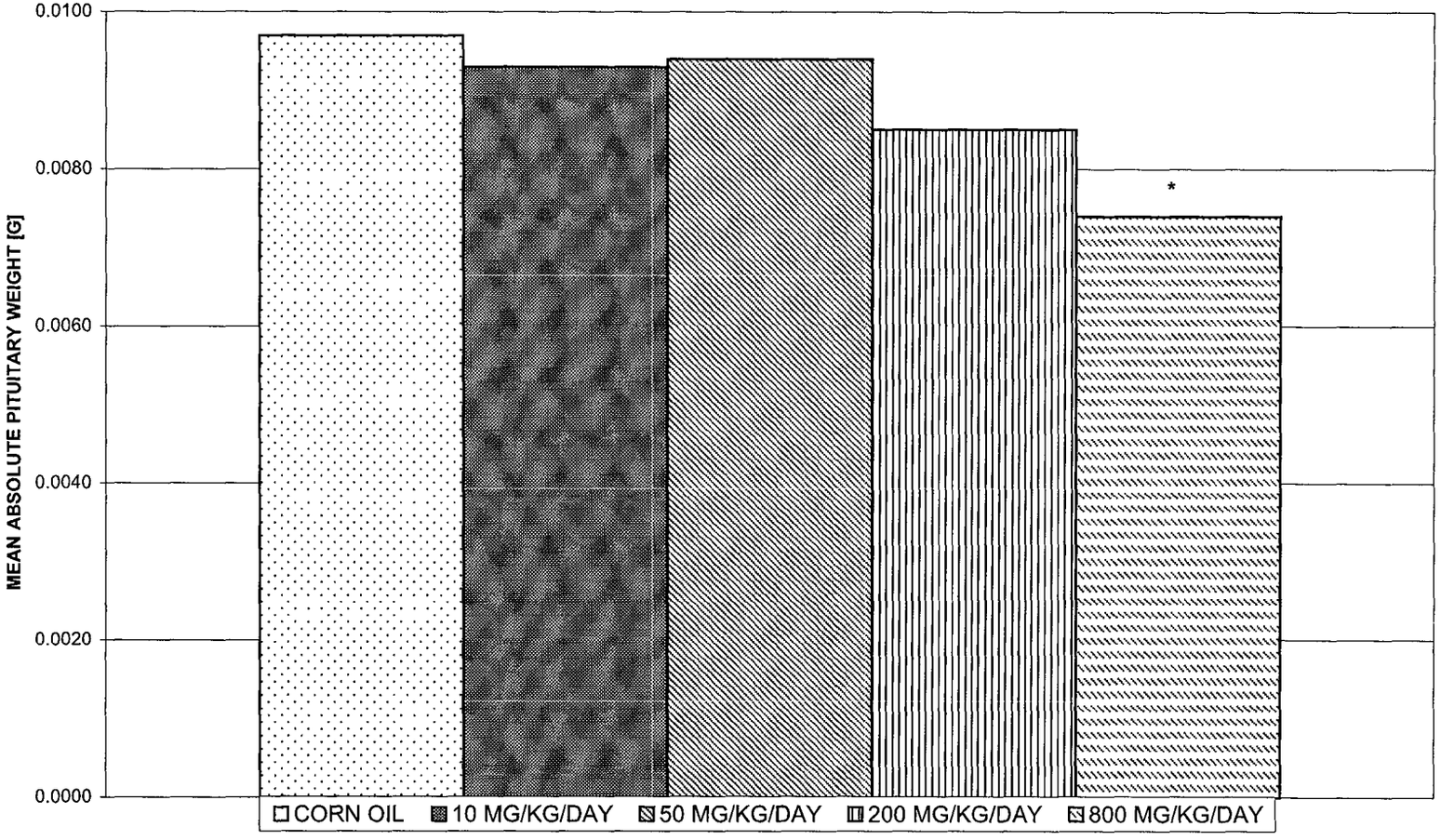
PROJECT [redacted]-187061
SPONSOR: [redacted]
SPONSOR 025

FIGURE 9
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
MEAN ABSOLU



* = Significantly different from control group at 0.05 using Dunnett's test

TABLES 1-25

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TABLE 1

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SUMMARY OF SURVIVAL AND DISPOSITION
SPONSOR NO.:06-025

FEMALES

GROUP :	1				2				3				4				5			
PND	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
22	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
23	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0
24	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	13	2	0	0
25	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	8	5	0	0
26	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	5	3	0	0
27	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	5	0	0	0
28	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	1	0	0
29	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
30	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
31	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
32	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
33	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
34	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
35	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
36	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
37	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
38	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
39	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
40	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
41	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4	0	0	0
42	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	15	0	0	0	4

PND = POSTNATAL DAY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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11/20/2006
R:11/21/2006

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TABLE 2 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS
SPONSOR NO.:06-025

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-18-06				
GROUP:	1	2	3	4	5
NORMAL					
-NO SIGNIFICANT CLINICAL OBSERVATIONS	315/15	298/15	315/15	315/15	89/15
DISPOSITION					
-FOUND DEAD	0/ 0	0/ 0	0/ 0	0/ 0	11/11
-SCHEDULED EUTHANASIA	15/15	15/15	15/15	15/15	4/ 4
BEHAVIOR/CNS					
-HUNCHED POSTURE	0/ 0	0/ 0	0/ 0	0/ 0	7/ 5
-ROCKS, LURCHES, OR SWAYS AS IT WALKS	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
BODY/INTEGUMENT					
-PORTION OF TAIL MISSING	0/ 0	17/ 1	0/ 0	0/ 0	0/ 0
-DRIED BROWN MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	9/ 6
-WET BROWN MATERIAL UROGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	10/ 9
-WET BROWN MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	12/11
-DRIED BROWN MATERIAL ANOGENITAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	14/ 7
-DRIED BROWN MATERIAL LEFT INGUINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
-DRIED BROWN MATERIAL RIGHT INGUINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2
-WET BROWN MATERIAL LEFT INGUINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	8/ 6
-WET BROWN MATERIAL RIGHT INGUINAL AREA	0/ 0	0/ 0	0/ 0	0/ 0	6/ 6
EYES/EARS/NOSE					
-EYELIDS HALF-CLOSED	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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PROJECT NO.:WIL-187061
SPONSOR: [redacted]
SPONSOR NO.:06-025

TABLE 2 (DAILY EXAMINATIONS)
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-18-06				
GROUP:	1	2	3	4	5
EYES/EARS/NOSE					
-DRIED RED MATERIAL AROUND NOSE	0/ 0	0/ 0	0/ 0	0/ 0	2/ 2

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

PCSUv4.07
11/21/2006

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TABLE 3 (AT TIME OF DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-025 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-17-06				
GROUP:	1	2	3	4	5
BEHAVIOR/CNS					
-HUNCHED POSTURE	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
EYES/EARS/NOSE					
-EYELIDS HALF-CLOSED	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
ORAL/DENTAL					
-SALIVATION PRIOR TO DOSING	0/ 0	0/ 0	0/ 0	46/10	30/ 3

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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11/20/2006
R:11/20/2006

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TABLE 4 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-025 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- F E M A L E -----

TABLE RANGE:	09-26-06 TO 10-17-06				
GROUP:	1	2	3	4	5
BEHAVIOR/CNS					
-HUNCHED POSTURE	0/ 0	0/ 0	0/ 0	0/ 0	12/ 9
ORAL/DENTAL					
-WET CLEAR MATERIAL AROUND MOUTH	0/ 0	0/ 0	0/ 0	56/10	34/ 4

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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11/20/2006
R:11/20/2006

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TABLE 5

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-025

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
		FEMALES			
DAY 22					
MEAN	51.7	48.8	48.8	49.9	49.9
% DIFFERENCE		-5.6	-5.6	-3.5	-3.5
S.D.	5.74	4.97	4.05	4.31	4.34
N	15	15	15	15	15
DAY 23					
MEAN	56.6	53.9	53.6	54.2	51.1
% DIFFERENCE		-4.8	-5.3	-4.2	-9.7
S.D.	5.94	4.71	3.90	4.21	5.88
N	15	15	15	15	15
DAY 24					
MEAN	61.5	59.4	59.0	59.7	49.1**
% DIFFERENCE		-3.4	-4.1	-2.9	-20.2
S.D.	5.86	4.81	3.77	4.84	5.86
N	15	15	15	15	13
DAY 25					
MEAN	66.1	64.4	64.2	65.1	49.9**
% DIFFERENCE		-2.6	-2.9	-1.5	-24.5
S.D.	5.82	5.15	3.74	4.65	7.41
N	15	15	15	15	8
DAY 26					
MEAN	72.6	69.5	69.3	70.4	56.6**
% DIFFERENCE		-4.3	-4.5	-3.0	-22.0
S.D.	6.46	5.20	3.87	5.17	10.64
N	15	15	15	15	5

** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF BODY WEIGHTS [G]

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
DAY 27					
MEAN	78.0	75.0	74.7	75.7	61.6**
% DIFFERENCE		-3.8	-4.2	-2.9	-21.0
S.D.	7.03	5.77	3.87	5.11	14.50
N	15	15	15	15	5
DAY 28					
MEAN	83.9	80.1	80.2	80.5	73.6*
% DIFFERENCE		-4.5	-4.4	-4.1	-12.3
S.D.	6.95	6.58	3.95	5.70	4.71
N	15	15	15	15	4
DAY 29					
MEAN	89.4	86.1	85.6	85.5	77.7**
% DIFFERENCE		-3.7	-4.3	-4.4	-13.1
S.D.	7.71	7.44	4.62	6.33	6.16
N	15	15	15	15	4
DAY 30					
MEAN	95.9	92.8	92.1	91.1	81.1**
% DIFFERENCE		-3.2	-4.0	-5.0	-15.4
S.D.	7.95	7.67	4.56	6.36	7.78
N	15	15	15	15	4
DAY 31					
MEAN	102.0	99.0	98.2	96.5	87.8**
% DIFFERENCE		-2.9	-3.7	-5.4	-13.9
S.D.	8.44	8.12	5.09	7.18	9.37
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 3
SPONSOR: [redacted]
SPONSOR NO.:06-025
SUMMARY OF BODY WEIGHTS [G]

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
DAY 32					
MEAN	108.8	105.5	104.4	102.0	94.9*
% DIFFERENCE		-3.0	-4.0	-6.3	-12.8
S.D.	9.98	9.35	5.01	6.98	10.80
N	15	15	15	15	4
DAY 33					
MEAN	115.2	111.8	110.7	107.4	101.3*
% DIFFERENCE		-3.0	-3.9	-6.8	-12.1
S.D.	10.79	9.78	5.33	6.93	9.15
N	15	15	15	15	4
DAY 34					
MEAN	121.8	118.1	118.3	113.1*	106.5*
% DIFFERENCE		-3.0	-2.9	-7.1	-12.6
S.D.	11.19	10.39	6.14	8.17	11.51
N	15	15	15	15	4
DAY 35					
MEAN	127.8	125.2	123.8	118.4*	111.7*
% DIFFERENCE		-2.0	-3.1	-7.4	-12.6
S.D.	12.33	11.12	6.49	7.63	12.97
N	15	15	15	15	4
DAY 36					
MEAN	133.8	130.0	129.4	123.2*	114.3**
% DIFFERENCE		-2.8	-3.3	-7.9	-14.6
S.D.	12.11	9.71	7.74	7.99	14.03
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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PROJECT NO.:WIL-187061
SPONSOR: [redacted]
SPONSOR NO.:06-025

TABLE 5
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SUMMARY OF BODY WEIGHTS [G]

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
		FEMALES			
DAY 37					
MEAN	138.7	136.8	134.3	127.3*	118.4**
% DIFFERENCE		-1.4	-3.2	-8.2	-14.6
S.D.	14.27	10.91	8.69	7.90	16.95
N	15	15	15	15	4
DAY 38					
MEAN	144.6	141.9	139.4	130.9**	124.2*
% DIFFERENCE		-1.9	-3.6	-9.5	-14.1
S.D.	15.14	10.26	8.03	9.31	19.53
N	15	15	15	15	4
DAY 39					
MEAN	149.7	147.4	146.2	136.3*	129.5*
% DIFFERENCE		-1.5	-2.3	-9.0	-13.5
S.D.	15.92	11.03	8.79	9.67	20.23
N	15	15	15	15	4
DAY 40					
MEAN	156.3	152.7	150.6	141.0**	135.3*
% DIFFERENCE		-2.3	-3.6	-9.8	-13.4
S.D.	17.06	11.33	8.93	10.19	17.42
N	15	15	15	15	4
DAY 41					
MEAN	159.2	157.5	154.1	145.6*	140.7*
% DIFFERENCE		-1.1	-3.2	-8.5	-11.6
S.D.	17.15	11.99	9.65	10.57	14.23
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 5

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALES

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
DAY 42					
MEAN	160.3	162.6	158.1	148.9	144.5
% DIFFERENCE		1.4	-1.4	-7.1	-9.9
S.D.	17.58	12.24	10.21	11.04	17.20
N	15	15	15	15	4

None significantly different from control group

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TABLE 6

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR: [redacted]
SPONSOR NO.:06-025
SUMMARY OF BODY WEIGHT CHANGES (G)

		FEMALES				
	GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
DAY 22- 23						
	MEAN	4.9	5.1	4.8	4.3	1.2**
	S.D.	1.30	0.76	1.33	0.70	2.31
	N	15	15	15	15	15
DAY 23- 24						
	MEAN	4.9	5.5	5.4	5.5	-3.3**
	S.D.	0.68	0.91	0.91	1.19	3.09
	N	15	15	15	15	13
DAY 24- 25						
	MEAN	4.6	5.0	5.2	5.4	-1.5**
	S.D.	0.96	1.21	0.60	1.20	2.56
	N	15	15	15	15	8
DAY 25- 26						
	MEAN	6.5	5.0	5.1	5.3	3.3**
	S.D.	1.33	0.92	1.01	1.30	4.49
	N	15	15	15	15	5
DAY 26- 27						
	MEAN	5.4	5.5	5.4	5.3	5.0
	S.D.	1.38	1.29	0.88	1.12	4.92
	N	15	15	15	15	5
DAY 27- 28						
	MEAN	5.9	5.1	5.5	4.8	5.7
	S.D.	0.53	1.29	0.95	1.03	2.77
	N	15	15	15	15	4

** = Significantly different from the control group at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

Revised Audited Draft

Modified: 4/30/2007

TABLE 6

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR: [redacted]
SPONSOR NO.:06-025
SUMMARY OF BODY WEIGHT CHANGES [G]

		FEMALES				
	GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
DAY 28- 29						
	MEAN	5.5	6.0	5.3	5.0	4.1
	S.D.	1.56	1.37	1.14	1.00	1.50
	N	15	15	15	15	4
DAY 29- 30						
	MEAN	6.5	6.7	6.5	5.6	3.4**
	S.D.	0.54	1.11	1.40	1.32	1.81
	N	15	15	15	15	4
DAY 30- 31						
	MEAN	6.1	6.2	6.1	5.4	6.7
	S.D.	1.71	1.57	0.87	1.76	3.51
	N	15	15	15	15	4
DAY 31- 32						
	MEAN	6.8	6.5	6.2	5.5	7.1
	S.D.	2.79	2.07	2.20	1.51	2.02
	N	15	15	15	15	4
DAY 32- 33						
	MEAN	6.4	6.2	6.3	5.4	6.5
	S.D.	2.68	1.98	1.67	1.64	2.36
	N	15	15	15	15	4
DAY 33- 34						
	MEAN	6.6	6.3	7.6	5.7	5.2
	S.D.	1.51	1.64	1.85	1.92	3.40
	N	15	15	15	15	4

** = Significantly different from the control group at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

		FEMALES				
GROUP:		0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
DAY 34- 35						
	MEAN	5.9	7.1	5.5	5.3	5.2
	S.D.	2.77	1.80	1.60	1.67	2.17
	N	15	15	15	15	4
DAY 35- 36						
	MEAN	6.0	4.8	5.6	4.8	2.7
	S.D.	2.39	3.36	3.08	1.89	1.35
	N	15	15	15	15	4
DAY 36- 37						
	MEAN	5.0	6.7	5.0	4.1	4.1
	S.D.	3.29	3.15	2.67	2.14	4.21
	N	15	15	15	15	4
DAY 37- 38						
	MEAN	5.8	5.1	5.0	3.6	5.8
	S.D.	4.22	2.15	1.98	3.43	2.63
	N	15	15	15	15	4
DAY 38- 39						
	MEAN	5.1	5.4	6.8	5.4	5.2
	S.D.	2.06	2.77	2.52	2.34	3.17
	N	15	15	15	15	4
DAY 39- 40						
	MEAN	6.6	5.3	4.4	4.7	5.8
	S.D.	2.99	3.06	1.68	2.27	3.34
	N	15	15	15	15	4

None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

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TABLE 6

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 4
SPONSOR:[redacted]
SUMMARY OF BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
		FEMALES			
DAY 40- 41					
MEAN	2.9	4.9	3.5	4.6	5.5
S.D.	2.94	2.95	3.14	2.07	4.59
N	15	15	15	15	4
DAY 41- 42					
MEAN	1.1	5.1**	3.9	3.3	3.8
S.D.	4.75	2.67	3.13	2.45	2.99
N	15	15	15	15	4
DAY 22- 42					
MEAN	108.7	113.8	109.3	99.1	90.7*
S.D.	15.81	10.44	11.05	8.63	16.81
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES

PJTBWSUv5.14
11/20/2006

187061 RAD

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PROJECT NO.:WIL-187061
SPONSOR: [redacted]
SPONSOR NO.:06-025

TABLE 7
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SUMMARY OF ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

FEMALES

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
VAGINAL PATENCY (PND)					
MEAN	32.5	32.3	29.3**	29.2**	29.4*
S.D.	1.81	2.77	1.67	1.93	3.78
N	15	15	15	15	5
BODY WEIGHT (GRAMS)					
MEAN	111.9	108.4	87.3**	86.1**	71.6**
S.D.	9.13	15.77	11.71	10.06	22.37
N	15	15	15	15	5

PND = POSTNATAL DAY
* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 8

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF ESTROUS CYCLE DATA

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
ESTROUS CYCLE LENGTH (DAYS)					
MEAN	4.8	5.2	5.5	5.5	3.0
S.D.	0.45	0.87	0.78	0.72	0.00
N	5	9	12	10	2
AGE AT FIRST OCCURRENCE OF ESTRUS (DAYS)					
MEAN	34.4	34.6	31.6	32.1	29.4*
S.D.	3.33	3.37	2.69	4.01	3.78
N	13	14	15	14	5

* = Significantly different from the control group at 0.05 using Dunnett's test

PCYCv5.25t
11/20/2006
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TABLE 9

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
SUMMARY OF SERUM HORMONE VALUES
SPONSOR NO.:06-025

ANALYSIS GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
		FEMALES			
TOTAL T4 (uG/dL)					
DAY 42 MEAN	6.65	6.09	7.03	7.25	5.90
% DIFFERENCE		-8.4	5.7	9.0	-11.3
S.D.	0.898	0.932	1.356	1.132	1.383
N	15	15	15	15	4
ESTRADIOL (pg/mL)					
DAY 42 MEAN	101.79	108.25	110.29	105.15	142.50**
% DIFFERENCE		6.3	8.4	3.3	40.0
S.D.	23.573	23.325	22.424	22.524	22.986
N	15	15	15	15	4
TSH (ng/mL)					
DAY 42 MEAN	8.16	9.35	11.40	9.60	14.73**
% DIFFERENCE		14.6	39.7	17.6	80.5
S.D.	2.903	2.197	4.903	3.130	4.730
N	15	13	13	13	4
LUTEIN' HORMONE (ng/mL)					
DAY 42 MEAN	3.1	1.7	1.5	1.7	1.2
% DIFFERENCE		-45.2	-51.6	-45.2	-61.3
S.D.	6.34	0.43	0.53	0.54	0.17
N	15	15	14	15	4

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

** = Significantly different from the control group at 0.01 using Dunnett's test

PCPSv5.23
11/17/2006
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TABLE 10 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SUMMARY OF MACROSCOPIC FINDINGS
SPONSOR NO.:06-025

FOUND DEAD OR EUTHANIZED MORIBUND OR IN EXTREMIS

	----- F E M A L E -----				
GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	0	0	0	0	11
SPLEEN					
-SMALL	0	0	0	0	1
UTERUS					
-CONTENTS, CLEAR FLUID	0	0	0	0	1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

PGRSI2v4.07
04/30/2007

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TABLE 10A (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR: [redacted]
SUMMARY OF MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	0	0	0	0	11
CERVIX					
TOTAL NUMBER EXAMINED	0	NA	NA	0	11
EXAMINED, UNREMARKABLE	0	NA	NA	0	4
-ATROPHY	0	NA	NA	0	7
MILD	NONE	NA	NA	NONE	3
MODERATE	NONE	NA	NA	NONE	4
OVARIES					
TOTAL NUMBER EXAMINED	0	NA	NA	0	11
EXAMINED, UNREMARKABLE	0	NA	NA	0	0
-DEGENERATION, OOCYTE(S)	0	NA	NA	0	11
MODERATE	NONE	NA	NA	NONE	8
SEVERE	NONE	NA	NA	NONE	3
-NECROSIS, GRANULOSA CELLS	0	NA	NA	0	11
MODERATE	NONE	NA	NA	NONE	11
-CORPORA LUTEA ABSENT	0	NA	NA	0	11
-CORPORA AMYLACEA	0	NA	NA	0	2
PRESENT	NONE	NA	NA	NONE	2
PARATHYROID					
TOTAL NUMBER EXAMINED	0	NA	NA	0	11
EXAMINED, UNREMARKABLE	0	NA	NA	0	11

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 10A (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	0	0	0	0	11
THYROID GLANDS					
TOTAL NUMBER EXAMINED	0	NA	NA	0	10
EXAMINED, UNREMARKABLE	0	NA	NA	0	0
NOT EXAMINED	0	NA	NA	0	1
-HYPERTROPHY, FOLLICULAR CELL	0	NA	NA	0	1
MILD	NONE	NA	NA	NONE	1
-DEPLETION, COLLOID	0	NA	NA	0	9
MINIMAL	NONE	NA	NA	NONE	3
MILD	NONE	NA	NA	NONE	6
-CYST, ULTIMOBRANCHIAL	0	NA	NA	0	3
PRESENT	NONE	NA	NA	NONE	3
-ECTOPIC THYMUS	0	NA	NA	0	2
PRESENT	NONE	NA	NA	NONE	2
UTERUS					
TOTAL NUMBER EXAMINED	0	NA	NA	0	11
EXAMINED, UNREMARKABLE	0	NA	NA	0	0
-ATROPHY	0	NA	NA	0	11
MODERATE	NONE	NA	NA	NONE	11
-DILATATION, LUMEN	0	NA	NA	0	1
MILD	NONE	NA	NA	NONE	1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 11 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SUMMARY OF MACROSCOPIC FINDINGS
SPONSOR NO.:06-025

SCHEDULED NECROPSY

	----- FEMALE -----				
GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	15	15	15	15	15
NUMBER OF ANIMALS EXAMINED	15	15	15	15	4
OVARIES					
-SMALL	0	0	0	0	1
-CYST(S)	0	0	0	0	1
OVIDUCTS					
-SMALL	0	0	0	0	1
THYMUS					
-SMALL	0	0	0	0	1
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	15	15	15	15	1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY

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TABLE 11A (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	15	0	0	15	4
CERVIX					
TOTAL NUMBER EXAMINED	15	NA	NA	15	4
EXAMINED, UNREMARKABLE	15	NA	NA	15	3
-ATROPHY	0	NA	NA	0	1
MILD	NONE	NA	NA	NONE	1
OVARIES					
TOTAL NUMBER EXAMINED	15	NA	NA	15	4
EXAMINED, UNREMARKABLE	15	NA	NA	0	0
-CYST, PARAOVARIAN	0	NA	NA	0	1
PRESENT	NONE	NA	NA	NONE	1
-CYST, LUTEAL	0	NA	NA	1	0
PRESENT	NONE	NA	NA	1	NONE
-DEGENERATION, OOCYTE(S)	0	NA	NA	14	4
MILD	NONE	NA	NA	1	2
MODERATE	NONE	NA	NA	13	1
SEVERE	NONE	NA	NA	NONE	1
-NECROSIS, GRANULOSA CELLS	0	NA	NA	14	4
MINIMAL	NONE	NA	NA	5	NONE
MILD	NONE	NA	NA	8	2
MODERATE	NONE	NA	NA	1	2
-CORPORA LUTEA ABSENT	0	NA	NA	1	4
-CYST, FOLLICULAR	0	NA	NA	3	0
PRESENT	NONE	NA	NA	3	NONE

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 11A (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	15	0	0	15	4
OVARIES - CONTINUED					
-DECREASED CORPORA LUTEA	0	NA	NA	3	0
MILD	NONE	NA	NA	1	NONE
MODERATE	NONE	NA	NA	2	NONE
OVIDUCTS					
TOTAL NUMBER EXAMINED	NA	NA	NA	NA	1
EXAMINED, UNREMARKABLE	NA	NA	NA	NA	1
PARATHYROID					
TOTAL NUMBER EXAMINED	13	NA	NA	15	4
EXAMINED, UNREMARKABLE	13	NA	NA	15	4
NOT EXAMINED	2	NA	NA	0	0
THYROID GLANDS					
TOTAL NUMBER EXAMINED	15	NA	NA	15	4
EXAMINED, UNREMARKABLE	11	NA	NA	5	0
-CYST, ULTIMOBRANCHIAL	2	NA	NA	0	1
PRESENT	2	NA	NA	NONE	1
-HYPERTROPHY, FOLLICULAR CELL	0	NA	NA	4	1
MINIMAL	NONE	NA	NA	2	NONE
MILD	NONE	NA	NA	2	1
-DEPLETION, COLLOID	0	NA	NA	2	1
MINIMAL	NONE	NA	NA	2	1

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 11A (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR: [redacted]
SPONSOR NO.:06-025
SUMMARY OF MICROSCOPIC FINDINGS

----- FEMALE -----

GROUP:	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	25	25	25	25	25
NUMBER OF ANIMALS EXAMINED	15	0	0	15	4
THYROID GLANDS - CONTINUED					
-CYST, ULTIMOBRANCHIAL	2	NA	NA	6	2
PRESENT	2	NA	NA	6	2
-ECTOPIC THYMUS	0	NA	NA	1	0
PRESENT	NONE	NA	NA	1	NONE
UTERUS					
TOTAL NUMBER EXAMINED	15	NA	NA	15	4
EXAMINED, UNREMARKABLE	14	NA	NA	7	0
-ATROPHY	0	NA	NA	8	4
MINIMAL	NONE	NA	NA	5	NONE
MILD	NONE	NA	NA	3	4
-INFLAMMATION, SUBACUTE	1	NA	NA	0	0
MINIMAL	1	NA	NA	NONE	NONE

1- 0 MG/KG/DAY 2- 10 MG/KG/DAY 3- 50 MG/KG/DAY 4- 200 MG/KG/DAY 5- 800 MG/KG/DAY
NA = NOT APPLICABLE

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TABLE 12

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
ADRENAL GLANDS (G)					
MEAN	0.0396	0.0372	0.0394	0.0410	0.0410
% DIFFERENCE		-6.1	-0.5	3.5	3.5
S.D.	0.00696	0.00426	0.00564	0.00478	0.00962
N	15	15	15	15	4
KIDNEYS (G)					
MEAN	1.6641	1.6109	1.5731	1.5352	1.5247
% DIFFERENCE		-3.2	-5.5	-7.7	-8.4
S.D.	0.22415	0.14976	0.13312	0.11602	0.16877
N	15	15	15	15	4
LIVER (G)					
MEAN	8.2487	7.9599	7.7336	7.6668	12.1067**
% DIFFERENCE		-3.5	-6.2	-7.1	46.8
S.D.	1.43299	1.26673	1.12220	0.65481	2.44273
N	15	15	15	15	4
OVARIES/OVIDUCTS (G)					
MEAN	0.0936	0.0796*	0.0793*	0.0603**	0.0441**
% DIFFERENCE		-15.0	-15.3	-35.6	-52.9
S.D.	0.01945	0.01385	0.01368	0.01294	0.01210
N	15	15	15	15	4
PITUITARY (G)					
MEAN	0.0097	0.0093	0.0094	0.0085	0.0074*
% DIFFERENCE		-4.1	-3.1	-12.4	-23.7
S.D.	0.00139	0.00153	0.00157	0.00151	0.00139
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 12

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF ORGAN AND LUMINAL FLUID WEIGHTS

GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
			FEMALES		
SPLEEN (G)					
MEAN	0.4681	0.4814	0.4170	0.3917*	0.3555*
% DIFFERENCE		2.8	-10.9	-16.3	-24.1
S.D.	0.06130	0.07722	0.05864	0.06775	0.11561
N	15	15	15	15	4
THYMUS (G)					
MEAN	0.5948	0.5931	0.5735	0.5127*	0.2482**
% DIFFERENCE		-0.3	-3.6	-13.8	-58.3
S.D.	0.05361	0.09380	0.10411	0.07532	0.05632
N	15	15	15	15	4
THYROIDS/PARA (G)					
MEAN	0.0155	0.0136	0.0142	0.0141	0.0169
% DIFFERENCE		-12.3	-8.4	-9.0	9.0
S.D.	0.00484	0.00274	0.00267	0.00290	0.00409
N	15	15	15	15	4
UTERUS- BLOTTED (G)					
MEAN	0.3371	0.2761*	0.2863	0.1988**	0.2071**
% DIFFERENCE		-18.1	-15.1	-41.0	-38.6
S.D.	0.07422	0.07350	0.06343	0.02875	0.00644
N	15	15	15	15	4
UTERUS- WET (G)					
MEAN	0.4201	0.3166	0.3398	0.2170**	0.2229*
% DIFFERENCE		-24.6	-19.1	-48.3	-46.9
S.D.	0.16366	0.12295	0.11363	0.03190	0.00436
N	15	15	15	15	4
UTERUS- LUMINAL FLUID (G)					
MEAN	0.0829	0.0405	0.0535	0.0182	0.0158
% DIFFERENCE		-51.1	-35.5	-78.0	-80.9
S.D.	0.12438	0.06528	0.06587	0.00680	0.00318
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 13

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
FINAL BODY WT (G)					
MEAN	160.	163.	158.	149.	145.
% DIFFERENCE		1.9	-1.3	-6.9	-9.4
S.D.	17.6	12.3	10.1	11.1	17.3
N	15	15	15	15	4
ADRENAL GLANDS (G/100 G FINAL BODY WEIGHT)					
MEAN	0.025	0.023	0.025	0.028	0.029
S.D.	0.0044	0.0023	0.0038	0.0029	0.0047
N	15	15	15	15	4
KIDNEYS (G/100 G FINAL BODY WEIGHT)					
MEAN	1.036	0.991	0.995	1.033	1.057
S.D.	0.0667	0.0584	0.0496	0.0560	0.0474
N	15	15	15	15	4
LIVER (G/100 G FINAL BODY WEIGHT)					
MEAN	5.117	4.872	4.878	5.157	8.318**
S.D.	0.4415	0.5123	0.4971	0.3374	0.8054
N	15	15	15	15	4
OVARIES/OVIDUCTS (G/100 G FINAL BODY WEIGHT)					
MEAN	0.059	0.049*	0.050	0.040**	0.030**
S.D.	0.0124	0.0086	0.0097	0.0074	0.0054
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 13

