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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

IN THE MATTER OF:	)	
	)	Docket No. FIFRA-08-2022-0028
HIGH TECH HEALTH INTERNATIONAL, INC.	)	FIFRA SECTION 13(a)
2770 Arapahoe Road, Suite 132-639 Layfette, Colorado 80026	)	STOP SALE, USE, or REMOVAL ORDER
Respondent.	)	

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 3(a) or section 19 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 25(c)(1)."

7. 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." 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."

9. EPA's implementing regulations at 40 C.F.R. § 152.500(a) provide the following:

   A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.

10. 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…."

11. 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."

12. 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."

13. 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 7 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 3(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 3(d) of this Act, is adequate to protect health and the environment."

14. 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 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.

15. 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

16. Respondent, High Tech Health International, Inc., is a corporation organized under the laws of the State of Colorado and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), and subject to FIFRA and the implementing regulations promulgated thereunder.

17. Respondent imported one shipment associated with entry number 336-31345399, containing the following products: forty-two Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, five hundred and fifty KA-P920T Replacement Cartridges, ten KA-P930T Replacement Cartridges, and one hundred UV Lamps. The shipment entered the United States at the Port of Denver, Colorado, from Japan on January 27, 2022.

18. As the importer of the shipment listed in paragraph 17, and by doing business in the United States, Respondent is subject to the requirements of FIFRA and its implementing regulations.

19. 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.

20. The "Akai MS-900UVH/HD Operators Manual" that accompanies the product includes the following claims:
    - "Mode indicators…purified water"
    - "Purified water can be used for taking medicine"
    - "There are two types of filter cartridges that can be used with this unit. 1. KA-P900T…eliminates unwanted odors such as chlorine odor, mold odor, metallic odor, etc.. Also eliminates rust, muddiness, mold, and various bacteria through the use of hollow fiber membranes."
    - "For increased safety, the water generated by the unit irradiated with electromagnetic waves produced by the ultraviolet lamp. The length of this electromagnetic wave is 253.7nm, which is an effective length for sterilizing drinking water."
    - "Filter cartridge specifications: KA-P900T-Substances that can be eliminated, microbes in the water (rust, mud, mold)…"

21. The KA-P920T and KA-P039T Replacement Cartridges are versions of the KA-P900T filter cartridge series referenced in the "Akai MS-900UVH/HD Operators Manual".

22. Based on their content, labeling claims, and directions for use, the Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps associated with entry number 336-31345399 are "devices" pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(h).

23. The labeling of the Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps associated with entry number 336-31345399 does not bear a registration number assigned under FIFRA section 7 to the establishment in which they were produced.

24. Because of the lack of an EPA establishment registration number on the label or labeling, the Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps associated with entry number 336-31345399 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 Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps 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: Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps, through Denver, Colorado, 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 failed to file a Notice of Arrival of Pesticides and Devices with EPA for each pesticidal device in the shipment of the Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps as required by 19 C.F.R. § 12.112.

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 Akai Ultraviolet System Activated Ionizing Water Equipment MS-900 UV units, KA-P920T Replacement Cartridges, KA-P930T Replacement Cartridges, and UV Lamps associated with entry number 336-31345399 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 section 7 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 May 1, 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 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 such products that have been reworked and released shall not be deemed a violation of this Order, provided the products are fully compliant with FIFRA.

32. All reporting to EPA provided by this Order and the rework plan shall be submitted to Christine Tokarz at tokarz.christine@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 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.

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)(1), 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 Digitally signed by DAVID COBB Date: 2022.05.12 15:23:19 -06'00'

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