

comments or objections were submitted for the notice.

Company	FR docket	Published
Navinta, LLC	84 FR 5498	February 21, 2019.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic class of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed company.

Dated: June 3, 2019.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2019-12504 Filed 6-12-19; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-392]
Bulk Manufacturer of Controlled Substances Application: Sigma Aldrich Research
ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 12, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 7, 2019, Sigma Aldrich Research, Biochemicals, Inc., 400-600 Summit Drive, Burlington, Massachusetts 01803 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
Lysergic acid diethylamide	7315	I
Tetrahydrocannabinols	7370	I
3,4-Methylenedioxymethamphetamine	7405	I
Alpha-methyltryptamine	7432	I
Dimethyltryptamine	7435	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
N-Benzylpiperazine	7493	I
2-(2,5-Dimethoxyphenyl) ethanamine (2C-H)	7517	I
MDPV (3,4-Methylenedioxypropylvalerone)	7535	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Heroin	9200	I
Normorphine	9313	I
Norlevorphanol	9634	I
Amphetamine	1100	II
Nabilone	7379	II
Phencyclidine	7471	II
Cocaine	9041	II
Codeine	9050	II
Ecgonine	9180	II
Levorphanol	9220	II
Meperidine	9230	II
Methadone	9250	II
Morphine	9300	II
Thebaine	9333	II
Levo-alphaacetylmethadol	9648	II
Noroxymorphone	9668	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Fentanyl	9801	II

The company plans to manufacture reference standards.

Dated: June 3, 2019.
John J. Martin,
Assistant Administrator.
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DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. 18-29]
Elizabeth C. Korcz, M.D.; Decision and Order

On March 28, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or

Government), issued an Order to Show Cause (hereinafter, OSC) to Elizabeth C. Korcz, M.D. (hereinafter, Respondent), who is registered in Hoover, Alabama. The OSC proposed to revoke Respondent's DEA Certificate of Registration (hereinafter, COR) No. FK0505428, pursuant to 21 U.S.C. §§ 823(f) and 824(a)(3), on the ground that she does not have authority to handle controlled substances in

Alabama, the State in which she is registered with the DEA. OSC, at 1.

With respect to the DEA's jurisdiction, the OSC alleged that Respondent is registered with the DEA as a practitioner authorized to handle controlled substances in schedules II through V under DEA COR No. FK0505428 at the registered address of 3421 S. Shades Crest Road, Suite 111, Hoover, Alabama 35244. *Id.* The OSC stated that Respondent's registration was current and not due to expire until December 31, 2019. *Id.*

Regarding the substantive grounds for the proceeding, the OSC specifically alleged that Respondent agreed to voluntarily surrender her Alabama Controlled Substance Certificate (hereinafter, CSC) No. ACSC.28343 pending the resolution of an investigation undertaken by the Alabama State Board of Medical Examiners (hereinafter, State Board) alleging Respondent dispensed controlled substances for no legitimate purpose. *Id.* Furthermore, the OSC alleged that the status of Respondent's CSC was listed as "inactive-failed to renew." *Id.* at 2. The OSC stated: "[T]he DEA must revoke . . . [her] COR based upon . . . [her] lack of authority to handle controlled substances in the State of Alabama." *Id.*, citing 21 U.S.C. §§ 823(f) and 824(a)(3).

The OSC then notified Respondent of her right to request a hearing on the allegations, or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to elect either option. *Id.* at 2, citing 21 CFR 1301.43. It also notified her of her right to submit a corrective action plan in accordance with 21 U.S.C. 824(c)(2)(C). *Id.* at 2–3.

By letter dated May 2, 2018, Respondent timely requested a hearing.¹ Hearing Request (hereinafter, HR), at 1. According to the HR, "[Respondent's] license to practice medicine and prescribe controlled substances was under review [by the State Board] when the United States Government raided her practice and served her with a target letter." *Id.* The HR continued: "In light of the federal investigation, . . . [Respondent] requested a stay of the [State Board's] scheduled hearing. In order for the Board to agree to a stay, they requested she voluntarily surrender her ability to prescribe controlled substances. On advice of counsel, she voluntarily agreed." *Id.* Furthermore, the HR stated that Respondent "objects

to the revocation of her DEA registration" and requested that the hearing "be stayed pending the outcome of the investigation." *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). On May 3, 2018, the ALJ issued an Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule.

On May 17, 2018, the Government filed a timely Motion for Summary Disposition (hereinafter, MSD) based on Respondent's lack of State authority to handle controlled substances. MSD, at 1. The Government attached five documents to its MSD. The Government attached a Certification of Registration Status, dated April 12, 2018, with a copy of DEA COR No. FK0505428. *Id.* at Att. 1. In addition, the Government attached a copy of Respondent's voluntary surrender of her Alabama CSC (hereinafter, Voluntary Surrender), which was dated August 23, 2017. *Id.* at Att. 2. Further, the Government attached a copy of the Medical Licensure Commission of Alabama's Order on Motion to Stay, which was dated August 25, 2017. *Id.* at Att. 3. Furthermore, the Government attached a copy of Respondent's License Details from the State Board, which was printed on May 7, 2018. *Id.* at Att. 4. Finally, the Government attached the Declaration of a DEA Diversion Investigator, which was dated May 8, 2018. *Id.* at Att. 5.