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR: [redacted]
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT
SPONSOR NO.:06-025

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
PITUITARY (G/100 G FINAL BODY WEIGHT)					
MEAN	0.006	0.006	0.006	0.006	0.005
S.D.	0.0008	0.0009	0.0012	0.0012	0.0005
N	15	15	15	15	4
SPLEEN (G/100 G FINAL BODY WEIGHT)					
MEAN	0.292	0.296	0.264	0.263	0.241*
S.D.	0.0265	0.0416	0.0299	0.0377	0.0527
N	15	15	15	15	4
THYMUS (G/100 G FINAL BODY WEIGHT)					
MEAN	0.374	0.365	0.362	0.345	0.170**
S.D.	0.0401	0.0568	0.0523	0.0456	0.0218
N	15	15	15	15	4
THYROIDS/PARA (G/100 G FINAL BODY WEIGHT)					
MEAN	0.010	0.008	0.009	0.009	0.012
S.D.	0.0037	0.0016	0.0020	0.0021	0.0026
N	15	15	15	15	4
UTERUS- BLOTTED (G/100 G FINAL BODY WEIGHT)					
MEAN	0.212	0.170*	0.183	0.133**	0.145*
S.D.	0.0474	0.0416	0.0460	0.0153	0.0191
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 13

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
SUMMARY OF ORGAN WEIGHTS RELATIVE TO FINAL BODY WEIGHT

	FEMALES				
GROUP:	0 MG/KG/DAY	10 MG/KG/DAY	50 MG/KG/DAY	200 MG/KG/DAY	800 MG/KG/DAY
UTERUS- WET (G/100 G FINAL BODY WEIGHT)					
MEAN	0.267	0.194*	0.217	0.145**	0.156*
S.D.	0.1176	0.0683	0.0754	0.0164	0.0207
N	15	15	15	15	4

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38694-07	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38696-08	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38695-01	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38695-07	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38694-04	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38696-04	F	0 MG/KG/DAY	DISPOSITION	10-16-06	7:52	P	SCHEDULED EUTHANASIA
38697-07	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38698-04	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38699-07	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38698-05	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38699-02	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38697-03	F	0 MG/KG/DAY	DISPOSITION	10-17-06	7:07	P	SCHEDULED EUTHANASIA
38703-06	F	0 MG/KG/DAY	DISPOSITION	10-18-06	7:58	P	SCHEDULED EUTHANASIA
38700-06	F	0 MG/KG/DAY	DISPOSITION	10-18-06	7:58	P	SCHEDULED EUTHANASIA
38702-05	F	0 MG/KG/DAY	DISPOSITION	10-18-06	7:59	P	SCHEDULED EUTHANASIA
38705-03	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:40	P	SCHEDULED EUTHANASIA
38704-05	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:41	P	SCHEDULED EUTHANASIA
38705-10	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:41	P	SCHEDULED EUTHANASIA
38705-10	F	10 MG/KG/DAY	BODY/INTEGUMENT	09-26-06	7:02	P	PORTION OF TAIL MISSING
				09-27-06	8:02	P	PORTION OF TAIL MISSING
				09-28-06	7:41	P	PORTION OF TAIL MISSING
				09-29-06	7:19	P	PORTION OF TAIL MISSING
				09-30-06	8:29	P	PORTION OF TAIL MISSING
				10-01-06	7:51	P	PORTION OF TAIL MISSING
				10-02-06	7:55	P	PORTION OF TAIL MISSING
				10-04-06	7:23	P	PORTION OF TAIL MISSING
				10-05-06	7:17	P	PORTION OF TAIL MISSING
				10-03-06	7:51	P	PORTION OF TAIL MISSING
				10-10-06	8:19	P	PORTION OF TAIL MISSING

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TABLE 14 (DAILY EXAMINATIONS)

SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38705-10	F	10 MG/KG/DAY	BODY/INTEGUMENT	10-12-06	7:31	P	PORTION OF TAIL MISSING
				10-11-06	7:07	P	PORTION OF TAIL MISSING
				10-13-06	7:08	P	PORTION OF TAIL MISSING
				10-14-06	6:35	P	PORTION OF TAIL MISSING
				10-15-06	6:39	P	PORTION OF TAIL MISSING
				10-16-06	7:06	P	PORTION OF TAIL MISSING
38704-10	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:41	P	SCHEDULED EUTHANASIA
38705-07	F	10 MG/KG/DAY	DISPOSITION	10-16-06	7:41	P	SCHEDULED EUTHANASIA
38707-07	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:58	P	SCHEDULED EUTHANASIA
38706-04	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:58	P	SCHEDULED EUTHANASIA
38708-04	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:58	P	SCHEDULED EUTHANASIA
38707-02	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:59	P	SCHEDULED EUTHANASIA
38708-03	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:59	P	SCHEDULED EUTHANASIA
38706-08	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:59	P	SCHEDULED EUTHANASIA
38707-03	F	10 MG/KG/DAY	DISPOSITION	10-17-06	6:59	P	SCHEDULED EUTHANASIA
38710-10	F	10 MG/KG/DAY	DISPOSITION	10-18-06	8:01	P	SCHEDULED EUTHANASIA
38711-01	F	10 MG/KG/DAY	DISPOSITION	10-18-06	8:01	P	SCHEDULED EUTHANASIA
38709-08	F	10 MG/KG/DAY	DISPOSITION	10-18-06	8:01	P	SCHEDULED EUTHANASIA
38704-08	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38705-05	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38704-04	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38705-06	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38704-07	F	50 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38706-03	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38707-01	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38708-05	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38708-01	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38706-02	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38707-05	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38706-10	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38708-06	F	50 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38710-05	F	50 MG/KG/DAY	DISPOSITION	10-18-06	8:01	P	SCHEDULED EUTHANASIA
38709-01	F	50 MG/KG/DAY	DISPOSITION	10-18-06	8:01	P	SCHEDULED EUTHANASIA
38705-08	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38704-09	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38704-01	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:42	P	SCHEDULED EUTHANASIA
38705-01	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:43	P	SCHEDULED EUTHANASIA
38704-03	F	200 MG/KG/DAY	DISPOSITION	10-16-06	7:43	P	SCHEDULED EUTHANASIA
38706-05	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38708-09	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:00	P	SCHEDULED EUTHANASIA
38707-10	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38708-10	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38706-01	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38707-04	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38707-08	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38706-07	F	200 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38710-09	F	200 MG/KG/DAY	DISPOSITION	10-18-06	8:02	P	SCHEDULED EUTHANASIA
38709-04	F	200 MG/KG/DAY	DISPOSITION	10-18-06	8:02	P	SCHEDULED EUTHANASIA
38705-09	F	800 MG/KG/DAY	DISPOSITION	10-16-06	7:43	P	SCHEDULED EUTHANASIA
38705-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-01-06	8:09	P	HUNCHED POSTURE
38705-09	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	8:15	1	DRIED BROWN MATERIAL UROGENITAL AREA
38704-06	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:35	P	FOUND DEAD
38704-06	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	8:17	1	WET BROWN MATERIAL UROGENITAL AREA
				09-28-06	8:17	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:50	1	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	7:50	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:50	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				09-29-06	7:51	1	WET BROWN MATERIAL RIGHT INGUINAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 14 (DAILY EXAMINATIONS)

SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38704-02	F	800 MG/KG/DAY	DISPOSITION	09-29-06	7:02	P	FOUND DEAD
38704-02	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	8:20	1	WET BROWN MATERIAL UROGENITAL AREA
				09-28-06	8:20	1	WET BROWN MATERIAL ANOGENITAL AREA
38705-02	F	800 MG/KG/DAY	DISPOSITION	10-16-06	7:43	P	SCHEDULED EUTHANASIA
38705-02	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	8:26	1	DRIED BROWN MATERIAL UROGENITAL AREA
				09-28-06	8:27	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:52	1	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	7:52	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-30-06	8:47	1	DRIED BROWN MATERIAL UROGENITAL AREA
				10-01-06	8:10	1	DRIED BROWN MATERIAL UROGENITAL AREA
				10-03-06	8:12	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-05-06	7:34	1	DRIED BROWN MATERIAL UROGENITAL AREA
				10-05-06	7:34	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-06-06	7:03	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38705-04	F	800 MG/KG/DAY	DISPOSITION	09-28-06	7:30	P	FOUND DEAD
38707-09	F	800 MG/KG/DAY	DISPOSITION	09-29-06	7:03	P	FOUND DEAD
38707-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-28-06	8:40	P	HUNCHED POSTURE
				09-28-06	8:40	1	ROCKS, LURCHES, OR SWAYS AS IT WALKS
38707-09	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	8:28	1	WET BROWN MATERIAL UROGENITAL AREA
				09-28-06	8:28	1	WET BROWN MATERIAL ANOGENITAL AREA
38707-09	F	800 MG/KG/DAY	EYES/EARS/NOSE	09-28-06	8:42	P	EYELIDS HALF-CLOSED
38708-08	F	800 MG/KG/DAY	DISPOSITION	10-01-06	6:34	P	FOUND DEAD
38708-08	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	8:49	P	HUNCHED POSTURE
38708-08	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	7:53	1	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	7:53	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:53	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
				09-30-06	8:48	1	DRIED BROWN MATERIAL UROGENITAL AREA
				09-30-06	8:48	1	DRIED BROWN MATERIAL LEFT INGUINAL AREA
				09-30-06	8:48	1	DRIED BROWN MATERIAL RIGHT INGUINAL AREA

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TABLE 14 (DAILY EXAMINATIONS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38708-08	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:48	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38706-06	F	800 MG/KG/DAY	DISPOSITION	10-17-06	7:01	P	SCHEDULED EUTHANASIA
38706-06	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:50	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-04-06	7:44	1	DRIED BROWN MATERIAL UROGENITAL AREA
				10-04-06	7:44	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38707-06	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:35	P	FOUND DEAD
38707-06	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	7:56	2	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	7:56	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:56	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				09-29-06	7:56	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
38706-09	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:36	P	FOUND DEAD
38706-09	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-28-06	8:48	1	DRIED BROWN MATERIAL UROGENITAL AREA
				09-28-06	8:48	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				09-28-06	8:49	1	DRIED BROWN MATERIAL LEFT INGUINAL AREA
				09-28-06	8:49	1	DRIED BROWN MATERIAL RIGHT INGUINAL AREA
				09-29-06	7:57	2	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	7:57	2	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:57	2	WET BROWN MATERIAL LEFT INGUINAL AREA
				09-29-06	7:57	2	WET BROWN MATERIAL RIGHT INGUINAL AREA
38706-09	F	800 MG/KG/DAY	EYES/EARS/NOSE	09-29-06	7:58	1	DRIED RED MATERIAL AROUND NOSE
38708-07	F	800 MG/KG/DAY	DISPOSITION	09-30-06	7:35	P	FOUND DEAD
38708-07	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	7:59	1	WET BROWN MATERIAL UROGENITAL AREA
				09-29-06	7:59	1	WET BROWN MATERIAL ANOGENITAL AREA
				09-29-06	7:59	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				09-29-06	7:59	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
38708-07	F	800 MG/KG/DAY	EYES/EARS/NOSE	09-29-06	7:59	1	DRIED RED MATERIAL AROUND NOSE
38708-02	F	800 MG/KG/DAY	DISPOSITION	10-01-06	6:34	P	FOUND DEAD
38708-02	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	8:51	P	HUNCHED POSTURE
38708-02	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:00	1	DRIED BROWN MATERIAL ANOGENITAL AREA

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TABLE 14 (DAILY EXAMINATIONS)

SPONSOR: [redacted]
INDIVIDUAL CLINICAL OBSERVATIONS [POSITIVE FINDINGS ONLY]
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-18-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38708-02	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-29-06	8:00	1	DRIED BROWN MATERIAL UROGENITAL AREA
				09-30-06	8:50	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				09-30-06	8:50	1	WET BROWN MATERIAL RIGHT INGUINAL AREA
38709-05	F	800 MG/KG/DAY	DISPOSITION	10-18-06	8:02	P	SCHEDULED EUTHANASIA
38709-05	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:52	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-01-06	8:12	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-02-06	8:19	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-04-06	7:44	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-06-06	7:05	1	DRIED BROWN MATERIAL ANOGENITAL AREA
38710-04	F	800 MG/KG/DAY	DISPOSITION	10-01-06	6:47	P	FOUND DEAD
38710-04	F	800 MG/KG/DAY	BODY/INTEGUMENT	09-30-06	8:52	1	WET BROWN MATERIAL UROGENITAL AREA
				09-30-06	8:52	1	WET BROWN MATERIAL ANOGENITAL AREA
38711-02	F	800 MG/KG/DAY	DISPOSITION	10-04-06	7:08	P	FOUND DEAD
38711-02	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-01-06	8:14	P	HUNCHED POSTURE
				10-02-06	8:20	P	HUNCHED POSTURE
				10-03-06	8:14	P	HUNCHED POSTURE
38711-02	F	800 MG/KG/DAY	BODY/INTEGUMENT	10-01-06	8:13	1	DRIED BROWN MATERIAL ANOGENITAL AREA
				10-01-06	8:13	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				10-02-06	8:20	1	WET BROWN MATERIAL LEFT INGUINAL AREA
				10-02-06	8:20	1	WET BROWN MATERIAL ANOGENITAL AREA
				10-03-06	8:14	1	WET BROWN MATERIAL LEFT INGUINAL AREA

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38705-08	F	200 MG/KG/DAY	ORAL/DENTAL	10-06-06	12:43	1	SALIVATION PRIOR TO DOSING
38704-09	F	200 MG/KG/DAY	ORAL/DENTAL	10-03-06	12:33	1	SALIVATION PRIOR TO DOSING
				10-06-06	12:44	2	SALIVATION PRIOR TO DOSING
				10-09-06	12:42	1	SALIVATION PRIOR TO DOSING
				10-13-06	12:32	2	SALIVATION PRIOR TO DOSING
				10-14-06	12:27	1	SALIVATION PRIOR TO DOSING
38705-01	F	200 MG/KG/DAY	ORAL/DENTAL	10-05-06	12:54	1	SALIVATION PRIOR TO DOSING
				10-07-06	12:47	1	SALIVATION PRIOR TO DOSING
				10-10-06	12:43	1	SALIVATION PRIOR TO DOSING
38706-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-04-06	12:52	1	SALIVATION PRIOR TO DOSING
				10-05-06	12:56	1	SALIVATION PRIOR TO DOSING
				10-10-06	12:44	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:29	1	SALIVATION PRIOR TO DOSING
38707-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-06-06	12:49	1	SALIVATION PRIOR TO DOSING
				10-11-06	12:33	1	SALIVATION PRIOR TO DOSING
				10-12-06	12:43	1	SALIVATION PRIOR TO DOSING
				10-13-06	12:36	2	SALIVATION PRIOR TO DOSING
				10-14-06	12:30	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:26	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:22	2	SALIVATION PRIOR TO DOSING
38706-01	F	200 MG/KG/DAY	ORAL/DENTAL	10-09-06	12:49	1	SALIVATION PRIOR TO DOSING
				10-12-06	12:44	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:24	1	SALIVATION PRIOR TO DOSING
38707-04	F	200 MG/KG/DAY	ORAL/DENTAL	10-06-06	12:53	2	SALIVATION PRIOR TO DOSING
				10-09-06	12:50	1	SALIVATION PRIOR TO DOSING
				10-13-06	12:38	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:32	1	SALIVATION PRIOR TO DOSING
				10-15-06	12:33	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:25	1	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 4/30/2007

TABLE 15 (AT TIME OF DOSING)

SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38707-08	F	200 MG/KG/DAY	ORAL/DENTAL	10-02-06	13:00	1	SALIVATION PRIOR TO DOSING
				10-03-06	12:39	1	SALIVATION PRIOR TO DOSING
				10-04-06	12:54	1	SALIVATION PRIOR TO DOSING
				10-05-06	13:00	1	SALIVATION PRIOR TO DOSING
				10-06-06	12:53	3	SALIVATION PRIOR TO DOSING
				10-07-06	12:51	1	SALIVATION PRIOR TO DOSING
				10-08-06	12:48	P	SALIVATION PRIOR TO DOSING
				10-09-06	12:51	2	SALIVATION PRIOR TO DOSING
				10-10-06	12:48	2	SALIVATION PRIOR TO DOSING
				10-11-06	12:36	2	SALIVATION PRIOR TO DOSING
				10-12-06	12:46	2	SALIVATION PRIOR TO DOSING
				10-13-06	12:38	1	SALIVATION PRIOR TO DOSING
				10-14-06	12:33	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:33	1	SALIVATION PRIOR TO DOSING
				10-16-06	12:24	2	SALIVATION PRIOR TO DOSING
38710-09	F	200 MG/KG/DAY	ORAL/DENTAL	10-16-06	12:27	2	SALIVATION PRIOR TO DOSING
38709-04	F	200 MG/KG/DAY	ORAL/DENTAL	10-16-06	12:28	1	SALIVATION PRIOR TO DOSING
38705-02	F	800 MG/KG/DAY	ORAL/DENTAL	10-02-06	13:08	2	SALIVATION PRIOR TO DOSING
				10-03-06	12:46	2	SALIVATION PRIOR TO DOSING
				10-05-06	13:04	1	SALIVATION PRIOR TO DOSING
				10-06-06	13:01	2	SALIVATION PRIOR TO DOSING
				10-09-06	12:57	1	SALIVATION PRIOR TO DOSING
				10-12-06	12:50	2	SALIVATION PRIOR TO DOSING
				10-13-06	12:44	2	SALIVATION PRIOR TO DOSING
				10-14-06	12:37	2	SALIVATION PRIOR TO DOSING
				10-15-06	12:38	1	SALIVATION PRIOR TO DOSING
38707-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-28-06	13:01	P	HUNCHED POSTURE
38707-09	F	800 MG/KG/DAY	EYES/EARS/NOSE	09-28-06	13:01	P	EYELIDS HALF-CLOSED
38706-06	F	800 MG/KG/DAY	ORAL/DENTAL	10-03-06	12:45	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 15 (AT TIME OF DOSING)

SPONSOR: [redacted]
SPONSOR NO.:06-025
INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38706-06	F	800 MG/KG/DAY	ORAL/DENTAL	10-04-06	13:04	1	SALIVATION PRIOR TO DOSING
				10-06-06	13:02	3	SALIVATION PRIOR TO DOSING
				10-07-06	12:57	2	SALIVATION PRIOR TO DOSING
				10-08-06	12:53	3	SALIVATION PRIOR TO DOSING
				10-09-06	12:58	2	SALIVATION PRIOR TO DOSING
				10-10-06	12:54	2	SALIVATION PRIOR TO DOSING
				10-11-06	12:43	2	SALIVATION PRIOR TO DOSING
				10-12-06	12:51	1	SALIVATION PRIOR TO DOSING
				10-13-06	12:45	1	SALIVATION PRIOR TO DOSING
38709-05	F	800 MG/KG/DAY	ORAL/DENTAL	10-04-06	13:05	1	SALIVATION PRIOR TO DOSING
				10-06-06	13:03	1	SALIVATION PRIOR TO DOSING
				10-07-06	12:58	2	SALIVATION PRIOR TO DOSING
				10-08-06	12:54	1	SALIVATION PRIOR TO DOSING
				10-09-06	12:59	2	SALIVATION PRIOR TO DOSING
				10-10-06	12:55	1	SALIVATION PRIOR TO DOSING
				10-11-06	12:44	2	SALIVATION PRIOR TO DOSING
				10-12-06	12:52	2	SALIVATION PRIOR TO DOSING
				10-13-06	12:45	3	SALIVATION PRIOR TO DOSING
				10-14-06	12:38	1	SALIVATION PRIOR TO DOSING
				10-15-06	12:39	2	SALIVATION PRIOR TO DOSING

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Revised Audited Draft

Modified: 4/30/2007

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38704-09	F	200 MG/KG/DAY	ORAL/DENTAL	10-11-06	13:29	2	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:37	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:25	2	WET CLEAR MATERIAL AROUND MOUTH
38704-01	F	200 MG/KG/DAY	ORAL/DENTAL	10-14-06	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
38705-01	F	200 MG/KG/DAY	ORAL/DENTAL	10-11-06	13:30	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
38704-03	F	200 MG/KG/DAY	ORAL/DENTAL	10-06-06	13:48	1	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:41	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:30	2	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:37	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:26	1	WET CLEAR MATERIAL AROUND MOUTH
38706-05	F	200 MG/KG/DAY	ORAL/DENTAL	10-07-06	13:44	2	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:41	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:30	3	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:18	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:16	1	WET CLEAR MATERIAL AROUND MOUTH
38708-09	F	200 MG/KG/DAY	ORAL/DENTAL	10-07-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:35	3	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	13:45	1	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:42	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38708-09	F	200 MG/KG/DAY	ORAL/DENTAL	10-11-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:18	1	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:27	1	WET CLEAR MATERIAL AROUND MOUTH
38707-10	F	200 MG/KG/DAY	ORAL/DENTAL	10-11-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:38	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:32	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:18	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:26	2	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:16	1	WET CLEAR MATERIAL AROUND MOUTH
38706-01	F	200 MG/KG/DAY	ORAL/DENTAL	10-08-06	13:35	2	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:31	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:33	2	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:19	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:27	1	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:17	2	WET CLEAR MATERIAL AROUND MOUTH
38707-04	F	200 MG/KG/DAY	ORAL/DENTAL	10-16-06	13:17	1	WET CLEAR MATERIAL AROUND MOUTH
38707-08	F	200 MG/KG/DAY	ORAL/DENTAL	10-06-06	13:49	1	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:35	1	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	13:46	2	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:32	3	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:39	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:33	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:19	2	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:27	2	WET CLEAR MATERIAL AROUND MOUTH
				10-16-06	13:17	2	WET CLEAR MATERIAL AROUND MOUTH
38705-09	F	800 MG/KG/DAY	ORAL/DENTAL	10-10-06	13:43	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:19	1	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

Revised Audited Draft

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TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38705-09	F	800 MG/KG/DAY	ORAL/DENTAL	10-15-06	13:28	1	WET CLEAR MATERIAL AROUND MOUTH
38704-06	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-29-06	13:49	P	HUNCHED POSTURE
38705-02	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	13:45	P	HUNCHED POSTURE
				10-02-06	14:00	P	HUNCHED POSTURE
38705-02	F	800 MG/KG/DAY	ORAL/DENTAL	10-01-06	13:43	1	WET CLEAR MATERIAL AROUND MOUTH
				10-02-06	13:59	1	WET CLEAR MATERIAL AROUND MOUTH
				10-04-06	13:52	1	WET CLEAR MATERIAL AROUND MOUTH
				10-05-06	13:55	2	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:50	2	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:46	1	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:36	1	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	13:47	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:34	1	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:19	1	WET CLEAR MATERIAL AROUND MOUTH
38707-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-28-06	13:59	P	HUNCHED POSTURE
38708-08	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	13:45	P	HUNCHED POSTURE
38706-06	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-02-06	14:01	P	HUNCHED POSTURE
38706-06	F	800 MG/KG/DAY	ORAL/DENTAL	10-02-06	14:01	2	WET CLEAR MATERIAL AROUND MOUTH
				10-03-06	13:36	2	WET CLEAR MATERIAL AROUND MOUTH
				10-05-06	13:56	2	WET CLEAR MATERIAL AROUND MOUTH
				10-06-06	13:51	3	WET CLEAR MATERIAL AROUND MOUTH
				10-07-06	13:46	2	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:36	3	WET CLEAR MATERIAL AROUND MOUTH
				10-09-06	13:48	3	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:33	3	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:40	2	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:35	3	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:20	3	WET CLEAR MATERIAL AROUND MOUTH
				10-15-06	13:29	3	WET CLEAR MATERIAL AROUND MOUTH

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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Modified: 4/30/2007

TABLE 16 (1 HOUR POST-DOSING)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL CLINICAL OBSERVATIONS
SPONSOR NO.:06-025

TABLE RANGE: 09-26-06 TO 10-17-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
38706-06	F	800 MG/KG/DAY	ORAL/DENTAL	10-16-06	13:18	2	WET CLEAR MATERIAL AROUND MOUTH
38706-09	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-29-06	13:51	P	HUNCHED POSTURE
38708-02	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	13:43	P	HUNCHED POSTURE
38709-05	F	800 MG/KG/DAY	ORAL/DENTAL	10-06-06	13:50	1	WET CLEAR MATERIAL AROUND MOUTH
				10-08-06	13:36	1	WET CLEAR MATERIAL AROUND MOUTH
				10-10-06	13:44	1	WET CLEAR MATERIAL AROUND MOUTH
				10-11-06	13:33	2	WET CLEAR MATERIAL AROUND MOUTH
				10-12-06	13:40	1	WET CLEAR MATERIAL AROUND MOUTH
				10-13-06	13:35	2	WET CLEAR MATERIAL AROUND MOUTH
				10-14-06	13:20	2	WET CLEAR MATERIAL AROUND MOUTH
				10-17-06	13:21	1	WET CLEAR MATERIAL AROUND MOUTH
38710-04	F	800 MG/KG/DAY	BEHAVIOR/CNS	09-30-06	13:46	P	HUNCHED POSTURE
38711-02	F	800 MG/KG/DAY	BEHAVIOR/CNS	10-01-06	13:45	P	HUNCHED POSTURE
				10-02-06	14:02	P	HUNCHED POSTURE
				10-03-06	13:38	P	HUNCHED POSTURE

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALES

DAY	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 1: 0 MG/KG/DAY												
38694-07	59.0	63.3	67.9	74.3	80.5	88.9	93.5	101.0	107.9	115.9	127.4	133.1
38696-08	48.1	55.6	61.4	65.7	73.8	80.8	87.4	95.2	101.4	109.1	118.3	124.6
38695-01	51.5	58.1	62.3	65.9	73.3	78.7	84.8	90.2	96.6	101.5	111.2	115.8
38695-07	49.9	56.3	61.1	64.1	71.5	77.0	83.7	87.8	94.2	102.1	108.2	113.0
38694-04	49.2	53.1	58.9	63.5	68.2	73.3	79.1	83.7	89.2	94.3	101.7	105.9
38696-04	50.3	55.7	60.9	64.2	69.6	76.4	82.2	85.1	91.6	95.8	101.0	104.1
38697-07	45.5	47.4	52.2	56.9	61.8	65.9	71.7	75.8	82.1	88.0	92.6	97.8
38698-04	52.6	56.8	61.3	67.2	72.0	77.8	83.2	90.6	96.8	103.0	112.2	116.9
38699-07	63.7	69.0	73.4	77.6	85.6	91.7	97.5	104.1	111.5	114.7	124.5	133.2
38698-05	60.5	64.7	69.2	72.8	80.2	84.4	90.3	95.3	100.8	107.8	110.4	118.9
38699-02	50.6	55.4	59.4	64.5	69.3	73.2	79.1	84.7	91.0	94.9	102.3	107.5
38697-03	47.7	52.6	58.4	63.2	71.6	77.4	83.8	90.1	97.0	104.4	106.4	120.6
38703-06	56.2	61.0	67.0	72.0	79.3	83.0	89.1	93.6	100.9	108.5	114.3	122.1
38700-06	46.0	50.6	54.7	60.2	66.8	72.7	77.9	85.4	92.2	100.4	108.0	114.9
38702-05	44.4	49.1	54.2	59.1	65.1	68.6	74.7	78.6	84.9	89.2	93.3	100.1
MEAN	51.7	56.6	61.5	66.1	72.6	78.0	83.9	89.4	95.9	102.0	108.8	115.2
S.D.	5.74	5.94	5.86	5.82	6.46	7.03	6.95	7.71	7.95	8.44	9.98	10.79
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR: [redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
DAY	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 1: 0 MG/KG/DAY									
38694-07	141.4	150.3	157.6	165.8	172.9	179.2	185.3	185.4	184.2
38696-08	132.5	139.9	141.7	144.2	149.3	156.1	166.3	164.5	164.8
38695-01	122.9	128.1	134.3	142.1	141.6	145.3	149.9	153.1	156.5
38695-07	120.2	126.4	134.0	140.1	139.7	145.4	147.1	155.4	160.8
38694-04	111.9	120.8	125.6	129.4	130.0	133.9	137.6	138.1	139.8
38696-04	110.5	117.5	122.4	125.6	125.6	132.0	137.8	143.1	143.4
38697-07	105.4	109.7	115.8	119.5	128.5	134.3	141.8	144.7	149.6
38698-04	120.9	120.2	128.6	132.1	137.3	143.2	144.9	151.2	144.0
38699-07	140.9	148.0	152.9	160.2	170.1	176.6	183.6	188.3	180.9
38698-05	122.9	128.0	134.6	135.1	144.1	149.1	154.1	153.1	154.0
38699-02	112.7	113.6	124.9	126.2	133.2	131.7	141.8	143.8	146.8
38697-03	125.1	134.2	141.5	148.5	159.2	163.9	174.1	178.2	184.2
38703-06	130.4	136.6	140.5	153.4	157.6	163.9	173.0	179.4	189.8
38700-06	122.7	129.6	136.2	141.5	151.3	157.4	167.8	169.8	168.1
38702-05	106.9	113.6	115.9	117.5	128.5	134.0	139.3	139.9	138.2
MEAN	121.8	127.8	133.8	138.7	144.6	149.7	156.3	159.2	160.3
S.D.	11.19	12.33	12.11	14.27	15.14	15.92	17.06	17.15	17.58
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
DAY	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 2: 10 MG/KG/DAY												
38705-03	53.6	58.8	63.9	70.0	74.2	81.4	87.1	92.5	99.2	103.8	115.0	121.6
38704-05	41.2	46.8	51.4	56.6	60.6	66.3	70.9	74.9	81.3	86.9	92.9	93.9
38705-10	51.1	56.4	60.9	66.9	71.2	78.2	84.8	91.3	99.1	107.9	115.8	122.1
38704-10	51.4	57.1	63.5	69.6	74.8	81.3	87.3	95.5	102.8	108.3	116.0	123.9
38705-07	50.7	55.0	60.1	66.4	69.6	76.5	79.7	85.8	93.7	98.0	105.8	110.3
38707-07	49.0	54.6	60.2	65.1	71.4	77.4	83.6	90.3	96.9	107.2	112.7	120.5
38706-04	52.8	57.8	62.9	68.5	73.7	78.5	85.1	91.4	98.0	104.5	111.7	117.0
38708-04	54.4	58.8	64.4	70.4	74.9	81.1	87.1	93.7	101.1	107.5	113.7	118.7
38707-02	52.4	57.4	63.0	67.8	73.4	79.2	84.2	93.3	99.3	105.3	112.4	119.5
38708-03	51.9	56.9	64.4	66.5	73.1	77.8	82.8	88.2	92.5	98.4	101.8	107.8
38706-08	44.6	48.4	54.9	59.2	64.9	70.4	73.7	78.9	84.1	91.3	96.8	103.8
38707-03	40.7	47.7	54.1	56.9	62.1	68.4	70.9	77.1	83.2	88.4	91.3	101.4
38710-10	53.3	57.6	62.0	66.6	72.1	75.8	82.0	86.3	94.9	100.4	108.6	115.3
38711-01	42.0	47.1	52.6	58.0	63.7	67.3	71.8	77.0	83.4	88.6	94.9	101.0
38709-08	43.4	48.5	52.8	57.8	62.3	65.4	70.6	75.3	83.1	89.2	93.7	99.9
MEAN	48.8	53.9	59.4	64.4	69.5	75.0	80.1	86.1	92.8	99.0	105.5	111.8
S.D.	4.97	4.71	4.81	5.15	5.20	5.77	6.58	7.44	7.67	8.12	9.35	9.78
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

