

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 marijuana, 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.

[FR Doc. 2022–25175 Filed 11–17–22; 8:45 am]

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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.<sup>1</sup> Florida Department of Health License Verification, <https://mqa-internet.doh.state.fl.us/MQASearch>

<sup>1</sup> 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](mailto: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).<sup>2</sup>

<sup>2</sup> 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.

According to Florida statute, “A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.” Fla. Stat. 893.05(1)(a) (2022). Further, a “practitioner” as defined by Florida statute includes “a physician assistant licensed under chapter 458 or 459.”<sup>3</sup> *Id.* at 893.02(23).

Here, the undisputed evidence in the record is that Respondent is not currently a licensed practitioner in Florida, and a physician assistant must be a licensed practitioner to dispense a controlled substance in Florida. Thus, because Respondent lacks authority to handle controlled substances in Florida, Respondent is not eligible to maintain a DEA registration based in Florida. Accordingly, the Agency will order that Respondent’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. MD4826915 issued to Adley Dasilva, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending applications of Adley Dasilva, P.A., to renew or modify this registration, as well as any other pending application of Adley Dasilva, P.A., for additional registration in Florida. This Order is effective December 19, 2022.

**Signing Authority**

This document of the Drug Enforcement Administration was signed on November 9, 2022, by Administrator 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. 2022–25103 Filed 11–17–22; 8:45 am]

**BILLING CODE 4410–09–P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA–1096]

**Bulk Manufacturer of Controlled Substances Application: Vici Health Sciences, LLC**

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of application.

**SUMMARY:** Vici Health Sciences, LLC has applied to be registered as a bulk manufacturer 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 January 17, 2023. Such persons may also file a written request for a hearing on the application on or before January 17, 2023.

**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.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.33(a), this is notice that on August 5, 2022, Vici Health Sciences, LLC, 6655 Amberton Drive, Suite N, Elkridge, Maryland 21075, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

| Controlled substance  | Drug code | Schedule |
|---|-----------|----------|
| lbogaine .....  | 7260      | I        |
| Fentanyl related-compounds as defined in 21 CFR 1308.11(h). | 9850      | I        |

The company plans to bulk manufacture the listed controlled

substances or their intermediates for sale to its customers. No other activities for these drug codes are authorized for this registration.

**Kristi O’Malley,**

*Assistant Administrator.*

[FR Doc. 2022–25174 Filed 11–17–22; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF JUSTICE**

**Notice of Lodging of Proposed Consent Decree Under the Clean Water Act**

On November 14, 2022, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Illinois in the lawsuit entitled *United States and the State of Illinois v. Prairie State Solar, LLC*, Civil Action No. 3:22–cv–02660.

In this case, the United States and the State seek to resolve claims against Defendant Prairie State Solar, LLC under the Clean Water Act. The United States and the State allege Prairie States violated its state stormwater permit during the construction of a large-scale solar farm in Perry County, Illinois. The proposed Consent Decree requires Prairie State to perform injunctive relief measures to ensure compliance until construction is complete and the stormwater permit is terminated. The Consent Decree also requires Prairie State to pay a civil penalty of \$225,000, with \$157,500 to the United States and \$67,500 to the State of Illinois.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and The State of Illinois v. Prairie State Solar*, D.J. Ref. No. 90–5–1–1–12558/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

| To submit comments: | Send them to:   |
|---------------------|---|
| By email .....      | <a href="mailto:pubcomment-ees.enrd@usdoj.gov">pubcomment-ees.enrd@usdoj.gov</a> .            |
| By mail .....       | Assistant Attorney General,<br>U.S. DOJ—ENRD, P.O.<br>Box 7611, Washington, DC<br>20044–7611. |

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>.

<sup>3</sup> Chapter 458 regulates medical practice and applies to Respondent. GX B, at 2.