

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION VII  
901 N. FIFTH STREET  
KANSAS CITY, KANSAS 66101**

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ENVIRONMENTAL PROTECTION  
AGENCY-REGION VII  
REGIONAL HEARING CLERK

IN THE MATTER OF )  
 )  
Wexford Labs, Inc. )  
325 Leffingwell Avenue ) Docket No. FIFRA-07-2007-0021  
Kirkwood, Missouri 63122 )  
 )  
Respondent )

**CONSENT AGREEMENT AND FINAL ORDER**

The U.S. Environmental Protection Agency (EPA), Region VII and Wexford Labs, Inc. (Respondent) have agreed to a settlement of this action before filing of a complaint, and thus this action is simultaneously commenced and concluded pursuant to Rules 22.13(b), 22.18(b)(2) and 22.18(b)(3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits (Consolidated Rules), 40 C.F.R. §§ 22.13(b), 22.18(b)(2) and 22.18(b)(3).

**ALLEGATIONS**

**Jurisdiction**

1. This is an administrative action for the assessment of civil penalties instituted pursuant to Section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136l.
2. This Consent Agreement and Final Order serves as notice that EPA has reason to believe that Respondent has violated Section 12 of FIFRA, 7 U.S.C. § 136j.

**Parties**

3. The Complainant, by delegation from the Administrator of the EPA and the Regional Administrator, EPA, Region VII, is the Director of the Water, Wetlands, and Pesticides Division, EPA, Region VII.
4. The Respondent is Wexford Labs, Inc., a registrant and pesticide manufacturer and distributor located at 325 Leffingwell Avenue, Kirkwood, Missouri. The Respondent is and was at all times referred to in this Consent Agreement and Final Order, a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and a corporation qualified to do business in the state of Missouri.

### **Statutory and Regulatory Background**

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

6. 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).

7. 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. 7 U.S.C. § 136(gg).

### **Factual Allegations**

8. Respondent, at all times relevant, operated a registered pesticide-producing establishment in Kirkwood, Missouri, under EPA Establishment Number 34810-MO-01.

9. Respondent is the registrant for Wex-San, Concentrated Detergent/Disinfectant, bearing the EPA Registration Number 34810-1. The Wex-San label bears the claim that that the product is a hospital disinfectant effective against the pathogenic organisms *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

10. On February 15, 2006, a representative of the Missouri Department of Agriculture (MDA) inspected the Respondent’s Kirkwood, Missouri facility. The MDA representative collected copies of the Wex-San label, documentary shipping records, and records of sales of Wex-San. The representative also collected samples of the Wex-San product.

11. The samples were shipped on February 17, 2006 to the OPP-Fort Meade Microbiology Laboratory in Fort Meade, Maryland for testing. The samples were tested by EPA using the Association of Official Analytical Chemists (AOAC) Use-Dilution Test.

12. The results of the analytical tests show that Wex-San is ineffective against the *Pseudomonas aeruginosa* pathogenic organism.

13. On February 20, 2007 a Stop Sale, Use, or Removal Order (SSURO) and Request for Voluntary Recall was issued by EPA to Respondent. The SSURO recommended Respondent take immediate steps to voluntarily withdraw Wex-San from the market and from customers who had purchased it after February 21, 2006.

14. Respondent identified all shipments of Wex-San shipped after February 21, 2006 and recalled the remaining product. Respondent has discontinued manufacture of Wex-San.

**VIOLATIONS**

15. The Complainant hereby states and alleges that Respondent has violated FIFRA and federal regulations promulgated thereunder, as follows:

**Count 1**

16. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

17. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to an Indianapolis, Indiana hospital on July 1, 2005.

18. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

19. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

**Count 2**

20. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

21. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to a San Antonio, Texas hospital on September 16, 2005.

22. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

23. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

**Count 3**

24. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

25. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to a Wichita Falls, Texas hospital on October 4, 2005.

26. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

27. Respondent violated Section 12(a)(1)(E) of FIFRA by holding for sale or distribution a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 4

28. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

29. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to a Tiffin, Ohio hospital on October 17, 2005.

30. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

31. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 5

32. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

33. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to an Indianapolis, Indiana hospital on October 26, 2005.

34. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

35. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 6

36. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

37. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to an Edison, New Jersey hospital on December 23, 2005.

38. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

39. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 7

40. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

41. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to a Flint, Michigan hospital on January 16, 2006.

42. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

43. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 8

44. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

45. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to an Indianapolis, Indiana hospital on January 19, 2006.

46. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

47. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 9

48. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

49. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to a Minot, North Dakota hospital on January 31, 2006.

50. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

51. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 10

52. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

53. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. A sales receipt shows that Wex-San was shipped to a Saint Genevieve, Missouri hospital on February 14, 2006.

54. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

55. Respondent violated Section 12(a)(1)(E) of FIFRA by distributing or selling a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

Count 11

56. Complainant hereby incorporates the allegations contained in paragraphs 1 through 14 above, as if fully set forth herein.

57. Respondent acknowledged during the inspection that the sample product was packaged, labeled, and released for shipment to customers. The MDA inspector observed inventory offered for sale or distribution at Respondent's facility.

58. Analytical results of samples collected during the February 2006 inspection determined Wex-San to be ineffective against *Pseudomonas aeruginosa* when used according to label directions. The label for Wex-San collected during the inspection claims it is effective against *Pseudomonas aeruginosa*.

59. Respondent violated Section 12(a)(1)(E) of FIFRA by holding for sale or distribution a misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

**CONSENT AGREEMENT**

It is hereby agreed and accepted by Respondent that:

1. Respondent and EPA agree to the terms of this Consent Agreement and Final Order and Respondent agrees to comply with the terms of the Final Order portion of this Consent Agreement and Final Order.
2. Respondent admits the jurisdictional allegations of this Consent Agreement and Final Order and agrees not to contest EPA's jurisdiction in this proceeding or any subsequent proceeding to enforce the terms of the Final Order set forth below.
3. Respondent neither admits nor denies the factual allegations and legal conclusions set forth in this Consent Agreement and Final Order.
4. Respondent waives its right to a judicial or administrative hearing on any issue of fact or law set forth above and its right to appeal the Final Order accompanying this Consent Agreement.
5. Respondent and Complainant agree to conciliate the matters set forth in this Consent Agreement and Final Order without the necessity of a formal hearing and to bear their respective costs and attorney's fees.

6. This Consent Agreement and Final Order addresses all civil administrative claims for the FIFRA violations identified above. Complainant reserves the right to take any enforcement action with respect to any other violations of FIFRA or any other applicable law.

7. Nothing contained in the Final Order portion of this Consent Agreement and Final Order shall alter or otherwise affect Respondent's obligation to comply with all applicable federal, state, and local environmental statutes and regulations and applicable permits.

8. The undersigned representative of Respondent certifies that he or she is fully authorized to enter the terms and conditions of this Consent Agreement and Final Order and to execute and legally bind Respondent to it.

9. Respondent certifies by signing this Consent Agreement and Final Order that, to its knowledge, it is presently in compliance with FIFRA, 7 U.S.C. § 136 *et. seq.* and all regulations promulgated thereunder.

10. Respondent agrees that, in settlement of the claims alleged in this Consent Agreement and Final Order, Respondent shall pay a penalty of Two Thousand Dollars (\$ 2,000.00) as set forth in Paragraph 1 of the Final Order.

11. The effect of settlement described in paragraph 10 above is conditioned upon the accuracy of the Respondent's representations to EPA, as memorialized in paragraph 9 above.

12. Nothing in this Consent Agreement shall be construed as a release from any other action under any law and/or regulation administered by the U. S. Environmental Protection Agency. Nothing contained in the Final Order portion of this Consent Agreement and Final Order shall alter or otherwise affect Respondent's obligation to comply with all applicable federal, state and local environmental statutes and regulations and applicable permits.

