



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

JAN - 4 2011

OVERNIGHT DELIVERY & ELECTRONIC MAIL

Vincent Robbins, President & CEO
Monmouth-Ocean Hospital Service Corporation ("MONOC")
4806 Megill Road
Wall Township
Neptune, NJ 07753

Re: Stop Sale, Use or Removal Order, MONOC
Docket No. FIFRA-02-2011-5101

Dear Mr. Robbins:

Enclosed is a Stop Sale, Use or Removal Order ("Order") from the United States Environmental Protection Agency ("EPA") concerning antimicrobial pesticides sold for the express purpose of application to the interior of ambulances via microparticle disinfecting systems manufactured by Zimek Technologies, LLC ("Zimek"). The Order prohibits the use of any antimicrobial pesticide acquired from Zimek or its representatives in MONOC's ambulances via any system that delivers such pesticides to the interior of the vehicle as microparticles or submicronparticles in a mist or fog. The Order also prohibits the sale or removal of any pesticide acquired from Zimek or its representative(s) as a product intended for use as a disinfectant of the interior of ambulances via a microparticle disinfecting system.

Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), authorizes the Administrator of EPA to issue an order prohibiting the sale, use or removal of any pesticide by any person who owns, controls or has custody of such pesticide whenever there is reason to believe that the pesticide has been distributed or sold in violation of FIFRA. EPA has reason to believe that in distributing the antimicrobial pesticides Sporicidin (EPA Reg. No. 8383-3) and Zimek QD (EPA Reg. No. 70263-6-81632) to MONOC, Zimek and/or its representative(s) made claims for a use not accepted in connection with the registration of either product. Neither Sporicidin (EPA Reg. No. 8383-3) nor Zimek QD (EPA Reg. No. 70263-6-81632) bears directions for fogging the interior of ambulances.

EPA further has reason to believe that MONOC has applied at least these two antimicrobial pesticides to the interior of its ambulances in a manner inconsistent with their labeling and likely to cause harm to humans. Section 12(a)(2)(G) of FIFRA, 7 U.S.C. § 136j(a)(2)(G), provides it shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling. Please be advised that any such application of pesticides in this manner is a violation of FIFRA.

If you have any questions about this matter or wish to request an informal conference to discuss the alleged violation(s), you may contact Dr. Adrian Enache, Manager, Pesticides Program, Pesticides & Toxic Substances Branch, at 732-321-6769 or Enache.Adrian@epa.gov. For any legal matters concerning this Order, please contact Naomi Shapiro, Assistant Regional Counsel, at 212-637-3221 or Shapiro.Naomi@epa.gov.

Sincerely yours,


Dore F. LaPosta
Director, Division of Enforcement and Compliance Assistance

Enclosure

cc: Marcedius Jameson, Administrator
Pesticide Control & Coastal and Land Use Compliance & Enforcement Program
New Jersey Department of Environmental Protection
Mail Code 401-04F
PO Box 420
Trenton, NJ 08625-0420

Robert Kulick, Regional Administrator
New York Regional Office
U.S. Dept. of Labor/OSHA
201 Varick St. Rm.670
New York, NY 10014



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Monmouth-Ocean Hospital Service Corporation ("MONOC")
4806 Megill Road
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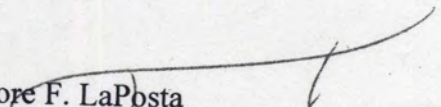
Enclosed is a Stop Sale, Use or Removal Order ("Order") from the United States Environmental Protection Agency ("EPA") concerning antimicrobial pesticides sold for the express purpose of application to the interior of ambulances via microparticle disinfecting systems manufactured by Zimek Technologies, LLC ("Zimek"). The Order prohibits the use of any antimicrobial pesticide acquired from Zimek or its representatives in MONOC's ambulances via any system that delivers such pesticides to the interior of the vehicle as microparticles or submicronparticles in a mist or fog. The Order also prohibits the sale or removal of any pesticide acquired from Zimek or its representative(s) as a product intended for use as a disinfectant of the interior of ambulances via a microparticle disinfecting system.