	FEMALES								
DAY	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 2: 10 MG/KG/DAY									
38705-03	126.8	137.0	140.7	150.7	156.4	166.0	174.1	179.9	185.1
38704-05	98.7	106.0	111.5	117.7	121.4	125.9	129.2	135.3	140.0
38705-10	128.4	139.3	136.3	148.1	151.3	160.1	163.0	172.9	176.8
38704-10	133.0	140.2	142.9	152.2	156.1	162.8	164.8	168.8	175.8
38705-07	115.5	122.3	127.9	132.9	138.9	144.9	142.4	151.5	153.9
38707-07	126.8	135.2	142.7	148.4	152.1	158.3	164.8	171.2	174.9
38706-04	122.4	127.6	136.3	141.8	143.6	144.6	152.9	159.1	162.3
38708-04	125.3	131.7	133.2	138.9	144.7	146.5	150.7	155.3	157.9
38707-02	127.0	133.3	133.3	142.6	145.3	148.1	151.9	153.7	160.8
38708-03	116.9	122.2	129.6	129.4	139.7	140.9	147.3	152.9	153.1
38706-08	112.0	116.3	124.0	129.3	135.6	141.5	150.1	148.9	154.4
38707-03	104.6	110.9	118.4	120.9	127.1	132.9	139.6	142.5	147.9
38710-10	120.6	129.0	134.9	141.8	147.6	152.5	159.9	163.6	171.4
38711-01	107.6	113.8	121.7	129.4	137.1	144.2	149.7	156.7	163.8
38709-08	105.4	113.3	117.1	127.5	131.9	141.1	149.5	150.5	161.6
MEAN	118.1	125.2	130.0	136.8	141.9	147.4	152.7	157.5	162.6
S.D.	10.39	11.12	9.71	10.91	10.26	11.03	11.33	11.99	12.24
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
DAY	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 3: 50 MG/KG/DAY												
38704-08	48.7	53.7	59.1	65.1	71.9	76.0	82.2	88.2	94.6	100.0	105.0	114.4
38705-05	43.9	47.0	51.7	57.0	62.1	65.8	71.1	74.3	81.7	86.2	94.4	98.1
38704-04	47.1	54.0	59.1	64.8	70.1	75.8	81.1	86.4	91.8	97.6	104.9	113.8
38705-06	49.6	53.8	58.8	64.8	71.3	76.0	82.5	87.0	96.1	101.5	110.7	115.0
38704-07	42.1	46.4	52.1	57.5	61.4	67.4	73.4	77.9	85.3	90.9	98.0	104.8
38706-03	45.1	52.1	58.0	62.4	66.6	71.8	76.6	81.8	89.5	95.6	98.9	106.4
38707-01	48.8	55.9	59.4	64.3	69.3	75.5	80.5	85.3	91.4	98.8	103.7	110.7
38708-05	54.1	58.5	63.9	68.4	72.3	77.3	81.9	86.3	91.3	96.9	103.2	109.5
38708-01	54.5	57.9	63.2	68.2	72.3	77.5	81.8	86.2	92.3	99.5	104.1	111.0
38706-02	47.4	53.3	60.4	66.1	72.1	78.0	84.3	90.9	97.3	103.5	108.6	114.6
38707-05	44.3	49.1	55.4	60.6	66.6	73.3	80.3	88.1	93.5	100.1	111.1	115.5
38706-10	48.7	52.5	59.1	63.2	69.0	74.5	78.2	84.6	88.8	94.8	99.3	104.2
38708-06	53.2	56.9	62.9	68.8	73.9	79.6	85.0	91.3	99.7	107.6	110.5	117.9
38710-05	55.2	59.5	63.9	68.7	73.2	78.0	84.3	89.9	95.0	100.8	107.2	113.9
38709-01	49.2	53.1	57.8	63.1	66.7	73.5	80.0	85.1	93.0	99.4	106.4	111.2
MEAN	48.8	53.6	59.0	64.2	69.3	74.7	80.2	85.6	92.1	98.2	104.4	110.7
S.D.	4.05	3.90	3.77	3.74	3.87	3.87	3.95	4.62	4.56	5.09	5.01	5.33
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
DAY	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 3: 50 MG/KG/DAY									
38704-08	121.3	124.9	133.8	140.4	147.5	153.5	158.1	162.7	164.2
38705-05	104.6	109.8	113.6	114.2	122.4	129.1	133.5	138.8	135.5
38704-04	122.0	127.6	135.8	144.7	151.2	156.1	159.9	161.8	167.3
38705-06	125.1	131.7	129.6	137.6	142.9	150.5	154.0	156.3	163.9
38704-07	112.2	120.8	125.4	134.5	138.1	147.4	153.4	152.9	160.8
38706-03	114.8	117.3	125.0	127.7	135.6	138.1	142.8	147.8	152.8
38707-01	114.5	119.7	124.6	127.5	131.5	132.7	137.9	142.6	145.1
38708-05	115.4	121.8	126.5	131.7	135.1	141.6	147.4	154.3	155.4
38708-01	118.4	121.7	125.5	131.2	137.7	143.0	148.1	149.1	154.8
38706-02	124.1	128.7	138.4	143.0	144.8	152.5	158.6	163.0	168.7
38707-05	126.7	132.8	141.1	145.1	149.5	158.7	162.3	171.2	173.9
38706-10	111.3	116.0	118.1	124.8	130.1	139.1	139.9	137.1	145.8
38708-06	124.7	131.6	137.7	142.6	147.3	154.6	157.0	157.6	160.2
38710-05	119.8	125.1	130.2	130.5	135.6	144.9	148.0	155.3	157.3
38709-01	119.8	127.0	135.0	139.4	141.1	150.7	158.3	161.7	165.4
MEAN	118.3	123.8	129.4	134.3	139.4	146.2	150.6	154.1	158.1
S.D.	6.14	6.49	7.74	8.69	8.03	8.79	8.93	9.65	10.21
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES											
DAY	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 4: 200 MG/KG/DAY												
38705-08	48.5	53.3	58.1	63.8	68.8	76.4	80.5	84.6	90.3	95.2	102.1	105.2
38704-09	41.4	45.3	49.4	54.7	59.1	64.7	67.4	70.9	76.8	81.3	86.4	92.6
38704-01	48.1	52.2	58.7	66.1	70.8	76.2	81.1	87.1	93.2	96.2	103.3	108.0
38705-01	52.8	57.1	62.0	68.2	74.1	79.9	86.1	90.5	92.8	97.2	101.3	107.0
38704-03	40.9	46.4	51.1	56.1	60.6	66.5	71.8	74.8	81.1	85.0	91.8	96.8
38706-05	49.1	52.0	57.4	64.5	71.9	76.0	81.5	87.3	91.5	97.4	104.1	109.7
38708-09	53.3	57.3	63.2	66.5	72.7	77.0	80.6	85.1	89.7	97.5	99.7	107.6
38707-10	54.9	58.9	65.4	69.3	74.4	79.5	85.8	90.8	97.2	106.8	111.1	115.5
38708-10	55.5	60.3	67.2	70.9	76.7	83.6	88.3	94.2	99.6	107.3	113.1	118.2
38706-01	48.2	53.9	59.8	65.2	71.4	74.5	78.4	83.7	88.5	93.1	98.8	103.6
38707-04	50.3	54.2	59.3	64.1	71.2	75.4	80.8	86.2	91.7	96.7	101.8	110.2
38707-08	49.9	54.3	60.8	66.9	72.7	78.1	83.4	88.1	96.2	99.7	107.5	110.2
38706-07	53.3	57.1	64.7	70.4	76.2	81.2	86.4	92.6	99.6	104.8	108.3	116.2
38710-09	52.9	57.6	60.9	67.4	70.3	75.4	81.0	87.4	93.3	98.7	104.5	109.4
38709-04	48.8	53.2	57.4	62.0	64.9	70.7	74.3	79.7	85.5	90.5	96.5	101.4
MEAN	49.9	54.2	59.7	65.1	70.4	75.7	80.5	85.5	91.1	96.5	102.0	107.4
S.D.	4.31	4.21	4.84	4.65	5.17	5.11	5.70	6.33	6.36	7.18	6.98	6.93
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
DAY	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 4: 200 MG/KG/DAY									
38705-08	110.2	119.3	122.6	131.8	130.8	133.0	142.4	148.0	157.3
38704-09	94.4	102.0	105.6	110.3	113.6	117.6	122.1	125.3	130.2
38704-01	116.0	120.0	126.1	128.7	133.5	141.2	143.2	145.7	150.8
38705-01	113.1	116.8	120.2	125.7	124.0	128.3	131.4	135.0	139.1
38704-03	100.6	105.7	110.2	116.0	120.9	125.8	127.9	131.6	133.4
38706-05	115.0	119.4	126.5	126.9	126.4	135.5	141.4	143.4	145.0
38708-09	110.3	115.1	121.1	123.7	131.8	138.0	137.8	145.3	147.0
38707-10	121.4	128.1	129.6	134.1	138.0	137.3	143.3	150.5	151.3
38708-10	123.4	128.6	132.2	136.1	146.1	151.7	157.1	159.8	163.1
38706-01	109.5	114.5	119.5	121.6	126.4	132.1	136.2	141.8	142.8
38707-04	117.7	122.1	129.3	132.2	137.3	143.7	149.1	153.9	159.5
38707-08	117.5	120.0	127.8	130.2	133.1	138.5	144.6	147.0	152.1
38706-07	123.3	128.0	133.4	138.2	142.9	149.6	155.2	158.9	162.9
38710-09	118.1	122.9	128.1	134.6	140.4	147.3	152.8	161.6	163.1
38709-04	106.5	113.5	115.4	119.7	118.4	124.7	130.6	136.1	136.2
MEAN	113.1	118.4	123.2	127.3	130.9	136.3	141.0	145.6	148.9
S.D.	8.17	7.63	7.99	7.90	9.31	9.67	10.19	10.57	11.04
N	15	15	15	15	15	15	15	15	15

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 9
SPONSOR: [redacted]
INDIVIDUAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

	FEMALES											
DAY	22	23	24	25	26	27	28	29	30	31	32	33
ANIMALS FROM GROUP 5: 800 MG/KG/DAY												
38705-09	52.3	54.3	50.3	52.1	54.6	63.4	67.6	69.9	72.0	76.0	80.6	88.9
38704-06	49.3	48.1	43.1	40.8	NA							
38704-02	47.3	47.3	41.2	NA								
38705-02	56.8	59.9	61.3	61.8	64.4	72.6	79.0	84.6	90.3	95.2	101.7	108.8
38705-04	48.1	48.3	NA									
38707-09	42.1	36.7	NA									
38708-08	49.7	52.4	49.0	44.8	NA							
38706-06	54.8	55.9	55.2	56.8	66.4	70.1	73.1	76.5	78.3	84.4	92.6	100.0
38707-06	55.3	58.3	52.1	NA								
38706-09	51.6	52.3	46.8	NA								
38708-07	47.5	49.6	44.6	NA								
38708-02	51.1	54.0	51.1	46.4	NA							
38709-05	51.1	54.9	55.2	53.7	58.2	65.4	74.7	79.7	83.6	95.4	104.6	107.6
38710-04	49.7	50.2	42.8	NA								
38711-02	41.3	43.8	45.8	42.5	39.6	36.5	NA					
MEAN	49.9	51.1	49.1	49.9	56.6	61.6	73.6	77.7	81.1	87.8	94.9	101.3
S.D.	4.34	5.88	5.86	7.41	10.64	14.50	4.71	6.16	7.78	9.37	10.80	9.15
N	15	15	13	8	5	5	4	4	4	4	4	4

NA = NOT APPLICABLE

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TABLE 17

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHTS [G]

	FEMALES								
DAY	34	35	36	37	38	39	40	41	42
ANIMALS FROM GROUP 5: 800 MG/KG/DAY									
38705-09	92.8	94.9	96.2	94.6	96.7	102.9	111.3	123.1	123.2
38705-02	115.3	120.5	125.0	128.5	136.5	142.8	146.8	152.6	158.5
38706-06	101.2	108.1	110.3	118.2	124.1	124.7	133.5	135.2	137.8
38709-05	116.7	123.2	125.8	132.3	139.6	147.4	149.4	151.9	158.4
MEAN	106.5	111.7	114.3	118.4	124.2	129.5	135.3	140.7	144.5
S.D.	11.51	12.97	14.03	16.95	19.53	20.23	17.42	14.23	17.20
N	4	4	4	4	4	4	4	4	4

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

FEMALES

DAY	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 1: 0 MG/KG/DAY												
38694-07	4.3	4.6	6.4	6.2	8.4	4.6	7.5	6.9	8.0	11.5	5.7	8.3
38696-08	7.5	5.8	4.3	8.1	7.0	6.6	7.8	6.2	7.7	9.2	6.3	7.9
38695-01	6.6	4.2	3.6	7.4	5.4	6.1	5.4	6.4	4.9	9.7	4.6	7.1
38695-07	6.4	4.8	3.0	7.4	5.5	6.7	4.1	6.4	7.9	6.1	4.8	7.2
38694-04	3.9	5.8	4.6	4.7	5.1	5.8	4.6	5.5	5.1	7.4	4.2	6.0
38696-04	5.4	5.2	3.3	5.4	6.8	5.8	2.9	6.5	4.2	5.2	3.1	6.4
38697-07	1.9	4.8	4.7	4.9	4.1	5.8	4.1	6.3	5.9	4.6	5.2	7.6
38698-04	4.2	4.5	5.9	4.8	5.8	5.4	7.4	6.2	6.2	9.2	4.7	4.0
38699-07	5.3	4.4	4.2	8.0	6.1	5.8	6.6	7.4	3.2	9.8	8.7	7.7
38698-05	4.2	4.5	3.6	7.4	4.2	5.9	5.0	5.5	7.0	2.6	8.5	4.0
38699-02	4.8	4.0	5.1	4.8	3.9	5.9	5.6	6.3	3.9	7.4	5.2	5.2
38697-03	4.9	5.8	4.8	8.4	5.8	6.4	6.3	6.9	7.4	2.0	14.2	4.5
38703-06	4.8	6.0	5.0	7.3	3.7	6.1	4.5	7.3	7.6	5.8	7.8	8.3
38700-06	4.6	4.1	5.5	6.6	5.9	5.2	7.5	6.8	8.2	7.6	6.9	7.8
38702-05	4.7	5.1	4.9	6.0	3.5	6.1	3.9	6.3	4.3	4.1	6.8	6.8
MEAN	4.9	4.9	4.6	6.5	5.4	5.9	5.5	6.5	6.1	6.8	6.4	6.6
S.D.	1.30	0.68	0.96	1.33	1.38	0.53	1.56	0.54	1.71	2.79	2.68	1.51
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL BODY WEIGHT CHANGES [G]

	FEMALES								
DAY	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 1: 0 MG/KG/DAY									
38694-07	8.9	7.3	8.2	7.1	6.3	6.1	0.1	-1.2	125.2
38696-08	7.4	1.8	2.5	5.1	6.8	10.2	-1.8	0.3	116.7
38695-01	5.2	6.2	7.8	-0.5	3.7	4.6	3.2	3.4	105.0
38695-07	6.2	7.6	6.1	-0.4	5.7	1.7	8.3	5.4	110.9
38694-04	8.9	4.8	3.8	0.6	3.9	3.7	0.5	1.7	90.6
38696-04	7.0	4.9	3.2	0.0	6.4	5.8	5.3	0.3	93.1
38697-07	4.3	6.1	3.7	9.0	5.8	7.5	2.9	4.9	104.1
38698-04	-0.7	8.4	3.5	5.2	5.9	1.7	6.3	-7.2	91.4
38699-07	7.1	4.9	7.3	9.9	6.5	7.0	4.7	-7.4	117.2
38698-05	5.1	6.6	0.5	9.0	5.0	5.0	-1.0	0.9	93.5
38699-02	0.9	11.3	1.3	7.0	-1.5	10.1	2.0	3.0	96.2
38697-03	9.1	7.3	7.0	10.7	4.7	10.2	4.1	6.0	136.5
38703-06	6.2	3.9	12.9	4.2	6.3	9.1	6.4	10.4	133.6
38700-06	6.9	6.6	5.3	9.8	6.1	10.4	2.0	-1.7	122.1
38702-05	6.7	2.3	1.6	11.0	5.5	5.3	0.6	-1.7	93.8
MEAN	5.9	6.0	5.0	5.8	5.1	6.6	2.9	1.1	108.7
S.D.	2.77	2.39	3.29	4.22	2.06	2.99	2.94	4.75	15.81
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR: [redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

FEMALES

DAY	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 2: 10 MG/KG/DAY												
38705-03	5.2	5.1	6.1	4.2	7.2	5.7	5.4	6.7	4.6	11.2	6.6	5.2
38704-05	5.6	4.6	5.2	4.0	5.7	4.6	4.0	6.4	5.6	6.0	1.0	4.8
38705-10	5.3	4.5	6.0	4.3	7.0	6.6	6.5	7.8	8.8	7.9	6.3	6.3
38704-10	5.7	6.4	6.1	5.2	6.5	6.0	8.2	7.3	5.5	7.7	7.9	9.1
38705-07	4.3	5.1	6.3	3.2	6.9	3.2	6.1	7.9	4.3	7.8	4.5	5.2
38707-07	5.6	5.6	4.9	6.3	6.0	6.2	6.7	6.6	10.3	5.5	7.8	6.3
38706-04	5.0	5.1	5.6	5.2	4.8	6.6	6.3	6.6	6.5	7.2	5.3	5.4
38708-04	4.4	5.6	6.0	4.5	6.2	6.0	6.6	7.4	6.4	6.2	5.0	6.6
38707-02	5.0	5.6	4.8	5.6	5.8	5.0	9.1	6.0	6.0	7.1	7.1	7.5
38708-03	5.0	7.5	2.1	6.6	4.7	5.0	5.4	4.3	5.9	3.4	6.0	9.1
38706-08	3.8	6.5	4.3	5.7	5.5	3.3	5.2	5.2	7.2	5.5	7.0	8.2
38707-03	7.0	6.4	2.8	5.2	6.3	2.5	6.2	6.1	5.2	2.9	10.1	3.2
38710-10	4.3	4.4	4.6	5.5	3.7	6.2	4.3	8.6	5.5	8.2	6.7	5.3
38711-01	5.1	5.5	5.4	5.7	3.6	4.5	5.2	6.4	5.2	6.3	6.1	6.6
38709-08	5.1	4.3	5.0	4.5	3.1	5.2	4.7	7.8	6.1	4.5	6.2	5.5
MEAN	5.1	5.5	5.0	5.0	5.5	5.1	6.0	6.7	6.2	6.5	6.2	6.3
S.D.	0.76	0.91	1.21	0.92	1.29	1.29	1.37	1.11	1.57	2.07	1.98	1.64
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

	FEMALES								
DAY	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 2: 10 MG/KG/DAY									
38705-03	10.2	3.7	10.0	5.7	9.6	8.1	5.8	5.2	131.5
38704-05	7.3	5.5	6.2	3.7	4.5	3.3	6.1	4.7	98.8
38705-10	10.9	-3.0	11.8	3.2	8.8	2.9	9.9	3.9	125.7
38704-10	7.2	2.7	9.3	3.9	6.7	2.0	4.0	7.0	124.4
38705-07	6.8	5.6	5.0	6.0	6.0	-2.5	9.1	2.4	103.2
38707-07	8.4	7.5	5.7	3.7	6.2	6.5	6.4	3.7	125.9
38706-04	5.2	8.7	5.5	1.8	1.0	8.3	6.2	3.2	109.5
38708-04	6.4	1.5	5.7	5.8	1.8	4.2	4.6	2.6	103.5
38707-02	6.3	0.0	9.3	2.7	2.8	3.8	1.8	7.1	108.4
38708-03	5.3	7.4	-0.2	10.3	1.2	6.4	5.6	0.2	101.2
38706-08	4.3	7.7	5.3	6.3	5.9	8.6	-1.2	5.5	109.8
38707-03	6.3	7.5	2.5	6.2	5.8	6.7	2.9	5.4	107.2
38710-10	8.4	5.9	6.9	5.8	4.9	7.4	3.7	7.8	118.1
38711-01	6.2	7.9	7.7	7.7	7.1	5.5	7.0	7.1	121.8
38709-08	7.9	3.8	10.4	4.4	9.2	8.4	1.0	11.1	118.2
MEAN	7.1	4.8	6.7	5.1	5.4	5.3	4.9	5.1	113.8
S.D.	1.80	3.36	3.15	2.15	2.77	3.06	2.95	2.67	10.44
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 5
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

	FEMALES											
DAY	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 3: 50 MG/KG/DAY												
38704-08	5.0	5.4	6.0	6.8	4.1	6.2	6.0	6.4	5.4	5.0	9.4	6.9
38705-05	3.1	4.7	5.3	5.1	3.7	5.3	3.2	7.4	4.5	8.2	3.7	6.5
38704-04	6.9	5.1	5.7	5.3	5.7	5.3	5.3	5.4	5.8	7.3	8.9	8.2
38705-06	4.2	5.0	6.0	6.5	4.7	6.5	4.5	9.1	5.4	9.2	4.3	10.1
38704-07	4.3	5.7	5.4	3.9	6.0	6.0	4.5	7.4	5.6	7.1	6.8	7.4
38706-03	7.0	5.9	4.4	4.2	5.2	4.8	5.2	7.7	6.1	3.3	7.5	8.4
38707-01	7.1	3.5	4.9	5.0	6.2	5.0	4.8	6.1	7.4	4.9	7.0	3.8
38708-05	4.4	5.4	4.5	3.9	5.0	4.6	4.4	5.0	5.6	6.3	6.3	5.9
38708-01	3.4	5.3	5.0	4.1	5.2	4.3	4.4	6.1	7.2	4.6	6.9	7.4
38706-02	5.9	7.1	5.7	6.0	5.9	6.3	6.6	6.4	6.2	5.1	6.0	9.5
38707-05	4.8	6.3	5.2	6.0	6.7	7.0	7.8	5.4	6.6	11.0	4.4	11.2
38706-10	3.8	6.6	4.1	5.8	5.5	3.7	6.4	4.2	6.0	4.5	4.9	7.1
38708-06	3.7	6.0	5.9	5.1	5.7	5.4	6.3	8.4	7.9	2.9	7.4	6.8
38710-05	4.3	4.4	4.8	4.5	4.8	6.3	5.6	5.1	5.8	6.4	6.7	5.9
38709-01	3.9	4.7	5.3	3.6	6.8	6.5	5.1	7.9	6.4	7.0	4.8	8.6
MEAN	4.8	5.4	5.2	5.1	5.4	5.5	5.3	6.5	6.1	6.2	6.3	7.6
S.D.	1.33	0.91	0.60	1.01	0.88	0.95	1.14	1.40	0.87	2.20	1.67	1.85
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

	FEMALES								
DAY	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 3: 50 MG/KG/DAY									
38704-08	3.6	8.9	6.6	7.1	6.0	4.6	4.6	1.5	115.5
38705-05	5.2	3.8	0.6	8.2	6.7	4.4	5.3	-3.3	91.6
38704-04	5.6	8.2	8.9	6.5	4.9	3.8	1.9	5.5	120.2
38705-06	6.6	-2.1	8.0	5.3	7.6	3.5	2.3	7.6	114.3
38704-07	8.6	4.6	9.1	3.6	9.3	6.0	-0.5	7.9	118.7
38706-03	2.5	7.7	2.7	7.9	2.5	4.7	5.0	5.0	107.7
38707-01	5.2	4.9	2.9	4.0	1.2	5.2	4.7	2.5	96.3
38708-05	6.4	4.7	5.2	3.4	6.5	5.8	6.9	1.1	101.3
38708-01	3.3	3.8	5.7	6.5	5.3	5.1	1.0	5.7	100.3
38706-02	4.6	9.7	4.6	1.8	7.7	6.1	4.4	5.7	121.3
38707-05	6.1	8.3	4.0	4.4	9.2	3.6	8.9	2.7	129.6
38706-10	4.7	2.1	6.7	5.3	9.0	0.8	-2.8	8.7	97.1
38708-06	6.9	6.1	4.9	4.7	7.3	2.4	0.6	2.6	107.0
38710-05	5.3	5.1	0.3	5.1	9.3	3.1	7.3	2.0	102.1
38709-01	7.2	8.0	4.4	1.7	9.6	7.6	3.4	3.7	116.2
MEAN	5.5	5.6	5.0	5.0	6.8	4.4	3.5	3.9	109.3
S.D.	1.60	3.08	2.67	1.98	2.52	1.68	3.14	3.13	11.05
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

FEMALES

DAY	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 4: 200 MG/KG/DAY												
38705-08	4.8	4.8	5.7	5.0	7.6	4.1	4.1	5.7	4.9	6.9	3.1	5.0
38704-09	3.9	4.1	5.3	4.4	5.6	2.7	3.5	5.9	4.5	5.1	6.2	1.8
38704-01	4.1	6.5	7.4	4.7	5.4	4.9	6.0	6.1	3.0	7.1	4.7	8.0
38705-01	4.3	4.9	6.2	5.9	5.8	6.2	4.4	2.3	4.4	4.1	5.7	6.1
38704-03	5.5	4.7	5.0	4.5	5.9	5.3	3.0	6.3	3.9	6.8	5.0	3.8
38706-05	2.9	5.4	7.1	7.4	4.1	5.5	5.8	4.2	5.9	6.7	5.6	5.3
38708-09	4.0	5.9	3.3	6.2	4.3	3.6	4.5	4.6	7.8	2.2	7.9	2.7
38707-10	4.0	6.5	3.9	5.1	5.1	6.3	5.0	6.4	9.6	4.3	4.4	5.9
38708-10	4.8	6.9	3.7	5.8	6.9	4.7	5.9	5.4	7.7	5.8	5.1	5.2
38706-01	5.7	5.9	5.4	6.2	3.1	3.9	5.3	4.8	4.6	5.7	4.8	5.9
38707-04	3.9	5.1	4.8	7.1	4.2	5.4	5.4	5.5	5.0	5.1	8.4	7.5
38707-08	4.4	6.5	6.1	5.8	5.4	5.3	4.7	8.1	3.5	7.8	2.7	7.3
38706-07	3.8	7.6	5.7	5.8	5.0	5.2	6.2	7.0	5.2	3.5	7.9	7.1
38710-09	4.7	3.3	6.5	2.9	5.1	5.6	6.4	5.9	5.4	5.8	4.9	8.7
38709-04	4.4	4.2	4.6	2.9	5.8	3.6	5.4	5.8	5.0	6.0	4.9	5.1
MEAN	4.3	5.5	5.4	5.3	5.3	4.8	5.0	5.6	5.4	5.5	5.4	5.7
S.D.	0.70	1.19	1.20	1.30	1.12	1.03	1.00	1.32	1.76	1.51	1.64	1.92
N	15	15	15	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

FEMALES

DAY	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 4: 200 MG/KG/DAY									
38705-08	9.1	3.3	9.2	-1.0	2.2	9.4	5.6	9.3	108.8
38704-09	7.6	3.6	4.7	3.3	4.0	4.5	3.2	4.9	88.8
38704-01	4.0	6.1	2.6	4.8	7.7	2.0	2.5	5.1	102.7
38705-01	3.7	3.4	5.5	-1.7	4.3	3.1	3.6	4.1	86.3
38704-03	5.1	4.5	5.8	4.9	4.9	2.1	3.7	1.8	92.5
38706-05	4.4	7.1	0.4	-0.5	9.1	5.9	2.0	1.6	95.9
38708-09	4.8	6.0	2.6	8.1	6.2	-0.2	7.5	1.7	93.7
38707-10	6.7	1.5	4.5	3.9	-0.7	6.0	7.2	0.8	96.4
38708-10	5.2	3.6	3.9	10.0	5.6	5.4	2.7	3.3	107.6
38706-01	5.0	5.0	2.1	4.8	5.7	4.1	5.6	1.0	94.6
38707-04	4.4	7.2	2.9	5.1	6.4	5.4	4.8	5.6	109.2
38707-08	2.5	7.8	2.4	2.9	5.4	6.1	2.4	5.1	102.2
38706-07	4.7	5.4	4.8	4.7	6.7	5.6	3.7	4.0	109.6
38710-09	4.8	5.2	6.5	5.8	6.9	5.5	8.8	1.5	110.2
38709-04	7.0	1.9	4.3	-1.3	6.3	5.9	5.5	0.1	87.4
MEAN	5.3	4.8	4.1	3.6	5.4	4.7	4.6	3.3	99.1
S.D.	1.67	1.89	2.14	3.43	2.34	2.27	2.07	2.45	8.63
N	15	15	15	15	15	15	15	15	15

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

	FEMALES											
DAY	22- 23	23- 24	24- 25	25- 26	26- 27	27- 28	28- 29	29- 30	30- 31	31- 32	32- 33	33- 34
ANIMALS FROM GROUP 5: 800 MG/KG/DAY												
38705-09	2.0	-4.0	1.8	2.5	8.8	4.2	2.3	2.1	4.0	4.6	8.3	3.9
38704-06	-1.2	-5.0	-2.3	NA								
38704-02	0.0	-6.1	NA									
38705-02	3.1	1.4	0.5	2.6	8.2	6.4	5.6	5.7	4.9	6.5	7.1	6.5
38705-04	0.2	NA										
38707-09	-5.4	NA										
38708-08	2.7	-3.4	-4.2	NA								
38706-06	1.1	-0.7	1.6	9.6	3.7	3.0	3.4	1.8	6.1	8.2	7.4	1.2
38707-06	3.0	-6.2	NA									
38706-09	0.7	-5.5	NA									
38708-07	2.1	-5.0	NA									
38708-02	2.9	-2.9	-4.7	NA								
38709-05	3.8	0.3	-1.5	4.5	7.2	9.3	5.0	3.9	11.8	9.2	3.0	9.1
38710-04	0.5	-7.4	NA									
38711-02	2.5	2.0	-3.3	-2.9	-3.1	NA						
MEAN	1.2	-3.3	-1.5	3.3	5.0	5.7	4.1	3.4	6.7	7.1	6.5	5.2
S.D.	2.31	3.09	2.56	4.49	4.92	2.77	1.50	1.81	3.51	2.02	2.36	3.40
N	15	13	8	5	5	4	4	4	4	4	4	4

NA = NOT APPLICABLE

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TABLE 18

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL BODY WEIGHT CHANGES [G]
SPONSOR NO.:06-025

	FEMALES								
DAY	34- 35	35- 36	36- 37	37- 38	38- 39	39- 40	40- 41	41- 42	22- 42
ANIMALS FROM GROUP 5: 800 MG/KG/DAY									
38705-09	2.1	1.3	-1.6	2.1	6.2	8.4	11.8	0.1	70.9
38705-02	5.2	4.5	3.5	8.0	6.3	4.0	5.8	5.9	101.7
38706-06	6.9	2.2	7.9	5.9	0.6	8.8	1.7	2.6	83.0
38709-05	6.5	2.6	6.5	7.3	7.8	2.0	2.5	6.5	107.3
MEAN	5.2	2.7	4.1	5.8	5.2	5.8	5.5	3.8	90.7
S.D.	2.17	1.35	4.21	2.63	3.17	3.34	4.59	2.99	16.81
N	4	4	4	4	4	4	4	4	4

