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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX SAN FRANCISCO, CALIFORNIA

,	
In the Matter of:)	
) Docket No. FIFR	A-09-2025-0033
Twin Med, LLC)	
) COMPLAINT AND	D NOTICE OF
) OPPORTUNITY F	OR 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

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("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 2.

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."

Section 2(t) of FIFRA, 7 U.S.C. § 136(t), provides that "pest" means "any insect, rodent, 4.

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)."

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

5.

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."

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."

8.

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.

Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for 11.

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").

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- 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 23. 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)(l), 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.

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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

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In addition, please send a copy of the Answer and all other documents that you file in this

action to:

Privam 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. <u>INFORMAL SETTLEMENT CONFERENCE</u>

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

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