



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590
June 12, 2014

REPLY TO THE ATTENTION OF:

LC- 8J

CERTIFIED MAIL

Receipt No.7009 1680 0000 7649 6711

Mr. Howard J. Bochnek
American Infection Control, Inc.
23950 Commerce Park
Beachwood, Ohio 44122

Consent Agreement and Final Order In the Matter of
American Infection Control, Inc. Docket No. FIFRA-05-2014-0021

Dear Mr. Bochnek:

Enclosed please find a copy of a fully executed Consent Agreement and Final Order, in resolution of the above case. This document was filed on June 12, 2014, with the Regional Hearing Clerk.

The civil penalty in the amount of \$7,500 is to be paid in the manner described in paragraphs 56 and 59. Please be certain that the docket number is written on both the transmittal letter and on the check. Payment is due by July 14, 2014, (within 30 calendar days of the filing date).

Thank you for your cooperation in resolving this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Claudia Niess".

Claudia Niess
Pesticides and Toxics Compliance Section

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5



In the Matter of:)
)
American Infection Control, Inc.)
Beachwood, Ohio)
)
)
Respondent.)
_____)

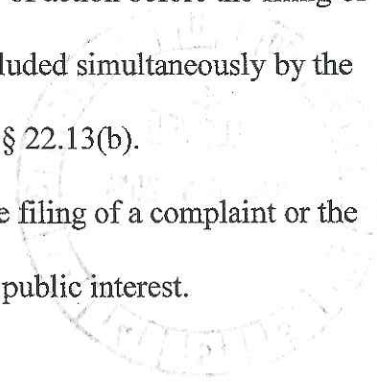
Docket No. FIFRA-05-2014-0021

Proceeding to Assess a Civil Penalty
Under Section 14(a) of the Federal
Insecticide, Fungicide, and Rodenticide
Act, 7 U.S.C. § 136l(a)

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136l(a), and Sections 22.13(b) and 22.18(b)(2) and (3) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules) as codified at 40 C.F.R. Part 22.
2. The Complainant is the Director of the Land and Chemicals Division, U.S. Environmental Protection Agency, Region 5.
3. Respondent is American Infection Control, Inc. (AIC), a corporation doing business in the State of Ohio.
4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).
5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.



6. Respondent consents to the assessment of the civil penalty specified in this CAFO, and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

9. Respondent certifies that it is complying with FIFRA, 7 U.S.C. §§ 136-136y.

Statutory and Regulatory Background

10. The importation of pesticides into the United States is governed by Sections 17(c) and (e) of FIFRA, 7 U.S.C. §§ 136o(c) and 136o(e), and the regulations promulgated thereunder by the Secretary of the Treasury in consultation with the Administrator of EPA (the Administrator). These regulations are found at 19 C.F.R. Part 12.

11. 19 C.F.R. § 12.111 states, in pertinent part, that all imported pesticides are required to be registered under the provisions of Section 3 of FIFRA, 7 U.S.C. § 136a, and under the regulations promulgated at 40 C.F.R. § 162.10 by the Administrator, before being permitted entry into the United States.

12. 19 C.F.R. § 12.112 states, in pertinent part, that an importer desiring to import pesticides into the United States shall submit to the Administrator a Notice of Arrival of Pesticides or Devices (NOA) (EPA Form 3540-1), prior to the arrival of the shipment in the United States. See also Section 17(c) of FIFRA, 7 U.S.C. § 136o(c).

13. Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), states that it is unlawful for any person in any state to distribute or sell any registered pesticide if any claims made for it

as part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration under FIFRA.

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

15. Section 2(q)(1)(E) of FIFRA, 7 U.S.C. § 136(q)(1)(E), defines a pesticide as “misbranded” if any word, statement, or other information required by or under authority of FIFRA to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase

16. Section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F), defines a pesticide as “misbranded” if 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 section 136a(d) of this title, are adequate to protect health and the environment.

17. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), defines a pesticide as “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.

18. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines the term “distribute or sell” to mean 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.

19. Section 2(p)(1) of FIFRA, 7 U.S.C. §136(p)(1), defines “label” to mean the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

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

21. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a “pesticide” to mean, among other things, any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

22. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a “person” as any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

23. Section 2(y) of FIFRA, 7 U.S.C. § 136(y) defines a “registrant” as a person who has registered any pesticide pursuant to the provisions of FIFRA.

24. 40 C.F.R. § 152.132 states that a registrant may distribute or sell his registered product under another person’s name and address instead of (or in addition to) his own. Such distribution and sale is termed “supplemental distribution” and the product is referred to as a “distributor product.” The distributor is considered an agent of the registrant for all intents and purposes under the Act, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product.

25. Supplemental distribution is permitted upon notification to the Agency if all the following conditions, among others, are met:

- (d) The label of the distributor product is the same as that of the registered product _____ except that:
- (1) The product name of the distributor product may be different (but may not be misleading);
 - (2) The name and address of the distributor may appear instead of the registrant;
 - (3) The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request);
 - (4) The establishment number must be that of the final establishment at which the product was produced; and
 - (5) Specific claims may be deleted, provided that no other changes are necessary.

26. A condition of supplemental distribution is that the label of the distributor product is the same as that of the registered product, except for the differences set forth in 40 C.F.R. § 152.132(d).

27. The Administrator may assess a civil penalty against any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of FIFRA of up to \$7,500 for each offense that occurred after January 12, 2009 pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and 40 C.F.R. Part 19.

Factual Allegations and Alleged Violations

28. Respondent is, and was at all times relevant to this CAFO, a corporation and therefore, a "person" as that term is defined at Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

29. At all times relevant to this CAFO, Respondent owned or operated a place of business located at 23950 Commerce Park, Beachwood, Ohio 44122.

30. On June 19, 2013, the pesticide "Wedge Disinfectant Wipes," EPA Reg. No. 88494-2, was registered under FIFRA.

31. North American Infection Control Ltd. (NAIC) is the “registrant” of “Wedge Disinfectant Wipes,” EPA Reg. No. 88494-2, as defined at Section 2(y) of FIFRA, 7 U.S.C. § 136(y).

32. On or about October 15, 2013, NAIC submitted a Notice of Supplemental Distribution of a Registered Pesticide Product (EPA Form 8570-5, hereafter referred to as a Notice of Supplemental Distribution) to EPA for the pesticide product “Wedge Disinfectant Wipes,” EPA Reg. No. 88494-2.

33. The Notice of Supplemental Distribution listed the supplemental distributor of “Wedge Disinfectant Wipes,” EPA Reg. No. 88494-2, as Medline Industries, Inc. and listed its Distributor Company number as “37459.”

34. The Notice of Supplemental Distribution listed the distributor product name as “Medline Micro-Kill One.”

35. On or about April 18, 2014, Respondent submitted a NOA to EPA for an import shipment of the pesticide “Medline Micro-Kill One Germicidal Alcohol Wipes,” EPA Registration Number (EPA Reg. No.) 88494-2-37549, from Turkey under entry number DSV-6201256-9.

36. DVS Air & Sea Inc., (DVS) located at 14843 Sprague Road, Suite 1, Strongsville, Ohio 44136, was a broker/agent for Respondent for the import shipment under entry number DSV-6201256-9.

37. The importer of record listed on the NOA for the shipment under entry number DSV-6201256-9 was Respondent.

38. The import shipment associated with entry number DSV-6201256-9 entered the United States on or about April 19, 2014.

39. Respondent, as importer of record for “Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, and by doing business in the United States is subject to the requirements of FIFRA and the regulations promulgated thereunder.

40. Respondent is a distributor of Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549.

41. “Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, is a pesticide as defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

42. “Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, is a “distributor product” as that term is defined at 40 C.F.R. § 152.132.

