

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Johnson Matthey Inc.

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 in accordance with 21 CFR 1301.33(a) on or before April 23, 2018.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on November 09, 2017, Johnson Matthey Inc., 2003 Nolte Drive, West Deptford, NJ 08066, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Propiram	9649	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II

Controlled substance	Drug code	Schedule
Diphenoxylate	9170	II
Ecgonine	9180	II
Hydrocodone	9193	II
Meperidine	9230	II
Methadone	9250	II
Methadone intermediate	9254	II
Morphine	9300	II
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to manufacture the above-listed controlled substances in bulk for sale to its customers. Thebaine (9333) will be used to manufacture other controlled substances for sale in bulk to its customers.

In reference to drug codes 7360 (marihuana), and 7370 (THC), the company plans to bulk manufacture these drugs as synthetics. No other activities for these drug codes are authorized for this registration.

Dated: February 6, 2018.

Susan A. Gibson,

Deputy Assistant Administrator.

[FR Doc. 2018-03293 Filed 2-16-18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Taylor Animal Shelter; Order

On October 4, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, issued an Order to Show Cause proposing the revocation of the DEA Certificate of Registration issued to Taylor Animal Shelter of Taylor, Michigan (Respondent). GX 1, at 1. The basis of the proposed action was that, on June 30, 2017, Respondent’s Michigan Controlled Substance Sodium Pentobarbital Facility license lapsed, and thus, it was “currently without authority to handle controlled substances in the State of Michigan, the [S]tate in which [it is] registered with the” Agency. *Id.*; see also 21 U.S.C. § 824(a)(3).

Following service of the Show Cause Order, Respondent submitted a timely written statement of position with exhibits while waiving its right to a hearing. In its position statement, Respondent represented that its state controlled substances registration was renewed on October 30, 2017. Resp.’s Statement at 3, ¶ 10. Respondent attached a copy of a document which states that it is a “Sodium Pentobarbital

Permit for Practice of Animal Euthanasia (Facility Permit).” Resp.’s Statement, at Exhibit E. While much of this document is unreadable, and it is unclear from the document when this permit was issued or expires, Respondent provided an affidavit of the Operations Manager for the Department of Public Works of the City of Taylor, Michigan, which states that on October 30, 2017, he received the renewed state license for the facility. Affidavit of Matt Bonza, at 2. Moreover, the Government does not dispute that the facility has re-obtained state authority to dispense controlled substances. Request for Order Dismissing Order to Show Cause, at 2.

As the Government acknowledges, the sole basis for seeking revocation of Respondent’s DEA registration was “its lack of state authority to handle controlled substances” and “this ground for revocation no longer exists.” *Id.* The Government thus seeks an order dismissing the Order to Show Cause. *Id.* at 3. Accordingly, I will grant the Government’s request and dismiss the Order to Show Cause. *Id.*

Order

Pursuant to the authority vested in me by 21 U.S.C. 824 and 28 CFR 0.100(b), I order that the Order to Show Cause issued to Taylor Animal Shelter be, and it hereby is, dismissed. This Order is effective immediately.

Dated: February 6, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018-03298 Filed 2-16-18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

James E. Ranochak, M.D.; Decision and Order

On September 11, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, issued an Order to Show Cause to James E. Ranochak, M.D. (hereinafter, Registrant), of Fort Wayne, Indiana. The Show Cause Order proposed the revocation of Registrant’s DEA Certificate of Registration No. AR1591913, on the ground that he “do[es] not have authority to handle controlled substances in . . . Indiana, the [S]tate in which [he is] registered with the” Agency. GX 2, at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

As to the jurisdictional basis of the proceeding, the Show Cause Order alleged that Registrant is registered “as a practitioner in Schedules II [through]

V,” under the above registration number, at the location of 3488–B Stellhorn Road, Fort Wayne, Indiana. *Id.* The Order further alleged that this registration does not expire until April 30, 2020. *Id.*

As to the substantive ground for the proceeding, the Show Cause Order alleged that “[o]n August 8, 2017, the Indiana Medical Licensing Board summarily suspended [Registrant’s] medical license for 90 days, effective July 27, 2017” and “[t]his order remains in effect.” *Id.* The Order thus alleged that Registrant is “without authority to handle controlled substances in the State . . . in which [he is] registered.” *Id.* The Order then asserted that Registrant is “required to possess authority from a state in order to obtain or retain a DEA registration,” and that “[c]onsequently, . . . DEA must revoke” his registration. *Id.* at 2 (citations omitted).

