

By order of the Commission.

Issued: November 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

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INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-682 and 731-TA-1592-1593 (Preliminary)]

Certain Freight Rail Couplers and Parts Thereof From China and Mexico

Determinations

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of certain freight rail couplers and parts thereof from China and Mexico, provided for in subheadings 8607.30.10 and 7326.90.86 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (“LTFV”) and to be subsidized by the government of China.²

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission’s rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission’s rules, upon notice from the U.S. Department of Commerce (“Commerce”) of affirmative preliminary determinations in the investigations under §§ 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right

to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On September 28, 2022, McConway & Torley LLC, Pittsburgh, Pennsylvania, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, CLC filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of freight rail couplers from China and LTFV imports of freight rail couplers from China and Mexico. Accordingly, effective September 28, 2022, the Commission instituted countervailing duty investigation no. 701-TA-682 and antidumping duty investigation nos. 731-TA-1592-1593 (Preliminary).

Notice of the institution of the Commission’s investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 5, 2022 (87 FR 60413). The Commission conducted its conference on October 19, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on November 14, 2022. The views of the Commission are contained in USITC Publication 5387 (November 2022), entitled *Certain Freight Rail Couplers and Parts Thereof: Investigation Nos. 701-TA-682 and 731-TA-1592-1593 (Preliminary)*.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1115]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Berkshire Roots, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

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 January 17, 2023.

ADDRESSES: The DEA 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.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice

¹ The record is defined in § 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

² 87 FR 64440 and 87 FR 64444 (October 25, 2022).

does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on October 17, 2022, Berkshire Roots, Inc., 501 Dalton Avenue, Pittsfield, Massachusetts 01201, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract.	7350	I
Marihuana	7360	I

Kristi O'Malley,
Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–50]

Adley Dasilva, P.A.; Decision and Order

On August 18, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Adley Dasilva, P.A. (Respondent). OSC, at 1, 3. The OSC proposed the revocation of Respondent's Certificate of Registration No. MD4826915 at the registered address of 1941 Southeast Port Saint

Lucie Boulevard, Port St. Lucie, Florida 34952. *Id.* at 1. The OSC alleged that Respondent's registration should be revoked because Respondent is “without authority to handle controlled substances in the State of Florida, the state in which [he is] registered with DEA.” *Id.* at 1–2 (citing 21 U.S.C. 824(a)(3)).

By letter dated September 2, 2022, Respondent requested a hearing. On September 15, 2022, the Government filed a Motion for Summary Disposition (Government's Motion), which Respondent opposed. On September 28, 2022, the ALJ granted the Government's Motion and recommended the revocation of Respondent's registration, finding that because Respondent lacks state authority to handle controlled substances in Florida, the state in which he is registered with DEA, there is no genuine issue of material fact. Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (Recommended Decision or RD), at 4–5.

The Agency issues this Decision and Order based on the entire record before it and makes the following findings of fact.

Findings of Fact

On June 8, 2022, the Florida Department of Health issued an Order of Emergency Suspension of License which ordered the immediate suspension of Respondent's Florida P.A. license. Government's Motion Exhibit (GX) B, at 1, 33–34.

According to Florida's online records, of which the Agency takes official notice, Respondent's Florida P.A. license is currently under an “emergency suspension” status and Respondent is not authorized to practice medicine in Florida.¹ Florida Department of Health License Verification, <https://mqa-internet.doh.state.fl.us/MQASearch>

¹ 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, Respondent 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.usdoj.gov.

Services (last visited date of signature of this Order). Accordingly, the Agency finds that Respondent is not currently licensed to engage in the practice of medicine in Florida, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (CSA) “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, the 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 (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).²

² 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 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(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the 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, M.D.*, 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 FR at 27,617. Moreover, because “the controlling question” in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner's registration “is currently authorized to handle controlled substances in the [S]tate,” *Hooper*, 76 FR at 71,371 (quoting *Anne Lazar Thorn*, 62 FR 12,847, 12,848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner is still challenging the underlying action. *Bourne Pharmacy*, 72 FR 18,273, 18,274 (2007); *Wingfield Drugs*, 52 FR 27,070, 27,071 (1987). Thus, it is of no consequence that Respondent is still challenging the underlying action here. *See* Respondent's Response to Government's Motion; RD, at 4–5. What is consequential is the Agency's finding that Respondent is not currently authorized to dispense controlled substances in Florida, the state in which he is registered with the DEA.