43. On June 19, 2013, the Office of Pesticide Programs, Registration Division (OPPRD) issued an “accepted” label for “Wedge Disinfecting Wipes, EPA Reg. No. 88494-2.

44. Between on or about June 19, 2013 and on or about May 22, 2014, the “accepted” label for “Wedge Disinfecting Wipes, EPA Reg. No. 88494-2, contained, among others, the following statements in the “Directions For Use” section (under “FUNGICIDAL”):

... is an effective fungicide against Trichophyton mentagrophytes [ATCC 9533]...
when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet. The surface must remain visibly wet for 1 minute. Allow surface to air dry (emphasis added).

45. The label affixed to the containers of “Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, imported on or about April 19, 2014, under entry number DSV-6201256-9, bore the following directions: “Micro-Kill One Germicidal Alcohol Wipes are an effective virucide, bactericide, tuberculocide and fungicide on hard non-porous surfaces in the presence of an organic load against... and Trichophyton mentagrophytes [ATCC

9533]; when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.”

46. Between on or about June 19, 2013 and on or about May 22, 2014, the “accepted” label for “Wedge Disinfecting Wipes, EPA Reg. No. 88494-2, contained, among others, the following statement (under NET CONTENTS): “Pre-Moistened Wipes.”

47. The label affixed to the containers of “Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, imported on or about April 19, 2014, under entry number DSV-6201256-9, bore the following claims or statements that had not been approved by EPA as part of the accepted label for “Wedge Disinfectant Wipes,” EPA Reg. No. 88494-2:

- a. “*Other ingredients do not include the weight of dry wipes.”
- b. “PRE-SATURATED WIPES”
- c. “Disinfecting wipe for hard, non-porous surfaces, patient care equipment and point of care equipment.”
- d. “Pesticide (wipe) Disposal”

48. On or about April 19, 2014, Respondent “distributed or sold” the pesticide product “Medline Micro-Kill One Germicidal Wipes,” EPA Reg. No. 88494-2-37549, as that term is defined in 2(gg) of FIFRA, 7 U.S.C. § 136(gg).

49. The label affixed to the containers of “Medline Micro-Kill One Germicidal Wipes” imported on or about April 18, 2014, under entry number DSV-6201256-9, did not contain the bolded directions for use set forth in paragraph 44 above, and bore the claims set forth at paragraph 47 that had not been approved by EPA as part of the accepted label for “Wedge Disinfectant Wipes,” EPA Reg. No. 88494-2 at that time.

50. On May 23, 2014, EPA approved a notification from the Registrant for the accepted label that added the claims set forth at paragraph 47 and provided alternative language to the language set forth at paragraph 44 that matched the language in the imported label.

Specific Allegations

51. Complainant incorporates by reference the allegations contained in paragraphs 1 through 51.

52. On or about April 19, 2014, Respondent distributed or sold the distributor product “Micro-Kill One Germicidal Alcohol Wipes,” EPA Reg. No. 88494-2-37549, with claims on the labelling that EPA had not approved and did not fall within the exceptions set forth at 40 C.F.R. § 152.132(d).

53. Therefore, On or about April 19, 2014, Respondent distributed or sold the pesticide product “Micro-Kill One Germicidal Alcohol Wipes,” EPA Reg. No. 88494-2-37549, with a label that bore claims which substantially differed from the claims accepted as part of its registration under FIFRA, which constitutes an unlawful act, in violation of Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).

54. Respondent’s violation of Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), subjects Respondent to the issuance of an Administrative Complaint assessing a civil penalty under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a).

Civil Penalty

55. Section 14(a)(4) of FIFRA, 7 U.S.C. §136l(4), requires the Administrator to consider the appropriateness of a penalty to the size of the business of the person charged, the effect on the person’s ability to continue in business, and the gravity of the violation, when determining the amount of the penalty for violations of FIFRA.