The Show Cause Order also notified Registrant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to elect either option. *Id.* (citing 21 CFR 1301.43). The Order also notified Registrant of his right to submit a corrective action plan in accordance with 21 U.S.C. 824(c)(2)(C). *Id.* at 2–3.

On September 14, 2017, a DEA Diversion Investigator went to Registrant’s home address and personally served the Show Cause Order on Registrant. GX 3, at 2 (affidavit of DI). Moreover, in its Request for Final Agency Action which it submitted on November 9, 2017, the Government represents that since the date of service of the Show Cause Order, Registrant has not requested a hearing, nor submitted a written statement or a corrective action plan. Based on the DI’s affidavit and the Government’s representation, I find that more than 30 days have now passed since the date of service of the Show Cause Order and that Registrant has neither requested a hearing nor submitted a written statement or corrective action plan. I therefore find that Registrant has waived his right to request a hearing or submit a written statement and issue this Decision and Order based on relevant evidence submitted by the Government¹ and matters of which I take official notice.

¹ On January 12, 2018, the Government submitted a Supplement to its Request for Final Agency Action which contained an additional exhibit, this being a December 20, 2017 Order of the Medical Licensing Board.

21 CFR 1301.43(d)–(e). I make the following findings.

Findings of Fact

Registrant is the holder of DEA Certificate of Registration No. AR1591913, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 3488–B Stellhorn Road, Fort Wayne, Indiana. GX 1. This registration does not expire until April 30, 2020. *Id.*

Registrant is also the holder of medical license No.01026732A issued by the Medical Licensing Board of Indiana (hereinafter, the Board). GX 3A (Order Granting Summary Suspension), at 1. However, on June 22, 2017, Registrant was indicted in the United States District Court for the Northern District of Indiana on 10 counts of Conspiracy to Commit Healthcare Fraud and Distributing a Controlled Substance. *Id.* at 2. Based on the indictment, on July 27, 2017, the Board summarily suspended Registrant’s medical license for 90 days. *Id.* On December 7, 2017, the Board extended the suspension for an additional 90 days. *See* GX 4, at 3 (Order Granting Summary Suspension Extension, at 2 (Dec. 20, 2017)). Also, according to the Board’s website (of which I take official notice),² the suspension remains in effect as of the date of this Decision an Order; the website also reflects that Registrant’s CSR-Physician License Nos. 01026732B and 01026732C have both expired.

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 . . . 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 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*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton*, 43 FR 27616 (1978).

The Agency’s rule derives from the text of two other provisions of the CSA: Section 802(21), which defines the term

² *See* 5 U.S.C. 556(e).

“practitioner,” and section 823(f), which sets forth the registration requirements applicable to practitioners. Notably, in section 802(21), 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). The text of this provision makes clear that a physician is not a practitioner within the meaning of the CSA if he is not “licensed, registered or otherwise permitted, by the jurisdiction in which he practices . . . to dispense [or] administer . . . a controlled substance in the course of professional practice.” *Id.*

To the same effect, Congress, in setting the requirements for obtaining a practitioner’s registration, 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). Thus, based on these provisions, the Agency held nearly forty years ago that “[s]tate authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance *and maintenance* of a Federal controlled substances registration.” *Blanton*, 43 FR at 27617 (revoking physician’s registration based on one-year suspension of his state license) (emphasis added).

Here, based on the Summary Suspension Order of Registrant’s medical license as well as the information that both of Registrant’s state controlled substance licenses have expired, I find that Registrant is currently without authority to dispense controlled substances in Indiana, the State in which he is registered with DEA. *See* Ind. Code § 35–48–3–3(b) (“Every person who dispenses . . . any controlled substance within Indiana must have a registration issued by the [pharmacy] board in accordance with its rules.”); *see also* Ind. Code § 25–22.5–1–1.1(a)(1)(B) (the “[p]ractice of medicine” includes the “prescription or administration of any form of treatment, without limitation”); *id.* § 25–22.5–1–1(g) (defining “[]physician” to “mean any person . . . who holds [a] valid unlimited license to practice medicine” in the state); *id.* § 25–22.5–8–1 (“It is unlawful for any person to practice medicine . . . in this state without holding a license or permit to do so, as provided in this article.”).

Moreover, because “the controlling question” in a proceeding brought

under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration “is currently authorized to handle controlled substances in the [S]tate,” *Hooper*, 76 FR at 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State’s use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the Indiana Board has employed summary process in suspending Registrant’s state license. What is consequential is that Registrant is no longer currently authorized to dispense controlled substances in Indiana, the State in which he is registered. I will therefore order that his registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration AR1591913, issued to James E. Ranochak, M.D., be, and it hereby is, revoked. This Order is effective immediately.³

Dated: February 6, 2018.

