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**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 HAWTHORNE STREET
SAN FRANCISCO, CA 94105**

In the matter of:)	Docket No. FIFRA-09-2014- 0007
)	
Advanced Sterilization)	CONSENT AGREEMENT
Products,)	and
Division of Ethicon, Inc.)	FINAL ORDER PURSUANT TO
Respondent.)	SECTIONS 22.13 AND 22.18
)	

I. CONSENT AGREEMENT

Complainant, the Assistant Director, Water and Pesticide Branch, of the Enforcement Division, United States Environmental Protection Agency, Region 9, ("EPA") and Respondent Advanced Sterilization Products, a division of Ethicon, Inc. ("Respondent") seek to settle this case and consent to the entry of this Consent Agreement and Final Order ("CAFO") which simultaneously commences and concludes this matter in accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b).

A. AUTHORITY AND PARTIES

1. This administrative proceeding is initiated pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136, et seq. (hereinafter referred to as

"FIFRA" or the "Act"), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 C.F.R. Part 22.

2. Complainant is the Assistant Director of the Water and Pesticide Branch, Enforcement Division, who has been duly delegated to commence and settle an enforcement action in this matter.

3. Respondent is a Delaware corporation that owns, operates, or otherwise controls a facility located at 33 Technology Drive, Irvine, California.

B. APPLICABLE STATUTES AND REGULATIONS

4. Section 2(u) of FIFRA, 7 U.S.C. §136(u), states that the term "pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

5. Section 2(t) of FIFRA, 7 U.S.C. §136(t), states that the term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under FIFRA section 25(c)(1).

6. Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), requires the registration of pesticide producing establishments.

7. Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1), requires each producer operating a pesticide producing establishment to inform the Administrator of the types, amounts, and active ingredients of pesticides: (A) which the producer is currently producing; (B) which the producer has produced during the past year; and (C) which the producer has sold or distributed during the past year. The producer is required to keep this information current and submitted to EPA

annually, as required under such regulations as the Administrator may prescribe.

8. Forty C.F.R. Part 167 are the regulations promulgated by EPA for submission of these pesticide production reports.

9. Each producer operating an establishment must submit a pesticide production report. 40 C.F.R. § 167.85(a).

10. *Producer* means any person, as defined by FIFRA, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling). 40 C.F.R. § 167.3.

11. *Establishment* means any site where a pesticidal product, active ingredient, or device is produced. 40 C.F.R. § 167.3.

12. The annual pesticide production report must include the name and address of the establishment, the amount of each pesticidal product: (i) produced during the past year, (ii) sold or distributed during the past year; and (iii) estimated to be produced during the current year. The report shall only include those pesticidal products actually produced at the reporting establishment. 40 C.F.R. § 167.85(b).

13. The pesticide product report is due on or before March 1 of each year, even if the producer has produced no pesticidal product for that reporting year. 40 C.F.R. § 167.85(d).

14. Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), makes it unlawful for any person who is a producer to violate any of the provisions of section 7 of FIFRA, 7 U.S.C. § 136e.

15. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), states that the term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.

16. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states that it shall be unlawful for any person to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a, or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter.

17. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it is an unlawful for any person in any state to distribute or sell to any person any pesticide which is adulterated or misbranded.

18. Section 2(q) of FIFRA, 7 U.S.C. § 136(q), states that a pesticide is “misbranded” if: (1) its label does not bear the registration number assigned under section 136(e) of FIFRA to each establishment in which it was produced; (2) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under FIFRA Section 3(d) (classification of pesticides), are adequate to protect health and the environment; or (3) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under FIFRA Section 3(d) (classification of pesticides), is adequate to protect health and the environment. 7 U.S.C. §§ 136(q)(1)(D); 136(q)(1)(F); and 136(q)(1)(G).

C. COMPLAINANT’S ALLEGATIONS

General Allegations

Complainant alleges:

19. Respondent is a “person” as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and a “producer” as defined in Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and as such is subject

to FIFRA and the regulations promulgated thereunder, including the requirements of Section 7 of FIFRA, 7 U.S.C. 136e, and implementing regulations promulgated at 40 C.F.R. Part 167.

