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FILED

2007 APR -5 AM 9:22

REGIONAL HEARING CLERK

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
SAN FRANCISCO, CALIFORNIA

In the Matter of:

Oculus Innovative
Sciences, Inc.,

Respondent.

)
)
) Docket No. FIFRA-9-2007- 0006

) CONSENT AGREEMENT AND FINAL
) ORDER PURSUANT TO
) 40 C.F.R. §§ 22.13 AND 22.18

I. COMPLAINT/CONSENT AGREEMENT

The United States Environmental Protection Agency, Region IX ("EPA"), and Oculus Innovative Sciences, Inc. ("Respondent") agree to settle this matter 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 and 22.18.

A. AUTHORITY AND PARTIES

1. This is a civil administrative action instituted pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or "the Act"), as amended, 7 U.S.C.

§136 et seq., for the assessment of a civil administrative penalty against Respondent for a violation of Section 12 of the Act.

2. Complainant is the Director of the Communities and Ecosystems Division, EPA, Region IX, who has been duly delegated the authority to bring this action and to sign a consent agreement settling this action.

B. APPLICABLE STATUTORY AND REGULATORY SECTIONS

3. Section 12(a)(1)(E) of FIFRA provides that it shall be unlawful for any person to distribute or sell to any person a pesticide which is adulterated or misbranded. 7 U.S.C. § 136j(a)(1)(E).

4. Under Section 2(gg) of FIFRA, "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." 7 U.S.C. § 136(gg).

5. Under Section 2(t) of FIFRA, "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. . . ." 7 U.S.C. § 136(t).

6. Under Section 2(u) of FIFRA, "pesticide" means "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C.

§ 136(u) and 40 C.F.R. § 152.3(s).

7. Section 2(q)(1)(A) of FIFRA states a pesticide is misbranded if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular. 7 U.S.C. § 136(q)(1)(A).

C. ALLEGATIONS

8. Respondent, a California corporation, is a "person" as that term is defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and is subject to FIFRA and the implementing regulations promulgated thereunder.

9. Respondent operates a facility (the "Facility") located at 1129 N. McDowell Boulevard, Petaluma, California.

10. Respondent engages in the distribution or sale of medical products at the Facility.

11. During 2005, Respondent distributed "Microcyn Disinfectant" under the trade name "Cidalcyn".

12. "Cidalcyn" is intended to kill or prevent growth of bacteria and viruses.

13. Bacteria and viruses are "pests" as that term is defined in Section 2(t) of FIFRA, 7 U.S.C. § 136(t).

14. "Cidalcyn" is a "pesticide" as that term is defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

15. At all times relevant to this action, "Microcyn

Disinfectant" was registered with EPA under the trade name "Cidalcyn" pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a.

16. At all times relevant to this action, the labeling on "Cidalcyn" claimed that the product was a "multi-purpose disinfectant cleaner for use on hard, non-porous, inanimate surfaces" and "kills odor-causing bacteria."

17. The sales brochure for "Cidalcyn" claimed that the product killed various bacteria, including *Staphylococcus aureus* and *Pseudomonas aeruginosa*, in ten minutes.

18. During December 2005 and January 2006, EPA tested a batch of Cidalcyn collected from the Facility for biological efficacy as part of its antimicrobial testing program.

19. EPA testing of Cidalcyn in December 2005 and January 2006 indicated that Cidalcyn was ineffective against *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

20. At all times relevant to this action, "Cidalcyn" was "misbranded" as that term is defined in Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).

21. On or about July 26, 2005, Respondent distributed the pesticide product "Cidalcyn" to Alamo Scientific, Inc. of San Antonio, Texas.

22. Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing the pesticide product "Cidalcyn" to Alamo Scientific, Inc. on or about July 26, 2005.

23. On or about July 26, 2005, Respondent distributed the pesticide product "Cidalcyn" to Kimberly Clark Corporation of Rosewell, Georgia.

24. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing the pesticide product "Cidalcyn" to Kimberly Clark Corporation, on or about July 26, 2005.

25. On or about August 29, 2005, Respondent distributed the pesticide product "Cidalcyn" to Alamo Scientific, Inc. of San Antonio, Texas.

26. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing the pesticide product "Cidalcyn" to Alamo Scientific, Inc. on or about August 29, 2005.

27. On or about September 22, 2005, Respondent distributed the pesticide product "Cidalcyn" to Alamo Scientific, Inc. of San Antonio, Texas.

28. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing the pesticide product "Cidalcyn" to Alamo Scientific, Inc., on or about September 22, 2005.

D. RESPONDENT'S ADMISSIONS

29. In accordance with 40 C.F.R. § 22.18(b)(2) and for the purpose of this proceeding, Respondent (i) admits that EPA has jurisdiction over the subject matter of this CAFO and over Respondent; (ii) neither admits nor denies the specific factual allegations contained in the Complaint; (iii) consents to any and

all conditions specified in this CAFO and to the assessment of the civil administrative penalty under Section I.F. of this CAFO; (iv) waives any right to contest the allegations contained in Section I.C. portion of the CAFO; and (v) waives the right to appeal the proposed final order contained in this CAFO.

E. CIVIL ADMINISTRATIVE PENALTY

30. Respondent agrees to the assessment of a penalty in the amount of TWENTY THOUSAND AND EIGHT HUNDRED DOLLARS (\$20,800) as final settlement of the civil claims against Respondent arising under the Act as alleged in Section I.C of the CAFO.

