

SUZANNE ANDREWS Regional Counsel

PRIYAM DESAI Assistant Regional Counsel (ORC-2-1) United States Environmental Protection Agency, Region IX 75 Hawthorne Street San Francisco, CA 94105 (415) 972-3276 Desai.priyam@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX SAN FRANCISCO, CALIFORNIA

)
In the Matter of:)
) Docket No. FIFRA-09-2025-0033
Twin Med, LLC)
) COMPLAINT AND NOTICE OF
) OPPORTUNITY FOR HEARING
)
Respondent.)

I. PRELIMINARY STATEMENT

This is a civil administrative action brought pursuant to section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"), 7 U.S.C. § 136/(a), for the assessment of a civil administrative penalty against Twin Med, LLC ("TwinMed") for violations of section 12 of FIFRA, 7 U.S.C. § 136j.

Complainant is the Manager of the Toxics Section in the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region IX, who has been duly delegated the authority to issue this Complaint and Notice of Opportunity for Hearing ("Complaint") pursuant to EPA Region 9 Delegation R9-5-14 (Feb. 11, 2013) and EPA Administrator Delegation 5-14 (May 11, 1994, updated Feb. 4, 2016).

Respondent is Twin Med LLC ("Respondent") is a Delaware limited liability company whose principal office is located at 11333 Greenstone Avenue in Santa Fe Springs, California.

II. APPLICABLE STATUTORY AND REGULATORY SECTIONS

- 1. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), provides that "person" means "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- Section 2(b) of FIFRA, 7 U.S.C. § 136(b), defines the term "Administrator" as " the Administrator of the Environmental Protection Agency."
- 3. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), provides that a "pesticide" means, in part, "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."
- 4. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), provides that "pest" means "any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other living 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, 7 U.S.C. § 136 w(c)(1)."
- 5. 40 C.F.R. § 152.15 states in pertinent part that "a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose..." and that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:
 (a) The person who distributes or sells the substance claims, states, or implies (by labeling

or otherwise) that: (1) the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or (2) the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or (b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

- 6. Section 2(mm)(A)(i) of FIFRA, 7 U.S.C. § 136(mm)(A)(i), defines the term "antimicrobial pesticide," in part, as "a pesticide that is intended to disinfect, sanitize, reduce or mitigate growth or development of microbial organisms."
- 7. Section 2(p)(1) of FIFRA, 7 U.S.C. § 136(p)(1), provides that the term "label" means "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." Section 2(p)(2)(A) of FIFRA, 7 U.S.C. § 136(p)(2)(A), provides that the term "labeling" means "all labels and all other written, printed, or graphic matter...accompanying the pesticide or device at any time."
- 8. Section 2(p)(2) of FIFRA, 7 U.S.C. § 136(p)(2), defines "labeling" 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 or device."

- 9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), provides that the term "distribute or sell" means "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. Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), provides that no person in any State may distribute or sell to any person any pesticide that is not registered under this Act.
- 11. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person to distribute or sell to any person a pesticide which is not registered with EPA under section 3 of FIFRA.
- 12. The Administrator of EPA may assess a civil penalty of up to \$24,255 against any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of FIFRA for each offense that occurred after November 2, 2015 and is assessed on or after December 27, 2023. See Section 14(a)(1) of FIFRA, 7 U.S.C. § 136/(a)(1), as amended by the Civil Monetary Penalty Inflation Adjustment Rule at 40 C.F.R. Part 19 (88 Fed. Reg. 988).

III. ALLEGATIONS

- 13. Paragraphs 1 through 12 above are hereby realleged and incorporated by reference.
- 14. At all times relevant to this Complaint, Respondent was a limited liability company and therefore a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- 15. At all times relevant to this Complaint, Respondent owned and/or operated a facility located at 11333 Greenstone Avenue, Santa Fe Springs, CA 90670 ("Facility").

- 16. At all times relevant to this Complaint, Respondent sold disinfecting products to various businesses including but not limited to convalescent homes, rehabilitation facilities, and other health and wellness organizations across the country from their regional warehouse in Los Angeles, California.
- 17. From August 17, 2021 to July 25, 2023, Respondent sold and dispatched the product, "WynnMed Germicidal Medical Disinfectant Wipes" ("Wynnmed Disinfectant Wipes"), from its Los Angeles regional warehouse located at 11333 Greenstone Avenue in Santa Fe Springs, CA to one hundred and thirty-five (135) unique customers.
- 18. The labeling on the product, WynnMed Disinfectant Wipes, contained the following language describing the product: "disinfect nonfood contract surfaces" and "germicide for . . . surface/objects . . . in healthcare settings in which there is an expected likelihood . . . in which the surfaces/objects likely to be soiled with blood or bodily fluids can be associated with the potential for transmission of germs."
- 19. "Germs" are "pests" as defined in section 2(t) of FIFRA, 7 U.S.C. § 136(t).
- 20. Based on its name and the claims on its label, the product, WynnMed Disinfectant Wipes, is a "pesticide" pursuant to section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15 and specifically, it is an "antimicrobial pesticide" pursuant to section 2(mm)(A)(i) of FIFRA, 7 U.S.C. § 136(mm)(A(i).
- 21. The pesticide, WynnMed Disinfectant Wipes, is not registered with EPA under section 3 of FIFRA, 7 U.S.C. § 136a.