20. STERRAD Hydrogen Peroxide Cassettes, EPA Reg. No. 71871-3, is a registered pesticide, and a “pesticidal product” as defined by 40 C.F.R. § 167.3. This pesticide contains the active ingredient hydrogen peroxide.

21. At the times relevant to this CAFO, STERRAD Hydrogen Peroxide Boosters is a “pesticide” as defined by Section 2(u) of FIFRA, 7 U.S.C. §136(u), and a “pesticidal product” as defined by 40 C.F.R. § 167.3. STERRAD Hydrogen Peroxide Boosters contain the active ingredient hydrogen peroxide.

22. At the times relevant to this CAFO, Respondent produces STERRAD Hydrogen Peroxide Cassettes and STERRAD Hydrogen Peroxide Boosters at its facility located at 33 Technology Drive, Irvine, California (the “Irvine Facility”).

23. The Irvine Facility is an “establishment” as defined in Section 2(dd) of FIFRA, 7 U.S.C. §§ 136(dd).

24. At the times relevant to this CAFO, for each calendar year, Respondent is required to submit an annual pesticide production report. Respondent must accurately report the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed, as required by Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1), and 40 C.F.R. Part 167.

Count I: Incomplete and/or Erroneous Annual Production Report for RY 2008

25. Paragraphs 1 through 24 are incorporated herein by reference.

26. For calendar year 2008, Respondent was required to submit to EPA, on or before March 1, 2009, an annual pesticide production report accurately reporting the types and amounts

of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed.

27. Respondent submitted to EPA an incomplete and erroneous annual pesticide production report for the Irvine Establishment for calendar year 2008. Respondent failed to accurately report the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed, during calendar year 2008, as required by Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1).

28. Respondent violated FIFRA section 12(a)(2)(L), 7 U.S.C. § 136j(a)(2)(L), by filing an incomplete and erroneous annual pesticide production report for the Irvine Establishment for calendar year 2008.

Count II: Incomplete and/or Erroneous Annual Production Report for RY 2009

29. Paragraphs 1 through 28 are incorporated herein by reference.

30. For calendar year 2009, Respondent was required to submit to EPA, on or before March 1, 2010, an annual pesticide production report accurately reporting the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed.

31. Respondent submitted to EPA an incomplete and erroneous annual pesticide production report for the Irvine Establishment for calendar year 2009. Respondent failed to accurately report the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed, during calendar year 2009, as required by Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1).

32. Respondent violated FIFRA section 12(a)(2)(L), 7 U.S.C. § 136j(a)(2)(L), by filing an incomplete and erroneous annual pesticide production report for the Irvine Establishment for

calendar year 2009.

Count III: Incomplete and/or Erroneous Annual Production Report for RY 2010

33. Paragraphs 1 through 32 are incorporated herein by reference.

34. For calendar year 2010, Respondent was required to submit to EPA, on or before March 1, 2011, an annual pesticide production report accurately reporting the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed.

35. Respondent submitted to EPA an incomplete and erroneous annual pesticide production report for the Irvine Establishment for calendar year 2010. Respondent failed to accurately report the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed, during calendar year 2010, as required by Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1).

36. Respondent violated FIFRA section 12(a)(2)(L), 7 U.S.C. § 136j(a)(2)(L), by filing an incomplete and erroneous annual pesticide production report for the Irvine Establishment for calendar year 2010.

Count IV: Failure to File Annual Production Report for RY 2011

37. Paragraphs 1 through 36 are incorporated herein by reference.

38. For calendar year 2011, Respondent was required to submit to EPA, on or before March 1, 2012, an annual pesticide production report accurately reporting the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed.

39. Respondent failed to submitted to EPA the annual pesticide production report for the Irvine Establishment for calendar year 2011 by March 1, 2012. Respondent failed to accurately

report the types and amounts of pesticides which the Irvine Establishment was producing, had produced, and had sold or distributed, during calendar year 2011, as required by Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1).

40. Respondent violated FIFRA section 12(a)(2)(L), 7 U.S.C. § 136j(a)(2)(L), by failing to file an accurate pesticide production report for the Irvine Establishment for calendar year 2011.

Count V: Distribution or Sale of Unregistered Pesticide

41. Paragraphs 1 through 40 are incorporated herein by reference.

42. At the times relevant to this CAFO, STERRAD Hydrogen Peroxide Boosters is a pesticide when sold for pesticidal use, including use by laboratories or veterinary facilities.

