January 5, 2021 3:11 PM Received by

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

EPA Region VIII Hearing Clerk

IN THE MATTER OF:)
	Docket No. FIFRA-08-2021-0021
PURE BELLA VITA LLC	
300 South Wilcox Street) FIFRA SECTION 13(a)
Castle Rock, Colorado 80104)
) STOP SALE, USE, or
Respondent.) REMOVAL ORDER
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I. <u>AUTHORITY</u>

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency (EPA) by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of the 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 the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. The undersigned EPA official has been duly authorized to issue this Order.

II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states that 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 of whose registration has been canceled or suspended..."
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it shall be unlawful for any person in any state to sell or distribute to any person any pesticide which is adulterated or misbranded.
- 5. "The term 'pesticide' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. . . ." FIFRA § 2(u), 7 U.S.C. § 136(u).
- 6. "The term 'pest' means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organisms . . . which the Administrator declares to be a pest under section 136w(c)(1) of this title." FIFRA § 2(t), 7 U.S.C. § 136(t).

- 7. 40 C.F.R. § 152.15(a) states "A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if ...[t]he person who distributes or sells the substance claims, states, or implies (by labelling or otherwise) ...[t]hat the substance...can or should be used as a pesticide."
- 8. Section 2(gg) of FIFRA, 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"
- 9. 40 C.F.R. § 152.3 further defines "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."
- 10. Section 2 of FIFRA, 7 U.S.C. § 136(q), states that a pesticide is misbranded if:
 - "(1)(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;

...

- (C) it is an imitation of, or is offered for sale under the name of, another pesticide...."
- 11. Section 2(p)(1) of FIFRA, 7 U.S.C. § 136(p)(1) states "the term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any ot its containers or wrappers."
- 12. Section 2(p)(2) of FIFRA, 7 U.S.C. § 136(p)(2), states "the term 'labeling; means all label and all other written, printed, or graphic matter—(A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authored by law to conduct research in the field of pesticides."

III. ALLEGATIONS OF FACT AND LAW

- 13. On August 26, 2020, the EPA Office of Pesticide Programs Laboratory, located in Fort Meade, Maryland, analyzed the contents of two containers of a product called Dr. Joe's Pro Commercial Strength Disinfectant, which were purchased from United States Cylinder Gas (US Gas) in Alsip, Illinois.
- 14. On September 9, 2020, the National Enforcement Investigation Center, located in Lakewood, Colorado, analyzed the contents of four containers of Dr. Joe's Pro Commercial Strength Disinfectant obtained in Castle Rock, Colorado.

- 15. Upon inspection, the label of Dr. Joe's Pro Commercial Strength Disinfectant features the following statements:
 - EPA Reg. No. 86054-1
 - Active Ingredients Chlorine Dioxide 0.005%
 - One-Step Process, Non-Toxic, Hospital-Medical Grade, Ready-to-Use Formula
 - Kills all known Viruses, Bacteria, Algae, Fungi, Mold, Yeast, Bacterial Spores, Beta Lactams, Protozoa, Microsporidis, and Chemical Decontamination. Includes Coronaviruses, SARS, Ebola Virus, E.coli, Cold and Flu Viruses, Staph, MRSA, Salmonella, Step, Kleb and more
 - MEETS BLOODBORNE PATHOGEN STANDARDS FOR DECONTAMINATING BLOOD AND BODILY FLUIDS
 - This product is designed for use on hard, non-porous surfaces in hospitals, medical and health care facilities, schools and colleges, offices, hotels, ships, arenas, convention centers, factories, restaurants, veterinary clinics, airports, residences, nurseries, and other locations that may be contaminated
 - Manufactured by: Dr. Joe's Pro Disinfectant, a TwinOxide product...EPA REG NO. 86054-1, EPA EST NO. 85158-BEL-001
 - Distributed by: Pure Bella Vita, Denver, CO
 - Powered by TwinOxide
 - TwinOxide/Chlorine dioxide (C1O2) is registered with the United States Environmental Protection Agency [EPA] as a disinfectant, sanitizer, and sterilizer which is defined as the ability "to destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores"
 - KILLS HIV-1, AND NCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency virus type 1 (HIV-1) (associated with AIDS), Human Hepatitis B virus, and Human Hepatitis C virus
 - No PPE required for handling or application of product
 - When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye coverings; and Allow surfaces to remain wet for 2 minutes

