UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Reckitt Benckiser LLC, et al.	)	FIFRA Docket No. 661
	)	
EPA Reg. Nos. 3282-3, 3282-4, 3282-9, 3282-15, 3282-65, 3282-66, 3282-74, 3282-81, 3282-85, 3282-86, 3282-87, and 3282-88; Application Nos. 3282-RNU and 3282-RNL	)	

RESPONDENT'S RESPONSE TO THE RECKITT BENCKISER LLC MOTION FOR ADDITIONAL DISCOVERY

The Assistant Administrator for Chemical Safety and Pollution Prevention ("Respondent") responds to the May 5, 2014 motion of petitioner Reckitt Benckiser LLC ("Reckitt") for additional discovery as follows.

I. Reckitt's Motion for Additional Discovery

As a general matter, Section 164.51 of the Rules of Practice governing this proceeding provides that discovery of the kind sought by Reckitt in its Motion for Additional Discovery shall be permitted only if the Administrative Law Judge determines that the discovery meets all of the following criteria:

- The discovery shall not in any way unreasonably delay the proceeding;
- The information to be obtained is not otherwise obtainable; and
- Such information has significant probative value.

While Respondent does not believe that a thirty day period for parties to respond to appropriate requests for documents "will unreasonably delay the proceeding," Respondent does submit that portions of Reckitt's Motion seek the production of documents that are either otherwise obtainable or would provide information that is of minimal relevance to this proceeding and therefore lacks "significant probative value," and accordingly objects to portions of Reckitt's Motion as set forth herein.

a. Documents Re Specific Exhibits

1. Respondent's Exhibits 22 and 30:

All responsive documents have already been provided to Reckitt in response to FOIAs, and are publicly available in EPA's rodenticide dockets EPA-HQ-OPP-2006-0955 and EPA-HQ-OPP-2011-0718 at http://www.regulations.gov/#!home. Accordingly, Respondent objects to Reckitt's request for discovery of documents related to Respondent's Exhibits 22 and 30.

2. Respondent's Exhibit 81:

Respondent will produce all responsive documents within its possession, custody or control.

3. Respondent's Exhibit 85:

Respondent will produce all responsive documents within its possession, custody or control.

4. Respondent's Exhibit 104:

Respondent will produce all responsive documents within its possession, custody or control.

5. Respondent's Exhibit 111:

There are no diagnostic reports, lab results, or case files responsive to Reckitt's request in Respondent's possession, custody or control that have not been previously provided to Reckitt. Accordingly, Respondent objects to Reckitt's request for discovery of documents related to Respondent's Exhibit 11.

6. Respondent's Exhibit 114:

The data regarding numbers of rodenticide placements which form the basis for the figures and tables in Respondent's Exhibit 114 are not in Respondent's possession, custody or control. Bell Laboratories considers significant portions of the underlying data proprietary, and out of respect for Bell Laboratories' concerns about disclosure, Respondent proposes to withdraw Respondent's Exhibit 114. Inasmuch as Respondent no longer intends to introduce Respondent's Exhibit 114 into evidence, facts regarding how its figures and tables were derived are not material and have no probative value in this proceeding. Accordingly, Respondent objects to Reckitt's request for discovery of documents related to Respondent's former Exhibit 114.

7. Respondent's Exhibit 124:

Respondent will produce all responsive documents within its possession, custody or control.

b. Witness Publications and Presentations

1. Steven P. Bradbury:

Reckitt seeks two documents co-authored by Dr. Bradbury: "Meeting the Common Needs of a More Effective and Efficient Testing and Assessment Paradigm for Chemical Risk

Management" and "Predictive Toxicology in Risk Assessment: Approaches in Predicting Mechanism of Toxic Action." While Reckitt maintains that it "limited its requests to documents that relate particularly to the topic of each witness' testimony," Respondent submits that neither of the documents identified appears to be particularly relevant to the Agency's rationale for determining that Reckitt's registrations at issue in this proceeding do not meet the standard for registration under FIFRA (the subject of the testimony that Dr. Bradbury would have provided) and therefore do not meet the "significant probative value" test for discovery. In any event, because of Dr. Bradbury's recent departure from the Office of Pesticide Programs, Respondent will be filing a motion in the near future to substitute another witness for Dr. Bradbury (which would make these documents even less relevant than they otherwise would have been). For those reasons, Respondent objects to Reckitt's motion that these two documents be provided in discovery.

