

Look Up, [https://elicense.ohio.gov/oh\\_verifylicense](https://elicense.ohio.gov/oh_verifylicense) (last visited date of signature of this Order). Accordingly, I find that Respondent is not currently licensed to practice medicine in Ohio, 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 (hereinafter, 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 27616, 27617 (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 71371–72; *Sheran Arden Yeates, M.D.*, 71 FR

39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton*, 43 FR 27617.

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 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (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 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the final outcome of the underlying action may still be pending. What is consequential is my finding that Respondent is not currently authorized to dispense controlled substances in Ohio, the state in which he is registered with the DEA.

Under Ohio law, “[n]o person shall knowingly obtain, possess, or use a controlled substance or a controlled substance analog,” except<sup>6</sup> 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 2021). Ohio law further states that a “[l]icensed health professional authorized to prescribe drugs’ or ‘prescriber’ means an individual who is authorized by law to prescribe drugs or dangerous drugs . . . in the course of the individual’s professional practice.” *Id.* at § 4729.01(I). 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)(5). 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. *Id.* at § 3719.06(A)(1)(a)–(b).

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.

### 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. FK6714504 issued to Austin J. Kosier, M.D. 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 Austin J. Kosier, M.D. to renew or modify this registration, as well as any other pending application of Austin J. Kosier, M.D., for additional registration in Ohio. This Order is effective March 2, 2022.

Anne Milgram,  
Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA–946]

#### Importer of Controlled Substances Application: Mylan Pharmaceuticals Inc.

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

**ACTION:** Notice of application.

**SUMMARY:** Mylan Pharmaceuticals Inc. has applied to be registered as an importer 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 file written comments on or objections to the issuance of the proposed registration on or before March 2, 2022. Such persons may also file a written request for a hearing on the application on or before March 2, 2022.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield,

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).

<sup>6</sup>Other irrelevant exceptions omitted.

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

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.34(a), this is notice that on December 7, 2021, Mylan Pharmaceuticals Inc., 2898 Manufacturers Road, Greensboro, North Carolina 27406-4600, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Remifentanyl .....	9739	II

The company plans to import the above controlled substance as a Federal Drug Administration-approved drug product in finished dosage form for commercial distribution to its customers.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2).

**Brian S. Besser,**

*Acting Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. 21-11]

**Michael E. Smith, D.V.M.; Decision and Order**

On December 3, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Michael E. Smith, D.V.M. (hereinafter, Respondent) of Zanesville, Ohio. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1 and 5. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration No. W20010614C (hereinafter, COR or registration) and the denial of any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(2) and 824(a)(4) because Respondent was convicted of a felony related to controlled substances and because "[Respondent's] registration

would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.* at 1.

On January 1, 2021, the Respondent timely requested a hearing, which commenced (and ended) on April 19, 2021, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On June 30, 2021, Administrative Law Judge Paul E. Soeffing (hereinafter, the ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD).

By letter dated August 5, 2021, the ALJ certified and transmitted the record to me for final Agency action. In the letter, the ALJ advised that the Respondent filed untimely exceptions to the Recommend Decision on July 26, 2021. The ALJ stated that the Respondent had received an extension of time to file his exceptions by 2:00 p.m. ET on July 26, but did not file them until 2:58 p.m. ET. The ALJ also advised that the Government filed its Response to the Respondent's Exceptions on August 5, 2021.

Having reviewed the entire record, I find Respondent's Exceptions without merit and I adopt the ALJ's rulings, findings of fact as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.\*<sup>A</sup> Although Respondent's Exceptions were untimely, in this case, I decided to nonetheless consider and address each of Respondent's Exceptions, and issue my final Order in this case following the Recommended Decision.

**Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge**

*Paul E. Soeffing*

*U.S. Administrative Law Judge*

June 30, 2021

\*<sup>B</sup>The issue in this case is whether the record as a whole establishes by a preponderance of the evidence that the Respondent's application for a DEA

<sup>A</sup>I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the Chief ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun "I" refers to myself—the Administrator.

<sup>B</sup>I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

COR, Control No. W20010614C, should be denied, and any other pending applications for additional registrations should be denied, pursuant to 21 U.S.C. 824(a)(2) and (a)(4), because the Respondent has been convicted of a felony relating to controlled substances, and because his registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

**I. Findings of Fact**

*A. Allegations*

The Government alleges that the Respondent's application for a DEA COR, Control No. W20010614C, should be denied and any applications by the Respondent for any other DEA registrations should be denied, pursuant to 21 U.S.C. 824, because (1) Respondent has been convicted of a felony relating to controlled substances; and (2) that registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).

*B. Stipulations*

The Government and the Respondent agreed to fourteen stipulations, which I recommend be accepted as fact in these proceedings:

1. Respondent was previously registered with the DEA to handle controlled substances in Schedules II through V under DEA COR No. FS1126146 at 100 Sally Road, Zanesville, Ohio 43701.
2. Respondent surrendered DEA COR No. FS1126146 for cause on or about July 20, 2015, pursuant to his plea agreement in Case CR2015-0052, *State of Ohio v. Michael E. Smith*.
3. Respondent submitted an electronic application for a new DEA COR on or about February 3, 2020.
4. Government Exhibit No. 1 is a true and correct copy of Respondent's February 3, 2020 application for a DEA COR.
5. Government Exhibit No. 2 is a true and correct copy of the Certification of Registration History showing Respondent's answers to the liability questions from his February 3, 2020 application for a DEA COR.
6. Government Exhibit No. 3 is a true and correct copy of the docket sheet in Case CR2015-0052, *State of Ohio v. Michael E. Smith*.
7. Government Exhibit No. 4 is a true and correct copy of Respondent's signed plea agreement, dated July 20, 2015, in Case CR2015-0052, *State of Ohio v. Michael E. Smith*.
8. Government Exhibit No. 5 is a true and correct copy of the court's entry of Respondent's plea agreement, dated July 23,