UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HEADQUARTERS

In the Matter of:	)	**ORDER**
	)	**SECTION 13(a)**
sBioMed, LLC	)	
1272 South 1380 West	)	**FEDERAL INSECTICIDE, FUNGICIDE**
Orem, Utah 84058	)	**AND RODENTICIDE ACT**
	)	
Respondent	)	**Docket No. FIFRA-HQ-2015-5018**
	)	

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. This authority has been delegated from the EPA Administrator to the Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, U.S. EPA.

3. 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."

4. 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.

5. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), states that 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."

6. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "labeling," in part, as "all labels and all other written, printed, or graphic matter . . . accompanying the pesticide or device at any

time," and defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers."

7. 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."

8. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "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)." Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator declared that a pest is "[a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics . . . ." 40 C.F.R. § 152.5.

9. 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."

10. 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."

II. BACKGROUND

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

12. sBioMed produces, distributes, sells, and is the registrant of Steriplex SD Part A (EPA Reg. No. 84545-11) ("Part A") and Steriplex SD Activator Part B (EPA Reg. No. 84545-10) ("Part B").

13. The EPA-approved labels of Part A and Part B state that users must combine the two mixtures to create a disinfectant ("Steriplex SD").

14. The approved label of Part A lists the active ingredient of Part A as Silver 0.015%.

15. The approved label of Part B lists the active ingredients of Part B as Hydrogen Peroxide – 22% and Peroxyacetic Acid – 15%.

16. The approved label of Part A contains the following statements:

    a. "*C. diff* Spore Disinfectant";

    b. "Steriplex SD® is a two-part system and when Part A and Part B are combined create an effective *C. diff* Sporicide . . .";

c. "Kills *Clostridium difficile** spores in 5 minutes";

d. "Kills 99.9999% *Clostridium difficile** spores"; and

e. "**CLOSTRIDIUM DIFFICILE* ACTIVITY- STERIPLEX SD** exhibits sporicidal efficacy against ***Clostridium difficile**** (spore form) (ATCC 43598) in 5 minutes according to the Standard Quantitative Disk Carrier Test Method when used as directed."

17. The approved label of Part B contains the following statements:

a. "*C. diff* Spore Disinfectant";

b. "Steriplex SD® is a two-part system and when Part A and Part B are combined create an effective *C. diff* Sporicide . . .";

c. "Sporicidal against *Clostridium difficile**;

d. "Kills *C diff** spores . . . in 5 minutes"; and

e. "**CLOSTRIDIUM DIFFICILE* ACTIVITY- STERIPLEX SD** exhibits sporicidal efficacy against ***Clostridium difficile**** (spore form) (ATCC 43598) in 5 minutes according to the Standard Quantitative Disk Carrier Test Method when used as directed."

III. BASIS FOR ORDER

18. On or about August 13 through September 2, 2015, an EPA laboratory located in Ft. Meade, Maryland, conducted efficacy testing of samples of Part A and Part B obtained from the Cleveland Veterans Administration Medical Center (VAMC).

19. EPA's efficacy testing of liquid and spray formulations of Steriplex SD (Part A and Part B combined), using the Standard Quantitative Disk Carrier Test, shows that the products are not effective against *Clostridium difficile* (ATCC 43598) when used as directed at a contact time of 5 minutes.

20. Because the testing shows that the representations in the labels of Part A and Part B, specifically as they claim efficacy against *Clostridium difficile*, are false and misleading, EPA has reason to believe that sBioMed distributed or sold pesticides that were misbranded, as that term is defined by section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

IV. ORDER

21. Pursuant to the authority in section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders sBioMed to **immediately stop** the sale, use, or removal of Steriplex SD Part A and Steriplex SD Activator Part B, under its ownership, control or custody, wherever such products are located, except in accordance with the provisions of this Order.

22. This Order shall extend to all quantities and sizes of the product Steriplex SD Part A, EPA Reg. No. 84545-11, and Steriplex SD Activator Part B, EPA Reg. No. 84545-10, intended for sale or distribution, including:

    a. Any Steriplex SD products, Part A products, and Part B products marketed under alternate brand names;

    b. Any Steriplex SD products, Part A products, and Part B products packaged separately, packaged together, and/or packaged with other products, such as wipes; and

    c. Any Steriplex SD product stocks, Part A product stocks, and Part B product stocks returned to sBioMed from its distributors, customers, or other end-users.

23. The products described in paragraph 22 shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, offered for delivery, moved or removed for disposal from any facility or establishment, for any reason, unless approved by EPA in writing. Any proposal for movement of the products so described shall be submitted to James Miles, Chief, Pesticides and Tanks Enforcement Branch (2249A), United States Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and shall include:

    a. The purpose for which the movement is being requested;

    b. An accounting of the quantities of product to be moved, including location(s), quantities from each location and container size for the products to be moved; and

    c. The destination location to which the product will be moved.

24. Within 10 days of receipt of this Order, sBioMed shall submit to EPA an accounting of all products subject to this Order. The report shall be submitted to James Miles, Chief, Pesticides and Tanks Enforcement Branch (2249A), United States Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and shall include:

    a. A description of all existing product inventory, including the location(s) where the products are held, quantities, and container size. This information must be updated on a weekly basis for four weeks, on a monthly basis for the following six months, and thereafter only upon further changes to the information;

    b. A complete list of sBioMed's distributors and direct-sale customers and records of all

sales and distributions made to such entities; and

c. Provisions to maintain records of the disposition (e.g., reformulation, repackaging, relabeling, disposal) of products and to make the records available to EPA upon request. Such records must include information on the method, the quantity, and the location of disposition and/or disposal.

25. Any agent, owner, or operator of sBioMed violating the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 136*l*.

26. 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.

27. This Order shall be **effective immediately** upon receipt by sBioMed or any agents of sBioMed.

28. This Order shall remain in effect unless and until revoked, terminated, suspended or modified in writing by EPA.

29. If any provision or provisions of this Order is/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 they shall remain in full force and effect.

V. OTHER MATTERS

30. For any additional information about this Order, please contact Brenda Mosley, Enforcement Case Officer, at 202-564-4174. For any legal matters concerning this Order, please contact Adrienne Fortin, Enforcement Attorney, at 202-564-7862.

Sept 11, 2015
Date

[redacted]
Gregory Sullivan, Acting Director
Waste and Chemical Enforcement Division
Office of Civil Enforcement
U.S. Environmental Protection Agency