According to the MSD, "DEA's investigation reveals that Respondent has agreed to the voluntary surrender of her Alabama . . . [CSC] pending resolution of a current investigation by the [State Board]." MSD, at 3. Furthermore, according to the MSD, Respondent's License Details shows that "the status of the Respondent's [CSC] is listed as 'Inactive-Failed to Renew,' and that [the CSC] expired on December 31, 2017." *Id.* Citing 21 U.S.C. 802(21), 823(f), and 824(a)(3), the Government argues that the DEA "cannot register or maintain the registration of a practitioner not duly authorized to handle controlled substances in the state in which . . . [the practitioner] conducts business." *Id.* Furthermore, the Government contends: "Respondent is currently not authorized to handle controlled substances in the state in which she currently holds a DEA COR." *Id.* at 4. Thus, according to the Government, Respondent is not authorized to possess a DEA COR in Alabama unless she is authorized to dispense controlled substances in the State of Alabama. *Id.* at 3.

Respondent did not file any response to the Government's MSD or evidence. 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 dated June 6, 2018 (hereinafter, R.D.), at 3.

The ALJ granted the MSD and recommended that Respondent's registration be revoked. *Id.* at 6. The ALJ determined: "At this juncture, no dispute exists over the fact that the Respondent currently lacks state authority to handle controlled substances in Alabama due to the voluntary surrender of her . . . [CSC] on August 23, 2017, and the Alabama State Board of Medical Examiner's acceptance of the Respondent's voluntary surrender on August 25, 2017." *Id.* at 5–6. The ALJ continued: "Because the Respondent lacks state authority at the present time, . . . [DEA] precedent dictates that she is not entitled to maintain her DEA registration." *Id.* at 6. The ALJ concluded: "Simply put, there is no contested factual matter that could be introduced at a hearing that would, in the Agency's view, provide authority to allow Respondent to continue to hold her DEA COR." *Id.* The ALJ recommended that Respondent's registration be revoked and that pending applications for renewal be denied. *Id.*

By letter dated July 3, 2018, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ stated that no exceptions were filed by either party.

I issue this Decision and Order based on the entire record before me. 21 CFR § 1301.43(e). I make the following findings of fact.

Findings of Fact

Respondent's DEA Registration

Respondent holds DEA COR No. FK0505428, pursuant to which she is authorized to handle controlled substances in schedules II through V as a practitioner, at the registered address of 3421 S. Shades Crest Road, Suite 111, Hoover, Alabama 35244. MSD, at Att. 1. This registration is in an active pending status and expires on December 31, 2019. *Id.*

The Status of Respondent's State License

On August 23, 2017, Respondent voluntarily surrendered her Alabama CSC after the State Board filed an Order to Show Cause whose allegations include excessive dispensing of controlled substances, dispensing controlled substances for no legitimate medical purpose, and dispensing

¹ Based on the undisputed evidence in the record regarding the date the OSC was served on Respondent, April 2, 2018, I find that Respondent timely requested a hearing.

controlled substances in amounts not reasonably related to the proper medical management of patients' illnesses or conditions. *Id.* at Att. 2. In her Voluntary Surrender, Respondent stated: "I understand and acknowledge I will have no authority to order, dispense, distribute, administer or prescribe controlled substances in the state of Alabama." *Id.* Thus, there is no dispute that Respondent voluntarily surrendered her authority to handle controlled substances in Alabama. Further, as recorded by the State Board, the status of Respondent's CSC is "Inactive-Failed to Renew." *Id.* at Att. 4. Based on my review of the website of the State Board and the Medical Licensure Commission of Alabama, the status of Respondent's CSC has not changed.² Alabama Board of Medical Examiners and Medical Licensure Commission of Alabama Online License Verification, https://abme.igovsolution.com/online/Lookups/Individual_Lookup.aspx (last visited May 22, 2019).

Accordingly, I find that Respondent currently is without authority to dispense controlled substances in Alabama, the State in which she is registered.

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 (hereinafter, CSA), "upon a finding that the registrant . . . has had [her] 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 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 Fed. Appx. 826 (4th Cir. 2012); *Frederick*

Marsh Blanton, M.D., 43 FR 27,616, 27,617 (1978).

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 [s]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 [s]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 a practitioner is no longer authorized to dispense controlled substances under the laws of the State in which she practices. *See, e.g., Hooper, supra*, 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), *Blanton, supra*, 43 FR at 27,617.

Here, the undisputed evidence in the record is that Respondent voluntarily surrendered her Alabama CSC. The fact that Respondent may, some day, regain her State registration to dispense controlled substances does not change the salient fact that Respondent is not currently authorized to handle controlled substances in the State in which she is registered. *Mehdi Nikparvarfard, M.D.*, 83 FR 14,503, 14,504 (2018). Respondent, therefore, is not eligible for a DEA COR. Accordingly, I will order that Respondent's DEA COR be revoked and that any pending application for the renewal or modification of that COR be denied. 21 U.S.C. §§ 823(f) and 824(a)(3).

Order

Pursuant to 28 CFR § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a), I order that DEA COR No. FK0505428 issued to Elizabeth C. Korcz, M.D., be, and it hereby is, revoked. Pursuant to 28 CFR § 0.100(b) and the authority vested in me by 21 U.S.C. § 823(f), I further order that any pending application of Elizabeth C. Korcz, M.D., to renew or modify this registration, as well as any other pending application by her for registration in the State of Alabama be, and it hereby is, denied. This Order is effective July 15, 2019.

Dated: May 22, 2019.

Uttam Dhillon,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Eli-Elsohly Laboratories

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 12, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 14, 2019, Eli-Elsohly Laboratories, Mahmoud A. Elsohly Ph.D., 5 Industrial Park Drive, Oxford, Mississippi 38655 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

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

² 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 my finding by filing a properly supported motion for reconsideration within 15 calendar days of the date of this Order.

Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government; in the event Respondent files a motion, the Government shall have 15 calendar days to file a response.