DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–21]

William S. Husel, D.O.; Decision and Order

On April 9, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to William S. Husel, D.O. (hereinafter, Respondent) of Columbus, Ohio. OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. FH4036667. It alleged that Respondent is without ''authority to handle controlled substances in the State of Ohio, the state in which [Respondent is] registered with the DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that the State Medical Board of Ohio (hereinafter, Board) summarily suspended Respondent's certificate to practice osteopathic medicine and surgery on January 25, 2019. *Id.* at 2.

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. OSC, at 1, 3 (citing 21 U.S.C. 824(c)(2)(C)).

Respondent, through his counsel, timely requested a hearing via an email dated April 30, 2019.[1] Hearing Request, at 1. In his hearing request, Respondent admitted that his Ohio Medical License was summarily suspended on January 25, 2019, and stated that he was preparing for his hearing before the State Medical Board of Ohio. *Id.* He also stated that ''he ha[d] not prescribed any controlled substances while on suspension.'' *Id.*

The Office of Administrative Law Judges (hereinafter, OALJ) put the matter on the docket and assigned it to Administrative Law Judge Charles Dorman (hereinafter, ALJ). The ALJ issued a briefing schedule to both parties on May 1, 2019, directing the Government ''to file evidence to support its allegation that Respondent lacks state authority to handle controlled substances, or any other grounds upon which it seeks summary disposition,'' and any motion for summary disposition, by May 15, 2019. Briefing Schedule for Lack of State Authority Allegations (hereinafter, Briefing Order), at 1. The ALJ directed that ''if the Government files a motion for summary disposition, Respondent's reply is due on May 29, 2019.'' *Id.* The ALJ also noted that Respondent's counsel's email address was included in Respondent's Hearing Request, and provided instructions in the event Respondent's counsel declined to participate in future electronic receipt of orders from the OALJ. *Id.* at 2.

The Government timely complied with the Briefing Order by filing a Motion for Summary Disposition on May 15, 2019. Government's Motion for Summary Disposition (hereinafter, MSD). In its MSD, the Government stated that Respondent ''lacks authority to handle controlled substances in the State of Ohio, the jurisdiction where he is licensed to practice osteopathic medicine and where he is registered with DEA, because his osteopathic medical license is suspended,'' and therefore, he ''does not have state authority to prescribe, administer, or dispense controlled substances in the State of Ohio.'' *Id.* at 3. Thus, the Government contends, ''Respondent is not authorized to possess a DEA registration'' in Ohio. *Id.* In support of its assertion, the Government provided a copy of the Board's ''Entry of Order'' (hereinafter, Order) dated January 25, 2019, which ordered that ''effective immediately,'' Respondent's ''certificate . . . to practice osteopathic medicine and surgery in the State of Ohio be summarily suspended,'' and that Respondent ''shall immediately cease the practice of osteopathic medicine and surgery in Ohio.'' MSD, Exhibit (hereinafter, EX) 2, at 7.

The Government's MSD included the Board's certification that the Order and Notice 1, dated January 25, 2019, and Notice 2, dated February 13, 2019, are ''true and correct copies'' of the proceedings of the Board. MSD, EX2, at 1, 6.

Respondent failed to file a response to the MSD by the filing deadline in the ALJ's Briefing Order, nor did he file a response by the date of the ALJ's recommended decision, and the ALJ deemed the Government's motion unopposed. Order Granting Summary Disposition and Recommended Findings of Fact, Conclusions of Law, and Decision (hereinafter, SD), at 4.

The ALJ granted the MSD, finding that '''there is no factual dispute of substance''' and that the Government ''has provided 'reliable and probative evidence' of 'appropriate evidentiary quality' that Respondent lacks state authority to handle controlled substances in Ohio.'' SD, at 8. (Citations omitted). The ALJ also found that ''summary disposition is additionally warranted because the Government carried its burden and [Respondent] failed to respond.'' *Id.*

The ALJ recommended revocation of Respondent's registration because ''the Government has presented sufficient evidence to establish that [Respondent] lacks state authority to dispense controlled substances in Ohio, the state in which [he] holds his DEA registration.'' *Id.* at 9.