31. Respondent shall pay the assessed penalty no later than thirty (30) days from the effective date of this CAFO. Payment shall be made by cashier's or certified check payable to the "Treasurer, United States of America," and shall be sent by certified mail, return receipt requested, to the following address:

U.S. Environmental Protection Agency
Region 9
P.O. Box 371099M
Pittsburgh, PA 15251

The payment shall be accompanied by a transmittal letter identifying the case name, the case docket number, and this CAFO. Concurrent with delivery of the payment of the penalty, Respondent shall send a copy of the check and transmittal letter 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

Jason Gerdes
Pesticide Section (CED-5)
U.S. Environmental Protection Agency, Region IX
75 Hawthorne Street
San Francisco, CA 94105

32. Payment of the above civil administrative penalty shall not be used by Respondent or any other person as a tax deduction from Respondent's federal, state, or local taxes.

33. If Respondent fails to pay the assessed civil administrative penalty as specified in Paragraph 31, then Respondent shall pay to EPA the stipulated penalty of TWENTY-SIX THOUSAND DOLLARS (\$26,000), which shall be immediately due and payable. In addition, failure to pay the civil administrative penalty by the deadline specified in Paragraph 31 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; or (ii) suspend or disqualify Respondent from doing business with EPA or engaging in programs EPA sponsors or funds. 40 C.F.R. § 13.17.

d. In accordance with the Debt Collection Act of 1982 and 40 C.F.R. Part 13 interest, penalties charges, and administrative costs will be assessed against the outstanding amount that Respondent owes to EPA for Respondent's failure to pay the civil administrative penalty by the deadline specified in Paragraph 31. Interest will be assessed at an annual rate that is equal to the rate of current value of funds to the United States Treasury (i.e., the Treasury tax and loan account rate) as prescribed and published by the Secretary of the Treasury in the Federal Register and the Treasury Fiscal Requirements Manual Bulletins. 40 C.F.R. § 13.11(a)(1). Penalty charges will be assessed monthly at a rate of 6% per annum. 40 C.F.R. § 13.11(c). Administrative costs for handling and collecting Respondent's overdue debt will be based on either actual or average cost incurred, and will

include both direct and indirect costs. 40 C.F.R. § 13.11(b). In addition, if this matter is referred to another department or agency (e.g., the Department of Justice, the Internal Revenue Service), that department or agency may assess its own administrative costs, in addition to EPA's administrative costs, for handling and collecting Respondent's overdue debt.

F. CERTIFICATION OF COMPLIANCE

34. In executing this CAFO, Respondent certifies that (1) it is no longer distributing or selling misbranded pesticides in violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), and (2) it is currently in compliance with all other FIFRA requirements for all its ongoing operations.

G. RETENTION OF RIGHTS

35. In accordance with 40 C.F.R. § 22.18(c), this CAFO only resolves Respondent's liability for federal civil penalties for the violations and facts specifically alleged in Section I.C of the 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 the 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 the CAFO.

36. This CAFO does not exempt, relieve, modify, or affect in any way Respondent's duty to comply with all applicable federal, state, and local laws, regulations, rules, ordinances, and permits.

H. ATTORNEYS' FEES AND COSTS

37. Each party shall bear its own attorneys' fees, costs, and disbursements incurred in this proceeding.

I. EFFECTIVE DATE

38. In accordance with 40 C.F.R. §§ 22.18(b)(3) and 22.31(b), this CAFO shall be effective on the date that the final order contained in this CAFO, having been approved and issued by either the Regional Judicial Officer or Regional Administrator, is filed.

J. BINDING EFFECT

39. The undersigned representative of Complainant and the undersigned representative of Respondent each certifies that he or she is fully authorized to enter into the terms and conditions of this CAFO and to bind the party he or she represents to this CAFO.

40. The provisions of this CAFO shall apply to and be binding upon Respondent and its officers, directors, employees, agents, trustees, servants, authorized representatives, successors, and assigns.

FOR RESPONDENT, OCULUS INNOVATIVE SCIENCES, INC.

5/4/07
DATE

[Signature]
NAME: James Schutz
TITLE: General Counsel
Oculus Innovative Sciences,
Inc.
1129 N. McDowell Boulevard
Petaluma, CA 94954

FOR COMPLAINANT, EPA REGION IX:

4/4/07
DATE

[Signature]
Enrique Manzanilla
Director
Communities and Ecosystems Division
U.S. Environmental Protection Agency,
Region IX

II. FINAL ORDER

Complainant and Respondent, Oculus Innovative Sciences, Inc., having entered into the foregoing Consent Agreement,

IT IS HEREBY ORDERED that this CAFO (Docket No. FIFRA-9-2007-0006) be entered, and that Respondent shall pay a civil administrative penalty in the amount of TWENTY THOUSAND AND EIGHT HUNDRED DOLLARS (\$20,800) and comply with the terms and conditions set forth in the Consent Agreement.

04/05/07

DATE



STEVEN JAWGIEL
Regional Judicial Officer
U.S. Environmental Protection
Agency, Region IX

CERTIFICATION

I hereby certify that the original and one copy of the foregoing Consent Agreement and Final Order, Docket Number FIFRA-9-2007-0006 have been filed with the Regional Hearing Clerk and a copy was sent, certified mail to:

James Schutz
General Counsel
Oculus Innovative Sciences, Inc.
1129 N. McDowell Boulevard
Petaluma, CA 94954

Lawrence E. Culleen, Esq.
Arnold & Porter, LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004

APR 05 2007

DATE



Danielle Carr
Regional Hearing Clerk
U.S. Environmental Protection Agency,
Region IX