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EPA further has reason to believe that MONOC has applied at least these two antimicrobial pesticides to the interior of its ambulances in a manner inconsistent with their labeling and likely to cause harm to humans. Section 12(a)(2)(G) of FIFRA, 7 U.S.C. § 136j(a)(2)(G), provides it shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling. Please be advised that any such application of pesticides in this manner is a violation of FIFRA.

If you have any questions about this matter or wish to request an informal conference to discuss the alleged violation(s), you may contact Dr. Adrian Enache, Manager, Pesticides Program, Pesticides & Toxic Substances Branch, at 732-321-6769 or Enache.Adrian@epa.gov. For any legal matters concerning this Order, please contact Naomi Shapiro, Assistant Regional Counsel, at 212-637-3221 or Shapiro.Naomi@epa.gov.

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201 Varick St. Rm.670
New York, NY 10014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In The Matter Of:)

Monmouth-Ocean Hospital Service Corporation)
4806 Megill Road)
Wall Township)
Neptune, NJ 07753,)

Respondent.)

**STOP SALE, USE, OR
REMOVAL ORDER,**
Docket No. FIFRA 02-2011-5101

I. AUTHORITY AND BACKGROUND

1. Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"), 7 U.S.C. § 136k(a), authorizes the Administrator of the U.S. Environmental Protection Agency ("EPA") to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, *inter alia*, the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
2. The Director of the Division of Enforcement and Compliance Assistance ("DECA"), EPA Region 2, has been duly delegated authority to issue such Stop Sale, Use, or Removal Orders.
3. For the purposes of this Stop Sale, Use, or Removal Order ("SSURO" or "Order"), the term "MONOC" herein refers to Monmouth-Ocean Hospital Service Corporation, its agents, officers and employees, all of whom are persons within the meaning of the definition of "person" in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).
4. MONOC's principal place of business is located at 4806 Megill Road, Wall Township, Neptune, NJ 07753.
5. MONOC is a non-profit company comprised of fifteen acute care hospitals throughout New Jersey.

6. MONOC operates a fleet of over 100 ambulances.
7. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term “pesticide” as, among other things, “(1) any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest.”
8. Section 2(mm)(1) of FIFRA, 7 U.S.C. § 136(mm)(1), defines the term “antimicrobial pesticide” as, among other things, “a pesticide that (A) is intended to- (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.”
9. On or about April 29, 2009, MONOC purchased a microparticle disinfecting system manufactured by Zimek Technologies, LLC for the express purpose of applying a “sub-micron fog of hospital-grade disinfectant” to surface areas inside ambulances, thereby “killing dangerous bacteria, viruses ... toxic mold ... [and] community acquired diseases.”
10. Upon information and belief, in choosing to purchase the microparticle disinfecting system manufactured by Zimek Technologies, LLC, MONOC relied on representations made on Zimek’s website, in Zimek publications, and by a Zimek representative(s) that broad-based hospital disinfectants may be used with the system for applications to the interiors of ambulances.
11. Broad-based hospital disinfectants specifically identified by Zimek and its representative(s) for use in the microparticle disinfecting system manufactured by Zimek Technologies, LLC include the antimicrobial pesticides Sporicidin (EPA Reg. No. 8383-3), Zimek QD (EPA Reg. No. 70263-6-81632), Zimek D & I Plus (EPA Reg. No. 70263-3-81632), Vital Oxide (EPA Reg. No. 82972-1), and Steriplex Ultra (EPA Reg. No. 84545-8).
12. Upon information and belief, the microparticle disinfecting system manufactured by Zimek Technologies, LLC was packaged with antimicrobial pesticides to be used in the system including Sporicidin (EPA Reg. No. 8383-3), Zimek QD (EPA Reg. No. 70263-6-81632), Zimek D & I Plus (EPA Reg. No. 70263-3-81632), Vital Oxide (EPA Reg. No. 82972-1), or Steriplex Ultra (EPA Reg. No. 84545-8).
13. Pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a, all pesticides intended for distribution or sale must be registered with EPA.
14. As part of the registration process, referenced in paragraph 13 above, pesticide registrants must provide *inter alia* proposed labeling, including application instructions, and data supporting the efficacy of the proposed product if applied according to the label instructions.

