

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Dale Fitzpatrick, M.D.; Decision and Order

On July 19, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Dale Fitzpatrick, M.D., of Modesto, CA (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BF0553455, alleging that Registrant's registration should be revoked because Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of California, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).¹

The OSC notified Registrant of his right to file with DEA a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.² "A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c),

¹ According to Agency records, Registrant's registration expired on September 30, 2024. The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68,474, 68,476–79 (2019).

² Based on the Government's submissions in its RFAA dated April 18, 2024, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on August 10, 2023, the OSC was successfully delivered to Registrant's registered address, though an individual who was not the Registrant signed to confirm the receipt of the OSC. RFAAX 3, at 2, Attachment A. Further, the DI's Declaration indicates that on August 29, 2023, the OSC was successfully delivered to Registrant's home address, however, it was never signed for. *Id.* at 2, Attachment B. Finally, the DI's Declaration indicates that on December 8, 2023, the OSC was emailed to Registrant's registered email address. *Id.* at 2, Attachment C.

(f), 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, effective January 6, 2023, Registrant surrendered his California physician and surgeon license. RFAAX 2, at 1. According to California online records, of which the Agency takes official notice, Registrant's California physician and surgeon license remains surrendered.³ California DCA License Search, <https://search.dca.ca.gov> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice as a physician in California, the state in which he is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.*, 76 FR 71,371, 71,372 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).⁴

³ Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

⁴ This rule derives from the text of two provisions of the CSA. First, Congress defined the term "practitioner" to mean "a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional

According to California statute, "dispense" means "to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery." Cal. Health & Safety Code § 11010 (West 2024). Further, a "practitioner" means a person "licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in [the] state." *Id.* § 11026(c).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice as a physician in California. As discussed above, an individual must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant currently lacks authority to practice as a physician in California and, therefore, is not currently authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BF0553455 issued to Dale Fitzpatrick, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Dale Fitzpatrick, M.D., to renew or modify this registration, as well as any other pending application of Dale Fitzpatrick, M.D., for additional registration in California. This Order is effective November 22, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 15, 2024, by Administrator

practice." 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 FR at 71,371–72; *Sheran Arden Yeates, D.O.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, D.O.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, D.O.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617.

Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach, Federal Register Liaison Officer, Drug Enforcement Administration. [FR Doc. 2024-24570 Filed 10-22-24; 8:45 am] BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1441]

Importer of Controlled Substances Application: Mylan Technologies Inc

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Mylan Technologies Inc to be registered as an importer of basic class(es) of controlled substance(s). Refer to SUPPLEMENTARY INFORMATION listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before November 22, 2024. Such persons may also file a written request for a hearing on the application on or before November 22, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on https://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All

requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 8, 2024, Mylan Technologies Inc., 110 Lake Street, Saint Albans, Vermont 05478-2266, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Table with 3 columns: Controlled substance, Drug code, Schedule. Rows include Methylphenidate (1724, II) and Fentanyl (9801, II).

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically manufactured FDF to foreign markets. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew Strait, Deputy Assistant Administrator. [FR Doc. 2024-24557 Filed 10-22-24; 8:45 am] BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1440]

Importer of Controlled Substances Application: Halo Pharmaceutical Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Halo Pharmaceutical Inc. to be registered as an importer of basic class(es) of controlled substance(s). Refer to SUPPLEMENTARY INFORMATION

listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before November 22, 2024. Such persons may also file a written request for a hearing on the application on or before November 22, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on https://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on September 11, 2024, Halo Pharmaceutical Inc., 30 North Jefferson Road, Whippany, New Jersey 07981-1030, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Table with 3 columns: Controlled substance, Drug code, Schedule. Row includes Psilocybin (7437, I).

The company plans to import the listed controlled substance to support formulation development and use in clinical trials. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2).