43. At the times relevant to this enforcement action, STERRAD Hydrogen Peroxide Boosters is not a registered pesticide.

44. On the occasion specifically described in Attachment A, Respondent distributed or sold STERRAD Hydrogen Peroxide Boosters for pesticidal use.

45. On the occasion specifically described in Attachment A, Respondent “distributed or sold,” as that term is defined in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), an unregistered pesticide.

46. On the occasion specifically described in Attachment A, Respondent violated section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), by distributing or selling STERRAD Hydrogen Peroxide Boosters, an unregistered pesticide.

Count VI: Distribution or Sale of Misbranded Pesticide

47. Paragraphs 1 through 46 are incorporated herein by reference.

48. On the thirty two occasions specifically described in Attachment A, Respondent distributed or sold STERRAD Hydrogen Peroxide Cassettes, EPA Reg. No. 71871-3, for

pesticidal use, including use by laboratories or veterinary facilities.

49. On the thirty two occasions specifically described in Attachment A, Respondent distributed or sold the STERRAD Hydrogen Peroxide Cassettes, EPA Reg. No. 71871-3, without the EPA-approved label. The label on the STERRAD Hydrogen Peroxide Cassettes lacked the product registration number, EPA establishment number, directions for use, first aid statements, precautionary statements, physical and chemical hazards, storage and disposal requirements, and environmental hazards and the required signal word “Danger”.

50. By using a label that lacked the signal word “Danger,” the pesticide registration number, EPA establishment number, directions for use, first aid statements, precautionary statements, physical and chemical hazards, storage and disposal requirements, and environmental hazards, Respondent misbranded STERRAD Hydrogen Peroxide Cassettes.

51. On the thirty two occasions specifically described in Attachment A, Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling misbranded STERRAD Hydrogen Peroxide Cassettes.

D. RESPONDENT’S ADMISSIONS

52. In accordance with 40 C.F.R. § 22.18(b)(2), and for the purpose of this proceeding, Respondents (i) admit that EPA has jurisdiction over the subject matter of this CAFO and over Respondents; (ii) neither admit nor deny the specific factual allegations contained in Section I.C. of this CAFO; (iii) consent to any and all conditions specified in this CAFO, (iv) agree to pay, and consents to the assessment of, the civil administrative penalty under Section I.E of this CAFO; (v) waive any right to contest the allegations contained in Section I.C. of this CAFO; and (vi) waive the right to appeal the proposed final order contained in this CAFO.

E. CIVIL ADMINISTRATIVE PENALTY

53. Respondent consents to the assessment of a penalty in the amount of **ONE HUNDRED THIRTY SIX THOUSAND EIGHT HUNDRED DOLLARS (\$136,800)** as final settlement and complete satisfaction of the civil claims against Respondent arising under the Act and from the facts alleged in Section I.C. of the CAFO. Respondent shall pay this civil penalty within thirty (30) days of the effective date of this CAFO. The civil penalty shall be paid by remitting a certified or cashier's check, including the name and docket number of this case, for the amount, payable to "Treasurer, United States of America," (or be paid by one of the other methods listed below) and sent as follows:

Regular Mail:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000

Wire Transfers:

Wire transfers must be sent directly to the Federal Reserve Bank in New York City with the following information:
Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045
Field Tag 4200 of the Fedwire message should read "D 68010727
Environmental Protection Agency"

Overnight Mail:

U.S. Bank
1005 Convention Plaza
Mail Station SL-MO-C2GL
ATTN Box 979077
St. Louis, MO 63101

ACH (also known as REX or remittance express):
Automated Clearinghouse (ACH) for receiving U.S. currency
PNC Bank
808 17th Street, NW
Washington, DC 20074
ABA = 051036706
Transaction Code 22 – checking
Environmental Protection Agency
Account 31006
CTX Format

On Line Payment:

This payment option can be accessed from the information below:
www.pay.gov
Enter “sfol.1” in the search field
Open form and complete required fields

If clarification regarding a particular method of payment remittance is needed, contact the EPA’s Cincinnati Finance Center at (513) 487-2091.

