

who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.”). The Agency has previously found that proof of a single act of intentional or knowing diversion is sufficient to satisfy the Government’s *prima facie* burden of showing that a practitioner’s continued registration is inconsistent with the public interest. *McNichol*, 77 FR at 57,145–46 (2012); *see also*, *Alan H. Olefsky*, 57 FR 928, 928–29 (1992) (revoking registration based on physician’s presentation of two fraudulent prescriptions to pharmacist in single act where physician failed to acknowledge his misconduct). Accordingly, I find that the evidence in this matter establishes Registrant “has committed such acts as would render his registration . . . inconsistent with the public interest.” *See* 21 U.S.C. 824(a)(4).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Registrant “failed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant” under the CSA. 21 U.S.C. 824(d)(2). The substantial evidence that Registrant was issuing prescriptions for controlled substances without a legitimate medical purpose and outside the usual course of professional practice also establishes that there was “a substantial likelihood [that an] . . . abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension” of Registrant’s registration. *Id.* As I found above, the recording of the February 16, 2018 visit between Registrant and the undercover officers and the undercover officers’ accountings of their other visits establish that Registrant unlawfully prescribed controlled substances to the officers without conducting physical examinations and wrote controlled substance prescriptions in TFO Two’s name for her to give to TFO One. Thus, at the time the Government issued the OSC, the Government had clear evidence of Registrant’s violations of law.

### III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that a Registrant’s continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.*, 83 FR 18,882, 18,910 (2018) (collecting cases). Registrant did not present any evidence of remorse for his past misconduct or evidence of

rehabilitative actions taken to correct his past unlawful behavior. Further, he provided no assurances that he would not engage in such conduct in the future. Absent such evidence and such assurances in this matter, I find that continued registration of Registrant is inconsistent with the public interest. Registrant’s silence weighs against his continued registration. *Zvi H. Perper, M.D.*, 77 FR 64,131, 64,142 (2012) (citing *Med. Shoppe-Jonesborough*, 73 FR at 387); *see also Samuel S. Jackson*, 72 FR 23,848, 23,853 (2007). Accordingly, I find that the factors weigh in favor of sanction, and I shall order the sanctions the Government requested, as contained in the Order below.

### IV. 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 FS3042885 issued to Zeljko Stjepanovic, 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 Zeljko Stjepanovic, M.D. to renew or modify this registration. This Order is effective January 11, 2021.

**Timothy J. Shea,**

*Acting Administrator.*

[FR Doc. 2020–27231 Filed 12–10–20; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Anindita Nandi, M.D.; Decision and Order

On January 31, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Anindita Nandi, M.D. (hereinafter, Registrant) of Jersey City, New Jersey. OSC, at 1. The OSC proposed the revocation of Registrant’s Certificate of Registration No. FN5040136. *Id.* It alleged that Registrant has “no state authority to handle controlled substances.” *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that, “[o]n September 25, 2018, the New Jersey State Board of Medical Examiners (hereinafter, BME) issued an Order of Temporary Suspension of License, suspending . . . [Registrant’s] license to practice medicine and surgery in the State of New Jersey, effective September 12, 2018.” OSC, at 2. The OSC further alleged that Registrant’s “State of New Jersey C[ontrolled] D[angerous]

S[ubstance] (hereinafter, CDS) license is in an ‘Inactive’ status, having expired on October 31, 2018.” *Id.* The OSC concluded that “[c]onsequently, the DEA must revoke . . . [her] DEA registration based on . . . [her] lack of authority to handle controlled substances in the State of New Jersey.” *Id.*

The OSC notified Registrant 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 Registrant of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

### Adequacy of Service

In a sworn Declaration, dated May 21, 2020, a DEA Diversion Investigator assigned to the Newark Division Office (hereinafter, DI) stated that he attempted personal service of the OSC on Registrant at the Hudson County Correctional Facility. Request for Final Agency Action (hereinafter, RFAA), EX 5 (DI Declaration), at 1. Registrant, however, refused to meet with DI. *Id.*

DI, therefore, sent the OSC to Registrant certified mail, return receipt requested. *Id.* He attached the executed return receipt card, dated February 26, to his Declaration. *Id.* at Attachment C. Further evidence of the adequacy of the Government’s service is Registrant’s proposed Corrective Action Plan (hereinafter, CAP) and waiver of hearing dated March 4, 2020. RFAA EX 6 (CAP), at 1. Accordingly, I find that the Government’s service of the OSC was adequate.