2. Raymond J. Kent

Reckitt seeks two documents authored or co-authored by Dr. Kent: "Risk Assessment/Integration in the New Chemicals Program" (a 1994 presentation to a subcommittee of the National Academy of Sciences); and "The New Chemicals Process at the Environmental Protection Agency (EPA): Structure-Activity Relationships for Hazard Identification and Risk Assessment (a 1995 paper of which Dr. Kent was one of three authors). Dr. Kent worked at that time for the EPA office that oversees the regulation of chemicals under the Toxic Substances Control Act (TSCA). Both of these documents address how EPA approached risk assessments twenty years ago in the context of a regulatory program (for toxic chemicals subject to TSCA) that relied heavily on "predictive" methodologies because EPA generally possessed far less data on toxic chemicals than it generally receives on pesticides. By contrast, pesticide risk

assessments rely far more heavily on reviews of studies performed on specific pesticides. The relevance of the requested documents to this proceeding appears questionable at best, and falls far short of the "significant probative value" test. Dr. Kent was able to locate an electronic copy of the 1995 document, and Respondent will provide that document to Reckitt notwithstanding questions about its relevance. But Respondent has been unable to locate the 1994 NAS presentation, and Respondent objects to that portion of Reckitt's motion that seeks production of the 1994 NAS presentation on the grounds that it does not have significant probative value on a material issue in this proceeding.

3. Jeanette C. Martinez:

Respondent will produce all responsive documents within its possession, custody or control.

4. Lewis S. Nelson:

Dr. Nelson is listed as a potential rebuttal witness to testify about potential exposures of children to rodenticides in homes and appropriate medical responses to those exposures. Of the many publications that Dr. Nelson has authored in whole or in part, Reckitt asks Respondent to provide an almost 2,000 page textbook (Goldfrank's Toxicologic Emergencies, 9th Edition); a chapter from another book (Melmon and Morelli's Clinical Pharmacology); and two journal publications (entitled Being Judge and Jury: A New Skill for Emergency Physicians; and A call to Arms for Medical Toxicologists: The Dose, not the Detection, Makes the Poison). As justification for requesting these particular documents, Reckitt suggests that these publications are "relevant to the subject of [Dr. Nelson's] expected testimony" and "the textbook and textbook chapter are likely to be particularly relevant to the question of the appropriate medical approach to rodenticide exposures and poisonings." But mere relevance is not the standard for

discovery under 40 CFR §164.51. None of the documents appears to focus on rodenticide exposures or poisonings, and Reckitt appears to already have significant access to information on the medical treatment of human exposures to rodenticides. Reckitt does not assert, or indeed provide any reason to believe, that these publications have or are likely to have "significant probative value" for this proceeding. In this regard, it is worth pointing out that Respondent has not obtained, and does not intend to obtain, these documents to assist in its own preparation for this hearing.

Although Respondent does not possess these documents, Respondent notes that it performed a quick Google search and all of them appear to be publicly available. Because Reckitt has not established that these documents have significant probative value, because the documents are not within Respondent's possession, custody or control, and because the documents are otherwise publicly available, Respondent objects to Reckitt's motion that these four documents be provided in discovery.

5. Kenneth L. Gage

The requested document is publicly available at http://www.cdc.gov/mmwr/PDF/rr/rr4514.pdf. Accordingly, Respondent objects to Reckitt's request for discovery of this document.

6. Michael E. Herring

Captain Herring is unavailable until mid-June at the earliest. Respondent respectfully requests that Reckitt's request for discovery of materials associated with his speaking engagements, and Respondent's response, be stayed until such time as Captain Herring is available. Respondent has discussed the situation with counsel for Reckitt, who have authorized

Respondent to report that Reckitt has no objection to the proposed stay so long as it does not unfairly compromise its ability to prepare for cross examination of this witness.

7. Elizabeth C. Matsui

Respondent will produce all responsive documents within its possession, custody or control.