By letter dated June 24, 2019, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions and that the time period to do so had expired.

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

On September 10, 2016, Respondent renewed DEA Certificate of Registration No. FH4036667, at the registered address of 793 West State Street, Columbus, Ohio. MSD, EX1 (Certification of Registration History), at 1. Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Respondent's registration expired on October 31, 2019.[2] *Id.* at 1.

The Status of Respondent's State License

On January 25, 2019, the Board issued an Order and Notice summarily suspending Respondent's certificate to practice osteopathic medicine and surgery in the State of Ohio, finding that there was ''clear and convincing evidence'' that Respondent violated Ohio law. MSD, EX2 at 7; *see also* MSD, EX2, at 9–11. In its Order, the Board found that Respondent's ''continued practice presents a danger of immediate and serious harm to the public.'' MSD, EX2, at 7. On the same date, the Board also issued a Notice of Summary Suspension and Opportunity for

[1] The Hearing Request was filed with the Office of Administrative Law by email after 5 p.m. on April 30, 2019, therefore the ALJ deemed the filing date to be May 1, 2019. Briefing Order, at 1. Respondent's Hearing Request was also filed by U.S. Mail, received on May 9, 2019.

[2] The fact that Respondent allowed his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, MD,* 84 FR 68,474 (2019).

Hearing (hereinafter, Notice) to Respondent, notifying him that his ''certificate/license to practice osteopathic medicine and surgery in the State of Ohio is summarily suspended'' and that ''at this time [he is] no longer authorized to practice osteopathic medicine and surgery in Ohio.'' *Id.* at 9. In its Notice, the Board specifically alleged that Respondent's employer hospital terminated his employment ''after determining that the medical treatment [Respondent] provided was below the standard of care and jeopardized the safety of patients'' because ''at least twenty-seven patients received doses of controlled substances that significantly exceeded the acceptable dose range and were at fatal levels.'' *Id.*

The Notice alleged that Respondent's conduct constituted a '' 'failure to maintain minimal standards applicable to the selection or administration of drugs' '' and '' 'a departure from . . . minimal standards of care of similar practitioners under the same or similar circumstances,' '' and his actions ''were in bad faith, and/or outside the scope of [his] authority, and/or not in accordance with reasonable medical standards.'' *Id.* at 10 (quoting Ohio Rev. Code Ann. §§ 4731.22(B)(2) and (B)(6).

The Notice also informed Respondent that he was entitled to a hearing on the Board's allegations. MSD, EX2, at 11. The Government also provided a copy of a second Notice of Opportunity for Hearing (hereinafter, Notice 2) issued by the Board on February 13, 2019, which contained additional allegations of violations of Ohio law and advised Respondent of his right to a hearing before the Board. *Id.* at 2–4. Respondent was ordered to ''immediately cease the practice of osteopathic medicine and surgery in Ohio.'' *Id.* at 7.

According to Ohio's online records, of which I take official notice, Respondent's license is still suspended. [3] *https://elicense.ohio.gov/oh_verifylicense?firstName=&lastName=Husel&licenseNumber=&searchType=individual* (last visited January 30, 2020).

Accordingly, I find that Respondent currently is not licensed to engage in the practice of medicine in Ohio, the state in which Respondent 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 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, MD,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, MD,* 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 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,* 76 FR at 71,371–72; *Sheran Arden Yeates, MD,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, MD,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, MD,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

Under Ohio law, ''No person shall knowingly obtain, possess, or use a controlled substance or a controlled substance analog,'' except [4] pursuant to a ''prescription issued by a licensed health professional authorized to prescribe drugs if the prescription was issued for a legitimate medical purpose.'' Ohio Rev. Code Ann. §§ 2925.11(A), (B)(1)(d) (West, Westlaw current through File 21 of the 133rd General Assembly (2019–2020)).

