

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

Received by
EPA Region VIII
Hearing Clerk

IN THE MATTER OF:)
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CARE.LIFE, INC.)
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1955 Ironton Boulevard)
Provo, Utah 84606)
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Respondent.)
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Docket No. FIFRA-08-2022-0043
FIFRA SECTION 13(a)
STOP SALE, USE, or
REMOVAL ORDER

I. AUTHORITY

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 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 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)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), provides that it shall be unlawful for any person in any state to distribute or sell to any person any device that is misbranded.
4. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136j(a)(2)(S), provides that it shall be unlawful for any person to violate any regulation issued under section 3a(a) (registration) or section 136q (storage, disposal, transportation, and recall) of FIFRA.
5. 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.”
6. 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 microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1).”

7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator has 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.” See 40 C.F.R. § 152.5(d).
8. Section 2(h) of FIFRA, 7 U.S.C. § 136(h), defines “device” as “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.” *See, also*, 40 C.F.R. § 152.500(a).
9. 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....”
10. The regulation at 40 C.F.R. § 152.3 further defines the term “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.”
11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines “label” as “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers” and defines “labeling” in part, as “all labels 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.”
12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, “a pesticide is misbranded if ...

[D] its label does not bear the registration number assigned under section 136e to each establishment in which it was produced; ...

[F] 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 Act, are adequate to protect health and the environment; [or]

[G] the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this Act, is adequate to protect health and the environment.”

13. The regulation at 40 C.F.R. § 156(a) requires that labels for pesticide products contain: the producing establishment number, hazard and precautionary statements, and directions for use.
14. The regulation at 40 C.F.R. § 152.500(b)(1) applies the requirements of section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), and the labeling requirements of 40 C.F.R. Part 156 to devices.
15. Section 17(c) of FIFRA, 7 U.S.C. § 136o(c), and the regulations implementing that provision set forth at 19 C.F.R. §§ 12.110 - 12.117, establish that importers of pesticides and devices must submit to the EPA, prior to the arrival of the shipment in the United States, a Notice of Arrival of Pesticides and Devices on U.S. Environmental Protection Agency Form 3540-1, or must file an electronic alternative to the Notice of Arrival with the filing of entry documentation via any CBP-authorized electronic data interchange system.
16. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), provides that it shall be unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by FIFRA.

III. BASIS FOR THE ORDER

17. Respondent, CareLife, Inc., is a corporation organized under the laws of the State of Utah and a “person” as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), and subject to FIFRA and its implementing regulations.
18. Respondent imported one shipment associated with the Department of Homeland Security United States Customs and Border Protection entry number 8GB-18043278, containing the following products: four hundred seventy-five air purifier pieces, five hundred HEPA air filters, and three hundred UV-C bulbs. The shipment entered the United States at the Port of Salt Lake City, Utah, from China on May 2, 2022.
19. As the importer of the shipment listed herein, and by doing business in the United States, Respondent is subject to the requirements of FIFRA and its implementing regulations.
20. Respondent is, and was at all times, relevant to the allegations herein, an “importer,” as that term is defined in 19 C.F.R. § 101.1 and was the importer of record for all of the unlawful imports alleged herein.
21. The manual for the air purifier, embedded HEPA air filters, and UV-C bulbs makes the following claims:
 - “This product adopts the form of circulating wind to drive the polluted air into the ultraviolet sterilizer, driven by the polluted air, combines high intensity ultraviolet ray, anion purification and primary and high efficiency filtration layer.” [sic]
 - “Physical filtration of bacteria and dust”
 - “disinfection method: UV + filters”

22. Based on their content, labeling claims, and directions for use, the air purifiers, HEPA air filters, and UV-C bulbs associated with entry number 8GB-18043278 are “devices” as defined in section 2(h) of FIFRA, 7 U.S.C. § 136(h).
23. Labels on the air purifiers, HEPA air filters, and UV-C bulbs, associated with entry number 8GB-18043278, does not bear an EPA establishment registration number as required by Section 2(q)(1)(D) of FIFRA; does not contain directions for use as required by Section 2(q)(1)(F) of FIFRA; and does not contain a warning or caution statement as required by Section 2(q)(1)(G) of FIFRA.
24. Because of the lack of an EPA establishment registration number, directions for use, and warning or caution statement on the label or labeling, the air purifiers, HEPA air filters, and UV-C bulbs associated with entry number 8GB-18043278 are misbranded pursuant to sections 2(q)(1)(D), (F) and (G) of FIFRA, 7 U.S.C. §§ 136(q)(1)(D), (F) and (G), 40 C.F.R. § 152.500(b)(1).
25. The shipment of the air purifiers, HEPA air filters, and UV-C bulbs is a “distribution or sale” pursuant to section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).
26. Respondent’s importation of the shipment of the following pesticidal devices: air purifiers, HEPA air filters, and UV-C bulbs through Salt Lake City, Utah, Port of Entry constitutes multiple violations of section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), which provides that it is unlawful for any person to distribute or sell to any person a device that is misbranded.
27. Respondent’s failure to file a Notice of Arrival of Pesticides and Devices with EPA for each pesticidal device in the shipment of the air purifiers, HEPA air filters, and UV-C bulbs as required by 19 C.F.R. § 12.112, is a violation of section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).

IV. ORDER

28. 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 air purifiers, HEPA air filters, and UV-C bulbs associated with entry number 8GB-18043278 (Products) under its ownership, control, or custody, wherever such Products are located, except in accordance with the provisions of this Order.
29. The Products shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
30. Respondent has proposed to EPA that it be allowed to rework the Products to make their sale or distribution compliant with FIFRA. Specifically, Respondent proposed that it be permitted to: consolidate the Products at facilities it has designated and relabel the Products in a FIFRA registered producing establishment with FIFRA compliant labels and labeling. As part of the rework plan, Respondent proposed to send regular updates to EPA on the movements of Products intended for rework and their status as it changes.

31. Pursuant to the terms of EPA's acceptance of Respondent's rework plan on July 26, 2022, the following provisions are established as part of this Order:
- a) All Products in the United States that are owned by, are in the custody of, or are controlled by Respondent may be transported as necessary to consolidate them at the rework locations identified in Respondent's rework plan. No Products shall be distributed except for the sole purpose of relocating them for inclusion in the rework plan.
 - b) Respondent will document such movements and rework activities and report to EPA in accordance with the terms set forth in the rework plan.
 - c) Products will be released from the requirements of this Order for distribution in commerce upon certification that the rework of those products, as specified in the rework plan, has been completed.
 - d) The distribution, sale, and use of Products that have been reworked and released shall not be deemed a violation of this Order, provided such Products otherwise are fully compliant with FIFRA.
32. All reporting to EPA provided by this Order and the rework plan shall be submitted to Devin Donaldson at donaldson.devin@epa.gov.

V. OTHER MATTERS

33. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
34. The issuance of this Order shall not constitute a waiver by EPA of any of its other 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.
35. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
36. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
37. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.

38. 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.

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY REGION 8**

Date: _____

By: _____
David Cobb, Section Supervisor
Toxics and Pesticides Enforcement Section
Enforcement and Compliance Assurance Division