PJTBWv4.22
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TABLE 19

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-025

GROUP: 0 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36	37	38
38694-07	28	94.1	N	Y										
38696-08	32	117.9	N	N	N	N	N	Y						
38695-01	33	116.2	N	N	N	N	N	N	Y					
38695-07	34	119.2	N	N	N	N	N	N	N	Y				
38694-04	34	112.5	N	N	N	N	N	N	N	Y				
38696-04	34	111.4	N	N	N	N	N	N	N	Y				
38697-07	34	105.0	N	N	N	N	N	N	N	Y				
38698-04	30	97.1	N	N	N	Y								
38699-07	30	112.3	N	N	N	Y								
38698-05	34	124.3	N	N	N	N	N	N	N	Y				
38699-02	33	108.2	N	N	N	N	N	N	Y					
38697-03	33	119.4	N	N	N	N	N	N	Y					
38703-06	33	121.5	N	N	N	N	N	N	Y					
38700-06	33	118.2	N	N	N	N	N	N	Y					
38702-05	33	101.0	N	N	N	N	N	N	Y					
MEAN	32.5	111.9												
S.D.	1.81	9.13												
N	15	15												

PND = POSTNATAL DAY
N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

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Revised Audited Draft

TABLE 19

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-025 INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY

GROUP: 10 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36	37	38
38705-03	33	121.6	N	N	N	N	N	N	Y					
38704-05	35	136.0	N	N	N	N	N	N	N	N	Y			
38705-10	31	106.9	N	N	N	N	Y							
38704-10	31	107.9	N	N	N	N	Y							
38705-07	34	115.6	N	N	N	N	N	N	N	Y				
38707-07	31	106.0	N	N	N	N	Y							
38706-04	29	91.1	N	N	Y									
38708-04	28	87.1	N	Y										
38707-02	28	85.2	N	Y										
38708-03	35	119.4	N	N	N	N	N	N	N	N	Y			
38706-08	38	134.9	N	N	N	N	N	N	N	N	N	N	N	Y
38707-03	33	99.8	N	N	N	N	N	N	Y					
38710-10	33	114.9	N	N	N	N	N	N	Y					
38711-01	32	92.5	N	N	N	N	N	Y						
38709-08	34	107.2	N	N	N	N	N	N	N	Y				
MEAN	32.3	108.4												
S.D.	2.77	15.77												
N	15	15												

PND = POSTNATAL DAY
N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

Revised Audited Draft

Modified: 4/30/2007

TABLE 19

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-025

GROUP: 50 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36	37	38
38704-08	29	87.9	N	N	Y									
38705-05	29	74.1	N	N	Y									
38704-04	29	86.4	N	N	Y									
38705-06	29	87.7	N	N	Y									
38704-07	29	77.4	N	N	Y									
38706-03	28	76.6	N	Y										
38707-01	28	80.7	N	Y										
38708-05	28	82.3	N	Y										
38708-01	28	81.4	N	Y										
38706-02	28	83.7	N	Y										
38707-05	29	87.4	N	N	Y									
38706-10	30	87.3	N	N	N	Y								
38708-06	29	91.4	N	N	Y									
38710-05	32	106.3	N	N	N	N	N	Y						
38709-01	34	119.5	N	N	N	N	N	N	N	Y				
MEAN	29.3	87.3												
S.D.	1.67	11.71												
N	15	15												

PND = POSTNATAL DAY
N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

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Modified: 4/30/2007

TABLE 19

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-025

GROUP: 200 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36	37	38
38705-08	29	84.1	N	N	Y									
38704-09	30	77.7	N	N	N	Y								
38704-01	31	96.8	N	N	N	N	Y							
38705-01	29	90.0	N	N	Y									
38704-03	30	80.0	N	N	N	Y								
38706-05	28	81.3	N	Y										
38708-09	35	114.8	N	N	N	N	N	N	N	N	Y			
38707-10	27	79.0	Y											
38708-10	28	87.7	N	Y										
38706-01	28	78.3	N	Y										
38707-04	29	86.5	N	N	Y									
38707-08	30	93.9	N	N	N	Y								
38706-07	28	86.0	N	Y										
38710-09	28	80.8	N	Y										
38709-04	28	74.9	N	Y										
MEAN	29.2	86.1												
S.D.	1.93	10.06												
N	15	15												

PND = POSTNATAL DAY
N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE

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TABLE 19

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ANIMAL DEVELOPMENTAL PARAMETERS - VAGINAL PATENCY
SPONSOR NO.:06-025

GROUP: 800 MG/KG/DAY SEX: FEMALES

ANIMAL	DAY OF RESPONSE	WEIGHT GRAMS	PND===> 27	28	29	30	31	32	33	34	35	36	37	38
38705-09	36	95.9	N	N	N	N	N	N	N	N	N	Y		
38704-06	A	A												
38704-02	B	B												
38705-02	29	86.3	N	N	Y									
38705-04	C	C												
38707-09	C	C												
38708-08	A	A												
38706-06	28	72.3	N	Y										
38707-06	B	B												
38706-09	B	B												
38708-07	B	B												
38708-02	A	A												
38709-05	27	65.9	Y											
38710-04	B	B												
38711-02	27	37.5	Y											
MEAN	29.4	71.6												
S.D.	3.78	22.37												
N	5	5												

PND = POSTNATAL DAY
N = NEGATIVE RESPONSE, Y = POSITIVE RESPONSE
A = RESPONSE NOT EXHIBITED BY DAY 25, THE DAY OF (OR DAY PRIOR TO) DEATH
B = RESPONSE NOT EXHIBITED BY DAY 24, THE DAY OF (OR DAY PRIOR TO) DEATH
C = RESPONSE NOT EXHIBITED BY DAY 23, THE DAY OF (OR DAY PRIOR TO) DEATH

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TABLE 20

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-025

FEMALES FROM GROUP 1: 0 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF E (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38694-07	28	E D D D D D D D D D D D D D E	28	A
38696-08	32	E D D D P E D D D D E	32	5.0
38695-01	33	E D D D D E D D D P	33	5.0
38695-07	34	E D D D P E M D D	34	5.0
38694-04	34	D D D P E D D D E	38	A
38696-04	34	D D D P E D D D E	38	A
38697-07	34	D D P E D D D D D	37	A
38698-04	30	E D D D P E M D D D D D E	30	5.0
38699-07	30	P E D D D D D D D D D D P	31	A
38698-05	34	D D P E D D D P E	37	A
38699-02	33	D D E D D D E D D P	35	4.0
38697-03	33	D D D D D D D D D D	NA	A
38703-06	33	D D D D D D D D D D	NA	A
38700-06	33	D D D P E D D D E E	37	A
38702-05	33	D D D P E D D D P E	37	A
		MEAN	34.4	4.8
		S.D.	33.3	0.45
		N	13	5

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
NA = NOT APPLICABLE, NO OCCURRENCE OF E

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TABLE 20

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 2: 10 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF E (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38705-03	33	N D D D D D D D D D	NA	A
38704-05	35	D D D D E D D D	39	A
38705-10	31	E D D D D E D D D D D D	31	5.0
38704-10	31	P M D D P E D D D E E D	36	5.0
38705-07	34	P E E D D P E D D	35	4.0
38707-07	31	E D D D D D D E D D D P	31	7.0
38706-04	29	P D D D P E D D D P E D D D	34	5.0
38708-04	28	D D D E D D D P E D D D E D D	31	4.5
38707-02	28	D D D E D D D P E D D D E E D	31	5.0
38708-03	35	D P E M D D P E	37	A
38706-08	38	D D D E D	41	A
38707-03	33	P D D D D D E D D D	39	6.0
38710-10	33	D E D D D P E D D D	34	5.0
38711-01	32	E D D D D D D D D D D	32	A
38709-08	34	E D D D D D D D D	34	A
		MEAN	34.6	5.2
		S.D.	3.37	0.87
		N	14	9

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
NA = NOT APPLICABLE, NO OCCURRENCE OF E
N = NOT RECORDED

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TABLE 20

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR: [redacted]
SPONSOR NO.:06-025
INDIVIDUAL ESTROUS CYCLE DATA

FEMALES FROM GROUP 3: 50 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF E (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38704-08	29	P E E D D D D D D D D D E	30	A
38705-05	29	D D E D D D D E E D D D D E	31	6.0
38704-04	29	E E D D D D D D D D D D D D	29	A
38705-06	29	D E E D D D P E D D D P E D	30	5.0
38704-07	29	D D D D D D D E D D D P E D	36	5.0
38706-03	28	D D P E E D D D D D E E M D D	31	7.0
38707-01	28	D P E E E D D D D E E D D D P	30	6.0
38708-05	28	D D D D D D D D D D E D D D P	38	A
38708-01	28	D D E E D D D D E D D D P E D	30	5.0
38706-02	28	D D D D D P E D D D D P E D D	34	6.0
38707-05	29	E E D D D P E D D D E E D D	29	5.0
38706-10	30	E D D D D P E D D D P E D	30	5.5
38708-06	29	P E E D D E P E D D D E E E	30	5.0
38710-05	32	E D D D D P E D D D D	32	6.0
38709-01	34	E D D P E D D D P	34	4.0
		MEAN	31.6	5.5
		S.D.	2.69	0.78
		N	15	12

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]

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TABLE 20

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR: [redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-025

FEMALES FROM GROUP 4: 200 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF E (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38705-08	29	E D E E E E D D D P E D D D	29	5.0
38704-09	30	D D D D D E E E D D D D D	35	A
38704-01	31	E E D E E D D D D D E D	31	4.5
38705-01	29	D E E E D E E E E E E E E E	30	A
38704-03	30	P D D D D D D D D D D E E	41	A
38706-05	28	E D E E D D D D D D E D D D D	28	5.0
38708-09	35	D D D D D P D D	NA	A
38707-10	27	E E D E E D E E E E E E E D E E	27	5.5
38708-10	28	D D E D D D E D D D D D D P D	30	5.5
38706-01	28	D D D D D D D D D E D D D D D	37	A
38707-04	29	P P E E D D D D D E D D D D	31	6.0
38707-08	30	D D E E D D D E E E D D D	32	6.0
38706-07	28	D D D P E E D D D D E D D D D	32	5.0
38710-09	28	D D P D D D D D D E D D D D D	37	7.0
38709-04	28	D E E D D E E E D D D D D D D	29	5.0
		MEAN	32.1	5.5
		S.D.	4.01	0.72
		N	14	10

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
NA = NOT APPLICABLE, NO OCCURRENCE OF E

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TABLE 20

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 5
SPONSOR:[redacted]
INDIVIDUAL ESTROUS CYCLE DATA
SPONSOR NO.:06-025

FEMALES FROM GROUP 5: 800 MG/KG/DAY

FEMALE NUMBER	1ST DET AGE	DETERMINATION DAY: 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7	AGE AT FIRST OCCURRENCE OF E (DAYS)	INDIVIDUAL MEAN LENGTH OF ESTROUS CYCLE (DAYS)
38705-09	36	E E D E E D E	36	3.0
38704-06	B		B	B
38704-02	B		B	B
38705-02	29	E E E E D E E D D D E E E E	29	3.0
38705-04	B		B	B
38707-09	B		B	B
38708-08	B		B	B
38706-06	28	E E E E E E E D E E E E E E E	28	A
38707-06	B		B	B
38706-09	B		B	B
38708-07	B		B	B
38708-02	B		B	B
38709-05	27	E E E E E E E E E E E E E E E	27	A
38710-04	B		B	B
38711-02	27	E	27	A
		MEAN	29.4	3.0
		S.D.	3.78	0.00
		N	5	2

ESTROUS STAGE CODE: E = ESTRUS, D = DIESTRUS, M = METESTRUS, P = PROESTRUS
A = UNABLE TO DETERMINE LENGTH OF ESTROUS CYCLE; CYCLE INCOMPLETE OR NO RETURN TO [M] OR [D] AFTER THE LAST [E] OR [P]
B = DIED PRIOR TO ATTAINMENT OF VAGINAL PATENCY

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TABLE 21

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-025

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 0 MG/KG/DAY FEMALES				
38694-07	6.20	105.00	5.20	0.4
38696-08	6.40	75.70	9.00	1.0
38695-01	7.10	145.00	15.20	1.3
38695-07	6.10	124.00	8.60	1.9
38694-04	8.00	138.00	10.30	25.9
38696-04	7.70	94.50	7.30	1.6
38697-07	4.80	105.00	7.60	0.8
38698-04	7.60	53.30	6.90	2.1
38699-07	8.00	87.60	12.60	2.0
38698-05	6.10	78.90	7.00	2.3
38699-02	6.60	99.50	5.00	1.1
38697-03	6.70	96.30	6.00	1.3
38703-06	6.00	102.00	10.00	1.6
38700-06	6.60	117.00	6.80	0.9
38702-05	5.80	105.00	4.90	1.7
MEAN	6.65	101.79	8.16	3.1
S.D.	0.898	23.573	2.903	6.34
N	15	15	15	15

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 21

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-025

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 10 MG/KG/DAY FEMALES				
38705-03	5.30	143.00	6.80	1.0
38704-05	4.90	102.00	10.80	1.4
38705-10	5.60	110.00	QNS	1.7
38704-10	4.90	140.00	5.40	1.7
38705-07	6.90	123.00	7.70	1.3
38707-07	6.40	97.30	QNS	2.6
38706-04	7.00	99.70	10.60	1.4
38708-04	5.90	87.60	13.20	1.9
38707-02	5.40	88.80	10.10	2.3
38708-03	7.50	114.00	9.70	1.2
38706-08	6.00	118.00	8.60	1.4
38707-03	5.70	152.00	9.20	2.1
38710-10	5.20	86.20	8.80	1.5
38711-01	6.80	72.70	8.00	1.8
38709-08	7.80	89.50	12.70	1.9
MEAN	6.09	108.25	9.35	1.7
S.D.	0.932	23.325	2.197	0.43
N	15	15	13	15

QNS = QUANTITY NOT SUFFICIENT

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Audited Draft

Modified: 4/30/2007

TABLE 21

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES
SPONSOR NO.:06-025

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 50 MG/KG/DAY FEMALES				
38704-08	9.50	140.00	QNS	1.2
38705-05	8.20	104.00	12.90	1.2
38704-04	6.70	162.00	7.60	1.6
38705-06	7.10	132.00	10.00	0.4
38704-07	5.50	86.20	7.50	1.8
38706-03	6.80	103.00	RU	1.2
38707-01	5.10	113.00	17.70	1.6
38708-05	6.00	86.00	11.80	2.7
38708-01	5.90	107.00	9.50	1.3
38706-02	7.20	105.00	10.70	1.3
38707-05	9.00	83.60	8.60	1.5
38706-10	6.70	135.00	8.40	1.2
38708-06	6.70	101.00	7.00	2.2
38710-05	5.90	99.60	24.60	RU
38709-01	9.10	96.90	11.90	1.6
MEAN	7.03	110.29	11.40	1.5
S.D.	1.356	22.424	4.903	0.53
N	15	15	13	14

QNS = QUANTITY NOT SUFFICIENT, RU = RESULT UNOBTAINABLE

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

Revised Audited Draft

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TABLE 21

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 4
SPONSOR:[redacted] INDIVIDUAL SERUM HORMONE VALUES DAY 42
SPONSOR NO.:06-025

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 200 MG/KG/DAY FEMALES				
38705-08	4.90	95.10	5.40	0.8
38704-09	7.00	94.40	QNS	2.1
38704-01	7.30	126.00	5.60	0.9
38705-01	7.80	71.70	9.20	1.5
38704-03	6.80	96.70	8.40	1.7
38706-05	5.70	115.00	QNS	1.7
38708-09	6.60	113.00	10.30	1.8
38707-10	8.20	86.20	12.20	2.3
38708-10	8.30	97.80	12.60	1.8
38706-01	9.60	160.00	11.40	2.1
38707-04	6.50	111.00	9.40	2.0
38707-08	8.00	100.00	7.50	1.7
38706-07	7.00	131.00	5.80	1.4
38710-09	7.80	105.00	16.10	2.8
38709-04	7.20	74.30	10.90	1.0
MEAN	7.25	105.15	9.60	1.7
S.D.	1.132	22.524	3.130	0.54
N	15	15	13	15

QNS = QUANTITY NOT SUFFICIENT

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

187061 RAD

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PROJECT NO.:WIL-187061
SPONSOR: [redacted]
SPONSOR NO.:06-025

TABLE 21
FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
INDIVIDUAL SERUM HORMONE VALUES

ANIMAL	TOTAL T4	ESTRA-DIOL	TSH	LUTEIN' HORMONE
	uG/dL	pg/mL	ng/mL	ng/mL
GROUP: 800 MG/KG/DAY FEMALES				
38705-09	6.10	116.00	13.60	1.0
38705-02	7.00	143.00	11.60	1.1
38706-06	6.60	139.00	12.00	1.4
38709-05	3.90	172.00	21.70	1.1
MEAN	5.90	142.50	14.73	1.2
S.D.	1.383	22.986	4.730	0.17
N	4	4	4	4

uG/dL = MICROGRAMS/DECILITER, ng/mL = NANOGRAMS/MILLILITER, pg/mL = PICOGRAMS/MILLILITER

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR: [redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38704-06 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

			GRADE
	GENERAL COMMENT	GROSS: PARTIALLY CANNIBALIZED AXILLARY LYMPH NODE, RIGHT; DORSAL THORACIC; RIGHT APICAL, RIGHT INTERMEDIATE AND RIGHT DIAPHRAGMATIC LOBES OF LUNGS	P
	OVARIES	MICRO: DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
		CORPORA AMYLACEA RARE CORPORA AMYLACEA-LIKE CONCRETIONS PRESENT WITHIN FOLLICLES	P
	PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
	THYROID GLANDS	MICRO: DEPLETION, COLLOID	2
	UTERUS	MICRO: ATROPHY	3
	CERVIX	MICRO: ATROPHY	3
	CAUSE OF DEATH	MICRO: UNKNOWN	P
	NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES; HEART, INTESTINE, KIDNEYS, LIVER; LYMPH NODE, MES, LUNGS, MAMMARY GLAND, OVIDUCTS; OVARIES, PANCREAS, PITUITARY, SPINAL CORD; SAL. GLAND MAND, SKIN, SPLEEN, STOMACH; THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER; UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI	
		MICRO: PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38704-02 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/29/06 DATE OF DEATH: 09/29/06

			GRADE
	GENERAL COMMENT	GROSS: PARTIALLY CANNIBALIZED SKIN MISSING: LEFT LATERAL THORACIC, NECK AND LEFT FORELIMB	P
	GENERAL COMMENT	GROSS: NOT POSITIVELY IDENTIFIED AXILLARY LYMPH NODE, LEFT	P
	OVARIES	MICRO: DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
	PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL BILATERAL	P
		DEPLETION, COLLOID	2
		ECTOPIC THYMUS MARKED DEGENERATION OF LYMPHOCYTES IN ECTOPIC THYMUS	P
	UTERUS	MICRO: ATROPHY	3
	CAUSE OF DEATH	MICRO: UNKNOWN	P
	NO SIGNIFICANT CHANGES OBSERVED	GROSS:	

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPINAL CORD
SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
UTERUS	CERVIX	VAGINA	LYMPH NODE, AXI

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38704-02 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/29/06 DATE OF DEATH: 09/29/06

	GRADE
MICRO:PARATHYROID CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-04 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/28/06 DATE OF DEATH: 09/28/06

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	3
	CORPORA LUTEA ABSENT	4
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
	DEPLETION, COLLOID	1
UTERUS	MICRO: ATROPHY	3
CAUSE OF DEATH	MICRO: UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
	HEART	INTESTINE	KIDNEYS	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	SPINAL CORD
	SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
	THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
	UTERUS	CERVIX	VAGINA	LYMPH NODE, AXI
MICRO:	PARATHYROID	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38707-09 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/29/06 DATE OF DEATH: 09/29/06

			GRADE
	OVARIES	MICRO: DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
	PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
	THYROID GLANDS	MICRO: DEPLETION, COLLOID	2
	UTERUS	MICRO: ATROPHY	3
	CAUSE OF DEATH	MICRO: UNKNOWN	P
	NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
	HEART	INTESTINE	KIDNEYS	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	SPINAL CORD
	SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
	THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
	UTERUS	CERVIX	VAGINA	LYMPH NODE, AXI
MICRO:	PARATHYROID	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-08 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/01/06 DATE OF DEATH: 10/01/06

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	3
	CORPORA LUTEA ABSENT	4
	CORPORA AMYLACEA	P
	RARE CORPORA AMYLACEA-LIKE CONCRETIONS PRESENT WITHIN FOLLICLES	
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: DEPLETION, COLLOID	2
UTERUS	MICRO: ATROPHY	3
CERVIX	MICRO: ATROPHY	2
CAUSE OF DEATH	MICRO: UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS: ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES; HEART, INTESTINE, KIDNEYS, LIVER; LYMPH NODE, MES, LUNGS, MAMMARY GLAND, OVIDUCTS; OVARIES, PANCREAS, PITUITARY, SPINAL CORD; SAL. GLAND MAND, SKIN, SPLEEN, STOMACH; THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER; UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI	
	MICRO: PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 7
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38707-06 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	4
	NECROSIS, GRANULOSA CELLS	
	CORPORA LUTEA ABSENT	3
THYROID GLANDS	MICRO: DEPLETION, COLLOID	4
	HYPERTROPHY, FOLLICULAR CELL	2
UTERUS	MICRO: ATROPHY	2
CERVIX	MICRO: ATROPHY	3
CAUSE OF DEATH	MICRO: UNKNOWN	3
NO SIGNIFICANT CHANGES OBSERVED		P

GROSS: ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES, HEART, INTESTINE, KIDNEYS, LIVER, LYMPH NODE, MES, LUNGS, MAMMARY GLAND, OVIDUCTS, OVARIES, PANCREAS, PITUITARY, SPINAL CORD, SAL. GLAND MAND, SKIN, SPLEEN, STOMACH, THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI
MICRO: PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

ANIMAL NO.38706-09 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
	NECROSIS, GRANULOSA CELLS	3
	CORPORA LUTEA ABSENT	4
THYROID GLANDS	MICRO: DEPLETION, COLLOID	1
UTERUS	MICRO: ATROPHY	3
CERVIX	MICRO: ATROPHY	2
CAUSE OF DEATH	MICRO: UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
	HEART	INTESTINE	KIDNEYS	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	SPINAL CORD
	SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
	THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
	UTERUS	CERVIX	VAGINA	LYMPH NODE, AXI
MICRO:	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-07 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 09/30/06 DATE OF DEATH: 09/30/06

			GRADE
	OVARIES	MICRO: DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
	PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
		DEPLETION, COLLOID	2
	UTERUS	MICRO: ATROPHY	3
	CERVIX	MICRO: ATROPHY	3
	CAUSE OF DEATH	MICRO: UNKNOWN	P
	NO SIGNIFICANT CHANGES OBSERVED		

GROSS:

ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
HEART	INTESTINE	KIDNEYS	LIVER
LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
OVARIES	PANCREAS	PITUITARY	SPINAL CORD
SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
UTERUS	CERVIX	VAGINA	LYMPH NODE, AXI

MICRO:PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-02 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/01/06 DATE OF DEATH: 10/01/06

			GRADE
GENERAL COMMENT	GROSS:	PARTIALLY CANNIBALIZED BRAIN; PITUITARY; TRACHEA; ESOPHAGUS; LUNGS, ALL LOBES; THYROID GLAND, BILATERAL; TONGUE; EYE/OPTIC NERVE, LEFT; FORELIMB, BILATERAL; AXILLARY LYMPH NODE, BILATERAL; THYMUS GLAND	P
OVARIES	MICRO:	DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	4
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
THYROID GLANDS	MICRO:	NOT EXAMINED NOT PRESENT AT TRIMMING	
UTERUS	MICRO:	ATROPHY	3
CERVIX	MICRO:	ATROPHY	2
CAUSE OF DEATH	MICRO:	UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES HEART, INTESTINE, KIDNEYS, LIVER LYMPH NODE, MES, LUNGS, MAMMARY GLAND, OVIDUCTS OVARIES, PANCREAS, PITUITARY, SPINAL CORD SAL. GLAND MAND, SKIN, SPLEEN, STOMACH THYMUS, THYROID GLANDS, TRACHEA, URINARY BLADDER UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI	
	MICRO:	PARATHYROID	
NOT EXAMINED	MICRO:	THYROID GLANDS	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38710-04 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/01/06 DATE OF DEATH: 10/01/06

			GRADE
OVARIES	MICRO:	DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	4
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
THYROID GLANDS	MICRO:	ECTOPIC THYMUS MARKED DEGENERATION OF LYMPHOCYTES IN ECTOPIC THYMUS	P
UTERUS	GROSS:	CONTENTS, CLEAR FLUID BOTH HORNS	P
UTERUS	MICRO:	ATROPHY	3
		DILATATION, LUMEN CORRELATES WITH GROSS OBSERVATION OF FLUID IN THE LUMEN	2
CAUSE OF DEATH NO SIGNIFICANT CHANGES OBSERVED	MICRO:	UNKNOWN	P

GROSS:	ADRENAL GLANDS	BRAIN	ESOPHAGUS	EYES
	HEART	INTESTINE	KIDNEYS	LIVER
	LYMPH NODE, MES	LUNGS	MAMMARY GLAND	OVIDUCTS
	OVARIES	PANCREAS	PITUITARY	SPINAL CORD
	SAL. GLAND MAND	SKIN	SPLEEN	STOMACH
	THYMUS	THYROID GLANDS	TRACHEA	URINARY BLADDER
	CERVIX	VAGINA	LYMPH NODE, AXI	
MICRO:	PARATHYROID	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 22 (UNSCHEDULED DEATHS)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38711-02 GROUP 5: 800 MG/KG/DAY FEMALE FOUND DEAD 10/04/06 DATE OF DEATH: 10/04/06

			GRADE
GENERAL COMMENT	GROSS:	PARTIALLY CANNIBALIZED INTESTINE; LIVER	P
OVARIES	MICRO:	DEGENERATION, OOCYTE(S) LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
		NECROSIS, GRANULOSA CELLS	3
		CORPORA LUTEA ABSENT	4
SPLEEN	GROSS:	SMALL	P
PARATHYROID	MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO:	DEPLETION, COLLOID	1
UTERUS	MICRO:	ATROPHY	3
CERVIX	MICRO:	ATROPHY	3
CAUSE OF DEATH	MICRO:	UNKNOWN	P
NO SIGNIFICANT CHANGES OBSERVED	GROSS:	ADRENAL GLANDS, BRAIN, ESOPHAGUS, EYES HEART, INTESTINE, KIDNEYS, LIVER LYMPH NODE, MES, LUNGS, MAMMARY GLAND, OVIDUCTS OVARIES, PANCREAS, PITUITARY, SPINAL CORD SAL. GLAND MAND, SKIN, STOMACH, THYMUS THYROID GLANDS, TRACHEA, URINARY BLADDER, UTERUS CERVIX, VAGINA, LYMPH NODE, AXI	
	MICRO:	PARATHYROID	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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04/30/2007

187061 RAD

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 1
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38694-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4096	0.223
UTERUS- BLOTTED	0.3827	0.208
LIVER	10.3255	5.612
KIDNEYS	1.9066	1.036
SPLEEN	0.5160	0.280
THYMUS	0.5059	0.275
OVARIES/OVIDUCTS	0.1108	0.060
ADRENAL GLANDS	0.0462	0.025
PITUITARY	0.0107	0.006
THYROIDS/PARA	0.0166	0.009
FINAL BODY WT(G)	184.	

PARATHYROID
THYROID GLANDS
UTERUS
NO SIGNIFICANT
CHANGES OBSERVED

GRADE

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED
MICRO: CYST, ULTIMOBRANCHIAL P
MICRO: INFLAMMATION, SUBACUTE 1

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, THYMUS
THYROID GLANDS, UTERUS, CERVIX, VAGINA
LYMPH NODE, AXI
MICRO: OVARIES, PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38696-08 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	PARATHYROID	GRADE
UTERUS- WET	0.3765	0.228		
UTERUS- BLOTTED	0.3497	0.212	NO SIGNIFICANT	
LIVER	9.5224	5.771	CHANGES OBSERVED	
KIDNEYS	1.9762	1.198		
SPLEEN	0.4364	0.264		
THYMUS	0.6582	0.399		
OVARIES/OVIDUCTS	0.1194	0.072		
ADRENAL GLANDS	0.0494	0.030		
			NOT EXAMINED	
PITUITARY	0.0101	0.006		
THYROIDS/PARA	0.0183	0.011		
FINAL BODY WT(G)	165.			

MICRO: NOT EXAMINED
BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	THYROID GLANDS	UTERUS	CERVIX
	PARATHYROID			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 3
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38695-01 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6982	0.445
UTERUS- BLOTTED	0.4641	0.296
LIVER	7.2835	4.639
KIDNEYS	1.6109	1.026
SPLEEN	0.5048	0.322
THYMUS	0.6153	0.392
OVARIES/OVIDUCTS	0.0772	0.049
ADRENAL GLANDS	0.0411	0.026
PITUITARY	0.0087	0.006
THYROIDS/PARA	0.0187	0.012
FINAL BODY WT(G)	157.	

PARATHYROID
THYROID GLANDS
NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED
MICRO: CYST, ULTIMOBRANCHIAL P
BILATERAL

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38695-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4985	0.310
UTERUS- BLOTTED	0.4342	0.270
LIVER	8.0222	4.983
KIDNEYS	1.5607	0.969
SPLEEN	0.4641	0.288
THYMUS	0.5436	0.338
OVARIES/OVIDUCTS	0.0799	0.050
ADRENAL GLANDS	0.0382	0.024
PITUITARY	0.0079	0.005
THYROIDS/PARA	0.0222	0.014
FINAL BODY WT(G)	161.	

PARATHYROID: NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED

GRADE

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38694-04 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.7364	0.526		GROSS: ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.3101	0.221		OVARIES	PITUITARY	SPLEEN	THYMUS
LIVER	6.3273	4.520		THYROID GLANDS	UTERUS	CERVIX	VAGINA
KIDNEYS	1.4132	1.009		LYMPH NODE, AXI			
SPLEEN	0.3951	0.282		MICRO: OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
THYMUS	0.5660	0.404		CERVIX			
OVARIES/OVIDUCTS	0.0720	0.051					
ADRENAL GLANDS	0.0417	0.030					
PITUITARY	0.0087	0.006					
THYROIDS/PARA	0.0164	0.012					
FINAL BODY WT(G)	140.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38696-04 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2853	0.200
UTERUS- BLOTTED	0.2699	0.189
LIVER	6.4839	4.534
KIDNEYS	1.3973	0.977
SPLEEN	0.3812	0.267
THYMUS	0.5184	0.363
OVARIES/OVIDUCTS	0.0812	0.057
ADRENAL GLANDS	0.0313	0.022
PITUITARY	0.0097	0.007
THYROIDS/PARA	0.0281	0.020
FINAL BODY WT(G)	143.	