A copy of each check, or notification that the payment has been made by one of the other methods listed above, including proof of the date payment was made, shall be sent with a transmittal letter, indicating Respondent’s name, the case title, and docket number, to the following addresses:

Regional Hearing Clerk
Office of Regional Counsel (ORC-1)
U.S. Environmental Protection Agency, Region IX
75 Hawthorne Street
San Francisco, CA 94105

Bill Lee
Enforcement Division (ENF 3-3)
U.S. Environmental Protection Agency, Region IX
75 Hawthorne Street
San Francisco, CA 94105

Margaret Alkon
Office of Regional Counsel (ORC-2)
U.S. Environmental Protection Agency, Region IX

75 Hawthorne Street
San Francisco, CA 94105

54. In the event that Respondent fails to pay the civil administrative penalty assessed above by its due date, Respondent shall pay to Complainant an additional stipulated penalty in the amount of **FIVE HUNDRED DOLLARS (\$500)** for each day that payment is late. Upon Complainant's written demand, stipulated penalties shall immediately become due and payable.

55. Respondent's failure to pay in full the civil administrative penalty by its due date also may lead to any or all of the following actions:

a. The debt being referred to a credit reporting agency, a collection agency, or to the Department of Justice for filing of a collection action in the appropriate United States District Court. 40 C.F.R. §§ 13.13, 13.14, and 13.33. In any such collection action, the validity, amount, and appropriateness of the assessed penalty and of this CAFO shall not be subject to review.

b. The debt being collected by administrative offset (i.e., the withholding of money payable by the United States to, or held by the United States for, a person to satisfy the debt the person owes the Government), which includes, but is not limited to, referral to the Internal Revenue Service for offset against income tax refunds. 40 C.F.R. Part 13, Subparts C and H.

c. EPA may (i) suspend or revoke Respondent's licenses or other privileges; (ii) suspend or disqualify Respondent from doing business with EPA or engaging in programs EPA sponsors or funds; (iii) convert the method of payment under a grant or contract from an advanced payment to a reimbursement method; or (iv) revoke a grantee's or contractor's letter-of-credit. 40 C.F.R. §§ 13.17.

F. CERTIFICATION OF COMPLIANCE

56. In executing this CAFO, Respondent certifies that: 1) it is not distributing or selling STERRAD Hydrogen Peroxide Boosters or any other unregistered pesticides intended for a pesticidal purpose, as the phrase “intended for a pesticidal purpose” is defined by 40 CFR 152.15; 2) it is not distributing or selling misbranded STERRAD Hydrogen Peroxide Cassettes and 2) that it is complying with all other FIFRA requirements at all facilities under its control.

G. RETENTION OF RIGHTS, BINDING EFFECT, ETC.

57. This Consent Agreement constitutes the entire agreement between the Respondent and EPA. This CAFO is for the purpose of fully and finally settling the civil claims against Respondent arising from the facts alleged in section I.C. of this CAFO. Full payment of the civil penalty and any applicable interest charges or late fees or penalties as set forth in this CAFO shall constitute full settlement and satisfaction of civil penalty liability against Respondent for the violations alleged in Section I.C. of this CAFO.

58. In accordance with 40 C.F.R. § 22.18(c), this CAFO only resolves Respondent’s liabilities for federal civil penalties for the violation and facts specifically alleged in Section I.C of this CAFO. Nothing in this CAFO is intended to or shall be construed to resolve: (i) any civil liability for violations of any provision of any federal, state, or local law, statute, regulation, rule, ordinance, or permit not specifically alleged in Section I.C of this CAFO; or (ii) any criminal liability. EPA specifically reserves any and all authorities, rights, and remedies available to it (including, but not limited to, injunctive or other equitable relief or criminal sanctions) to address any violation of this CAFO or any violation not specifically alleged in Section I.C of this CAFO. This CAFO does not exempt, relieve, modify, or affect in any way Respondent’s duties to comply with all applicable federal, state, and local laws, regulations, rules, ordinances, and

permits.

59. The provisions of this CAFO shall be binding on Respondent and on Respondent's officers, directors, employees, agents, servants, authorized representatives, successors, and assigns.