Robert W. Patterson,
Acting Administrator.

[FR Doc. 2018–03301 Filed 2–16–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–37]

Kenneth N. Woliner, M.D.; Decision and Order

On June 6, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Kenneth N. Woliner, M.D. (Respondent), of Boca Raton, Florida. The Show Cause Order proposed the revocation of Respondent’s DEA Certificate of Registration No. BW6830500 on the ground that he “do[es] not have authority to handle controlled substances in the State of Florida, the [S]tate in which [he is] registered with

the DEA.” Order to Show Cause, at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

With respect to the Agency’s jurisdiction, the Show Cause Order alleged that Respondent is the holder of Certificate of Registration No. BW6830500, pursuant to which he is authorized to dispense controlled substances as a practitioner in schedules II through V, at the registered address of 9325 Glades Road, Suite 104, Boca Raton, Florida. *Id.* The Order also alleged that this registration does not expire until May 31, 2018. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on December 29, 2016, the Florida Board of Medicine “revoked [his] authority to practice medicine,” and he is therefore “without authority to handle controlled substances in Florida, the [S]tate in which [he is] registered with the DEA.” *Id.* Based on his “lack of authority to [dispense] controlled substances in . . . Florida,” the Order asserted that “DEA must revoke” his registration. *Id.* (citing 21 U.S.C. 823(f)(1) and 824(a)(3)).

The Show Cause Order notified Respondent of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either option, and (3) the consequence for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of his right to submit a corrective action plan (hereinafter, CAP) to the Assistant Administrator, Diversion Control Division, and the procedure for doing so. *Id.* at 2–3.

On July 6, 2017, Respondent filed a letter with the Office of Administrative Law Judges pursuant to which he requested a hearing on the allegations of the Show Cause Order. Letter from Respondent to Hearing Clerk (dated July 3, 2017) (hereinafter, Hearing Request). In his letter, Respondent did not dispute that his Florida medical license “was revoked.” *Id.* at 1. He maintained, however, that his license “was revoked for issues not relating to controlled substances; and that the revocation . . . is currently under appeal at Florida’s District Court of Appeal.” *Id.* Respondent also advised that he “has not been convicted of any crime, much less one involving controlled substances.” *Id.* Also on July 6, 2017, Respondent submitted his CAP by letter to the Assistant Administrator, Diversion Control Division. Letter from Respondent to Assistant Administrator Louis J. Milione (dated July 3, 2017). In his CAP, Respondent explained:

My corrective action plan is to have my case overturned on appeal. The Initial Brief on the Merits was filed on 6/7/2017. Barring the Court granting extensions of time (if filed), the Department of Health is was [sic] required to file their Answer Brief by 6/27/2017, and our Reply is due 20 days after service of the Answer Brief.

It would seem prudent for the DEA to “postpone the proceedings” until the 1st District Court of Appeal rules on this matter. *Id.* at 1.

Upon receipt of Respondent’s Hearing Request and CAP, the matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). On July 6, 2017, the CALJ issued an order noting that Respondent was appearing *pro se* and advised him “that he has the right to seek representation by a qualified attorney at his own expense.” Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1 & n.1 (citing 21 CFR 1316.50). The CALJ also ordered the Government to file evidence to support the allegation that Respondent lacks state authority to handle controlled substances and an accompanying motion for summary disposition no later than July 18, 2017. *Id.* The CALJ further directed Respondent to file his response to any summary disposition motion no later than August 1, 2017. *Id.* at 2.

On July 6, 2017, the Acting Assistant Administrator received Respondent’s CAP letter. *See* Letter from Acting Assistant Administrator Demetra Ashley to Respondent (dated July 11, 2017) (hereinafter CAP Rejection Ltr), at 1. However, on July 10, 2017, before the Acting Assistant Administrator had ruled on Respondent’s CAP (and eight days before its summary disposition motion was due), the Government filed its Motion for Summary Disposition. In its Motion, the Government argued that it is undisputed that the Florida Board of Medicine revoked Respondent’s Florida medical license. Government’s Motion for Summary Disposition (Govt. Mot.), at 2. The Government further argued “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 both obtaining and maintaining a practitioner’s registration” under the Controlled Substances Act (CSA). *Id.* at 3 (citation omitted). As support for its summary disposition request, the Government attached, *inter alia*, a certified copy of the Florida Board of Medicine’s December 29, 2016 “Final Order” revoking Respondent’s license to

³ For the same reasons that led the Indiana Board to summarily suspend Registrant’s medical license (his indictment in federal district court on 10 counts of Conspiracy to Commit Health Care Fraud and Distributing a Controlled Substance), I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.