PARATHYROID: NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED

GRADE

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38697-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2601	0.173		GROSS: ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2388	0.159		OVARIES	PITUITARY	SPLEEN	THYMUS
LIVER	8.2656	5.510		THYROID GLANDS	UTERUS	CERVIX	VAGINA
KIDNEYS	1.5263	1.018		LYMPH NODE, AXI			
SPLEEN	0.5124	0.342		MICRO: OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
THYMUS	0.6001	0.400		CERVIX			
OVARIES/OVIDUCTS	0.0824	0.055					
ADRENAL GLANDS	0.0317	0.021					
PITUITARY	0.0077	0.005					
THYROIDS/PARA	0.0112	0.007					
FINAL BODY WT(G)	150.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38698-04 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3536	0.246
UTERUS- BLOTTED	0.3328	0.231
LIVER	6.9727	4.842
KIDNEYS	1.5737	1.093
SPLEEN	0.4764	0.331
THYMUS	0.6105	0.424
OVARIES/OVIDUCTS	0.1148	0.080
ADRENAL GLANDS	0.0492	0.034
PITUITARY	0.0107	0.007
THYROIDS/PARA	0.0134	0.009
FINAL BODY WT(G)	144.	

PARATHYROID: NO SIGNIFICANT CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED

	GRADE			
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38699-07 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4452	0.246
UTERUS- BLOTTED	0.4138	0.229
LIVER	9.5810	5.293
KIDNEYS	1.8506	1.022
SPLEEN	0.4591	0.254
THYMUS	0.6633	0.366
OVARIES/OVIDUCTS	0.1160	0.064
ADRENAL GLANDS	0.0512	0.028
PITUITARY	0.0116	0.006
THYROIDS/PARA	0.0146	0.008
FINAL BODY WT(G)	181.	

PARATHYROID
NO SIGNIFICANT
CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION RECUT MADE AND EXAMINED

GRADE

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38698-05 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2768	0.180
UTERUS- BLOTTED	0.2571	0.167
LIVER	7.1187	4.623
KIDNEYS	1.6701	1.084
SPLEEN	0.4346	0.282
THYMUS	0.6528	0.424
OVARIES/OVIDUCTS	0.0976	0.063
ADRENAL GLANDS	0.0418	0.027
PITUITARY	0.0113	0.007
THYROIDS/PARA	0.0135	0.009
FINAL BODY WT(G)	154.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE				
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38699-02 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.6801	0.463
UTERUS- BLOTTED	0.4095	0.279
LIVER	7.1187	4.843
KIDNEYS	1.3740	0.935
SPLEEN	0.3868	0.263
THYMUS	0.5356	0.364
OVARIES/OVIDUCTS	0.0847	0.058
ADRENAL GLANDS	0.0331	0.023
PITUITARY	0.0077	0.005
THYROIDS/PARA	0.0121	0.008
FINAL BODY WT(G)	147.	

PARATHYROID
NO SIGNIFICANT
CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED

GRADE

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38697-03 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2826	0.154
UTERUS- BLOTTED	0.2618	0.142
LIVER	9.2621	5.034
KIDNEYS	1.7678	0.961
SPLEEN	0.5384	0.293
THYMUS	0.6155	0.335
OVARIES/OVIDUCTS	0.0721	0.039
ADRENAL GLANDS	0.0323	0.018
PITUITARY	0.0095	0.005
THYROIDS/PARA	0.0105	0.006
FINAL BODY WT(G)	184.	

PARATHYROID
THYROID GLANDS
NO SIGNIFICANT
CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION RECUT MADE AND EXAMINED
MICRO: CYST, ULTIMOBRANCHIAL P

GRADE			
GROSS:ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	THYMUS
THYROID GLANDS	UTERUS	CERVIX	VAGINA
LYMPH NODE, AXI			
MICRO:OVARIES	PARATHYROID	UTERUS	CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38703-06 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2869	0.151
UTERUS- BLOTTED	0.2673	0.141
LIVER	10.7276	5.646
KIDNEYS	2.0827	1.096
SPLEEN	0.6022	0.317
THYMUS	0.6689	0.352
OVARIES/OVIDUCTS	0.0720	0.038
ADRENAL GLANDS	0.0388	0.020
PITUITARY	0.0087	0.005
THYROIDS/PARA	0.0100	0.005
FINAL BODY WT(G)	190.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	THYROID GLANDS	UTERUS
	CERVIX			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38700-06 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4172	0.248
UTERUS- BLOTTED	0.3887	0.231
LIVER	9.3264	5.551
KIDNEYS	1.8054	1.075
SPLEEN	0.4890	0.291
THYMUS	0.6015	0.358
OVARIES/OVIDUCTS	0.1275	0.076
ADRENAL GLANDS	0.0343	0.020
PITUITARY	0.0118	0.007
THYROIDS/PARA	0.0136	0.008
FINAL BODY WT(G)	168.	

PARATHYROID
THYROID GLANDS
NO SIGNIFICANT
CHANGES OBSERVED

MICRO: NO SIGNIFICANT CHANGES OBSERVED
ONE NOT IN PLANE OF SECTION RECUT MADE AND EXAMINED
MICRO: CYST, ULTIMOBRANCHIAL P

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	OVARIES	PARATHYROID	UTERUS	CERVIX

GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38702-05 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2943	0.213
UTERUS- BLOTTED	0.2766	0.200
LIVER	7.3925	5.357
KIDNEYS	1.4462	1.048
SPLEEN	0.4249	0.308
THYMUS	0.5665	0.411
OVARIES/OVIDUCTS	0.0963	0.070
ADRENAL GLANDS	0.0331	0.024
PITUITARY	0.0100	0.007
THYROIDS/PARA	0.0130	0.009
FINAL BODY WT(G)	138.	

PARATHYROID: NO SIGNIFICANT CHANGES OBSERVED

MICRO: NOT EXAMINED
BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: OVARIES, THYROID GLANDS, UTERUS, CERVIX

NOT EXAMINED

MICRO: PARATHYROID

GRADE

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-03 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2653	0.143	
UTERUS- BLOTTED	0.2414	0.130	
LIVER	9.0240	4.878	
KIDNEYS	1.6397	0.886	
SPLEEN	0.6057	0.327	
THYMUS	0.6544	0.354	
OVARIES/OVIDUCTS	0.0689	0.037	
ADRENAL GLANDS	0.0388	0.021	
PITUITARY	0.0093	0.005	
THYROIDS/PARA	0.0177	0.010	
FINAL BODY WT(G)	185.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	THYMUS
THYROID GLANDS	UTERUS	CERVIX	VAGINA
LYMPH NODE, AXI			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38704-05 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2315	0.165	
UTERUS- BLOTTED	0.2140	0.153	
LIVER	6.8343	4.882	
KIDNEYS	1.4714	1.051	
SPLEEN	0.4137	0.296	
THYMUS	0.6067	0.433	
OVARIES/OVIDUCTS	0.0816	0.058	
ADRENAL GLANDS	0.0339	0.024	
PITUITARY	0.0076	0.005	
THYROIDS/PARA	0.0123	0.009	
FINAL BODY WT(G)	140.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-10 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2740	0.155		
UTERUS- BLOTTED	0.2545	0.144		
LIVER	8.9876	5.078		
KIDNEYS	1.9010	1.074		
SPLEEN	0.4128	0.233		
THYMUS	0.5841	0.330		
OVARIES/OVIDUCTS	0.0924	0.052		
ADRENAL GLANDS	0.0434	0.025		
PITUITARY	0.0108	0.006		
THYROIDS/PARA	0.0159	0.009		
FINAL BODY WT(G)	177.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	THYMUS	
THYROID GLANDS	UTERUS	CERVIX	VAGINA	
LYMPH NODE, AXI				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38704-10 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2701	0.153
UTERUS- BLOTTED	0.2509	0.143
LIVER	9.4492	5.369
KIDNEYS	1.7511	0.995
SPLEEN	0.5826	0.331
THYMUS	0.6169	0.351
OVARIES/OVIDUCTS	0.1079	0.061
ADRENAL GLANDS	0.0397	0.023
PITUITARY	0.0117	0.007
THYROIDS/PARA	0.0177	0.010
FINAL BODY WT(G)	176.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-07 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2284	0.148
UTERUS- BLOTTED	0.2105	0.137
LIVER	6.5338	4.243
KIDNEYS	1.4532	0.944
SPLEEN	0.5657	0.367
THYMUS	0.4975	0.323
OVARIES/OVIDUCTS	0.0697	0.045
ADRENAL GLANDS	0.0331	0.021
PITUITARY	0.0069	0.004
THYROIDS/PARA	0.0187	0.012
FINAL BODY WT(G)	154.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187061 RAD

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38707-07 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE GROSS:			
UTERUS- WET	0.6693	0.382		ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.3958	0.226		OVARIES	PITUITARY	SPLEEN	THYMUS
LIVER	9.5744	5.471		THYROID GLANDS	UTERUS	CERVIX	VAGINA
KIDNEYS	1.8546	1.060		LYMPH NODE, AXI			
SPLEEN	0.4725	0.270					
THYMUS	0.8354	0.477					
OVARIES/OVIDUCTS	0.0730	0.042					
ADRENAL GLANDS	0.0412	0.024					
PITUITARY	0.0094	0.005					
THYROIDS/PARA	0.0139	0.008					
FINAL BODY WT(G)	175.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187061 RAD

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-04 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4285	0.265	
UTERUS- BLOTTED	0.3882	0.240	
LIVER	8.3665	5.165	
KIDNEYS	1.6954	1.047	
SPLEEN	0.5250	0.324	
THYMUS	0.5138	0.317	
OVARIES/OVIDUCTS	0.0938	0.058	
ADRENAL GLANDS	0.0413	0.025	
PITUITARY	0.0092	0.006	
THYROIDS/PARA	0.0137	0.008	
FINAL BODY WT(G)	162.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR: [redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-04 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2934	0.186	
UTERUS- BLOTTED	0.2708	0.171	
LIVER	7.2575	4.593	
KIDNEYS	1.6133	1.021	
SPLEEN	0.5046	0.319	
THYMUS	0.6213	0.393	
OVARIES/OVIDUCTS	0.0823	0.052	
ADRENAL GLANDS	0.0304	0.019	
PITUITARY	0.0086	0.005	
THYROIDS/PARA	0.0120	0.008	
FINAL BODY WT(G)	158.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	THYMUS
THYROID GLANDS	UTERUS	CERVIX	VAGINA
LYMPH NODE, AXI			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS

SPONSOR:[redacted]

SPONSOR NO.:06-025

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38707-02 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3153	0.196	
UTERUS- BLOTTED	0.2985	0.185	
LIVER	8.1864	5.085	
KIDNEYS	1.6237	1.009	
SPLEEN	0.5134	0.319	
THYMUS	0.5799	0.360	
OVARIES/OVIDUCTS	0.0916	0.057	
ADRENAL GLANDS	0.0413	0.026	
PITUITARY	0.0120	0.007	
THYROIDS/PARA	0.0141	0.009	
FINAL BODY WT(G)	161.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-03 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2473	0.162	NO SIGNIFICANT
UTERUS- BLOTTED	0.2325	0.152	CHANGES OBSERVED
LIVER	6.6725	4.361	
KIDNEYS	1.4376	0.940	
SPLEEN	0.5154	0.337	
THYMUS	0.4651	0.304	
OVARIES/OVIDUCTS	0.0905	0.059	
ADRENAL GLANDS	0.0362	0.024	
PITUITARY	0.0089	0.006	
THYROIDS/PARA	0.0132	0.009	
FINAL BODY WT(G)	153.		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-08 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2053	0.133
UTERUS- BLOTTED	0.1907	0.124
LIVER	6.5984	4.285
KIDNEYS	1.6080	1.044
SPLEEN	0.4000	0.260
THYMUS	0.7140	0.464
OVARIES/OVIDUCTS	0.0716	0.046
ADRENAL GLANDS	0.0370	0.024
PITUITARY	0.0074	0.005
THYROIDS/PARA	0.0113	0.007
FINAL BODY WT(G)	154.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38707-03 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3193	0.216		
UTERUS- BLOTTED	0.2838	0.192		
LIVER	5.7606	3.892		
KIDNEYS	1.3739	0.928		
SPLEEN	0.3397	0.230		
THYMUS	0.6096	0.412		
OVARIES/OVIDUCTS	0.0689	0.047		
ADRENAL GLANDS	0.0343	0.023		
PITUITARY	0.0110	0.007		
THYROIDS/PARA	0.0106	0.007		
FINAL BODY WT(G)	148.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38710-10 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.4721	0.276
UTERUS- BLOTTED	0.4216	0.247
LIVER	9.0215	5.276
KIDNEYS	1.6338	0.955
SPLEEN	0.5245	0.307
THYMUS	0.5554	0.325
OVARIES/OVIDUCTS	0.0805	0.047
ADRENAL GLANDS	0.0397	0.023
PITUITARY	0.0098	0.006
THYROIDS/PARA	0.0105	0.006
FINAL BODY WT(G)	171.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38711-01 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3176	0.194	
UTERUS- BLOTTED	0.2953	0.180	
LIVER	9.3504	5.701	
KIDNEYS	1.6041	0.978	
SPLEEN	0.4476	0.273	
THYMUS	0.5342	0.326	
OVARIES/OVIDUCTS	0.0678	0.041	
ADRENAL GLANDS	0.0291	0.018	
PITUITARY	0.0082	0.005	
THYROIDS/PARA	0.0123	0.007	
FINAL BODY WT(G)	164.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS

SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-025

ANIMAL NO.38709-08 GROUP 2: 10 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2110	0.130	GROSS:	
UTERUS- BLOTTED	0.1927	0.119		
LIVER	7.7808	4.803		
KIDNEYS	1.5034	0.928		
SPLEEN	0.3978	0.246		
THYMUS	0.5075	0.313		
OVARIES/OVIDUCTS	0.0537	0.033		
ADRENAL GLANDS	0.0387	0.024		
PITUITARY	0.0091	0.006		
THYROIDS/PARA	0.0105	0.006		
FINAL BODY WT(G)	162.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN THYMUS
THYROID GLANDS UTERUS CERVIX VAGINA
LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38704-08 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3506	0.214		
UTERUS- BLOTTED	0.3292	0.201		
LIVER	9.1961	5.607		
KIDNEYS	1.5432	0.941		
SPLEEN	0.4779	0.291		
THYMUS	0.6323	0.386		
OVARIES/OVIDUCTS	0.0801	0.049		
ADRENAL GLANDS	0.0331	0.020		
PITUITARY	0.0109	0.007		
THYROIDS/PARA	0.0173	0.011		
FINAL BODY WT(G)	164.			

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	THYMUS	
THYROID GLANDS	UTERUS	CERVIX	VAGINA	
LYMPH NODE, AXI				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR: [redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-025

ANIMAL NO.38705-05 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.3802	0.280
UTERUS- BLOTTED	0.3644	0.268
LIVER	6.6708	4.905
KIDNEYS	1.3815	1.016
SPLEEN	0.3928	0.289
THYMUS	0.4661	0.343
OVARIES/OVIDUCTS	0.1020	0.075
ADRENAL GLANDS	0.0449	0.033
PITUITARY	0.0111	0.008
THYROIDS/PARA	0.0189	0.014
FINAL BODY WT(G)	136.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38704-04 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2204	0.132
UTERUS- BLOTTED	0.2031	0.122
LIVER	9.6308	5.767
KIDNEYS	1.6588	0.993
SPLEEN	0.4499	0.269
THYMUS	0.4907	0.294
OVARIES/OVIDUCTS	0.0879	0.053
ADRENAL GLANDS	0.0325	0.019
PITUITARY	0.0101	0.006
THYROIDS/PARA	0.0151	0.009
FINAL BODY WT(G)	167.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-06 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2863	0.175	
UTERUS- BLOTTED	0.2649	0.162	
LIVER	8.5628	5.221	
KIDNEYS	1.7393	1.061	
SPLEEN	0.3587	0.219	
THYMUS	0.5241	0.320	
OVARIES/OVIDUCTS	0.1087	0.066	
ADRENAL GLANDS	0.0444	0.027	
PITUITARY	0.0093	0.006	
THYROIDS/PARA	0.0156	0.010	
FINAL BODY WT(G)	164.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38704-07 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.2133	0.132	NO SIGNIFICANT
UTERUS- BLOTTED	0.1978	0.123	CHANGES OBSERVED
LIVER	7.8712	4.889	
KIDNEYS	1.6544	1.028	
SPLEEN	0.4954	0.308	
THYMUS	0.6570	0.408	
OVARIES/OVIDUCTS	0.0758	0.047	
ADRENAL GLANDS	0.0363	0.023	
PITUITARY	0.0090	0.006	
THYROIDS/PARA	0.0157	0.010	
FINAL BODY WT(G)	161.		

GROSS:

ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
OVARIES	PITUITARY	SPLEEN	THYMUS
THYROID GLANDS	UTERUS	CERVIX	VAGINA
LYMPH NODE, AXI			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS

SPONSOR:[redacted]

SPONSOR NO.:06-025

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38706-03 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.3310	0.216	
UTERUS- BLOTTED	0.3037	0.198	
LIVER	7.8054	5.102	
KIDNEYS	1.6214	1.060	
SPLEEN	0.4015	0.262	
THYMUS	0.6366	0.416	
OVARIES/OVIDUCTS	0.0752	0.049	
ADRENAL GLANDS	0.0386	0.025	
PITUITARY	0.0122	0.008	
THYROIDS/PARA	0.0148	0.010	
FINAL BODY WT(G)	153.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-025

ANIMAL NO.38707-01 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.4022	0.277		
UTERUS- BLOTTED	0.2909	0.201		
LIVER	6.6962	4.618		
KIDNEYS	1.4054	0.969		
SPLEEN	0.4169	0.288		
THYMUS	0.5171	0.357		
OVARIES/OVIDUCTS	0.0600	0.041		
ADRENAL GLANDS	0.0339	0.023		
PITUITARY	0.0082	0.006		
THYROIDS/PARA	0.0129	0.009		
FINAL BODY WT(G)	145.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-025

ANIMAL NO.38708-05 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.5493	0.354	
UTERUS- BLOTTED	0.3360	0.217	
LIVER	6.6309	4.278	
KIDNEYS	1.4636	0.944	
SPLEEN	0.3715	0.240	
THYMUS	0.5278	0.341	
OVARIES/OVIDUCTS	0.0723	0.047	
ADRENAL GLANDS	0.0331	0.021	
PITUITARY	0.0062	0.004	
THYROIDS/PARA	0.0134	0.009	
FINAL BODY WT(G)	155.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-01 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.2427	0.157	GROSS:	
UTERUS- BLOTTED	0.2241	0.145		
LIVER	6.9123	4.460		
KIDNEYS	1.4350	0.926		
SPLEEN	0.3629	0.234		
THYMUS	0.4814	0.311		
OVARIES/OVIDUCTS	0.0832	0.054		
ADRENAL GLANDS	0.0340	0.022		
PITUITARY	0.0098	0.006		
THYROIDS/PARA	0.0123	0.008		
FINAL BODY WT(G)	155.			

ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS
OVARIES PITUITARY SPLEEN THYMUS
THYROID GLANDS UTERUS CERVIX VAGINA
LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-02 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2083	0.123
UTERUS- BLOTTED	0.1933	0.114
LIVER	7.5680	4.478
KIDNEYS	1.5885	0.940
SPLEEN	0.4460	0.264
THYMUS	0.6740	0.399
OVARIES/OVIDUCTS	0.0664	0.039
ADRENAL GLANDS	0.0409	0.024
PITUITARY	0.0072	0.004
THYROIDS/PARA	0.0118	0.007
FINAL BODY WT(G)	169.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38707-05 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE			
UTERUS- WET	0.2946	0.169	GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
UTERUS- BLOTTED	0.2721	0.156		OVARIES	PITUITARY	SPLEEN	THYMUS
LIVER	9.5866	5.510		THYROID GLANDS	UTERUS	CERVIX	VAGINA
KIDNEYS	1.8290	1.051		LYMPH NODE, AXI			
SPLEEN	0.5536	0.318					
THYMUS	0.8360	0.480					
OVARIES/OVIDUCTS	0.0930	0.053					
ADRENAL GLANDS	0.0489	0.028					
PITUITARY	0.0095	0.005					
THYROIDS/PARA	0.0161	0.009					
FINAL BODY WT(G)	174.						

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-10 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2983	0.204
UTERUS- BLOTTED	0.2781	0.190
LIVER	5.8496	4.007
KIDNEYS	1.4781	1.012
SPLEEN	0.3330	0.228
THYMUS	0.5007	0.343
OVARIES/OVIDUCTS	0.0787	0.054
ADRENAL GLANDS	0.0388	0.027
PITUITARY	0.0085	0.006
THYROIDS/PARA	0.0106	0.007
FINAL BODY WT(G)	146.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38708-06 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	NO SIGNIFICANT CHANGES OBSERVED	GRADE
UTERUS- WET	0.3104	0.194		
UTERUS- BLOTTED	0.2786	0.174		
LIVER	7.5024	4.689		
KIDNEYS	1.6631	1.039		
SPLEEN	0.4143	0.259		
THYMUS	0.6476	0.405		
OVARIES/OVIDUCTS	0.0686	0.043		
ADRENAL GLANDS	0.0442	0.028		
PITUITARY	0.0109	0.007		
THYROIDS/PARA	0.0155	0.010		
FINAL BODY WT(G)	160.			

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

187061 RAD

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38710-05 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.	GRADE
UTERUS- WET	0.4263	0.272	
UTERUS- BLOTTED	0.3695	0.235	
LIVER	7.6627	4.881	
KIDNEYS	1.4572	0.928	
SPLEEN	0.3874	0.247	
THYMUS	0.4625	0.295	
OVARIES/OVIDUCTS	0.0692	0.044	
ADRENAL GLANDS	0.0389	0.025	
PITUITARY	0.0101	0.006	
THYROIDS/PARA	0.0085	0.005	
FINAL BODY WT(G)	157.		

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38709-01 GROUP 3: 50 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.5831	0.353
UTERUS- BLOTTED	0.3893	0.236
LIVER	7.8581	4.762
KIDNEYS	1.6785	1.017
SPLEEN	0.3937	0.239
THYMUS	0.5486	0.332
OVARIES/OVIDUCTS	0.0680	0.041
ADRENAL GLANDS	0.0482	0.029
PITUITARY	0.0086	0.005
THYROIDS/PARA	0.0143	0.009
FINAL BODY WT(G)	165.	

NO SIGNIFICANT CHANGES OBSERVED

GRADE

GROSS:				
ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	THYMUS	
THYROID GLANDS	UTERUS	CERVIX	VAGINA	
LYMPH NODE, AXI				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-08 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.			GRADE
UTERUS- WET	0.2338	0.149	OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
UTERUS- BLOTTED	0.2157	0.137		LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
LIVER	8.1216	5.173		NECROSIS, GRANULOSA CELLS	2
KIDNEYS	1.6510	1.052	PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
SPLEEN	0.4263	0.272		ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYMUS	0.4851	0.309	THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
OVARIES/OVIDUCTS	0.0844	0.054		BILATERAL	
ADRENAL GLANDS	0.0458	0.029	UTERUS	MICRO: ATROPHY	1
PITUITARY	0.0104	0.007	NO SIGNIFICANT		
THYROIDS/PARA	0.0171	0.011	CHANGES OBSERVED	GROSS:ADRENAL GLANDS KIDNEYS LIVER OVIDUCTS	
FINAL BODY WT(G)	157.			OVARIES PITUITARY SPLEEN THYMUS	
				THYROID GLANDS UTERUS CERVIX VAGINA	
				LYMPH NODE, AXI	
				MICRO:PARATHYROID CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

Modified: 4/30/2007

TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38704-09 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1728	0.133
UTERUS- BLOTTED	0.1625	0.125
LIVER	7.3869	5.682
KIDNEYS	1.4273	1.098
SPLEEN	0.4124	0.317
THYMUS	0.5047	0.388
OVARIES/OVIDUCTS	0.0445	0.034
ADRENAL GLANDS	0.0360	0.028
PITUITARY	0.0070	0.005
THYROIDS/PARA	0.0178	0.014
FINAL BODY WT(G)	130.	

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	2
	CYST, FOLLICULAR	P
	MULTIPLE, EARLY FOLLICULAR CYSTS	
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
	BILATERAL	
UTERUS	MICRO: ATROPHY	1
NO SIGNIFICANT CHANGES OBSERVED		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 48
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38704-01 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2044	0.135
UTERUS- BLOTTED	0.1860	0.123
LIVER	8.2498	5.463
KIDNEYS	1.5976	1.058
SPLEEN	0.4783	0.317
THYMUS	0.5235	0.347
OVARIES/OVIDUCTS	0.0745	0.049
ADRENAL GLANDS	0.0439	0.029
PITUITARY	0.0100	0.007
THYROIDS/PARA	0.0202	0.013
FINAL BODY WT(G)	151.	

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	3
	NECROSIS, GRANULOSA CELLS	1
	CYST, FOLLICULAR	P
	MULTIPLE, EARLY FOLLICULAR CYSTS	
	DECREASED CORPORA LUTEA	2
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	
	BILATERAL	P
UTERUS	MICRO: ATROPHY	1
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS
OVARIES, PITUITARY, SPLEEN, THYMUS
THYROID GLANDS, UTERUS, CERVIX, VAGINA
LYMPH NODE, AXI
MICRO:PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-01 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2382	0.171
UTERUS- BLOTTED	0.2165	0.156
LIVER	7.4228	5.340
KIDNEYS	1.5021	1.081
SPLEEN	0.3492	0.251
THYMUS	0.3908	0.281
OVARIES/OVIDUCTS	0.0612	0.044
ADRENAL GLANDS	0.0480	0.035
PITUITARY	0.0105	0.008
THYROIDS/PARA	0.0145	0.010
FINAL BODY WT(G)	139.	

NO SIGNIFICANT CHANGES OBSERVED

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	1
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
	HYPERTROPHY, FOLLICULAR CELL	1

GROSS:ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO:PARATHYROID, UTERUS, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38704-03 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1822	0.137
UTERUS- BLOTTED	0.1692	0.127
LIVER	7.0864	5.328
KIDNEYS	1.4436	1.085
SPLEEN	0.3691	0.278
THYMUS	0.4602	0.346
OVARIES/OVIDUCTS	0.0469	0.035
ADRENAL GLANDS	0.0333	0.025
PITUITARY	0.0098	0.007
THYROIDS/PARA	0.0132	0.010
FINAL BODY WT(G)	133.	

		GRADE
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	1
	CORPORA LUTEA ABSENT	4
	CYST, FOLLICULAR	P
	MULTIPLE, EARLY FOLLICULAR CYSTS	
PARATHYROID	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	1
	DEPLETION, COLLOID	1
UTERUS	MICRO: ATROPHY	2
NO SIGNIFICANT CHANGES OBSERVED		

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-05 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2466	0.170
UTERUS- BLOTTED	0.2346	0.162
LIVER	7.4957	5.169
KIDNEYS	1.4763	1.018
SPLEEN	0.3020	0.208
THYMUS	0.5616	0.387
OVARIES/OVIDUCTS	0.0675	0.047
ADRENAL GLANDS	0.0365	0.025
PITUITARY	0.0078	0.005
THYROIDS/PARA	0.0108	0.007
FINAL BODY WT(G)	145.	

OVARIES: NO SIGNIFICANT CHANGES OBSERVED

					GRADE
MICRO:	DEGENERATION, OOCYTE(S)				3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES				
	NECROSIS, GRANULOSA CELLS				1
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
	OVARIES	PITUITARY	SPLEEN	THYMUS	
	THYROID GLANDS	UTERUS	CERVIX	VAGINA	
	LYMPH NODE, AXI				
MICRO:	PARATHYROID	THYROID GLANDS	UTERUS	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

ANIMAL NO.38708-09 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1926	0.131
UTERUS- BLOTTED	0.1827	0.124
LIVER	7.6507	5.205
KIDNEYS	1.4640	0.996
SPLEEN	0.3852	0.262
THYMUS	0.4421	0.301
OVARIES/OVIDUCTS	0.0734	0.050
ADRENAL GLANDS	0.0396	0.027
PITUITARY	0.0085	0.006
THYROIDS/PARA	0.0097	0.007
FINAL BODY WT(G)	147.	

OVARIES
PARATHYROID
THYROID GLANDS
UTERUS
NO SIGNIFICANT
CHANGES OBSERVED

		GRADE
MICRO:	DEGENERATION, OOCYTE(S)	
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	2
	NECROSIS, GRANULOSA CELLS	2
MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
	BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	P
MICRO:	CYST, ULTIMOBRANCHIAL	2
MICRO:	ATROPHY	

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38707-10 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2267	0.150
UTERUS- BLOTTED	0.1919	0.127
LIVER	7.8990	5.231
KIDNEYS	1.6171	1.071
SPLEEN	0.3491	0.231
THYMUS	0.4370	0.289
OVARIES/OVIDUCTS	0.0472	0.031
ADRENAL GLANDS	0.0455	0.030
PITUITARY	0.0088	0.006
THYROIDS/PARA	0.0130	0.009
FINAL BODY WT(G)	151.	

OVARIES
NO SIGNIFICANT CHANGES OBSERVED

THYROID GLANDS
UTERUS

		GRADE
MICRO:	DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	2
	DECREASED CORPORA LUTEA	3
MICRO:	DEPLETION, COLLOID	1
	ECTOPIC THYMUS	P
MICRO:	ATROPHY	1

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38708-10 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2224	0.136
UTERUS- BLOTTED	0.2016	0.124
LIVER	8.5952	5.273
KIDNEYS	1.8056	1.108
SPLEEN	0.4808	0.295
THYMUS	0.5558	0.341
OVARIES/OVIDUCTS	0.0714	0.044
ADRENAL GLANDS	0.0448	0.027
PITUITARY	0.0098	0.006
THYROIDS/PARA	0.0165	0.010
FINAL BODY WT(G)	163.	

OVARIES
UTERUS
NO SIGNIFICANT
CHANGES OBSERVED

				GRADE
MICRO: DEGENERATION, OOCYTE(S)				3
LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES				
NECROSIS, GRANULOSA CELLS				2
MICRO: ATROPHY				2
GROSS:ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
OVARIES	PITUITARY	SPLEEN	THYMUS	
THYROID GLANDS	UTERUS	CERVIX	VAGINA	
LYMPH NODE, AXI				
MICRO:PARATHYROID	THYROID GLANDS	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-01 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1865	0.130
UTERUS- BLOTTED	0.1658	0.116
LIVER	6.6000	4.615
KIDNEYS	1.3379	0.936
SPLEEN	0.2897	0.203
THYMUS	0.4953	0.346
OVARIES/OVIDUCTS	0.0470	0.033
ADRENAL GLANDS	0.0366	0.026
PITUITARY	0.0064	0.004
THYROIDS/PARA	0.0135	0.009
FINAL BODY WT(G)	143.	

OVARIES
PARATHYROID
THYROID GLANDS
NO SIGNIFICANT
CHANGES OBSERVED

		GRADE
MICRO:	DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	2
MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
MICRO:	CYST, ULTIMOBRANCHIAL	P

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	PARATHYROID	UTERUS	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 56
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38707-04 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2228	0.139
UTERUS- BLOTTED	0.2095	0.131
LIVER	7.9392	4.962
KIDNEYS	1.5484	0.968
SPLEEN	0.4929	0.308
THYMUS	0.5277	0.330
OVARIES/OVIDUCTS	0.0602	0.038
ADRENAL GLANDS	0.0349	0.022
PITUITARY	0.0079	0.005
THYROIDS/PARA	0.0162	0.010
FINAL BODY WT(G)	160.	