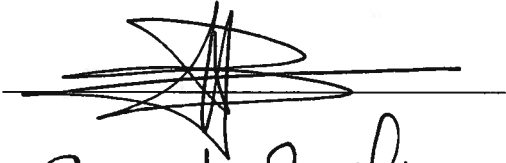
60. Except as set forth in Paragraph 55 above, each party shall bear its own fees, costs, and disbursements in this action.

61. For the purposes of state and federal income taxation, Respondent shall not claim a deduction for any civil penalty payment made pursuant to this CAFO.

62. In accordance with 40 C.F.R. §§ 22.18(b)(3) and 22.31(b), the effective date of this CAFO shall be the date on which the accompanying Final Order, having been signed by the Regional Judicial Officer, is filed.

63. The undersigned representatives of each party to this Consent Agreement certify that each is duly authorized by the party whom he or she represents to enter into the terms and conditions of this Consent Agreement and Final Order and bind that party to it.

ADVANCED STERILIZATION PRODUCTS, DIVISION OF ETHICON INC.:

Date: May 1st 2014 By: 
Name: Bernard Zughian
Title: WW President

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY:

Date: May 15, 2014 By:



DAVID WAMPLER
Acting Assistant Director
Water and Pesticide Branch, Enforcement Division
U.S. Environmental Protection Agency,
Region IX

APPENDIX A to CONSENT AGREEMENT

Count V. The table below contains the customer identification (number and name), order date, and order number of Respondent's distribution or sale of STERRAD hydrogen Peroxide Boosters:

<u>order date</u>	<u>order number</u>
5/25/2012	106678073

Count VI. The table below contains the customer identification (number and name), order dates, and order numbers of Respondent's thirty-two distribution and sales of misbranded STERRAD Hydrogen Peroxide Cassettes:

	<u>order date</u>	<u>order number</u>
1	7/31/2012	107024591
2	8/1/2012	107026361
3	8/6/2012	107046987
4	8/7/2012	107059882
5	8/9/2012	107072030
6	8/13/2012	107085438
7	8/21/2012	107130403
8	8/23/2012	107149476
9	8/28/2012	107173617
10	8/29/2012	107180081
11	9/11/2012	107242253
12	9/11/2012	107242417
13	9/12/2012	107244460
14	9/18/2012	107275166
15	9/20/2012	107293128
16	9/24/2012	107306223
17	9/28/2012	107333121
18	10/1/2012	107344291
19	10/9/2012	107391680
20	10/11/2012	107405149
21	10/12/2012	107407949
22	10/16/2012	107423730
23	10/24/2012	107464878
24	10/24/2012	107470937
25	10/25/2012	107473139
26	10/31/2012	107501680
27	11/16/2012	600115353
28	12/3/2012	600116390
29	12/6/2012	107686459
30	12/27/2012	107784344
31	1/2/2013	107806984
32	2/12/2013	108011859

II. FINAL ORDER

IT IS HEREBY ORDERED that this Consent Agreement and Final Order, Docket No. FIFRA-09-2014-⁰⁰⁰⁷___, be entered and that Respondent shall pay a civil administrative penalty in the amount of **ONE HUNDRED THIRTY SIX THOUSAND EIGHT HUNDRED DOLLARS (\$136,800)** in accordance with the terms set forth in the Consent Agreement.

Date: 05/16/14


Steven Jawgiel
Regional Judicial Officer
U.S. EPA, Region IX

CERTIFICATE OF SERVICE

I certify that the original of the fully executed Consent Agreement and Final Order, (Docket No FIFRA-09-2014-0007) was filed with the Regional Hearing Clerk, U.S. EPA, Region IX, 75 Hawthorne Street, San Francisco, CA 91405, and that a true and correct copy of the same was sent to the following parties:

A copy was mailed via CERTIFIED MAIL to:

Bernard Zovighian, WW President
Advanced Sterilization Products, Division of Ethicon
33 Technology Drive
Irvine, CA 92618

CERTIFIED MAIL NUMBER: 7012 1640 0001 2190 7885

An additional copy was hand-delivered to the following U.S. EPA case attorney:

Margaret Alkon, Esq
Office of Regional Counsel
U.S. EPA, Region IX
75 Hawthorne Street
San Francisco, CA 94105



For: _____
Regional Hearing Clerk
U.S. EPA, Region IX

5/19/14

Date