15. The EPA-registered antimicrobial pesticides Sporicidin (EPA Reg. No. 8383-3), Zimek QD (EPA Reg. No. 70263-6-81632), Zimek D & I Plus (EPA Reg. No. 70263-3-81632), Vital Oxide (EPA Reg. No. 82972-1), and Steriplex Ultra (EPA Reg. No. 84545-8) have never been accepted for registration bearing directions for application as a microparticle, nanoparticle, or a "sub-micron" fog to the interior of ambulances.
16. The sale or distribution of any of the antimicrobial pesticides identified in paragraph 11, above, with claims for a use not accepted in connection with its registration under Section 3 of FIFRA is a violation of Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).
17. Upon information and belief, antimicrobial pesticides applied to MONOC ambulances include Sporicidin (EPA Reg. No. 8383-3), a Phenol-based broad-spectrum disinfectant.
18. Upon information and belief, MONOC applied Sporicidin to the interior of its ambulances via microparticle disinfecting system on at least September 7, 2010.
19. The EPA-approved label for Sporicidin does not contain directions for use for Sporicidin via a microparticle disinfecting system to the interior of ambulances.
20. Upon information and belief, individuals working in MONOC ambulances in which Sporicidin was applied using the microparticle disinfecting system referenced in paragraph 9, above, have been hospitalized for Phenol poisoning.
21. Upon information and belief, individuals working in MONOC ambulances in which Sporicidin was applied using the microparticle disinfecting system referenced in paragraph 9, above, continue to suffer ill-effects associated with exposure to Phenol.
22. Upon information and belief, antimicrobial pesticides applied to MONOC ambulances include Zimek QD (EPA Reg. No. 70263-6-81632), a broad-spectrum disinfectant.
23. Upon information and belief, MONOC applied Zimek QD to the interior of its ambulances via microparticle disinfecting system on multiple occasions.
24. Zimek QD (EPA Reg. No. 70263-6-81632) is a supplemental registration or distributor product of Microban QGC (EPA Reg. No. 70385-6) (hereinafter "the basic product").
25. The label submitted by the registrant of the basic product is the only EPA-approved label for the basic product and any distributor product.
26. Pursuant to 40 C.F.R. § 152.132(d)(5), the supplemental registrant of a distributor product may omit specific claims from the EPA-approved label of the basic product.

27. Both the basic product and Zimek QD are antimicrobial pesticides as defined by FIFRA.
28. The registrant of the basic product has never had a label for the basic product accepted for registration bearing directions for application as a microparticle, nanoparticle, or a "sub-micron" fog to the interior of ambulances.
29. The label of Zimek QD omits ambulances as a site of application for the product and does not contain directions for use for Zimek QD via a microparticle disinfecting system to the interior of ambulances.
30. Upon information and belief, individuals working in MONOC ambulances in which Zimek QD was applied using the microparticle disinfecting system referenced in paragraph 9, above, have been treated for ailments associated with pesticide poisoning.
31. Upon information and belief, individuals working in MONOC ambulances in which Zimek QD was applied using the microparticle disinfecting system referenced in paragraph 9, above, continue to suffer ill-effects associated with pesticide poisoning.