OVARIES: NO SIGNIFICANT CHANGES OBSERVED

					GRADE
MICRO:	DEGENERATION, OOCYTE(S)				3
	NECROSIS, GRANULOSA CELLS				3
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
	OVARIES	PITUITARY	SPLEEN	THYMUS	
	THYROID GLANDS	UTERUS	CERVIX	VAGINA	
	LYMPH NODE, AXI				
MICRO:	PARATHYROID	THYROID GLANDS	UTERUS	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

Revised Audited Draft

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38707-08 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.	OVARIES	MICRO: CYST, LUTEAL				GRADE
UTERUS- WET	0.2161	0.142	NO SIGNIFICANT					P
UTERUS- BLOTTED	0.1967	0.129	CHANGES OBSERVED	GROSS:ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS	
LIVER	7.2768	4.787		OVARIES	PITUITARY	SPLEEN	THYMUS	
KIDNEYS	1.6009	1.053		THYROID GLANDS	UTERUS	CERVIX	VAGINA	
SPLEEN	0.3614	0.238		LYMPH NODE, AXI				
THYMUS	0.6701	0.441		MICRO:PARATHYROID	THYROID GLANDS	UTERUS	CERVIX	
OVARIES/OVIDUCTS	0.0528	0.035						
ADRENAL GLANDS	0.0418	0.028						
PITUITARY	0.0062	0.004						
THYROIDS/PARA	0.0121	0.008						
FINAL BODY WT(G)	152.							

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-07 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2229	0.137
UTERUS- BLOTTED	0.2049	0.126
LIVER	7.2539	4.450
KIDNEYS	1.5332	0.941
SPLEEN	0.3998	0.245
THYMUS	0.6530	0.401
OVARIES/OVIDUCTS	0.0549	0.034
ADRENAL GLANDS	0.0465	0.029
PITUITARY	0.0073	0.004
THYROIDS/PARA	0.0121	0.007
FINAL BODY WT(G)	163.	

OVARIES

THYROID GLANDS
NO SIGNIFICANT
CHANGES OBSERVED

		GRADE
MICRO:	DEGENERATION, OOCYTE(S)	3
	NECROSIS, GRANULOSA CELLS	2
MICRO:	HYPERTROPHY, FOLLICULAR CELL	2

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	PARATHYROID	UTERUS	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38710-09 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2991	0.183
UTERUS- BLOTTED	0.2704	0.166
LIVER	9.0758	5.568
KIDNEYS	1.6036	0.984
SPLEEN	0.4715	0.289
THYMUS	0.4880	0.299
OVARIES/OVIDUCTS	0.0726	0.045
ADRENAL GLANDS	0.0429	0.026
PITUITARY	0.0101	0.006
THYROIDS/PARA	0.0117	0.007
FINAL BODY WT(G)	163.	

OVARIES
PARATHYROID
THYROID GLANDS
NO SIGNIFICANT
CHANGES OBSERVED

		GRADE
MICRO:	DEGENERATION, OOCYTE(S)	3
	NECROSIS, GRANULOSA CELLS	1
MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
	ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
MICRO:	HYPERTROPHY, FOLLICULAR CELL	2

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	PARATHYROID	UTERUS	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38709-04 GROUP 4: 200 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.1878	0.138
UTERUS- BLOTTED	0.1733	0.127
LIVER	6.9485	5.109
KIDNEYS	1.4188	1.043
SPLEEN	0.3081	0.227
THYMUS	0.4954	0.364
OVARIES/OVIDUCTS	0.0462	0.034
ADRENAL GLANDS	0.0383	0.028
PITUITARY	0.0071	0.005
THYROIDS/PARA	0.0131	0.010
FINAL BODY WT(G)	136.	

OVARIES
CHANGES OBSERVED

PARATHYROID
UTERUS
NO SIGNIFICANT

				GRADE
MICRO:	DEGENERATION, OOCYTE(S)			3
	NECROSIS, GRANULOSA CELLS			2
	DECREASED CORPORA LUTEA			3
MICRO:	NO SIGNIFICANT CHANGES OBSERVED			
	ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED			
MICRO:	ATROPHY			1
GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYMUS
	THYROID GLANDS	UTERUS	CERVIX	VAGINA
	LYMPH NODE, AXI			
MICRO:	PARATHYROID	THYROID GLANDS	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]

INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

SPONSOR NO.:06-025

ANIMAL NO.38705-09 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2238	0.182
UTERUS- BLOTTED	0.2048	0.167
LIVER	8.9307	7.261
KIDNEYS	1.3157	1.070
SPLEEN	0.2203	0.179
THYMUS	0.1772	0.144
OVARIES/OVIDUCTS	0.0336	0.027
ADRENAL GLANDS	0.0329	0.027
PITUITARY	0.0054	0.004
THYROIDS/PARA	0.0173	0.014
FINAL BODY WT(G)	123.	

OVARIES
PARATHYROID
THYMUS
THYROID GLANDS
UTEROS
NO SIGNIFICANT CHANGES OBSERVED

		GRADE
MICRO:	NECROSIS, GRANULOSA CELLS	3
	DEGENERATION, OOCYTE(S)	2
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	CORPORA LUTEA ABSENT	4
MICRO:	NO SIGNIFICANT CHANGES OBSERVED ONE NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
GROSS:	SMALL	P
MICRO:	CYST, ULTIMOBRANCHIAL	P
MICRO:	ATROPHY	2

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	OVIDUCTS
	OVARIES	PITUITARY	SPLEEN	THYROID GLANDS
	UTERUS	CERVIX	VAGINA	LYMPH NODE, AXI
MICRO:	PARATHYROID	CERVIX		

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38705-02 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/16/06 DATE OF DEATH: 10/16/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2262	0.142
UTERUS- BLOTTED	0.2112	0.133
LIVER	13.3257	8.381
KIDNEYS	1.5692	0.987
SPLEEN	0.4531	0.285
THYMUS	0.3125	0.197
OVARIES/OVIDUCTS	0.0544	0.034
ADRENAL GLANDS	0.0549	0.035
PITUITARY	0.0084	0.005
THYROIDS/PARA	0.0225	0.014
FINAL BODY WT(G)	159.	

OVARIES
PARATHYROID
THYROID GLANDS
UTERUS
NO SIGNIFICANT
CHANGES OBSERVED

		GRADE
MICRO:	DEGENERATION, OOCYTE(S)	2
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	2
	CORPORA LUTEA ABSENT	4
MICRO:	NO SIGNIFICANT CHANGES OBSERVED	
	BOTH NOT IN PLANE OF SECTION; RECUT MADE AND EXAMINED	
MICRO:	CYST, ULTIMOBRANCHIAL	P
MICRO:	ATROPHY	2

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, OVARIES, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: PARATHYROID, CERVIX

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

SPONSOR:[redacted]
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS
SPONSOR NO.:06-025

ANIMAL NO.38706-06 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/17/06 DATE OF DEATH: 10/17/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2250	0.163
UTERUS- BLOTTED	0.2133	0.155
LIVER	11.5997	8.406
KIDNEYS	1.4922	1.081
SPLEEN	0.2982	0.216
THYMUS	0.2389	0.173
OVARIES/OVIDUCTS	0.0337	0.024
ADRENAL GLANDS	0.0386	0.028
PITUITARY	0.0073	0.005
THYROIDS/PARA	0.0140	0.010
FINAL BODY WT(G)	138.	

		GRADE
OVIDUCTS	GROSS: SMALL	P
	BILATERAL	
OVIDUCTS	MICRO: NO SIGNIFICANT CHANGES OBSERVED	
	PLEASE LOOK UNDER OVARY FOR CORRELATING STATEMENT	
OVARIES	GROSS: SMALL	P
	BILATERAL	
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	3
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE IMMATURE FOLLICLES	
	NECROSIS, GRANULOSA CELLS	2
	CORPORA LUTEA ABSENT	4
	ABSENT CORPORA LUTEA; A FEATURE OF OVARIAN ATROPHY CORRELATES WITH GROSS FINDING OF SMALL OVARY; NO MICROSCOPIC CORRELATE FOR GROSS OBSERVATION(S) IN THE OVIDUCT	
THYROID GLANDS	MICRO: CYST, ULTIMOBRANCHIAL	P
UTERUS	MICRO: ATROPHY	2
NO SIGNIFICANT CHANGES OBSERVED		

GROSS:	ADRENAL GLANDS	KIDNEYS	LIVER	PITUITARY
	SPLEEN	THYMUS	THYROID GLANDS	UTERUS
	CERVIX	VAGINA	LYMPH NODE, AXI	
MICRO:	OVIDUCTS	PARATHYROID	CERVIX	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

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TABLE 23 (SCHEDULED NECROPSY)

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

ANIMAL NO.38709-05 GROUP 5: 800 MG/KG/DAY FEMALE SCHEDULED EUTH 10/18/06 DATE OF DEATH: 10/18/06

ORGAN WEIGHT	ABS.(G)	REL.
UTERUS- WET	0.2165	0.137
UTERUS- BLOTTED	0.1991	0.126
LIVER	14.5706	9.222
KIDNEYS	1.7215	1.090
SPLEEN	0.4504	0.285
THYMUS	0.2641	0.167
OVARIES/OVIDUCTS	0.0548	0.035
ADRENAL GLANDS	0.0374	0.024
PITUITARY	0.0083	0.005
THYROIDS/PARA	0.0137	0.009
FINAL BODY WT(G)	158.	

		GRADE
OVARIES	GROSS: CYST(S)	P
	ONE, 2 MM IN DIAMETER, LEFT	
OVARIES	MICRO: DEGENERATION, OOCYTE(S)	4
	LATER STAGE FOLLICLES AFFECTED WITH RELATIVE SPARING OF MORE	
	IMMATURE FOLLICLES	
	CYST, PARAOVARIAN	P
	CORRELATES WITH GROSS FINDING OF CYST	
	NECROSIS, GRANULOSA CELLS	3
	CORPORA LUTEA ABSENT	4
THYROID GLANDS	MICRO: HYPERTROPHY, FOLLICULAR CELL	2
	DEPLETION, COLLOID	1
UTERUS	MICRO: ATROPHY	2
CERVIX	MICRO: ATROPHY	2

NO SIGNIFICANT CHANGES OBSERVED

GROSS: ADRENAL GLANDS, KIDNEYS, LIVER, OVIDUCTS, PITUITARY, SPLEEN, THYMUS, THYROID GLANDS, UTERUS, CERVIX, VAGINA, LYMPH NODE, AXI

MICRO: PARATHYROID

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL, 2-MILD, 3-MODERATE, 4-SEVERE, P-PRESENT

PGRHv4.54
04/24/2007

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38694-07	0.4096	0.3827	0.0269	10.3255	1.9066	0.5160	0.5059	0.1108	0.0462	0.0107	0.0166
38696-08	0.3765	0.3497	0.0268	9.5224	1.9762	0.4364	0.6582	0.1194	0.0494	0.0101	0.0183
38695-01	0.6982	0.4641	0.2341	7.2835	1.6109	0.5048	0.6153	0.0772	0.0411	0.0087	0.0187
38695-07	0.4985	0.4342	0.0643	8.0222	1.5607	0.4641	0.5436	0.0799	0.0382	0.0079	0.0222
38694-04	0.7364	0.3101	0.4263	6.3273	1.4132	0.3951	0.5660	0.0720	0.0417	0.0087	0.0164
38696-04	0.2853	0.2699	0.0154	6.4839	1.3973	0.3812	0.5184	0.0812	0.0313	0.0097	0.0281
38697-07	0.2601	0.2388	0.0213	8.2656	1.5263	0.5124	0.6001	0.0824	0.0317	0.0077	0.0112
38698-04	0.3536	0.3328	0.0208	6.9727	1.5737	0.4764	0.6105	0.1148	0.0492	0.0107	0.0134
38699-07	0.4452	0.4138	0.0314	9.5810	1.8506	0.4591	0.6633	0.1160	0.0512	0.0116	0.0146
38698-05	0.2768	0.2571	0.0197	7.1187	1.6701	0.4346	0.6528	0.0976	0.0418	0.0113	0.0135
38699-02	0.6801	0.4095	0.2706	7.1187	1.3740	0.3868	0.5356	0.0847	0.0331	0.0077	0.0121
38697-03	0.2826	0.2618	0.0208	9.2621	1.7678	0.5384	0.6155	0.0721	0.0323	0.0095	0.0105
38703-06	0.2869	0.2673	0.0196	10.7276	2.0827	0.6022	0.6689	0.0720	0.0388	0.0087	0.0100
38700-06	0.4172	0.3887	0.0285	9.3264	1.8054	0.4890	0.6015	0.1275	0.0343	0.0118	0.0136
38702-05	0.2943	0.2766	0.0177	7.3925	1.4462	0.4249	0.5665	0.0963	0.0331	0.0100	0.0130
MEAN	0.4201	0.3371	0.0829	8.2487	1.6641	0.4681	0.5948	0.0936	0.0396	0.0097	0.0155
S.D.	0.16366	0.07422	0.12438	1.43299	0.22415	0.06130	0.05361	0.01945	0.00696	0.00139	0.00484
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS PAGE 2
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)
38694-07	184.
38696-08	165.
38695-01	157.
38695-07	161.
38694-04	140.
38696-04	143.
38697-07	150.
38698-04	144.
38699-07	181.
38698-05	154.
38699-02	147.
38697-03	184.
38703-06	190.
38700-06	168.
38702-05	138.
MEAN	160.
S.D.	17.6
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 10 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38705-03	0.2653	0.2414	0.0239	9.0240	1.6397	0.6057	0.6544	0.0689	0.0388	0.0093	0.0177
38704-05	0.2315	0.2140	0.0175	6.8343	1.4714	0.4137	0.6067	0.0816	0.0339	0.0076	0.0123
38705-10	0.2740	0.2545	0.0195	8.9876	1.9010	0.4128	0.5841	0.0924	0.0434	0.0108	0.0159
38704-10	0.2701	0.2509	0.0192	9.4492	1.7511	0.5826	0.6169	0.1079	0.0397	0.0117	0.0177
38705-07	0.2284	0.2105	0.0179	6.5338	1.4532	0.5657	0.4975	0.0697	0.0331	0.0069	0.0187
38707-07	0.6693	0.3958	0.2735	9.5744	1.8546	0.4725	0.8354	0.0730	0.0412	0.0094	0.0139
38706-04	0.4285	0.3882	0.0403	8.3665	1.6954	0.5250	0.5138	0.0938	0.0413	0.0092	0.0137
38708-04	0.2934	0.2708	0.0226	7.2575	1.6133	0.5046	0.6213	0.0823	0.0304	0.0086	0.0120
38707-02	0.3153	0.2985	0.0168	8.1864	1.6237	0.5134	0.5799	0.0916	0.0413	0.0120	0.0141
38708-03	0.2473	0.2325	0.0148	6.6725	1.4376	0.5154	0.4651	0.0905	0.0362	0.0089	0.0132
38706-08	0.2053	0.1907	0.0146	6.5984	1.6080	0.4000	0.7140	0.0716	0.0370	0.0074	0.0113
38707-03	0.3193	0.2838	0.0355	5.7606	1.3739	0.3397	0.6096	0.0689	0.0343	0.0110	0.0106
38710-10	0.4721	0.4216	0.0505	9.0215	1.6338	0.5245	0.5554	0.0805	0.0397	0.0098	0.0105
38711-01	0.3176	0.2953	0.0223	9.3504	1.6041	0.4476	0.5342	0.0678	0.0291	0.0082	0.0123
38709-08	0.2110	0.1927	0.0183	7.7808	1.5034	0.3978	0.5075	0.0537	0.0387	0.0091	0.0105
MEAN	0.3166	0.2761	0.0405	7.9599	1.6109	0.4814	0.5931	0.0796	0.0372	0.0093	0.0136
S.D.	0.12295	0.07350	0.06528	1.26673	0.14976	0.07722	0.09380	0.01385	0.00426	0.00153	0.00274
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 10 MG/KG/DAY

ANIMAL	FBW(G)
38705-03	185.
38704-05	140.
38705-10	177.
38704-10	176.
38705-07	154.
38707-07	175.
38706-04	162.
38708-04	158.
38707-02	161.
38708-03	153.
38706-08	154.
38707-03	148.
38710-10	171.
38711-01	164.
38709-08	162.
MEAN	163.
S.D.	12.3
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 50 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38704-08	0.3506	0.3292	0.0214	9.1961	1.5432	0.4779	0.6323	0.0801	0.0331	0.0109	0.0173
38705-05	0.3802	0.3644	0.0158	6.6708	1.3815	0.3928	0.4661	0.1020	0.0449	0.0111	0.0189
38704-04	0.2204	0.2031	0.0173	9.6308	1.6588	0.4499	0.4907	0.0879	0.0325	0.0101	0.0151
38705-06	0.2863	0.2649	0.0214	8.5628	1.7393	0.3587	0.5241	0.1087	0.0444	0.0093	0.0156
38704-07	0.2133	0.1978	0.0155	7.8712	1.6544	0.4954	0.6570	0.0758	0.0363	0.0090	0.0157
38706-03	0.3310	0.3037	0.0273	7.8054	1.6214	0.4015	0.6366	0.0752	0.0386	0.0122	0.0148
38707-01	0.4022	0.2909	0.1113	6.6962	1.4054	0.4169	0.5171	0.0600	0.0339	0.0082	0.0129
38708-05	0.5493	0.3360	0.2133	6.6309	1.4636	0.3715	0.5278	0.0723	0.0331	0.0062	0.0134
38708-01	0.2427	0.2241	0.0186	6.9123	1.4350	0.3629	0.4814	0.0832	0.0340	0.0098	0.0123
38706-02	0.2083	0.1933	0.0150	7.5680	1.5885	0.4460	0.6740	0.0664	0.0409	0.0072	0.0118
38707-05	0.2946	0.2721	0.0225	9.5866	1.8290	0.5536	0.8360	0.0930	0.0489	0.0095	0.0161
38706-10	0.2983	0.2781	0.0202	5.8496	1.4781	0.3330	0.5007	0.0787	0.0388	0.0085	0.0106
38708-06	0.3104	0.2786	0.0318	7.5024	1.6631	0.4143	0.6476	0.0686	0.0442	0.0109	0.0155
38710-05	0.4263	0.3695	0.0568	7.6627	1.4572	0.3874	0.4625	0.0692	0.0389	0.0101	0.0085
38709-01	0.5831	0.3893	0.1938	7.8581	1.6785	0.3937	0.5486	0.0680	0.0482	0.0086	0.0143
MEAN	0.3398	0.2863	0.0535	7.7336	1.5731	0.4170	0.5735	0.0793	0.0394	0.0094	0.0142
S.D.	0.11363	0.06343	0.06587	1.12220	0.13312	0.05864	0.10411	0.01368	0.00564	0.00157	0.00267
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 24

INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]

FEMALE GROUP: 50 MG/KG/DAY

ANIMAL	FBW(G)
38704-08	164.
38705-05	136.
38704-04	167.
38705-06	164.
38704-07	161.
38706-03	153.
38707-01	145.
38708-05	155.
38708-01	155.
38706-02	169.
38707-05	174.
38706-10	146.
38708-06	160.
38710-05	157.
38709-01	165.
MEAN	158.
S.D.	10.1
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 200 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38705-08	0.2338	0.2157	0.0181	8.1216	1.6510	0.4263	0.4851	0.0844	0.0458	0.0104	0.0171
38704-09	0.1728	0.1625	0.0103	7.3869	1.4273	0.4124	0.5047	0.0445	0.0360	0.0070	0.0178
38704-01	0.2044	0.1860	0.0184	8.2498	1.5976	0.4783	0.5235	0.0745	0.0439	0.0100	0.0202
38705-01	0.2382	0.2165	0.0217	7.4228	1.5021	0.3492	0.3908	0.0612	0.0480	0.0105	0.0145
38704-03	0.1822	0.1692	0.0130	7.0864	1.4436	0.3691	0.4602	0.0469	0.0333	0.0098	0.0132
38706-05	0.2466	0.2346	0.0120	7.4957	1.4763	0.3020	0.5616	0.0675	0.0365	0.0078	0.0108
38708-09	0.1926	0.1827	0.0099	7.6507	1.4640	0.3852	0.4421	0.0734	0.0396	0.0085	0.0097
38707-10	0.2267	0.1919	0.0348	7.8990	1.6171	0.3491	0.4370	0.0472	0.0455	0.0088	0.0130
38708-10	0.2224	0.2016	0.0208	8.5952	1.8056	0.4808	0.5558	0.0714	0.0448	0.0098	0.0165
38706-01	0.1865	0.1658	0.0207	6.6000	1.3379	0.2897	0.4953	0.0470	0.0366	0.0064	0.0135
38707-04	0.2228	0.2095	0.0133	7.9392	1.5484	0.4929	0.5277	0.0602	0.0349	0.0079	0.0162
38707-08	0.2161	0.1967	0.0194	7.2768	1.6009	0.3614	0.6701	0.0528	0.0418	0.0062	0.0121
38706-07	0.2229	0.2049	0.0180	7.2539	1.5332	0.3998	0.6530	0.0549	0.0465	0.0073	0.0121
38710-09	0.2991	0.2704	0.0287	9.0758	1.6036	0.4715	0.4880	0.0726	0.0429	0.0101	0.0117
38709-04	0.1878	0.1733	0.0145	6.9485	1.4188	0.3081	0.4954	0.0462	0.0383	0.0071	0.0131
MEAN	0.2170	0.1988	0.0182	7.6668	1.5352	0.3917	0.5127	0.0603	0.0410	0.0085	0.0141
S.D.	0.03190	0.02875	0.00680	0.65481	0.11602	0.06775	0.07532	0.01294	0.00478	0.00151	0.00290
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

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TABLE 24

SPONSOR:[redacted]
INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 200 MG/KG/DAY

ANIMAL	FBW(G)
38705-08	157.
38704-09	130.
38704-01	151.
38705-01	139.
38704-03	133.
38706-05	145.
38708-09	147.
38707-10	151.
38708-10	163.
38706-01	143.
38707-04	160.
38707-08	152.
38706-07	163.
38710-09	163.
38709-04	136.
MEAN	149.
S.D.	11.1
N	15

FBW = FINAL BODY WEIGHT

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TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 800 MG/KG/DAY

ANIMAL	UTERUS-WET	UTERUS-BLOTTED	LUMINAL FLUID	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38705-09	0.2238	0.2048	0.0190	8.9307	1.3157	0.2203	0.1772	0.0336	0.0329	0.0054	0.0173
38705-02	0.2262	0.2112	0.0150	13.3257	1.5692	0.4531	0.3125	0.0544	0.0549	0.0084	0.0225
38706-06	0.2250	0.2133	0.0117	11.5997	1.4922	0.2982	0.2389	0.0337	0.0386	0.0073	0.0140
38709-05	0.2165	0.1991	0.0174	14.5706	1.7215	0.4504	0.2641	0.0548	0.0374	0.0083	0.0137
MEAN	0.2229	0.2071	0.0158	12.1067	1.5247	0.3555	0.2482	0.0441	0.0410	0.0074	0.0169
S.D.	0.00436	0.00644	0.00318	2.44273	0.16877	0.11561	0.05632	0.01210	0.00962	0.00139	0.00409
N	4	4	4	4	4	4	4	4	4	4	4

FBW = FINAL BODY WEIGHT

Revised Audited Draft

Modified: 4/30/2007

TABLE 24

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WEIGHTS, LUMINAL FLUID AND FINAL BODY WEIGHTS [G]
SPONSOR NO.:06-025

FEMALE GROUP: 800 MG/KG/DAY

ANIMAL	FBW(G)
38705-09	123.
38705-02	159.
38706-06	138.
38709-05	158.
MEAN	145.
S.D.	17.3
N	4

FBW = FINAL BODY WEIGHT

POFBWv4.14
11/16/2006
R:11/29/2006

187061 RAD

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Modified: 4/30/2007

TABLE 25

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-025

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38694-07	184.	0.223	0.208	5.612	1.036	0.280	0.275	0.060	0.025	0.006	0.009
38696-08	165.	0.228	0.212	5.771	1.198	0.264	0.399	0.072	0.030	0.006	0.011
38695-01	157.	0.445	0.296	4.639	1.026	0.322	0.392	0.049	0.026	0.006	0.012
38695-07	161.	0.310	0.270	4.983	0.969	0.288	0.338	0.050	0.024	0.005	0.014
38694-04	140.	0.526	0.222	4.520	1.009	0.282	0.404	0.051	0.030	0.006	0.012
38696-04	143.	0.200	0.189	4.534	0.977	0.267	0.363	0.057	0.022	0.007	0.020
38697-07	150.	0.173	0.159	5.510	1.018	0.342	0.400	0.055	0.021	0.005	0.007
38698-04	144.	0.246	0.231	4.842	1.093	0.331	0.424	0.080	0.034	0.007	0.009
38699-07	181.	0.246	0.229	5.293	1.022	0.254	0.366	0.064	0.028	0.006	0.008
38698-05	154.	0.180	0.167	4.623	1.084	0.282	0.424	0.063	0.027	0.007	0.009
38699-02	147.	0.463	0.279	4.843	0.935	0.263	0.364	0.058	0.023	0.005	0.008
38697-03	184.	0.154	0.142	5.034	0.961	0.293	0.335	0.039	0.018	0.005	0.006
38703-06	190.	0.151	0.141	5.646	1.096	0.317	0.352	0.038	0.020	0.005	0.005
38700-06	168.	0.248	0.231	5.551	1.075	0.291	0.358	0.076	0.020	0.007	0.008
38702-05	138.	0.213	0.200	5.357	1.048	0.308	0.411	0.070	0.024	0.007	0.009
MEAN	160.	0.267	0.212	5.117	1.036	0.292	0.374	0.059	0.025	0.006	0.010
S.D.	17.6	0.1176	0.0474	0.4415	0.0667	0.0265	0.0401	0.0124	0.0044	0.0008	0.0037
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

Revised Audited Draft

Modified: 4/30/2007

TABLE 25

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted]
SPONSOR NO.:06-025
INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

FEMALE GROUP: 10 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38705-03	185.	0.143	0.130	4.878	0.886	0.327	0.354	0.037	0.021	0.005	0.010
38704-05	140.	0.165	0.153	4.882	1.051	0.296	0.433	0.058	0.024	0.005	0.009
38705-10	177.	0.155	0.144	5.078	1.074	0.233	0.330	0.052	0.025	0.006	0.009
38704-10	176.	0.153	0.143	5.369	0.995	0.331	0.351	0.061	0.023	0.007	0.010
38705-07	154.	0.148	0.137	4.243	0.944	0.367	0.323	0.045	0.021	0.004	0.012
38707-07	175.	0.382	0.226	5.471	1.060	0.270	0.477	0.042	0.024	0.005	0.008
38706-04	162.	0.265	0.240	5.165	1.047	0.324	0.317	0.058	0.025	0.006	0.008
38708-04	158.	0.186	0.171	4.593	1.021	0.319	0.393	0.052	0.019	0.005	0.008
38707-02	161.	0.196	0.185	5.085	1.009	0.319	0.360	0.057	0.026	0.007	0.009
38708-03	153.	0.162	0.152	4.361	0.940	0.337	0.304	0.059	0.024	0.006	0.009
38706-08	154.	0.133	0.124	4.285	1.044	0.260	0.464	0.046	0.024	0.005	0.007
38707-03	148.	0.216	0.192	3.892	0.928	0.230	0.412	0.047	0.023	0.007	0.007
38710-10	171.	0.276	0.247	5.276	0.955	0.307	0.325	0.047	0.023	0.006	0.006
38711-01	164.	0.194	0.180	5.701	0.978	0.273	0.326	0.041	0.018	0.005	0.008
38709-08	162.	0.130	0.119	4.803	0.928	0.246	0.313	0.033	0.024	0.006	0.006
MEAN	163.	0.194	0.170	4.872	0.991	0.296	0.365	0.049	0.023	0.006	0.008
S.D.	12.3	0.0683	0.0416	0.5123	0.0584	0.0416	0.0568	0.0086	0.0023	0.0009	0.0016
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

187061 RAD

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Modified: 4/30/2007

TABLE 25

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-025

FEMALE GROUP: 50 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38704-08	164.	0.214	0.201	5.607	0.941	0.291	0.386	0.049	0.020	0.007	0.011
38705-05	136.	0.280	0.268	4.905	1.016	0.289	0.343	0.075	0.033	0.008	0.014
38704-04	167.	0.132	0.122	5.767	0.993	0.269	0.294	0.053	0.019	0.006	0.009
38705-06	164.	0.175	0.162	5.221	1.061	0.219	0.320	0.066	0.027	0.006	0.010
38704-07	161.	0.132	0.123	4.889	1.028	0.308	0.408	0.047	0.023	0.006	0.010
38706-03	153.	0.216	0.198	5.102	1.060	0.262	0.416	0.049	0.025	0.008	0.010
38707-01	145.	0.277	0.201	4.618	0.969	0.288	0.357	0.041	0.023	0.006	0.009
38708-05	155.	0.354	0.217	4.278	0.944	0.240	0.341	0.047	0.021	0.004	0.009
38708-01	155.	0.157	0.145	4.460	0.926	0.234	0.311	0.054	0.022	0.006	0.008
38706-02	169.	0.123	0.114	4.478	0.940	0.264	0.399	0.039	0.024	0.004	0.007
38707-05	174.	0.169	0.156	5.510	1.051	0.318	0.480	0.053	0.028	0.005	0.009
38706-10	146.	0.204	0.190	4.007	1.012	0.228	0.343	0.054	0.027	0.006	0.007
38708-06	160.	0.194	0.174	4.689	1.039	0.259	0.405	0.043	0.028	0.007	0.010
38710-05	157.	0.272	0.235	4.881	0.928	0.247	0.295	0.044	0.025	0.006	0.005
38709-01	165.	0.353	0.236	4.762	1.017	0.239	0.332	0.041	0.029	0.005	0.009
MEAN	158.	0.217	0.183	4.878	0.995	0.264	0.362	0.050	0.025	0.006	0.009
S.D.	10.1	0.0754	0.0460	0.4971	0.0496	0.0299	0.0523	0.0097	0.0038	0.0012	0.0020
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