13. Failure to pay the assessed penalty may result in the referral of this matter to the United States Department of Justice for collection. If payment is not received on or before the due date, interest will be assessed at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717. The interest will be assessed on the overdue amount from the due date through the date of payment.

### **FINAL ORDER**

Pursuant to Section 14 of FIFRA, as amended, 7 U.S.C. § 136~~l~~, and according to the terms of the Consent Agreement set forth above, IT IS HEREBY ORDERED THAT:

1. Respondent, in settlement of the allegations set forth above, shall pay by cashier or certified check, a civil penalty, for the violations cited herein, in the amount of Two Thousand Dollars (\$ 2,000.00), on or before sixty (60) days of the effective date this Final Order.

2. Payment of the penalty shall be by cashier or certified check which shall reference Docket Number FIFRA-07-2007-0021, and made payable to “Treasurer, United States of America” and remitted to:

United States Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
P.O. Box 979077  
St. Louis, Missouri 63197-9000.

3. A copy of the check shall simultaneously be sent to the following:

Kelley Hickman  
Office of Regional Counsel  
United States Environmental Protection Agency  
Region VII  
901 North 5th Street  
Kansas City, Kansas 66101

and

Kathy Robinson  
Regional Hearing Clerk  
United States Environmental Protection Agency  
Region VII  
901 North 5th Street  
Kansas City, Kansas 66101

4. No portion of the civil penalty or interest paid by Respondent pursuant to the requirements of this Consent Agreement and Final Order shall be claimed by Respondent as a deduction for federal, state, or local income tax purposes.

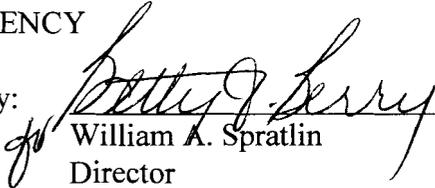
5. The effective date of this Order shall be the date on which it is signed by the Regional Judicial Officer.

6. This executed Consent Agreement and Final Order shall be filed with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region VII, 901 North 5th Street, Kansas City, Kansas, 66101.

COMPLAINANT:

U.S. ENVIRONMENTAL PROTECTION AGENCY

Date: 09/20/07

By:   
William A. Spratlin  
Director  
Water, Wetlands, and Pesticides Division

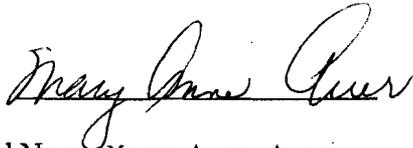
Date: 9/19/07

By:   
Kelley Hickman  
Assistant Regional Counsel

RESPONDENT:

Wexford Labs, Inc.

Date: September 19, 2007

By: 

Printed Name: Mary Anne Auer

Title: CEO

IT IS SO ORDERED. This Order shall become effective immediately.

Date: September 21, 2007

  
ROBERT L. PATRICK  
Regional Judicial Officer  
U.S. Environmental Protection Agency  
Region VII

IN THE MATTER OF Wexford Labs, Inc., Respondent  
Docket No. FIFRA-07-2007-0021

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Consent Agreement and Final Order was sent this day in the following manner to the addressees:

Copy hand delivered to  
Attorney for Complainant:

Kelley Hickman  
Assistant Regional Counsel  
Region VII  
United States Environmental Protection Agency  
901 N. 5<sup>th</sup> Street  
Kansas City, Kansas 66101

Copy by Certified Mail Return Receipt to:

Mary Anne Auer  
Chief Executive Officer  
Wexford Labs, Inc.  
325 Leffingwell Avenue  
Kirkwood, Missouri 63122

and

Stanley H. Abramson, Esq.  
Arent Fox LLP  
1050 Connecticut Ave. NW  
Washington, DC 22036

Dated: 9/21/07

  
Kathy Robinson  
Hearing Clerk, Region 7