8. Peter Martin and Steve Levy

Reckitt requested *curricula vitae* ("CVs") or resumes for Peter Martin and Steve Levy. Respondent did not include these witnesses' CVs or resumes in its prehearing exchange because these individuals are expected to testify as fact witnesses, and the February 10, 2014 Prehearing Order did not require the exchange of CVs or resumes of fact witnesses. Neither of these witnesses has a CV or a current resume. Respondent objects to this discovery request on the grounds that Reckitt has not established that the CVs or resumes of fact witnesses generally, or of these fact witnesses in particular, have significant probative value on a material issue in this proceeding.

c. Documents Re Rodenticide Regulation

i. Freedom Of Information Act ("FOIA") Requests

Reckitt has reprised a number of information requests it previously submitted in one or more of the eighteen rodenticide-related Freedom of Information Act ("FOIA") requests Arnold & Porter has filed on behalf of Reckitt since 2008.[1] Respondent will produce all responsive documents within its possession, custody or control, however, Respondent notes that these discovery requests are particularly burdensome and cannot be satisfied quickly. EPA has

[1] Respondent notes that EPA has already produced roughly two thousand records in response to these FOIA requests, which has already consumed roughly 500 staff hours. EPA has necessarily reviewed many more documents in order to identify the responsive documents, and often more than once owing to similarities between the FOIAs.

identified over 20,000 records as potentially responsive to the FOIA-related discovery requests that have not yet been reviewed for relevance, claims of business confidentiality, personally identifiable information, and applicable privileges.

Reckitt's claim that production of these documents will not cause unreasonable delay owing to EPA's having previously assembled these documents in response to the FOIA requests (Reckitt's Motion at 14) is misleading because it disregards the review burden. Reckitt's contention that a lower level of scrutiny is appropriate (Reckitt's Motion at 14, n.9) is also misleading, because the review burdens for FOIA and discovery are the same: Each record must be individually reviewed for relevance, claims of business confidentiality, personally identifiable information, and applicable privileges – the difference is simply whether certain of those factors preclude disclosure or lead to a limited disclosure under seal, and it is likely that tracking the status of documents produced under a protective order will increase the Agency's burden rather than reduce it. Moreover, owing to the fact that documents withheld under FOIA might meet the disclosure criteria of discovery, EPA must review once again those documents previously reviewed and withheld under past FOIAs.

Nevertheless, Respondent will produce all responsive documents within its possession, custody or control, provided a reasonable period of time is allowed for it to complete the required reviews. Respondent believes that these FOIA-related discovery requests can be satisfied within 60 days.

ii. Executive Orders

Reckitt moved for additional discovery of documents concerning Respondent's compliance with various Executive Orders, asserting that the NOIC is legally insufficient absence such compliance. Reckitt's Motion at 15-16. As a matter of law, compliance with these

Executive Orders is not material to the outcome of this proceeding, because even if Respondent had failed to comply, such noncompliance would have no probative value on any issue within the scope of this proceeding, and could not affect the Tribunal's decision:

> This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Exec. Order No. 12866 (Oct. 4, 1993).

> This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Exec. Order No. 13563 (Jan. 18, 2011)

> This order is not intended, and should not be construed to create, any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or its employees. This order shall not be construed to create any right to judicial review involving the compliance or noncompliance with this order by the United States, its agencies, its officers, or any other person.

Exec. Order No. 13045 (Apr. 21, 1997)

> This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person. This order shall not be construed to create any right to judicial review involving the compliance or noncompliance of the United States, its agencies, its officers, or any other person with this order.

Exec. Order No. 12898 (Feb. 11, 1994)

> This order is intended only to improve the internal management of the executive branch, and is not intended to create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any person.

Exec. Order No. 13175 (Nov. 6, 2000)

By their own terms, each these Executive Orders expressly negates the possibility of their creating any substantive or procedural right that Reckitt could rely upon in this proceeding. Nor is there anything in FIFRA or the Administrative Procedure Act that requires compliance with

any of these Executive Orders, or makes compliance with any of these Executive Orders a factor pertinent to this proceeding. The purpose of this FIFRA section 6(b) proceeding is to determine whether the pesticide products identified in the NOIC meet the statutory standard for registration in FIFRA section 3(c)(5). That standard requires a finding that the risks associated with the use of a pesticide are justified by the benefits of such use, when the pesticide is used in compliance with the terms and conditions of registration or in accordance with commonly recognized practices. *See Defenders of Wildlife v. Administrator, EPA*, 882 F.2d 1294, 1298-99 (8th Cir. 1989) (describing FIFRA's required balancing of risks and benefits). Inasmuch as Respondent's compliance or noncompliance with any of these Executive Orders has no probative value on any issue within the scope of this proceeding, Reckitt's motion for discovery of documents concerning Respondent's compliance with various Executive Orders should be denied.