187061 RAD

Revised Audited Draft

Modified: 4/30/2007

TABLE 25

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-025

FEMALE GROUP: 200 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38705-08	157.	0.149	0.137	5.173	1.052	0.272	0.309	0.054	0.029	0.007	0.011
38704-09	130.	0.133	0.125	5.682	1.098	0.317	0.388	0.034	0.028	0.005	0.014
38704-01	151.	0.135	0.123	5.463	1.058	0.317	0.347	0.049	0.029	0.007	0.013
38705-01	139.	0.171	0.156	5.340	1.081	0.251	0.281	0.044	0.035	0.008	0.010
38704-03	133.	0.137	0.127	5.328	1.085	0.278	0.346	0.035	0.025	0.007	0.010
38706-05	145.	0.170	0.162	5.169	1.018	0.208	0.387	0.047	0.025	0.005	0.007
38708-09	147.	0.131	0.124	5.205	0.996	0.262	0.301	0.050	0.027	0.006	0.007
38707-10	151.	0.150	0.127	5.231	1.071	0.231	0.289	0.031	0.030	0.006	0.009
38708-10	163.	0.136	0.124	5.273	1.108	0.295	0.341	0.044	0.027	0.006	0.010
38706-01	143.	0.130	0.116	4.615	0.936	0.203	0.346	0.033	0.026	0.004	0.009
38707-04	160.	0.139	0.131	4.962	0.968	0.308	0.330	0.038	0.022	0.005	0.010
38707-08	152.	0.142	0.129	4.787	1.053	0.238	0.441	0.035	0.028	0.004	0.008
38706-07	163.	0.137	0.126	4.450	0.941	0.245	0.401	0.034	0.029	0.004	0.007
38710-09	163.	0.183	0.166	5.568	0.984	0.289	0.299	0.045	0.026	0.006	0.007
38709-04	136.	0.138	0.127	5.109	1.043	0.227	0.364	0.034	0.028	0.005	0.010
MEAN	149.	0.145	0.133	5.157	1.033	0.263	0.345	0.040	0.028	0.006	0.009
S.D.	11.1	0.0164	0.0153	0.3374	0.0560	0.0377	0.0456	0.0074	0.0029	0.0012	0.0021
N	15	15	15	15	15	15	15	15	15	15	15

FBW = FINAL BODY WEIGHT

187061 RAD

Revised Audited Draft

Modified: 4/30/2007

TABLE 25

PROJECT NO.:WIL-187061 FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
SPONSOR:[redacted] INDIVIDUAL ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]
SPONSOR NO.:06-025

FEMALE GROUP: 800 MG/KG/DAY

ANIMAL	FBW(G)	UTERUS-WET	UTERUS-BLOTTED	LIVER	KIDNEYS	SPLEEN	THYMUS	OVARIES/OVIDUCTS	ADRENAL GLANDS	PITUITARY	THYROIDS/PARA
38705-09	123.	0.182	0.167	7.261	1.070	0.179	0.144	0.027	0.027	0.004	0.014
38705-02	159.	0.142	0.133	8.381	0.987	0.285	0.197	0.034	0.035	0.005	0.014
38706-06	138.	0.163	0.155	8.406	1.081	0.216	0.173	0.024	0.028	0.005	0.010
38709-05	158.	0.137	0.126	9.222	1.090	0.285	0.167	0.035	0.024	0.005	0.009
MEAN	145.	0.156	0.145	8.318	1.057	0.241	0.170	0.030	0.029	0.005	0.012
S.D.	17.3	0.0207	0.0191	0.8054	0.0474	0.0527	0.0218	0.0054	0.0047	0.0005	0.0026
N	4	4	4	4	4	4	4	4	4	4	4

FBW = FINAL BODY WEIGHT

POFBWv4.14
11/16/2006
R:11/29/2006

APPENDIX A

Certificate Of Analysis (Sponsor-Provided Data)

Revised Audited Draft

[redacted]

Revised Audited Draft

Test Substance Certificate

Test Substance
[redacted]

Lot #
[redacted]

Purity
100%

Physical Description
Clear, colorless viscous liquid

Storage Conditions
Ambient

Expiration Date
1 September 2007

Additional Comments
None

[redacted]

13 September 2006
Date

APPENDIX B

Analytical Chemistry Report (Sponsor-Provided Data)

Revised Audited Draft

APPENDIX C

Animal Room Environmental Conditions

Revised Audited Draft

Revised Audited Draft

Modified: 11/2/2006

FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
TEMPERATURE/HUMIDI STUDY

PROJECT NO [redacted] 187061
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187061

DATE IN: 09/12/06 TIME IN: 11:00
DATE OUT: 10/18/06 TIME OUT: 9:00

ROOM SPECIFICATIONS: B ROOM 32
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

DATE	TEMPERATURE MEAN (°F)	TEMPERATURE MEAN (°C)	HUMIDITY MEAN (%RH)
12-Sep-06	70.9	21.6	46.6
13-Sep-06	70.8	21.5	46.7
14-Sep-06	71.0	21.7	46.4
15-Sep-06	71.0	21.6	45.6
16-Sep-06	70.7	21.5	45.3
17-Sep-06	71.0	21.7	45.9
18-Sep-06	70.9	21.6	46.3
19-Sep-06	70.9	21.6	43.5
20-Sep-06	70.9	21.6	39.7
21-Sep-06	70.5	21.4	37.7
22-Sep-06	70.8	21.6	43.1
23-Sep-06	70.7	21.5	46.4
24-Sep-06	70.8	21.6	44.9
25-Sep-06	70.3	21.3	40.3
26-Sep-06	71.0	21.7	42.5
27-Sep-06	70.4	21.3	45.6
28-Sep-06	70.8	21.5	42.9
29-Sep-06	71.0	21.7	36.9
30-Sep-06	70.7	21.5	41.6
01-Oct-06	70.7	21.5	41.8
02-Oct-06	70.7	21.5	42.8
03-Oct-06	70.8	21.5	45.3
04-Oct-06	70.5	21.4	47.7

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
11/2/2006 16:48

Revised Audited Draft

Modified: 11/2/2006

FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
TEMPERATURE/HUMIDI STUDY

PROJECT NO [redacted] 187061
SPONSOR: [redacted]

STUDY SPECIFICATIONS: 187061

ROOM SPECIFICATIONS: B ROOM 32
SPECIES: RAT

DATE IN: 09/12/06 TIME IN: 11:00
DATE OUT: 10/18/06 TIME OUT: 9:00

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
05-Oct-06	70.7	21.5	41.0
06-Oct-06	70.6	21.4	39.1
07-Oct-06	70.9	21.6	40.0
08-Oct-06	70.8	21.5	42.4
09-Oct-06	70.6	21.4	46.5
10-Oct-06	70.5	21.4	45.3
11-Oct-06	70.9	21.6	46.8
12-Oct-06	70.6	21.4	39.0
13-Oct-06	70.7	21.5	39.3
14-Oct-06	70.9	21.6	38.8
15-Oct-06	70.5	21.4	38.9
16-Oct-06	70.4	21.3	39.3
17-Oct-06	70.8	21.6	44.8
18-Oct-06	71.0	21.7	45.0

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.7	70.3	71.0
TEMPERATURE °C	21.5	21.3	21.7
HUMIDITY (%RH)	43.0	36.9	47.7
N DAYS	37		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
11/2/2006 16:48

Revised Audited Draft

Modified: 11/2/2006

FEMALE PUBERTAL ASSAY OF [redacted] JUV RATS
PROJECT NO [redacted] 187061 TEMPERATURE/HUMID PORT 16:41 02-Nov-06 PAGE 1
SPONSOR: [redacted]

ROOM SPECIFICATIONS:	B ROOM 32		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	09/12/06
HIGH TEMPERATURE:	76.0	TIME IN:	11:00
LOW HUMIDITY:	30.0	DATE OUT:	10/18/06
HIGH HUMIDITY:	70.0	TIME OUT:	9:00

ROOM B ROOM 32 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.7	42.9
MIN	69.0	34.2
MAX	73.0	62.1
SD	1.06	3.85
N SAMPLES	862	862
FIRST DAY	09/12/06	
LAST DAY	10/18/06	
N DAYS	37	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

REPORT 5
VERSION 1.10
11/2/2006 16:41

Revised Audited Draft

Modified: 11/2/2006

STUDY 187061 SUMMARY

MEAN	70.7	42.9
MIN	69.0	34.2
MAX	73.0	62.1
SD	1.06	3.85
N SAMPLES	862	862
FIRST DAY	09/12/06	
LAST DAY	10/18/06	
N DAYS	37	

187061 RAD

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

APPENDIX D

Clinical Pathology, Methods, Procedures And References

Revised Audited Draft

CLINICAL PATHOLOGY METHODS, PROCEDURES AND REFERENCES

Immunoassay- DPC Immulite®

Estradiol (estradiol-17β) - Competitive Immunoassay for the quantitative measurement of estradiol in serum. Default unit: pg/mL.

Total T4 - Solid-phase, chemiluminescent enzyme immunoassay for the quantitative measurement of total circulating thyroxide. Default unit: µg/dL.

Immunoassay-GAMMA-C12 Gamma Counter (continued)

Rat Luteinizing Hormone (rLH) - ^{125}I radioimmunoassay system for the quantitative determination of (rLH) DPC GAMMA C-12 gamma counter. Default unit: mIU/mL. Biotrak™ rat luteinizing hormone [^{125}I] assay system©. Amersham Life Science Ltd. Package Insert.

Rat Thyroid Stimulating Hormone (rTSH) - ^{125}I assay system with magnetic separation for the quantitative measurement of (rTSH). DPC GAMMA C-12 gamma counter. Biotrak™ rat thyroid stimulating hormone ^{125}I assay system. Amersham Pharmacia Biotech. Package insert.

References:

Immulite®. Diagnostics Products Corporation. Package Insert.

Revised Audited Draft

APPENDIX E

Pathology Report (WIL Research Laboratories, LLC)

Revised Audited Draft

WIL-187061
[redacted]

[redacted]
06-025

Revised Audited Draft

A FEMALE PUBERTAL ASSAY OF [redacted]
[redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

PATHOLOGY REPORT

Pathology Department

WIL Research Laboratories, LLC

Revised Audited Draft

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1. INTRODUCTION

The objective of this study was to evaluate the ability of the test article to induce effects on pubertal development in the intact juvenile female rat.

2. STUDY DESIGN

Female Crl:CD(SD) rats were administered [redacted] via oral gavage as single daily doses beginning on post-natal day (PND) 22 and continuing through PND 41. All animals were dosed at approximately the same time each day (after 12:00 pm). The dosage volume was 5 mL/kg for all groups.

Group Number	Test Article	Dosage Level (mg/kg/day)	Number of Females
1*	Vehicle [a]	0	15
2	[redacted]	10	15
3		50	15
4		200	15
5		800	15

[a] = The vehicle was corn oil.
*Control group data were collected in the companion study, WIL-187060.

All surviving animals were euthanized by carbon dioxide inhalation on PND 42.

3. METHODS

3.1. HORMONE ANALYSES

Following euthanasia on PND 42, blood was collected from the vena cava of all surviving animals. All blood samples were allowed to clot, placed in an ice bath and processed to generate serum. The following hormone concentrations were determined from all serum samples:

Thyroid Stimulating Hormone (TSH)	Thyroxine (Total T_4)
Estradiol	Luteinizing Hormone (Lutein' Hormone)

( ) - Designates tabular abbreviation

3.2. ANATOMIC PATHOLOGY

3.2.1. MACROSCOPIC EXAMINATION

Complete postmortem examinations were performed on all animals found dead, or euthanized in extremis. At the scheduled necropsy, animals were euthanized by carbon dioxide inhalation and exsanguinated. At the time of necropsy, the following tissues and organs [including gross lesions (i.e., masses)] were collected and placed in 10% neutral-buffered formalin fixative unless otherwise noted:

Axillary Lymph Node	Thymus
Cervix and Uterine Body (1 longitudinal section)	Thyroid with parathyroids
	Uterine horns (4 sections per horn)
Ovaries/Oviducts	Vagina
Pituitary	All gross (internal) lesions (when possible)
Spleen	

3.2.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsy:

Adrenal glands	Pituitary gland
Kidneys	Spleen
Liver	Thymus
Ovaries and oviducts	Thyroid with parathyroids *

Paired organs were weighed together. Designated (*) organs were weighed after fixation. Organ-to-final-body-weight ratios were calculated.

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In addition, wet and blotted uterine weights were measured for all animals that survived to the scheduled necropsy. The uterus harvesting and weighing procedure was performed as described below.

1) Animal was euthanized and uterus harvested.
2) Uterus (with luminal fluid) was immediately transferred to a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3) The uterus' wet weight was recorded to the nearest 0.1 mg.
4) The uterus was opened and blotted.
5) The uterus was placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6) The uterus' blotted weight was recorded to the nearest 0.1 mg.

3.2.3. MICROSCOPIC EXAMINATION

Microscopic examination of routinely prepared hematoxylin-eosin stained paraffin sections was performed on the cervix and uterine body (1 longitudinal section), ovaries, thyroids with parathyroids and uterine horns (4 sections per horn) collected at necropsy from all animals in the 0, 200 and 800 mg/kg/day groups.

The stained histologic sections were examined by routine light microscopy and histologic observations were entered in the WIL Toxicology Data Management System (WTDMS™) by the pathologist at the time of examination. Due to sectioning difficulties or minor laboratory errors, the number of tissues examined from each dosage group does not necessarily correlate with the number of animals included in the group. The number of missing tissues was small and did not interfere with detection of test article-related histologic alterations in the study. The histologic sections were of adequate size and quality for detailed histologic evaluation. The WTDMS™ histopathology tables contain a record of tissues examined and histologic findings, and serve as the basis for this narrative report. Histopathology lesions were classified using standard published terminology to the extent possible.

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3.3. ABBREVIATIONS

The following abbreviations may apply to this report:

Interval - point in the study at which an animal died or was euthanized
FD - found dead
SN - scheduled necropsy

3.4. DATA INTERPRETATION

In the discussion of hormones, values derived from the control group animals were considered as concurrent control values for purposes of constructing a 'normal' range for the present study. Unless otherwise stated in this report, the 'normal' historical control range was considered to be the mean value ± 2 standard deviations. This narrative report addresses all clinical pathology values that were identified as statistically significantly different from control group values on the clinical pathology data tables.

In the discussion of organ weight changes, the indication of higher or lower mean organ weights refers to a statistically significant ($p<0.05$ or $p<0.01$ using Dunnett's test) difference between test article-treated versus control group animals in the present study. In addition, historical control values for this laboratory were consulted to refine data interpretation. This narrative report addresses all organ weight values that were identified as statistically significantly different from control group values on the organ weight data tables.

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4. RESULTS

4.1. SURVIVAL

Eleven of 15 rats administered the test article at 800 mg/kg/day (Group 5) died at various time points during the study. In the 800 mg/kg/day group, 2 animals died on postnatal day (PND) 24, 5 animals died on PND 25, 3 animals died on PND 26, 1 animal died on PND 28. The rats from the control group, the 200 mg/kg/day group (Group 4) and the remaining 4/15 rats from the 800 mg/kg/day group survived until the scheduled necropsy. The cause of death was not determined for any of the animals that died during the course of the study.

4.2. HORMONES ANALYSES

The following **bolded and underlined** alterations in hormone levels were considered to be related to test article administration:

Text Table 1. Selected Hormonal Findings - Females

Group (mg/kg/day) Analysis:	0	10	50	200	800
Estradiol (pg/mL)					
Day 42 Mean	101.79	108.25	110.29	105.15	**142.50****
% Difference		6.3	8.4	3.3	40.0
TSH (ng/mL)					
Day 42 Mean	8.16	9.35	11.40	9.60	**14.73****
% Difference		14.6	39.7	17.6	80.5

** = Significantly different from the control group at 0.01 using Dunnett's test

Estradiol and TSH levels were significantly higher in the 800 mg/kg/day group females.

There were no other test article-related effects or statistically significant differences on hormone analyses.

4.3. GROSS OBSERVATIONS

Test article-related macroscopic changes were not observed in the 200 mg/kg/day group. Small ovaries and oviducts were noted in 1 rat from the 800 mg/kg/day group. Decreased

size of the ovaries was confirmed microscopically to be resulting from the loss of parenchyma characterized by absence of corpora lutea, necrosis of granulosa cells and degeneration of oocytes in this rat. A 2-mm cyst in 1 ovary of a rat from the 800 mg/kg/day group was microscopically consistent with a paraovarian cyst. This alteration was considered unrelated to test article administration due to its absence in other test article-treated animals in the same dose group and also due the absence of a dose-related response.

Descriptions of test article-related histologic alterations are discussed in Section 4.5. (Histologic Changes).

4.4. ORGAN WEIGHTS

The weight of ovaries and oviducts of rats administered the test article at dosage levels of 10, 50, 200 and 800 mg/kg/day were statistically significantly lower compared to the control group animals. The extent of weight loss paralleled the increase in the dose rate and therefore was considered to be related to administration of the test article.

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Text Table 2. Toxicologically Relevant Ovary/Oviduct Weight Changes - Scheduled Necropsy

Organ	Direction & magnitude of change - absolute weight (% difference)	Direction & magnitude of change - relative to final body weight (% difference)	Dosage Level(s) (mg/kg/day)	Histologic Correlates
Ovaries& oviducts	↓52.9**	↓49.2**	800	Absence of corpora lutea Necrosis of granulosa cells Degeneration of oocytes
Ovaries& oviducts	↓35.6**	↓32.2**	200	Decreased/absent corpora lutea Necrosis of granulosa cells Degeneration of oocytes

** = Significantly different from the control group at 0.01 using Dunnett's test

Similarly, the weight of the uterus in rats administered the test article at dosage levels of rates of 10 (blotted weight), 200 (wet and blotted weight) and 800 mg/kg/day (wet and blotted weight) were statistically significantly lower than the control group animals. Although the magnitude of weight change did not correlate with the increasing dose rate, more severe microscopic alterations were present in rats administered the high dose level (800 mg/kg/day). Accordingly, weight changes in the uterus were considered significant and attributable to administration of the test article.

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Text Table 3. Toxicologically Relevant Uterine Weight Changes - Scheduled Necropsy

Organ	Direction & magnitude of change - absolute weight (% difference)	Direction & magnitude of change - relative to final body weight (% difference)	Dosage Level(s) (mg/kg/day)	Histologic Correlate
Uterus-wet	↓46.9*	↓41.6*	800	Atrophy
Uterus-blotted	↓38.6**	↓31.6*	800	Atrophy
Uterus-wet	↓48.3**	↓45.7**	200	Atrophy
Uterus-blotted	↓41.0**	↓37.3**	200	Atrophy

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

The following organ weight changes were statistically significant when compared to the control group. Microscopic examination of the corresponding tissue sections was not performed. Therefore, the histologic basis of these weight changes was not determined.

Text Table 4. Other Toxicologically Relevant Organ Weight Changes

Organ	Direction and magnitude of change - absolute weight (% difference)	Direction and magnitude of change - relative to final body weight (% difference)	Dosage Level(s) (mg/kg/day)
Pituitary	↓23.7*	↓16.7	800
Liver	↑46.8**	↑62.6**	800
Thymus	↓58.3**	↓54.5**	800
Thymus	↓13.8*	↓7.8	200
Spleen	↓24.1*	↓17.5*	800
Spleen	↓16.3*	↓9.9	200

* = Significantly different from the control group at 0.05 using Dunnett's test
** = Significantly different from the control group at 0.01 using Dunnett's test

4.5. HISTOLOGIC CHANGES

4.5.1. CHANGES ASSOCIATED WITH TEST ARTICLE ADMINISTRATION

The following microscopic alterations were present in the ovaries of rats administered the test article at dosage levels 200 and 800 mg/kg/day.

- Degeneration of oocytes
- Necrosis of granulosa cells in the ovarian follicles and,
- Complete absence or decrease in the number of corpora lutea.

In all of the female rats (15/15) administered the test article at the highest dose level (800 mg/kg/day), all of the ovaries were completely devoid of corpora lutea. Corpora lutea were occasionally reduced in number (3/15) or completely absent (1/15) in the ovaries of rats of the 200 mg/kg/day group.

An increase in severity of microscopic alterations (as mentioned above) were observed in the ovaries of rats in the 800 mg/kg/day group, relative to rats administered the test article at 200 mg/kg/day. Since the severity of the microscopic alterations correlated with increasing dose rate, these microscopic alterations were considered to be related to administration of the test article.

Microscopic alterations present in the uterus of rats administered the test article were most consistent with atrophy affecting the muscular and mucosal tunics characterized by reduced thickness of the tunica muscularis and/or tunica mucosa or generalized reduction in size of the organ due to symmetric atrophy of all the tunics. The uterine atrophy was more severe in rats administered the test article at 800 mg/kg/day versus 200 mg/kg/day. Additionally, mild (4/15) to moderate (4/15) atrophy of the cervix was present in rats from the 800 mg/kg/day group. This alteration was also attributed to administration of the test article.

Microscopic alterations in ovaries, uterus and cervix considered to be related to administration of the test article are summarized in Text Table 5 below.

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Text Table 5. Summary Of Microscopic Findings

Dosage (mg/kg/day)	0	200	800
Tissue			
Ovaries [a]	15	15	15
Corpora Lutea Absent	0	1	15
Decreased corpora lutea	0	3	0
Mild	0	1	0
Severe	0	2	0
Granulosa cell necrosis	0	14	15
Minimal	0	5	0
Mild	0	8	2
Moderate	0	1	13
Oocyte degeneration	0	14	15
Mild	0	1	2
Moderate	0	13	9
Severe	0	0	4

[a] = Number of tissues examined from each group.

Text Table 5. Summary Of Microscopic Findings (continued)

Dosage (mg/kg/day)	0	200	800
Tissue			
Uterus [a]	15	15	15
Atrophy	0	8	15
Minimal	0	5	0
Mild	0	3	4
Moderate	0	0	11
Cervix [a]	15	15	15
Atrophy	0	0	8
Mild	0	0	4
Moderate	0	0	4

[a] = Number of tissues examined from each group.

Minimal to mild depletion of colloid in the thyroid glands was present in 11/15 rats administered the test article at 800 mg/kg/day. Occasionally, colloid depletion occurred in conjunction with hypertrophy of the follicular epithelial cells. Similar microscopic

alterations were also present in rats administered the test article at 200 mg/kg/day; albeit at a much reduced frequency (colloid depletion was present in 2/15 rats). Microscopic alterations in the thyroid gland were also considered related to test article administration because of the higher frequency of incidence and severity of colloid depletion in rats administered the test article at 800 mg/kg/day.

Microscopic alterations in thyroid gland considered to be related to administration of the test article are summarized in Text Table 6 below.

Text Table 6. Summary Of Microscopic Findings In The Thyroid Gland

Dosage (mg/kg/day)	0	200	800
Thyroid [a]	15	15	15
Colloid depletion	0	2	11
Minimal	0	2	4
Mild	0	0	7
Follicular cell hypertrophy	0	4	2
Minimal	0	2	0
Mild	0	2	2
Ectopic thymus	0	1	2

[a] = Number of tissues examined from each group.

4.5.2. CHANGES OF UNCERTAIN RELATIONSHIP TO TEST ARTICLE ADMINISTRATION

No histologic changes of uncertain relationship to administration of the test article were observed in tissues evaluated microscopically.

4.5.3. CHANGES UNRELATED TO TEST ARTICLE ADMINISTRATION

There were no other test article-related histologic changes. Remaining histologic changes were considered to be incidental findings, manifestations of spontaneous diseases, or related to some aspect of experimental manipulation other than administration of the test

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article. There was no test article-related alteration in the incidence, severity or histologic character of those incidental and spontaneous tissue alterations.

5. DISCUSSION

The suspected test article-related changes in the ovaries involved a much larger number of follicles than would be expected with typical physiologic follicular atresia, and tended to involve more late stage rather than immature follicles.

There was significantly ($p<0.01$) lower thymus weight (58.3% absolute and 54.5% relative to body weight) in animals administered the test article at 800 mg/kg/day.

Colloid depletion in the thyroid glands of 11/15 rats administered test article at 800 mg/kg/day may be due to enhanced stimulation to the thyroid glands from elevated levels of thyroid stimulating hormone, which was demonstrated in the present study.

6. CONCLUSIONS

Female Crl:CD(SD) rats were administered [redacted] via oral gavage as single daily doses beginning on post-natal day (PND) 22 and continuing through PND 41. Groups 1-5 were administered the test article at dosages of 0, 10, 50, 200 and 800 mg/kg/day, respectively. Thyroid stimulating hormone (TSH), thyroxine (Total T_4), estradiol (E2) and luteinizing hormone (LH) were determined on PND 42. Estradiol and TSH levels were significantly higher in the 800 mg/kg/day group females than control group values.

Ovaries/oviduct and uterus weights of rats administered [redacted] at 200 and 800 mg/kg/day were significantly lower than control group values. Microscopic correlates in the ovary included absence or reduction in the number of corpora lutea, degeneration of oocytes and necrosis of granulosa cells in ovarian follicles. Severity of the ovarian and uterine changes was generally dose-associated.

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7. REFERENCES

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Montgomery, C.A.; Alison, R.H.; Nonneoplastic lesions of the ovary in Fischer 344 rats and B6C3F1 mice. *Environ Health Perspect* 1987 73, 53–75.

Yuan, Y.D. Female reproductive system. In: *Handbook of Toxicologic Pathology*, Academic Press, 1991; pp 891-924.

8. REPORT SUBMISSION

Report Submitted By:

[redacted]
Study Clinical Pathologist

Date

[redacted]
Study Pathologist

Date

Report Reviewed By:

[redacted]
Reviewing Pathologist

Date

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APPENDIX F

Pathology Peer Review Statement (WIL Research Laboratories, LLC)

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WIL Study No. 187061

Peer Review Statement

A peer review of histopathology data was performed as follows for this study:

1. All processed tissues and diagnoses were reviewed from five numbered female rats selected randomly from the control and high dose groups. Identification numbers for the control animals evaluated were 38694-07, 38695-01, 38694-04, 38697-03 and 38702-05 and for the high-dose animals were 38705-09, 38705-02, 38706-06, 38709-05 and 38711-02.

2. Potential target organs for which all diagnoses were verified from all animals in all treatment groups were as follows: ovary, uterus, cervix and vagina.

Following review of the microscopic findings reported by the study pathologist, the results were discussed and appropriate terminology and diagnoses were mutually agreed upon. Differences of opinion between the study and reviewing pathologists were resolved with agreement on the final diagnoses. The tables contained in the final report reflect the mutually agreed-upon diagnoses.

[redacted] 13 April 2007

Reviewing Pathologist — Date

APPENDIX F

WIL Female Pubertal Assay Historical Control Data Version 1.1 [Crl:CD(SD) Rats]

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WIL Research Laboratories, LLC Historical Control

FEMALE PUBERTAL ASSAYS - Crl:CD(SD) RATS

	Grand Mean	SD	N	Min	Max	25th Quartile	75th Quartile
Vaginal Patency (PND)	33.7	1.3	11	31.8	36.5	33.0	34.4
Body Weight At Patency (g)	110.9	4.4	11	102.1	116.4	108.5	114.1
Estrous Cycle Length (days)	5.1	0.4	10	4.8	6.1	4.9	5.2
Age At First Estrus (PND)	35.6	1.4	11	34.1	38	34.5	36.4
T4 (µg/dL)	4.6	0.5	7	3.89	5.23	4.3	5.0
TSH (ng/mL)	9.0	1.7	7	7.3	11.4	7.8	10.4
Estradiol (pg/mL)	138	24	2	121	155	130	147
Luteinizing Hormone (ng/mL)	3.5	0.3	2	3.3	3.7	3.4	3.6
Uterus - Wet (g)	0.3542	0.0528	11	0.2932	0.4400	0.3149	0.4026
Uterus - Blotted (g)	0.2930	0.0296	11	0.2621	0.3610	0.2764	0.3079
Luminal Fluid (g)	0.0619	0.0272	11	0.0306	0.1001	0.0383	0.0894
Liver (g)	7.6484	0.6662	11	6.6900	8.9920	7.2418	7.9729
Kidney (g)	1.6135	0.0358	7	1.5682	1.6573	1.5874	1.6389
Ovaries/Oviducts (g)	0.0835	0.0048	10	0.0769	0.0940	0.0804	0.0855
Adrenal Glands (g)	0.0381	0.0035	11	0.0321	0.0428	0.0365	0.0405
Pituitary (g)	0.0086	0.0008	11	0.0074	0.0101	0.0080	0.0092
Thyroid Glands (g)	0.0163	0.0029	7	0.0129	0.0213	0.0143	0.0178
Spleen (g)	0.4386	0.0062	2	0.4342	0.4430	0.4364	0.4408
Thymus Glands (g)	0.6013	0.0170	2	0.5892	0.6133	0.5952	0.6073

Version 1.1 - 16 November 2006

APPENDIX G

WIL Reproductive Historical Control Data Version 2.4 [Crl:CD(SD) Rats]

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Reproductive Performance

Sex: Male/Female | Species: Rat | Number of Studies/Data Sets: 62 / 96
Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Total	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Number of Males in Control Group	1600						
Male Mating Index (%)		96.8	3.69	61	89.42 / 100.00	85.73 / 100.00	86.7 / 100.0
Male Fertility Index (%)		89.8	6.89	61	76.02 / 100.00	69.13 / 100.00	72.0 / 100.0
Male Copulation Index (%)		92.7	6.08	61	80.54 / 100.00	74.46 / 100.00	75.0 / 100.0
Number of Females in Control Group	2248						
Female Mating Index (%)		97.8	3.26	73	91.28 / 100.00	88.02 / 100.00	86.7 / 100.0
Female Fertility Index (%)		91.3	7.17	82	76.96 / 100.00	69.79 / 100.00	72.0 / 100.0
Female Conception Index (%)		92.9	5.82	73	81.26 / 100.00	75.44 / 100.00	75.0 / 100.0
Number of Females Selected to Deliver	1301						
Number that Delivered	1151						
Number that did not Deliver	145						
Number with Total Litter Loss	11						
Number with Dystocia	3						

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WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Reproductive Performance

Sex: Female | Species: Rat | Number of Studies/Control Groups: 62 / 96

Study Type: All | Strain: Crl:CD(SD) | Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Min/Max Value
Mean Estrous Cycle Length (days)	4.5	0.41	63	3.68 / 5.32	3.27 / 5.73	4.0 / 5.8
Mean Pre-Coital Interval (days)	3.0	0.52	74	1.96 / 4.04	1.44 / 4.56	1.8 / 4.7
Mean Gestation Length (days)	21.9	0.20	46	21.50 / 22.30	21.30 / 22.50	21.5 / 22.3
Mean Number of Pups Born	14.3	0.91	46	12.48 / 16.12	11.57 / 17.03	12.2 / 16.0
Mean Viable Litter Size (PND 0)	14.1	0.94	46	12.22 / 15.98	11.28 / 16.92	12.0 / 16.0
Mean % Males/ Litter	50.08	2.78	58	44.52 / 55.64	41.74 / 58.42	42.7 / 58.5
Mean % Females/ Litter	49.92	2.78	58	44.36 / 55.48	41.58 / 58.26	41.5 / 57.3
Mean No. of Former Implantation Sites at Weaning	15.2	0.87	44	13.46 / 16.94	12.59 / 17.81	13.2 / 17.1
Mean No. of Sites Unaccounted for at Weaning	0.9	0.24	44	0.00 / 1.38	0.18 / 1.62	0.4 / 1.4
Mean Viable Embryos/Dam (GD 15)	14.9	0.79	25	13.32 / 16.48	12.53 / 17.27	13.5 / 16.3
Mean Viable Embryos (%/Litter)	95.0	1.84	25	91.32 / 98.68	89.48 / 100.00	90.0 / 97.1
Mean Viable Fetuses/Dam (GD 20)	14.3	0.79	16	12.72 / 15.88	11.93 / 16.67	13.0 / 15.6
Mean Viable Fetuses (%/Litter)	94.6	1.34	16	91.92 / 97.28	90.58 / 98.62	91.9 / 96.8
Mean Post-Implantation Loss/Dam	0.8	0.24	41	0.32 / 1.28	0.08 / 1.52	0.4 / 1.5
Mean Post-Implantation Loss (%/Litter)	5.1	1.65	41	1.80 / 8.40	0.15 / 10.05	2.9 / 10.0
Mean No. of Corpora Lutea/Dam	16.7	0.88	41	14.94 / 18.46	14.06 / 19.34	15.3 / 18.8
Mean No. of Implantation Sites/Dam	15.3	0.81	41	13.68 / 16.92	12.87 / 17.73	13.9 / 16.8
Mean Pre-Implantation Loss/Dam	1.4	0.41	41	0.58 / 2.22	0.17 / 2.63	0.5 / 2.1
Mean Pre-Implantation Loss (%/Litter)	8.2	2.42	41	3.36 / 13.04	0.94 / 15.46	2.7 / 13.8
Mean Fetal Body Weight (GD 20) (g)	3.6	0.16	16	3.28 / 3.92	3.12 / 4.08	3.3 / 3.8
Mean Primordial Follical Count of 10 Sections/Dam	115.2	31.74	11	51.72 / 178.68	19.98 / 210.42	50.4 / 148.8