- 16. Claims on the label of Dr. Joe's Pro Commercial Strength Disinfectant demonstrate that Dr. Joe's Pro Commercial Strength Disinfectant is intended for preventing, destroying, repelling, or mitigating pests.
- 17. Dr. Joe's Pro Commercial Strength Disinfectant is a "pesticide" as that term is defined by FIFRA § 2(u), 7 U.S.C. § 136(u).
- 18. Dr. Joe's Pro Commercial Strength Disinfectant was sold and distributed by Respondent, Pure Bella Vita LLC.
- 19. Respondent is a limited liability company organized under the laws of the State of Colorado and is authorized to do business in the State of Colorado.
- 20. Respondent's principal place of business is located at 300 South Wilcox Street, Castle Rock, Colorado 80104.
- 21. Respondent is a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), and is subject to FIFRA and the implementing regulations promulgated thereunder.
- 22. The EPA registered the pesticide product Twin Oxide, Component A, with EPA Registration No. 86054-1, on December 8, 2009.
- 23. Twin Oxide, Component A, EPA Reg. No. 86054-1, was registered by TwinOxide International B.V. to contain the active ingredient sodium chlorite 64%.
- 24. There are no supplemental distributor or bulk repackaging agreements between TwinOxide International B.V. and Respondent regarding Twin Oxide, Component A, EPA Reg. No. 86054-1, on record with the EPA.
- 25. Results from the laboratory analyses conducted on August 26, 2020, and September 9, 2020, demonstrate to EPA that those samples of Dr. Joe's Pro Commercial Strength Disinfectant's ingredients did not match the ingredients set forth in the registration of Twin Oxide, Component A, EPA Reg. No. 86054-1.
- 26. The EPA determined that Dr. Joe's Pro Commercial Strength Disinfectant was not Twin Oxide, Component A, EPA Reg. No. 86054-1, despite being labeled with that registration number.
- 27. Dr. Joe's Pro Commercial Strength Disinfectant is not registered with the EPA pursuant to FIFRA section 3, 7 U.S.C. § 136a.
- 28. Therefore, the sale or distribution of Dr. Joe's Pro Commercial Strength Disinfectant constitutes the sale or distribution of an unregistered pesticide, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 29. Dr. Joe's Pro Commercial Strength Disinfectant is "misbranded" as that term is defined by section 2(q) of FIFRA, 7 U.S.C. § 136(q), because:

- its label bears statements, designs, or graphic representations relative thereto or to its ingredients which are false and misleading (7 U.S.C. § 136(q)(1)(A)), including the following: the label states that the product kills all viruses, bacteria, algae, fungi, mold, yeast, bacterial spores, Beta Lactams, Protozoa, Microsporidis, and chemical decontamination; that it "MEETS BLOODBORNE PATHOGEN STANDARDS FOR DECONTAMINATING BLOOD AND BODILY FLUIDS"; that it may be used "in hospitals, medical and health care facilities, schools and colleges, offices, hotels, ships, arenas, convention centers, factories, restaurants, veterinary clinics, airports, residences, nurseries, and other locations that may be contaminated; that it "KILLS HIV-1, AND NCV"; that no PPE is required for application; and it includes the registration number for a different product that is a registered pesticide, misleading users into thinking that the product is registered with the EPA.
- the product is an imitation of, or is offered for sale under the name of, another pesticide (7 U.S.C. § 136(q)(1)(C)); specifically, the label bears the registration number of Twin Oxide, Component A, and states that it is "Powered by TwinOxide," leading consumers to believe they are buying Twin Oxide, Component A, EPA Reg. No. 86054-1.
- 30. Therefore, the sale or distribution of Dr. Joe's Pro Commercial Strength Disinfectant constitutes the sale or distribution of a misbranded pesticide, in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

IV. BASIS FOR THE ORDER

- 31. As demonstrated in section III, EPA has reason to believe Respondent sold or distributed an unregistered pesticide in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 32. As demonstrated in section III, EPA has reason to believe Respondent sold or distributed a misbranded pesticide in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

V. ORDER

- 33. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all quantities of Dr. Joe's Pro Commercial Strength Disinfectant that are under its ownership, control, or custody, wherever such products are located, unless in accordance with the provisions of this Order.
- 34. This Order extends to all quantities of Dr. Joe's Pro Commercial Strength Disinfectant intended for sale, distribution, and any stocks of Dr. Joe's Pro Commercial Strength Disinfectant returned to Respondent from its sellers, customers, or other end users.
- 35. Respondent shall not use, sell, offer for sale, hold for sale, ship, deliver, or offer for delivery any Dr. Joe's Pro Commercial Strength Disinfectant under its ownership, control or custody, unless in accordance with the provisions of this Order.

- 36. Respondent may ONLY move or remove any Dr. Joe's Pro Commercial Strength Disinfectant after obtaining prior written approval from EPA, in accordance with the following:
 - Movement or removal requests must be made in writing addressed to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, 1595 Wynkoop Street, Denver, Colorado 80202, or at tokarz.christine@epa.gov.
 - Any request for movement or removal must include a written accounting of the products to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and a description of the reasons for the movement or removal.
 - If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA and the disposal must comply with all applicable federal, state, and local laws.
 - Any movement or removal of any Dr. Joe's Pro Commercial Strength Disinfectant made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the unlawful distribution or sale of unregistered pesticides, in violation of FIFRA.
- 37. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of Respondent's inventory of Dr. Joe's Pro Commercial Strength Disinfectant. The accounting must be submitted to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, 1595 Wynkoop Street, Denver, Colorado 80202, or at tokarz.christine@epa.gov, and must include an accounting of all existing product inventory, including the locations(s) where the products are held, quantities, and container sizes. Unless EPA provides otherwise, Respondent must provide EPA with an updated accounting at least every 30 days until Respondent no longer has any Dr. Joe's Pro Commercial Strength Disinfectant in its ownership, custody or control.
- 38. Should Respondent assert a claim of business confidentiality for any information submitted to EPA pursuant to paragraphs 36 and 37, it may do so in the manner described at 40 C.F.R. section 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. Unless Respondent makes a claim at the time that it submits the information in the manner described in 40 C.F.R. section 2.203(b), EPA may make this information available to the public without further notice to Respondent.
- 39. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 40. 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.

- 41. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 42. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 43. If any provision of this Order is 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.
- 44. To confer with EPA about the allegations set forth herein or the basis of this Order, you may contact Shaula Eakins at (303) 312-6317 or eakins.shaula@epa.gov. Any such conference will not stay the effectiveness of this order.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

Date:	By:	
		David Cobb, Section Chief
		Toxics and Pesticides Enforcement Section
		Enforcement and Compliance Assurance Division