iii. Rodenticide labels

Reckitt moved for additional discovery of copies of all labels and label amendments, and dates of cancellations, transfers or other discontinuations, for certain rodenticide products from 2000 to the present. Respondent will provide to Reckitt a list of all rodenticides by registration number, and identifying the dates of any transfers, cancellations, or suspensions. Using the Registration Numbers or product names from that list, all of the requested information is publicly available through EPA's Pesticide Product Label System ("PPLS") at http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1. Owing to the fact that all of the requested information is either being provided or publicly available, Reckitt's motion for discovery of copies of all labels and label amendments, and dates of cancellations, transfers or other discontinuations, for certain rodenticide products does not meet the criteria of 40 CFR 164.51 and should therefore be denied.

II. Reckitt's Proposal for Prehearing Conference

Noting that there are a number of prehearing issues outstanding, Reckitt proposed that the Tribunal convene a prehearing conference in conjunction with, or as an alternative to a "meet and confer" suggested by staff of the Office of Administrative Law Judges. It is unclear whether Reckitt's "proposal" is or should be considered a motion, but regardless, Respondent agrees that one or more prehearing conferences would be useful and supports this proposal.

III. Reckitt's Query Regarding the Timing of Motions *In Limine* and for Consideration of Other Evidentiary Issues

Noting uncertainties regarding the order and timing of the proceeding, Reckitt requested that the Tribunal clarify whether there are any deadlines for non-dispositive motions and the timing for consideration of certain unspecified evidentiary issues. Respondent agrees that clarification of both the order of the proceeding and the likely schedule would be welcome. Respondent believes that a prehearing conference, or dialogue through other media, would enable the Tribunal to better tailor the order of the proceeding and the likely schedule to the specific issues of this case.

IV. Reckitt's Motion to Clarify the Scope of the Hearing

Reckitt moved[2] for a ruling on whether certain proposed amendments to the registrations of products subject to this proceeding, and Respondent's denial of these amendments (see PRX

[2] Reckitt appears to be asking the Tribunal for a binding determination regarding the scope of the proceeding. Although Reckitt's brief says "Petitioner *seeks affirmation* from the ALJ that these amendments and Respondent's denial of these amendments, introduced in Petitioner's Prehearing Exchange as Exhibits 61-84 and 87-88, are appropriately within the scope of this hearing" (Reckitt's Motion at 17, emphasis added), Respondent believes this is in fact a motion. Respondent believes Reckitt's request should be identified and treated as a motion, and distinguished from Reckitt's motion for additional discovery.

61-84 and 87-88), are within the scope of this hearing. The proposed amendments were submitted to Respondent between 2010 and 2013, and were formally denied by Respondent contemporaneously with the issuance of the NOIC. EPA's practice has been to treat applications for amended registration in the same manner as applications for new registrations; accordingly, Respondent does not object to the ALJ determining in this proceeding whether the products subject to the denied applications for amended registration might be eligible for registration under the terms and conditions proposed in those applications for amended registration.

However, Respondent notes that in some past cancellation proceedings, extensive delays resulted when petitioners were permitted to continue to propose additional alternative terms and conditions of registration during the course of the proceeding. In the interest of an efficient and expeditious evidentiary hearing, Respondent believes that further variants on the currently approved terms and conditions of registration of the products subject to this proceeding should not be entertained, and anticipates opposing the consideration of any terms and conditions of registration other than the aforementioned and those currently in effect.

V. Conclusion

For the aforementioned reasons, Respondent objects to Reckitt's motion for additional discovery. To the extent that discovery is ordered, Respondent believes that it should generally be allowed 30 days to comply with the discovery order, except for the FOIA-related portions of the motion, for which Respondent should be allowed 60 days to comply with a discovery order, and the request for materials related to Captain Herring's speaking engagements, for which Respondent requests an indefinite stay. Inasmuch as Respondent is not affected by discovery

requests directed to other parties, Respondent takes no position on Reckitt's requests for discovery of other parties.

Respectfully submitted,

May 15, 2014
Date

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CERTIFICATE OF SERVICE

I hereby certify that the original and one copy of *Respondent's Response to the Reckitt Benckiser LLC Motion For Additional Discovery* were filed with the Headquarters Hearing Clerk, and a copy hand delivered to the office of:

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