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Survival Indices (%)

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Age Range: 0 - 21 Days
Number of Studies/Data Sets: 62 / 96
Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Number of Pups Born	14.3	0.91	46	12.48 / 16.12	11.57 / 17.03	12.2 / 16.0
Survival (%)						
PND 0 (Relative to No. Born)	98.0	1.53	46	94.94 / 100.00	93.41 / 100.00	93.3 / 100.0
PND 0 to PND 1	99.1	0.89	46	97.32 / 100.00	96.43 / 100.00	95.8 / 100.0
PND 1 to PND 4 (Before Selection)	98.6	1.33	45	95.94 / 100.00	94.61 / 100.00	94.1 / 100.0
PND 4 (After Selection) to PND 7	98.9	1.76	44	95.38 / 100.00	93.62 / 100.00	91.7 / 100.0
PND 7 to PND 14	99.3	1.46	41	96.38 / 100.00	94.92 / 100.00	93.5 / 100.0
PND 14 to PND 21	99.5	1.11	41	97.28 / 100.00	96.17 / 100.00	94.7 / 100.0
Birth to PND 4 (Before Selection)	95.8	2.26	43	91.28 / 100.00	89.02 / 100.00	86.6 / 98.7
PND 4 (After Selection) to PND 21	97.8	2.50	40	92.80 / 100.00	90.30 / 100.00	91.1 / 100.0

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23-Aug-06

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Body Weights (g)

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Age Range: 1 - 28 Days
Number of Studies/Data Sets: 62 / 96
Range of Study Dates: 08/00 - 09/05

Males (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	7.1	0.25	46	6.60 / 7.60	6.35 / 7.85	6.7 / 7.6
PND 4	10.0	0.58	45	8.84 / 11.16	8.26 / 11.74	9.0 / 11.4
PND 7	15.3	1.22	44	12.86 / 17.74	11.64 / 18.96	11.9 / 17.5
PND 14	30.4	3.70	36	23.00 / 37.80	19.30 / 41.50	20.2 / 35.3
PND 21	47.5	5.18	41	37.14 / 57.86	31.96 / 63.04	32.8 / 56.7
PND 28 (weaned PND 28)	82.0	6.86	15	68.28 / 95.72	61.42 / 102.58	69.8 / 94.0

Females (g)

PND	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
PND 1	6.7	0.25	46	6.20 / 7.20	5.95 / 7.45	6.3 / 7.3
PND 4	9.5	0.56	45	8.38 / 10.62	7.82 / 11.18	8.6 / 10.9
PND 7	14.5	1.17	44	12.16 / 16.84	10.99 / 18.01	11.3 / 16.7
PND 14	29.2	3.46	36	22.28 / 36.12	18.82 / 39.58	20.3 / 33.9
PND 21	45.6	4.76	41	36.08 / 55.12	31.32 / 59.88	32.8 / 53.5
PND 28 (weaned PND 28)	75.8	6.11	15	63.58 / 88.02	57.47 / 94.13	66.7 / 86.2

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Modified: 11/3/2006

WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Pup Organ Weights (PND 21)

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Age: 21 Days
Number of Studies/Number Data Sets: 62 / 96
Range of Study Dates: 08/00 - 09/05

Males

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Brain (g)	1.4397	0.04072	21	1.35826 / 1.52114	1.31754 / 1.56186	1.3451 / 1.4899
Spleen (g)	0.2058	0.03054	21	0.14472 / 0.26688	0.11418 / 0.29742	0.1471 / 0.2480
Thymus (g)	0.1963	0.02035	21	0.15560 / 0.23700	0.13525 / 0.25735	0.1617 / 0.2330

Females

Brain (g)	1.3931	0.03322	21	1.32666 / 1.45954	1.29344 / 1.49276	1.3142 / 1.4378
Spleen (g)	0.2020	0.03048	21	0.14104 / 0.26296	0.11056 / 0.29344	0.1471 / 0.2448
Thymus (g)	0.1987	0.02387	21	0.15096 / 0.24644	0.12709 / 0.27031	0.1669 / 0.2547

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WIL Research Laboratories - Developmental and Reproductive Toxicology

Historical Control Summary of Developmental Landmarks

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Number of Studies/Control Groups: 62 / 96
Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Male Anogenital Distance (PND1) (mm)	4.37	0.171	6	4.028 / 4.712	3.857 / 4.883	4.1 / 4.7
Mean Female Anogenital Distance (PND1) (mm)	2.38	0.175	6	2.030 / 2.730	1.855 / 2.905	2.1 / 2.6
Mean Day of Balanopreputial Separation	44.8	1.30	31	42.20 / 47.40	40.90 / 48.70	42.0 / 49.0
Mean Body Weight at Aquisition (g)	225.9	9.72	31	206.46 / 245.34	196.74 / 255.06	203.7 / 246.8
Mean Day of Vaginal Patency	33.6	1.05	31	31.50 / 35.70	30.45 / 36.75	31.7 / 37.0
Mean Body Weight at Aquisition (g)	111.9	6.42	31	99.06 / 124.74	92.64 / 131.16	99.5 / 127.4
Mean Day of Surface Righting Response						
Males	5.0	0.06	3	4.88 / 5.12	4.82 / 5.18	5.0 / 5.1
Females	5.2	0.10	3	5.00 / 5.40	4.90 / 5.50	5.1 / 5.3
Mean Day of Pinnal Detachment						
Males	4.1	0.15	4	3.80 / 4.40	3.65 / 4.55	4.0 / 4.3
Females	4.1	0.10	4	3.90 / 4.30	3.80 / 4.40	4.0 / 4.2
Mean Day of Eye Opening						
Males	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Females	16.4	1.20	4	14.00 / 18.80	12.80 / 20.00	15.1 / 17.8
Mean Day of Air Drop Righting Reflex						
Males	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Females	14.9	NA	1	NA / NA	NA / NA	14.9 / 14.9
Mean Day of Hair Growth						
Males	13.5	1.43	4	10.64 / 16.36	9.21 / 17.79	11.7 / 15.0
Females	13.6	1.51	4	10.58 / 16.62	9.07 / 18.13	11.8 / 15.2
Mean Day of Incisor Eruption						
Males	9.9	0.41	5	9.08 / 10.72	8.67 / 11.13	9.3 / 10.4
Females	9.9	0.34	5	9.22 / 10.58	8.88 / 10.92	9.3 / 10.2

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Male and Female Organ Weights (Necropsy)

Sex: Male/Female
Species: Rat
Number of Studies/Number Data Sets: 62 / 96
Study Type: All
Strain: Crl:CD(SD)
Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Males						
Mean Age of Males at Necropsy (weeks)	22.2	4.20	27	13.80 / 30.60	9.60 / 34.80	16.4 / 30.6
Mean Seminal Vesicle/Coagulating Gland Weight (g)	2.21	0.169	36	1.872 / 2.548	1.703 / 2.717	1.82 / 2.57
Mean Prostate Weight (g)	1.07	0.102	22	0.866 / 1.274	0.764 / 1.376	0.76 / 1.27
Mean Right Testis Weight (g)	1.79	0.069	48	1.652 / 1.928	1.583 / 1.997	1.66 / 1.93
Mean Left Testis Weight (g)	1.80	0.077	48	1.646 / 1.954	1.569 / 2.031	1.67 / 2.09
Mean Right Epididymis Weight (g)	0.72	0.041	48	0.638 / 0.802	0.597 / 0.843	0.63 / 0.80
Mean Left Epididymis Weight (g)	0.72	0.041	48	0.638 / 0.802	0.597 / 0.843	0.62 / 0.78
Mean Right Cauda Epididymis Weight (g)	0.3275	0.02230	48	0.28290 / 0.37210	0.26060 / 0.39440	0.2629 / 0.3693
Mean Left Cauda Epididymis Weight (g)	0.3309	0.02064	48	0.28962 / 0.37218	0.26898 / 0.39282	0.2714 / 0.3706
Females						
Mean Age of Females at Necropsy (weeks)	23.2	5.03	19	13.14 / 33.26	8.11 / 38.29	16.0 / 32.0
Mean Combined Ovary Weight (g)	0.1448	0.03004	19	0.08472 / 0.20488	0.05468 / 0.23492	0.0926 / 0.1779

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WIL Research Laboratories - Developmental and Reproductive Toxicology
Historical Control Summary of Sperm Concentration and Morphology

Sex: Male/Female
Study Type: All
Species: Rat
Strain: Crl:CD(SD)
Number of Studies/Control Groups: 62 / 96
Range of Study Dates: 08/00 - 09/05

	Mean	S.D.	N	Mean -/+ 2 S.D.	Mean -/+ 3 S.D.	Observed Low/High Value
Mean Sperm Concentration (millions/ gram of tissue)						
Left Testis	80.9	7.33	43	66.24 / 95.56	58.91 / 102.89	68.2 / 96.6
Left Epididymis	454.5	49.37	37	355.76 / 553.24	306.39 / 602.61	339.1 / 619.2
Left Cauda Epididymis	666.2	57.99	7	550.22 / 782.18	492.23 / 840.17	568.0 / 738.9
Mean Sperm Production Rate (millions/ gram of tissue/ day)	13.4	1.21	23	10.98 / 15.82	9.77 / 17.03	11.4 / 15.8
Mean Sperm Motility (%)	85.4	3.01	44	79.38 / 91.42	76.37 / 94.43	78.9 / 91.0
Mean Progressive Sperm Motility (%)	72.5	3.70	15	65.10 / 79.90	61.40 / 83.60	67.0 / 80.0
Sperm Morphology Differential Count (%)						
Normal	99.1	0.81	43	97.48 / 100.00	96.67 / 100.00	96.1 / 99.9
Normal Head Separated from Flagellum	0.4	0.40	43	0.00 / 1.20	0.00 / 1.60	0.1 / 1.8
Head Absent w/ Normal Flagellum	0.3	0.39	43	0.00 / 1.08	0.00 / 1.47	0.0 / 2.3
Head Absent w/ Abnormal Flagellum	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Misshapen Head w/ Normal Flagellum	0.0	0.17	43	0.00 / 0.34	0.00 / 0.51	0.0 / 1.1
Misshapen Head w/ Abnormal Flagellum	0.0	0.06	43	0.00 / 0.12	0.00 / 0.18	0.0 / 0.4
Degenerative Flagellar Defects w/ Normal Head	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0
Other Flagellar Defects w/ Normal Head	0.0	0.00	43	0.00 / 0.00	0.00 / 0.00	0.0 / 0.0

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APPENDIX H

Study Protocol

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Study Number: WIL-187061

PROTOCOL AMENDMENT II

Sponsor: [redacted]

Sponsor No.: 06-025

A. Title:

A Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **9.3 Microscopic Examination:**

The second paragraph is changed to read:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on the following tissues from the 0, 200 and 800 mg/kg/day animals.

C. Reason for Protocol Modifications:

1) The client has authorized microscopic examination of the preserved tissues.

Approved By:

[redacted]

19 Jan 07
Date

Sponsor Representative

WIL Research Laboratories, LLC

[redacted]

18 Jan 2007
Date

Study Director

[redacted]

18 Jan 2007
Date

Director, Developmental and Reproductive Toxicology

Study Number: WIL-187061

PROTOCOL AMENDMENT I

Sponsor: [redacted]

Sponsor No.: 06-025

A. Title:

A Female Pubertal Assay of [redacted] Administered Orally in Juvenile Female Rats

B. Protocol Modification/Addition/Clarification:

1) **3** **STUDY SCHEDULE:**

Proposed Audited Report Date: January 4, 2007

2) **7.4.1** **Organization of Test Groups:**

The second sentence provided in footnote "*" is changed to the following:

Record of dose administration will be collected and maintained under the companion study (WIL-187060).

3) **7.6.3** **Vaginal Perforation:**

The first sentence is changed to the following:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 23 (Adams, 1985).

C. Reason for Protocol Modifications:

1) The proposed audited report date has been determined.

2) To designate that the dose administration records for the control group will be maintained with the companion study.

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3) To correct the postnatal day on which to begin observation for vaginal perforation to PND 23.

Approved By:

[redacted]

22 Sept 2006
Date

WIL Research Laboratories, LLC

[redacted]

20 Sept. 2006
Date

Study Director

[redacted]

20 Sept. 2006
Date

Director, Developmental and
Reproductive Toxicology

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PROTOCOL

A FEMALE PUBERTAL ASSAY OF [redacted] ADMINISTERED ORALLY IN JUVENILE FEMALE RATS

Sponsor Study Number: 06-025

Submitted To:

[redacted]

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-9281

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1 OBJECTIVE:

The objective of this study is to evaluate the ability of the test article to induce effects on pubertal development in the intact juvenile female rat.

This study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF), Law No. 82, 1984, Good Laboratory Practice (GLP) Standards. The study will be performed according to the protocol and WIL Standard Operating Procedures.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representatives:

[redacted]

2.2 Principal Investigator – Dose Formulation Analysis:

[redacted]

2.3 WIL Study Director:

[redacted]

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2.4 WIL Deputy Director:

[redacted]

2.5 WIL Departmental Responsibilities:

[redacted]

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3 STUDY SCHEDULE:

Proposed Animal Receipt Date: (Experimental Starting Date)	September 12, 2006
Proposed Experimental Start Date:	September 26, 2006
Proposed Experimental Termination/Completion Date:	October 18, 2006
Proposed Audited Report Date:	To be determined.

4 TEST ARTICLE DATA:

4.1 Identification:

[redacted]

4.2 Lot Number:

To be determined.

4.3 Purity:

100%

4.4 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.5 Physical Description:

To be determined.

4.6 Storage Conditions:

Store at ambient conditions.

4.7 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL standard operating procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely unless otherwise specified.

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5.7 Identification System:

The maternal animals will be uniquely identified by a Monel® metal ear tag displaying the animal number. The pups will be identified by tail tattoo. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal. Following randomization the pups will be individually identified by an ear tag.

5.8 Justification for Selection:

This species and strain of animal is recognized as appropriate for reproduction studies. WIL Research Laboratories, LLC has reproductive historical control data in this species and strain of rat. This animal model has been proven to be susceptible to the effects of reproductive toxicants. This number of animals is considered the minimum number required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

All animals will be initially housed by litter with their own or another (fostering) dam in plastic maternity cages containing ground corncob nesting material (Bed O'Cobs®). Following randomization, the juvenile female animals will be weaned and housed three animals per cage in plastic maternity (shoebox) cages. Exposed animals from a companion study, housed concurrently in the same animal room, will be housed on a separate rack. A separate control group will be housed in the room on its own separate rack. The cage bedding will be changed at least three times each week. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL standard operating procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12 hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

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6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Each lot utilized will be identified and recorded. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean. Each of 4 groups

4.8 Personnel Safety Data:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) will accompany the test article upon arrival at the laboratory.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Crl:CD(SD)

5.3 Source:

Charles River Laboratories
Raleigh, NC

5.4 Number on Study:

Sixty females (maximum of 80 females and 8 dams purchased). Immature females will be supplied in litters of 10 animals with their own or another (fostering) dam. The immature females will be 6-8 days old upon receipt. Pups not expected to survive to the next observation period (moribund) will be euthanized by intraperitoneal injection of sodium pentobarbital (prior to PND11) or by carbon dioxide inhalation (after PND11) and the carcass discarded. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded. Following weaning, the dams will be euthanized by carbon dioxide inhalation and the carcasses discarded.

5.5 Body Weight Range:

At randomization: 30-50 g for immature females. All animals assigned to study will be approximately ± 5 g of the mean.

5.6 Age:

At start of dosing animals will be 22 days of age.

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will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel, ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses, or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1*	Corn Oil	0	0	5	15
2	[redacted]	10	2	5	15
3	[redacted]	50	10	5	15
4	[redacted]	200	40	5	15
5	[redacted]	800	160	5	15

* – The control group data will be collected under a companion study (WIL-187060). Record of dose administration will be collected under the companion study and transferred to the computer protocol for this study.

7.4.2 Vehicle Control Article:

Corn oil.

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 and continuing through 41 days of age. All animals

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6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer and will be placed in the study records. Each lot utilized will be identified and recorded. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of nine days. All rats will be initially sexed and weighed. Maternal animals will be permanently identified with a metal ear tag, and juvenile animals will be identified by tail tattoo. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Prior to the start of the in-life phase, those animals judged to be suitable test subjects will be identified and receive a detailed physical examination at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the quarantine period (animals 21 days of age), animals judged to be suitable test subjects and meeting acceptable body weight requirements, will be assigned at random using a computer program. At that time, the animal numbers and corresponding body weights will be entered into the WIL Toxicology Data Management System (WTDMS™). A printout containing the animal numbers and individual group assignments will be generated based on body weight stratification into a block design. Animals will then be weaned and arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean. Each of 4 groups

will consist of fifteen females. If after randomization statistically significant differences between groups exist, new randomizations will be generated until group mean body weights are homogeneous.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be oral (gavage). Historically, this route has been used extensively for studies of this nature. Appropriate-sized flexible, Teflon®-shafted, stainless steel, ball-tipped dosing cannulae will be used for the oral administration by gavage. Any losses, or incomplete dosing will be recorded.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels were determined from the results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director. The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dose Concentration (mg/mL)	Dose Volume (mL/kg)	Number of Females
1*	Corn Oil	0	0	5	15
2	[redacted]	10	2	5	15
3	[redacted]	50	10	5	15
4	[redacted]	200	40	5	15
5	[redacted]	800	160	5	15

* – The control group data will be collected under a companion study (WIL-187060). Record of dose administration will be collected under the companion study and transferred to the computer protocol for this study.

7.4.2 Vehicle Control Article:

Corn oil.

7.4.3 Treatment Regimen:

The test and control articles will be administered as single daily doses beginning on day 22 and continuing through 41 days of age. All animals

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will be dosed at approximately the same time each day, after 12:00 p.m., and the time of dosing will be recorded for each animal.

7.4.4 Adjustment of Dosages:

Individual doses will be calculated based on each daily body weight to provide the proper dosage. Individual animal body weights and individual animal dosages will be recorded.

7.5 Preparation and Analysis of Test Article Formulations:

7.5.1 Method and Frequency of Preparation:

Based on the physical characteristics of the test article, appropriate methods will be used to ensure the best possible formulations of the test article in the vehicle. Dosing formulations of the test article will be prepared weekly and stored at room temperature. The study director or the deputy director or designee will visually inspect the formulations prior to initiation of dosing. This visual inspection will be performed to assure that the formulations are visibly homogeneous and acceptable for dosing. Any special procedures required for formulation will be documented according to Good Laboratory Practices and presented in the final report of this study.

7.5.2 Homogeneity and Stability of Test Article Formulation:

Dosing mixture homogeneity in bulk preparations will be collected prior to the initiation of test article administration, if possible. While undergoing stirring in the beaker, the following sample aliquots (5 mL) will be drawn for analysis: control, three aliquots (from the middle); all treatment groups, nine aliquots (3 each from the top, middle and bottom). Test article formulations will be divided into aliquots for daily dispensation. Resuspension homogeneity of aliquots will be determined over the longest period of aliquot storage. Three samples (5mL) from the top and bottom of each group will be collected to assess the homogeneity after storage and resuspension. Two of the three samples will be sent to [redacted] c/o [redacted] for analysis of homogeneity and stability over a ten-day period. The samples will be shipped under ambient conditions. The remaining sample from each dose level and strata will be stored under normal laboratory conditions for possible future analysis.

7.5.3 Concentration Analysis:

Samples of the dosing mixtures will be collected on the first and last day of each weekly preparation. At each time point, two 5-mL aliquots will

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be taken from each dose level (middle stratum), including the control group. The dosing mixture will be thoroughly mixed before taking each sample. One sample from each dose level will be analyzed; the remaining sample will be retained by the Testing Laboratory for possible future analysis.

Dosing mixture samples for homogeneity, stability and concentration of the test article at all dose levels, including the control, will be analyzed by the Sponsor. Quality assurance (QA) auditing of the conduct, results and reporting of the analyses, as well as archiving of these data will be the responsibility of the Sponsor. Critical phase inspection reports and report audits will be submitted to the Study Director and management at WIL Research Laboratories, LLC. A QA statement will be issued for inclusion in the overall final report. The methods and results of the analysis will be provided by the Sponsor and included as an appendix to the WIL final report. The methods employed will be listed in the analytical report.

Concentration and stability data will be evaluated using percent difference. The acceptable tolerance between the theoretical and measured values is 15%.

Mixtures will be considered homogeneous if the difference between the overall group mean and the strata mean is 10% or less.

7.5.4 Sample Handling and Shipment:

Each 5-mL sample will be placed in a glass vial with a Teflon-lined lid. The vial plus sample weight will be recorded with an accuracy of ± 0.0005 g. Each sample will be stored at ambient temperature. Each sample container will be labeled with the following information:

Accession Number
Sponsor's Reference Number
Testing Laboratory Study Number
Test Article Name
Dose Level (mg/kg)
Dosing Mixture Concentration (mg/mL)
Preparation Date
Sampling Date
Weight of Sample

The sample shall be packed in a suitable container to maintain the temperature conditions specified in Section 4 during transit plus an

adequate margin of safety for any transit delays. The sample shall be sent by express courier to:

[redacted]

[redacted] shall be notified in advance of shipping by telefax at [redacted] This notification shall include test article and study identification, carrier, and estimated time/date of arrival. Sample shipments shall be accompanied by an inventory sheet describing the samples contained in the shipment with the information described above.

7.6 General Observations During the Experimental Period:

All control group data will be collected under a companion study (WIL-187060) which will be housed concurrently in the same animal room. The control group data will be transferred to this study for reporting purposes.

7.6.1 Clinical Signs:

The rats will be observed twice daily for appearance, behavior, moribundity and mortality. A detailed physical examination will be conducted at the time of randomization. Clinical observations regarding general appearance and behavior will be recorded daily prior to dosing. During the treatment period, the rats will also be observed at the time of dosing and again approximately one hour after administration. Additional post-dosing observation periods may be necessary and will be documented in the study records. Observations shall include, but are not limited to, evaluations for changes in appearance of the skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous system functions, somatomotor activity and behavior patterns. Observations will be recorded. Findings noted outside of the scheduled observation time periods will be recorded at the time they are observed.

7.6.2 Body Weights:

Body weights will be recorded individually (to the nearest 0.1 gram PND 22-42) beginning one day prior to the start of dosing. Final body weights will be collected prior to euthanasia.

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7.6.3 Vaginal Perforation:

Each female pup (15/group) will be observed daily for vaginal perforation beginning on PND 25 (Adams, 1985). Examination of the females will be performed at approximately the same time each day and will continue daily until vaginal perforation is present. The body weight of each female will be recorded on the day of acquisition of vaginal perforation.

7.6.4 Determination of Estrous Cycles:

Daily vaginal lavages will be performed to determine the stage of estrus beginning on the day vaginal perforation is observed. Lavages will be performed at approximately the same time each day (with the exception that the lavages performed on the day of necropsy will be collected immediately prior to euthanasia) and will continue through the day of necropsy. The mean age of first estrous will be determined.

7.7 Euthanasia:

On PND 42, the animals will be euthanized by carbon dioxide inhalation, and the time of euthanasia will be recorded for each animal. Any animals not expected to survive until the following dosing period or until the scheduled euthanasia will be euthanized by carbon dioxide inhalation and necropsied as described in section 9.

8 HORMONE ANALYSIS:

8.1 Thyroid Hormones:

Following euthanasia, blood will be collected from the vena cava of all animals. Following collection, all blood samples (target volume of 2 mL) will be allowed to clot and then be placed in an ice bath and processed to generate serum. The following hormone concentrations will be determined from all serum samples:

Thyroid Stimulating Hormone (TSH)	Thyroxine (T_4)
Estradiol (E_2)	Lutenizing Hormone (LH)

9 ANATOMIC PATHOLOGY:

9.1 Macroscopic Examination:

A complete necropsy examination will be conducted on all animals dying spontaneously or euthanized *in extremis*. This will include examination of the external surface, all orifices, the external surface of the brain and spinal cord and the thoracic, abdominal and pelvic cavities including viscera. A complete

necropsy will not be conducted on animals surviving to study termination. Gross lesions (i.e., masses) will be collected and placed in 10% neutral-buffered formalin. The following tissues will be collected and placed in 10% neutral-buffered formalin:

Axillary Lymph Node	Spleen
Cervix and Uterine Body (one longitudinal section)	Thymus
	Thyroid with parathyroids
Ovaries	Uterine Horns (four sections per horn)
Pituitary	Vagina
	All gross (internal) lesions

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9.2 Organ Weights:

9.2.1 Uterine Weights:

Wet and blotted uterine weights will be measured for all animals surviving to the scheduled necropsy. Uterine weights will not be collected for any animals found dead or euthanized *in extremis*.

The uterus will be harvested from all animals using the following procedure. The harvesting of uteri will be performed in a round-robin order. The pubic symphysis will be opened and each ovary and uterine horn will be detached from the dorsal abdominal wall. The ovaries are separated from the uterine horns at the oviduct/uterus junction. The urinary bladder and ureters will be removed from the ventral and lateral side of the uterus and vagina. The fibrous adhesion between the rectum and vagina is then detached until the junction of the vaginal orifice and perineal skin is identified. The uterus and vagina are detached from the body by incising the vaginal wall just above the junction between the perineal skin. The excess fat and adnexa will be trimmed away. The vagina is then removed from the uterus, leaving the cervix intact and attached to the uterus for uterus weight measurement. Care is to be taken during uterus harvesting such that the luminal contents are retained. A record will be made if any luminal contents are lost. The uterus will be transferred to a uniquely marked and tared plastic Petri dish with care to avoid desiccation before weighing. The Petri dish should be lined with saline-moistened filter paper (or equivalent) and covered to minimize desiccation.

The uterus harvesting and weighing procedure will be done in the order described below.

1. Animal is euthanized and uterus harvested.
2. Uterus (with luminal fluid) is immediately transferred to a Petri dish

(lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
3. The uterus' wet weight is recorded to the nearest 0.1 mg.
4. The uterus is opened and blotted (see below).

5. The uterus is placed in a Petri dish (lined with saline-moistened filter paper or equivalent) that was tared immediately prior to the transfer.
6. The uterus' blotted weight is recorded to the nearest 0.1 mg.

Immediately following collection of the wet weight, the uterus will be individually processed by opening the uterine wall and carefully blotting the excess fluid. Both uterine horns will be pierced and cut longitudinally with small surgical scissors, placed on filter paper (ex. Whatman No. 3) and gently pressed with another piece of dry filter paper to absorb the luminal fluid. The procedure will not be so severe as to render the tissue unacceptable for histopathologic analysis, as this additional investigation may be performed at the discretion of the Sponsor (by protocol amendment).

9.2.2 Ovary, Liver, Pituitary, Kidney, Spleen, Thymus, Thyroid and Adrenal Weights:

The following organs from all females euthanized at scheduled termination will be weighed (to the nearest 0.1 mg):

Adrenal glands	Pituitary gland
Kidneys	Spleen
Liver	Thymus
Ovaries and oviducts	Thyroid with parathyroids (following fixation)

Paired organs will be weighed together.

To minimize systematic bias in the weighing procedures, organ harvesting and weighing procedures will be divided as equally as possible among the prosecting and weighing technicians, such that all animals from a group are not processed by a single individual.

9.3 <u>Microscopic Examination:</u>

Following collection of wet uterine weight, blotting of the uterus and collection of blotted uterine weight, each uterus will be placed in a uniquely identified jar of 10% neutral-buffered formalin and preserved for microscopic examination. The vagina, ovaries, and thyroids and parathyroids from each animal will be similarly preserved.

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Microscopic examination of hematoxylin-eosin stained paraffin sections may be performed on the following tissues from all animals at the discretion of the Sponsor (additional cost).

- Cervix and Uterine Body (one longitudinal section)
- Ovaries
- Thyroids with parathyroids
- Uterine Horns (four sections per horn)

10 DURATION OF STUDY:

The conduct of this study will require approximately five weeks for acclimation, dosing and necropsy.

11 STATISTICAL METHODS:

Body weights, body weight gains, organ weights, organ weights relative to body weights, uterine weights (wet and blotted), luminal fluid weights, mean days of acquisition of vaginal perforation, mean age at first estrous, estrous cycle length and serum hormone concentrations will be analyzed by a parametric one-way analysis of variance (ANOVA) (Snedecor, 1980) to determine intergroup difference. If the results of the ANOVA are significant ($p<0.05$), Dunnett's test (Dunnett, 1964) will be applied to the data to compare the treated groups to the control group.

12 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol, protocol amendments and WIL Standard Operating Procedures. The study will be conducted in compliance with the U.S. Environmental Protection Agency (EPA), 40 CFR Part 792, the OECD [C(97) 186/Final] and the Ministry of Agricultural, Forestry and Fisheries (MAFF) Law No. 82, 1984, Good Laboratory Practice (GLP) Standards. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

13 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 14 in the Archives at WIL Research Laboratories, LLC.

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14 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. All work product, including raw paper data, pertinent electronic storage media and specimens will be returned to the Sponsor after a period of six months or following issuance of the final report. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

15 REPORTS:

The final report will consist of an abbreviated summary report, including data tables and an interpretation and discussion of the study results.

WIL Research Laboratories, LLC will provide one copy of an audited draft report, submitted in a timely manner upon completion of the study prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL within a two-month time frame following submission. WIL will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL within one year following submission of the draft report, WIL may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R and one paper copy will be provided. Requests for additional paper copies of the final report may result in additional charges.

16 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

17 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the written permission of the Sponsor. In the event that the Sponsor requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

18 REFERENCES:

Adams, J.; Buelke-Sam, J.; Kimmel, C.A.; Nelson, C.J.; Reiter, L.W.; Sobotka, T.J.; Tilson, H.A.; Nelson, B.K. Collaborative behavioral teratology study: protocol design and testing procedure. *Neurobehavioral Toxicology and Teratology* **1985,** *7,* 579-586.

Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964,** *20,* 482-491.

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Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.

19 PROTOCOL APPROVAL:

Sponsor approval received via e-mail on September 5, 2006.

[redacted]

[redacted]

11 Sept 06
Date

Sponsor Representative

WIL Research Laboratories, LLC

[redacted]

7 Sept. 2006
Date

Study Director

[redacted]

7 Sept. 2006
Date

Director, Developmental and
Reproductive Toxicology

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