56. Based on an evaluation of the facts alleged in this CAFO and the factors in Section 14(a)(4) of FIFRA, Complainant calculated a civil penalty against Respondent in the amount of \$7,500.

57. Within 30 days of the effective date of this CAFO, Respondent must pay a \$7,500 civil penalty for the FIFRA violation. Respondent must pay the penalty by sending a cashier's or certified check, payable to the "Treasurer, United States of America," to:

U.S. EPA
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

58. The check must note "In the Matter of American Infection Control, Inc.," and the docket number of this CAFO.

59. Respondent must send a notice of payment that states Respondent's name and the case docket number to EPA at the following addresses when it pays the penalty:

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Claudia Niess (LC-8J)
Pesticides and Toxics Compliance Section
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Maria Gonzalez (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

60. This civil penalty is not deductible for federal tax purposes.

61. If Respondent does not timely pay the civil penalty, EPA may refer the matter to

the Attorney General who will recover such amount by action in the appropriate United States district court under Section 14(a)(5) of FIFRA, 7 U.S.C. § 136l(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

62. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any amount overdue from the date payment was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a 6 percent per year penalty on any principal amount 90 days past due.

General Provisions

63. This CAFO resolves only Respondent's liability for federal civil penalties for the violations and facts alleged in the CAFO.

64. This CAFO does not affect the right of the EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

65. This CAFO does not affect Respondent's responsibilities to comply with FIFRA and other applicable federal, state, and local laws.

66. This CAFO is a "final order" for purposes of EPA's FIFRA Enforcement Response Policy.

67. The terms of this CAFO bind Respondent, its successors and assigns.

68. Each person signing this agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

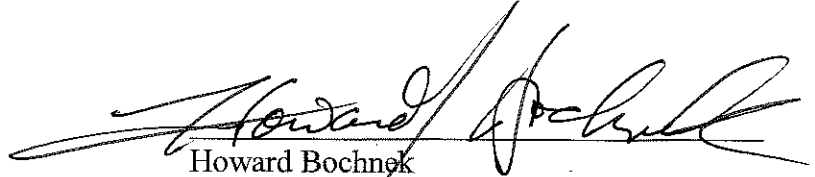
69. Each party agrees to bear its own costs and attorney fees, in this action.

70. This CAFO constitutes the entire agreement between the parties.

In the Matter of:
American Infection Control, Inc.
Docket No.


American Infection Control, Inc., Respondent

JUNE 3, 2014
Date


Howard Bochnek
Vice President
American Infection Control, Inc.

United States Environmental Protection Agency, Complainant

6/6/2014
Date


Margaret M. Guerriero
Director
Land and Chemicals Division



In the Matter of:
American Infection Control, Inc.
Docket No. FIFRA-05-2014-0021

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

6/10/2014

Date

Susan Hedman
Regional Administrator
United States Environmental Protection Agency
Region 5

CERTIFICATE OF SERVICE

I hereby certify that the original signed copy of the Consent Agreement and Final Order in resolution of the civil administrative action involving, American Infection Control, Inc., was filed on June 12, 2014, with the Regional Hearing Clerk (E-19J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604, and that I mailed by Certified Mail, Receipt No. 7009 1680 0000 7649 6711, a copy of the original to the Respondents:

Mr. Howard J. Bochnek
American Infection Control, Inc.
23950 Commerce Park
Beachwood, Ohio 44122



and forwarded copies (intra-Agency) to:

Ann Coyle, Regional Judicial Officer, ORC/C-14J
Maria Gonzalez, Regional Judicial Officer, ORC/C-14J
Eric Volck, Cincinnati Finance/MWD

A handwritten signature in blue ink that reads "Frederick Brown".

Frederick Brown
Pesticides and Toxics Compliance Section
U.S. EPA - Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604

Docket No. FIFRA-05-2014-0021