- Thus, from August 17, 2021 to July 25, 2023, Respondent "distributed or sold" the unregistered pesticide, WynnMed Disinfectant Wipes, as defined in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).
- 24. Consequently, Respondent's distributions or sales of the pesticide, WynnMed Disinfectant Wipes, from August 17, 2021 to July 25, 2023 constitutes one hundred and thirty-five (135) violations of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which provides that it is unlawful for any person to distribute or sell to any person a pesticide which is not registered with EPA under section 3 of FIFRA, 7 U.S.C. § 136a.

IV. PROPOSED CIVIL PENALTY

Section 14(a)(1) of FIFRA, 7 U.S.C. § 136/(a)(I), and the Civil Monetary Penalty Inflation Adjustment Rule at 40 C.F.R. Part 19 provide that any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of FIFRA may be assessed a civil penalty of not more than \$24,255 for each offense that occurred after November 2, 2015 and is assessed on or after December 27, 2023. When determining an appropriate civil penalty, section 14(a)(4) of FIFRA, 7 U.S.C. § 136/(a)(4), requires EPA to consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Accordingly, Complainant requests that, after consideration of the statutory assessment factors, Respondent be assessed a civil administrative penalty of up to \$24,255 for each of the violations of FIFRA set forth above.

V. NOTICE OF OPPORTUNITY TO REQUEST HEARING

You have the right to request a formal hearing to contest any material fact set forth in this Complaint or to contest the appropriateness of the proposed penalty. Any hearing requested will be conducted in accordance with the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits ("Consolidated Rules of Practice") at 40 C.F.R. Part 22. A copy of the Consolidated Rules of Practice is enclosed with this Complaint.

You must file a written Answer within thirty (30) days of receiving this Complaint to avoid being found in default, which constitutes an admission of all facts alleged in the Complaint and a waiver of the right to a hearing and to avoid having the above penalty assessed without further proceedings. If you choose to file an Answer, you are required by the Consolidated Rules of Practice to clearly and directly admit, deny, or explain each of the factual allegations contained in this Complaint to which you have any knowledge. If you have no knowledge of a particular fact and so state, the allegation is considered denied. Failure to deny any of the allegations in this Complaint will constitute an admission of the undenied allegation.

The Answer shall also state the circumstances and arguments, if any, which are alleged to constitute the grounds of defense, and shall specifically request an administrative hearing, if desired. If you deny any material fact or raise any affirmative defense, you will be considered to have requested a hearing. The Answer must be filed with:

Regional Hearing Clerk (ORC-1) U.S. Environmental Protection Agency, Region IX 75 Hawthorne Street San Francisco, CA 94105 In addition, please send a copy of the Answer and all other documents that you file in this action to:

Priyam Desai Office of Regional Counsel (ORC-2-2) U.S. Environmental Protection Agency, Region IX 75 Hawthorne Street San Francisco, CA 94105 desai.priyam@epa.gov

Priyam Desai is the attorney assigned to represent EPA in this matter and can be contacted at desai.priyam@epa.gov or (415) 972-3276.

You are further informed that the Consolidated Rules of Practice prohibit any *ex parte* (unilateral) discussion of the merits of any action with the Regional Administrator, Regional Judicial Officer, Administrative Law Judge, or any person likely to advise these officials in the decision of the case, after the Complaint is issued.

VI. INFORMAL SETTLEMENT CONFERENCE

EPA encourages all parties against whom a civil penalty is proposed to pursue the possibility of settlement through informal conferences. Therefore, regardless of whether you request a hearing or not, you may confer informally with EPA through Ms. Desai, the EPA attorney assigned to this case, regarding the facts of this case, the amount of the proposed penalty, and the possibility of settlement. An informal settlement conference does not, however, affect your obligation to file an Answer to this Complaint.

VII. ALTERNATIVE DISPUTE RESOLUTION

The parties also may engage in any process within the scope of the Alternative Dispute Resolution Act, 5 U.S.C. § 581 *et seq.*, which may facilitate voluntary settlement efforts. Dispute resolution using alternative means of dispute resolution does not divest the Presiding Officer of jurisdiction nor does it automatically stay the proceeding.

VIII. CONSENT AGREEMENT AND FINAL ORDER

EPA has the authority, where appropriate, to modify the amount of the proposed penalty to reflect any settlement reached with you in an informal conference or through alternative dispute resolution. The terms of such an agreement would be embodied in a Consent Agreement and Final Order. A Consent Agreement signed by both parties would be binding as to all terms and conditions specified therein when the Regional Judicial Officer signs the Final Order.

Dated on this 13th day of January 2025.

MATTHEW SALAZAR

Digitally signed by MATTHEW SALAZAR Date: 2025.01.13 10:15:48 -08'00'

Matt Salazar, PE Manager, Toxics Section Enforcement & Compliance Assurance Division U.S. Environmental Protection Agency, Region IX