II. ORDER

32. EPA hereby ORDERS MONOC to stop the **use** (application) of any antimicrobial pesticide acquired from Zimek or its representatives in its ambulances via any system that delivers such pesticides to the interior of a vehicle as microparticles or submicronparticles in a mist or fog.
33. EPA hereby further ORDERS MONOC to stop the **use** (application) of Zimek QD in its ambulances in any manner.
34. EPA hereby further ORDERS MONOC not to **sell** or otherwise **remove** any antimicrobial pesticide acquired from Zimek or its representatives as a product intended for use as a disinfectant of the interiors of ambulances via a microparticle disinfecting system until otherwise instructed by EPA.
35. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by MONOC.
36. MONOC shall, immediately upon receipt of this Order, comply with FIFRA and its implementing regulations, with respect to all pesticides it applies.
37. This Order shall remain in effect until after EPA vacates the Order in writing.
38. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), states that it shall be unlawful for any person to violate any order issued under Section 13 of FIFRA.

39. Violations of the terms or provisions of this Order may be subject to civil and/or criminal penalties prescribed in Section 14 of FIFRA, 7 U.S.C. § 136l.
40. Within ten (10) days of the effective date of this Order, MONOC shall provide written documentation to EPA that MONOC, or any person or organization on its behalf, has stopped the uses as ordered by paragraphs 32 and 33, above, and maintained the pesticides on hand as ordered by paragraph 34, above.
41. In the event that MONOC needs to clean any of the treated ambulances in any way, within ten (10) days of making such determination, MONOC shall provide EPA with a written description of the efforts made, including, but not limited to, the products used and the disposal of any wastes generated by such efforts.
42. In the event that MONOC elects to use any of the pesticides acquired from Zimek or its representatives, MONOC shall certify that such use will be conducted in strict compliance with the directions for use on the product labeling.
43. Any information provided pursuant to paragraphs 40-42, above, shall contain the following certification:

"I certify that the information contained in or accompanying this statement is true, accurate and complete. As to the identified portion(s) of this statement the truth or accuracy of which I cannot personally verify, as the supervising company official, I certify that person(s) under my supervision has/have verified that this information is true, accurate and complete."
44. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law, to address this matter or any other matters or unlawful acts not specified in this Order.

III. BASIS FOR ORDER

45. EPA's basis for this Order is information provided to the Agency by the New Jersey Department of Environmental Protection ("NJDEP"), the Occupational Safety and Health Administration ("OSHA"), and individuals affected by applications described herein.

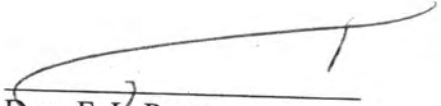
IV. OTHER MATTERS

46. Please send any written documentation required by this Order and any other additional information or comments regarding this Stop Sale, Use, or Removal Order, to:

Dr. Adrian J. Enache, Ph.D., M.P.H.
Manager, Pesticides Team
US EPA Region 2, Pesticides and Toxic Substances Branch
2890 Woodbridge Avenue - MS-500
Edison, NJ 08837
(732)-321-6769 (phone)
(732)- 321-6771 (fax)
Enache.Adrian@epa.gov

47. For assistance regarding legal matters surrounding this SSURO, your attorney is encouraged to contact:

Naomi Shapiro, Esq.
Assistant Regional Counsel
U.S. EPA, Region 2
Office of Regional Counsel
290 Broadway, 16th Floor
New York, NY 10007-1866
212-637-3221 (phone)
212-637-3199 (fax)


Dore F. LaPosta
Director, Division of Enforcement and Compliance Assistance
U.S. EPA, Region 2
290 Broadway, 21st Floor
New York, NY 10007-1866

JANUARY 4, 2011
Date

CERTIFICATE OF SERVICE

This is to certify that on this day I caused to be mailed, via overnight service, the original of the Stop, Sale, Use and Removal Order bearing Docket Number FIFRA-02-2011-5101, to Vincent Robbins, President and CEO, Monmouth-Ocean Hospital Service Corporation, 4806 Megill Road, Wall Township, Neptune, NJ 07753.

Dated: _____, 2011