Ohio law further states that a '' '[l]icensed health professional authorized to prescribe drugs' or a 'prescriber' means an individual who is authorized by law to prescribe drugs or dangerous drugs . . . in the course of the individual's professional practice.'' Ohio Rev. Code Ann. § 4729.01(I) (West, Westlaw current through Files 1 to 20 of the 133rd General Assembly (2019–2020)). The definition further provides a limited list of authorized prescribers, the relevant provision of which is ''[a] physician authorized under Chapter 4731[ ] of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.'' *Id.* at § 4729.01(I)(4). In addition, the Ohio Uniform Controlled Substances Act permits ''[a] licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the professional's practice'' to prescribe or administer schedule II, III, IV, and V controlled substances to patients. Ohio Rev. Code Ann. § 3719.06(A)(1)(a)–(b) (West, Westlaw current through Files 1 to 20 of the 133rd General Assembly (2019–2020)).

Here, the undisputed evidence in the record is that Respondent currently lacks authority to practice medicine in Ohio. As already discussed, a physician is authorized by law to prescribe or administer drugs in Ohio only when authorized to practice medicine and surgery under Ohio law. Thus, because Respondent lacks authority to practice medicine in Ohio and, therefore, is not authorized to handle controlled substances in Ohio, Respondent is not eligible to maintain a DEA registration. Accordingly, I will order that Respondent's DEA registration be revoked.

[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, Respondent may dispute my finding by filing a properly supported motion for reconsideration within fifteen 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 fifteen calendar days to file a response. Any such motion and response may be filed and served by email (*dea.addo.attorneys@dea.usdoj.gov*) or by mail to Office of the Administrator, Attn: ADDO, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

[4] Other irrelevant exceptions omitted.

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. FH4036667 issued to William S. Husel, D.O. 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 application of William S. Husel to renew or modify this registration, as well as any other applications of William S. Husel for an additional registration in Ohio. This Order is effective April 9, 2020.

Dated: January 29, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–04837 Filed 3–9–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–592]

Importer of Controlled Substances Application: Johnson Matthey Inc.

ACTION: Notice of application.

DATES: Registered importers 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 April 9, 2020. Such persons may also file a written request for a hearing on the application on or before April 9, 2020.

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

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on September 11, 2019, Johnson Matthey Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066–1742 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Coca Leaves	9040	II
Thebaine	9333	II
Opium, raw	9600	II
Noroxymorophone	9668	II
Poppy Straw Concentrate	9670	II
Fentanyl	9801	II

The company plans to import Coca Leaves (9040), Opium, raw (9600), and Poppy Straw Concentrate (9670) in order to bulk manufacture active pharmaceutical ingredients (API) for distribution to its customers. The company plans to also import Thebaine (9333), Noroxymorophone (9668), and Fentanyl (9801) to use as analytical reference standards, both internally and to be sold to their customers to support testing of Johnson Matthey Inc.'s active pharmaceutical ingredients (API's) only.

Dated: February 10, 2020.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–04836 Filed 3–9–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–582]

Bulk Manufacturer of Controlled Substances Application: S&B Pharma, Inc.; Correction

ACTION: Notice of application; correction.

SUMMARY: The Drug Enforcement Administration (DEA) published a document in the **Federal Register** on November 22, 2019, concerning a notice of application. As that document correctly indicated, the applicant, S&B Pharma, Inc., DBA Norac Pharma, 405 South Motor Avenue, Azusa, California 91702–3232 applied to be registered as a bulk manufacturer of a number of controlled substances, to include applying for authorization in order to synthetically manufacture using drug code 7360 (marihuana). However, on the notice of application published, drug code 7360 was inadvertently identified and listed as Gamma Hydroxybutyric Acid instead of Marihuana.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 22, 2019, in FR Doc. 2019–25402 (84 FR 64563), on page 64564, correct the listing of drug code 7360 to be identified as Marihuana, as is shown below.

Controlled substance	Drug code	Schedule
Marihuana	7360	I

Dated: February 11, 2020.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–04829 Filed 3–9–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–594]

Importer of Controlled Substances Application: Arizona Department of Corrections

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 9, 2020. Such persons may also file a written request for a hearing on the application on or before April 9, 2020.

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