VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED
AND ELECTRONIC TRANSMISSION

Brian G. Larson, Registered Agent
for sBioMed, LLC
1272 South 1380 West
Orem, UT 84058

Re: STOP SALE, USE OR REMOVAL ORDER
sBioMed, LLC (sBioMed)

Dear Mr. Larson:

Enclosed is a Stop Sale, Use or Removal Order (Order) issued by the United States Environmental Protection Agency Region 8 (EPA) to sBioMed, LLC for sBioMed’s unregistered Steriplex SD pesticide wipe products. **The Order is effective immediately upon receipt by you, as registered agent for sBioMed.**

Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136k(a), authorizes the 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 the pesticide is in violation of any provision of FIFRA or such pesticide has been or is intended to be distributed or sold in violation of FIFRA. As explained further in the enclosed Order, sBioMed has been and is producing, distributing, or selling, misbranded and unregistered pesticide products. In addition, the Order informs sBioMed that false and misleading claims were found multiple times on the company’s steriplex.com website prior to the website being closed for maintenance.

If you or sBioMed have any questions about this matter, you may contact Dan Webster of my staff at 303-312-7076, or by email at webster.daniel@epa.gov. For any legal questions, please contact Charles L. Figur, Senior Enforcement Attorney by phone (303-312-6915) or by email at figur.charles@epa.gov.

Sincerely,

David Cobb, Acting Unit Chief
Technical Enforcement Program
Office of Enforcement, Compliance and Environmental Justice

Enclosure
I. AUTHORITIES

1. The United States Environmental Protection Agency issues this Stop Sale, Use, or Removal Order (Order) pursuant to the authority vested in the Administrator of the EPA by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. § 136k(a), which authorizes the Administrator of the EPA to issue orders 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 the pesticide or device is in violation of any provision of FIFRA, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration has been cancelled by a final order.

2. Supervisors in the Technical Enforcement Program and the Legal Enforcement Program have been jointly delegated the authority to issue such orders.

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

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

5. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), states it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.

6. 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.”

7. Section 2(gg), 7 U.S.C. § 136(gg) defines “to distribute or sell” as “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.”
8. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a “pesticide”, in part, as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”

9. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines “pest,” in part as “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 section [25(c)(1) of FIFRA].”

10. A “pesticide product” is defined at 40 C.F.R. § 152.3 as “a pesticide in a particular form (including composition, packaging and labeling) in which the pesticides is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.”

11. As stated at 40 C.F.R. § 152.15, with certain exceptions not applicable in this circumstance, “[n]o person may distribute or sell any pesticide product that is not registered under [FIFRA].”

II. BACKGROUND

12. sBioMed, LLC (sBioMed) is a corporation organized under the laws of the State of Utah and is authorized to do business in the State of Utah.

13. sBioMed is a “person” as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).


15. Steriplex SD Part A is formulated as one component of a two-part system and it must not be used alone as a sanitizer or disinfectant without activating.

16. Steriplex SD Activator Part B is formulated as one component of a two-part system and it must not be used alone as a sanitizer or disinfectant without activating.

17. Steriplex SD is a two-part system wherein Part A and Part B are combined to create a disinfectant.

III. BASIS FOR ORDER

18. On May 12, 2014, an EPA inspector conducted a FIFRA inspection at the sBioMed facility located at 1272 South 1380 West, Orem, Utah 84058 (inspection).

19. During the inspection, the inspector obtained a label for a “secondary container for wipes”. The label clearly states the EPA registration number for Steriplex SD, EPA Reg. No. 84545-11. This label also indicates that the container includes “85 wipes, 12” x 8/4”, and directions to “add 1450 mL activated Steriplex SD” to dry wipes or to “follow instructions below” for wet wipes.

20. The EPA-approved label for 84545-11 does not have any language relating to wipes, including, but not limited to directions for use. The EPA did not approve, or evaluate, “wipes” as part of the registration of EPA Reg. No 84545-11.
21. Based on the clear wording of the label the wipes are a pesticide product that is intended to be used to deliver or apply a pesticide. The wipes pesticide product is a “pesticide in a particular form” that is not registered under FIFRA.

22. sBioMed has been and is producing, distributing, or selling a misbranded and unregistered pesticide in a violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

23. On multiple dates since the date of the inspection, an EPA inspector conducted a review of the sBioMed website (found at steriplex.com). Several false and misleading statements were identified as part of the website review, including the statements below. On February 25, 2015, an EPA inspector attempted to review the website. The link, however, led to a page that informed visitors that the website was undergoing maintenance.

   a. “This stuff is a thousand times more powerful than Lysol.”
   b. “HMIS health and physical hazard rating of zero(0).”
   c. “used by the federal government in bioterror remediation”
   d. “not toxic”.
   e. multiple inappropriate comparisons with other active ingredients of other products.
   f. multiple claims as to the safety of the pesticide or its ingredients.

IV. ORDER

24. The EPA hereby orders sBioMed to stop the sale, use, or removal of all pesticide products subject to this Order, which includes all wipes associated by label or other statement with the Steriplex SD products, EFFECTIVE IMMEDIATELY.

25. The EPA hereby orders sBioMed to stop the advertising of and for the use of wipes with the Steriplex SD products subject to this Order, EFFECTIVE IMMEDIATELY.

26. This Order pertains to all quantities and sizes of wipes distributed with the Steriplex SD products or labeled with any variant of the Steriplex SD labels, within the ownership, control, or custody of sBioMed or any other entity producing the products. The wipes distributed with the Steriplex SD products or labeled with any variant of the Steriplex SD labels shall not be sold, used, or removed other than in accordance with the provisions of this Order or any further Stop Sale, Use, or Removal Order that may be issued in connection with such pesticide products.

27. The EPA hereby orders sBioMed to remove all false and misleading statements from their website and any other forms of advertising media.

28. No later than two weeks from receipt of this Order, sBioMed must submit a list of each person (as defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s)) to whom sBioMed has transferred wipes with the unapproved Steriplex SD label (whether with or without Steriplex SD (and so state)), from January 1, 2014, to the date of submittal.
29. No later than two weeks from receipt of this Order, sBioMed must submit a written inventory for all wipes within its custody or control and subject to this Order. The inventory shall list the quantity and location of all pesticide products subject to this Order and include plans for product storage or disposal. The pesticide products subject to this Order shall not be moved, destroyed or disposed of without prior written consent from EPA.

30. The list described in paragraph 28 and the inventory described in paragraph 29 must be submitted to:

Dan Webster
US EPA Region 8 (ENF-UFO)
1595 Wynkoop Street
Denver, CO 80202

31. Any violation of the terms or provisions of this Order by an officer, agent, or other person acting for or employed by sBioMed may subject such person as well as sBioMed to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 136j.

32. The issuance of this Order shall not constitute a waiver by the 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.

33. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by Respondent.

34. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.

35. If any provision(s) of this Order are subsequently held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and shall remain in full force and effect. The terms of this Order shall remain in effect unless and until the EPA modifies or terminates either the Order or certain provisions of the Order in writing.

Date: 3/17/15

David Cobb, Acting Unit Chief
Technical Enforcement Program
Office of Enforcement, Compliance and Environmental Justice

Date: 3/19/15

James H. Eppers, Supervisory Attorney
Legal Enforcement Program
Office of Enforcement, Compliance and Environmental Justice