### Registrant’s Proposed CAP

As already discussed, Registrant timely submitted a proposed CAP and waiver of hearing. *Id.* In her CAP, Registrant asked that this proceeding be discontinued or postponed. *Id.* She alleged that she received notification of the reactivation of her medical license in July 2019. *Id.* at 2. Further, she alleged that she timely renewed her “second State of NJ CDS Account.” *Id.*

I find that Registrant waived her right to a hearing and proposed a CAP. I find that the Assistant Administrator, Diversion Control Division, denied Registrant’s CAP request that the administrative proceeding be discontinued or deferred. RFAA EX 7 (Letter Denying Proposed CAP), at 1. I also find that the Assistant Administrator concluded that “there is no potential modification of . . . [her proposed CAP] that could or would alter

. . . [his] decision in this regard.” *Id.* I agree.

The Government forwarded its RFAA, along with the evidentiary record, to my office on May 26, 2020. In its RFAA, the Government represented that “Registrant has no valid medical license or CDS registration in New Jersey.” RFAA, at 3. The Government requested that Registrant’s registration be revoked. *Id.* at 4.

I issue this Decision and Order based on the record submitted by the Government in its RFAA, which constitutes the entire record before me.<sup>1</sup> 21 CFR 1301.43(e).

## Findings of Fact

### Registrant’s DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FN5040136 at the registered address of 610 Washington Boulevard, Jersey City, NJ 07310. RFAA, EX 1 (Certification of Registration History), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant’s registration expired on October 31, 2020.<sup>2</sup> *Id.*

### The Status of Registrant’s State License and Registration

The Government submitted a certified copy of the “Order of Temporary Suspension of License” concerning Registrant that the BME issued on September 25, 2018. RFAA, EX 3 (hereinafter, Temporary Suspension Order). The Temporary Suspension Order “temporarily suspended (Registrant’s New Jersey medical license) pending final adjudication of the allegations of the Verified Complaint.” *Id.* at 12. It ordered Registrant immediately to cease and desist practicing medicine in New Jersey and it set out the steps required for Registrant’s reinstatement. *Id.* at 12–13.

The Government also submitted a Certification from the New Jersey Drug Control Unit stating that Registrant’s “CDS registration became inactive on September 25, 2018, when a suspension was imposed on her medical license. Her CDS registration remains inactive.” RFAA, EX 4 (New Jersey Attorney General, Division of Consumer Affairs, Drug Control Unit, Certification that Registrant’s CDS registration is

“Inactive”), at 1. The Certification is dated January 17, 2020. *Id.*

As already discussed, Registrant’s proposed CAP alleged that her New Jersey medical license was “reactivated” in July 2019 and that her controlled dangerous substance registration was “timely . . . renewed.” RFAA, EX 6, at 2. Her proposed CAP, however, did not include evidence documenting or supporting her allegations.

According to New Jersey’s online records, Registrant’s medical license is still suspended today.<sup>3</sup> New Jersey Division of Consumer Affairs License Information, <https://www.njconsumeraffairs.gov> (last visited date of signature of this Order). The evidence that the Government submitted with its RFAA, EX 3 and EX 8, and the evidence from today’s New Jersey online records outweigh Registrant’s unsupported allegation about her “reactivated” medical license. Accordingly, I find that Registrant’s New Jersey medical license is currently suspended.

The Government’s RFAA includes evidence that Registrant’s New Jersey controlled dangerous substance registration is inactive. RFAA, EX 4, at 1. Registrant’s CAP did not include evidence supporting her allegation that she “timely . . . renewed” her New Jersey controlled dangerous substance registration. RFAA, EX 6, at 2. The Government’s evidence outweighs Registrant’s unsupported allegation. Accordingly, I find that Registrant is not authorized in New Jersey to dispense controlled substances. *See also infra* Discussion section.

## Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued

<sup>3</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, Applicant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact 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 Applicant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response shall be filed and served by email on the other party at the email address the party submitted for receipt of communications related to this administrative proceeding, and on the Office of the Administrator, Drug Enforcement Administration at [dea.addo.attorneys@dea.usdoj.gov](mailto:dea.addo.attorneys@dea.usdoj.gov).

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 Agency has long stated that the possession of authority to dispense controlled substances under the laws of the state in which the 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).

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 Agency has repeatedly stated that revocation of a practitioner’s registration is the appropriate sanction whenever she is no longer authorized to dispense controlled substances under the laws of the state in which she 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, M.D.*, 43 FR at 27,617.

According to New Jersey statute, “Practitioners shall be registered to dispense substances in Schedules II through IV if they are authorized to dispense or conduct research under the law of this State.” N.J. Stat. Ann. § 24:21–11(c) (West, current with laws through L. 2020, c. 109 and J.R. No. 2); *see also* N.J. Stat. Ann. § 24:21–10(a) (West, current with laws through L. 2020, c. 109 and J.R. No. 2) (“Every person who manufactures, distributes, or dispenses any controlled dangerous

<sup>1</sup> The RFAA includes Registrant’s proposed CAP/hearing waiver.

<sup>2</sup> The fact that a Registrant’s registration expires 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, M.D.*, 84 FR 68,474 (2019).

substance within this State . . . shall obtain a registration issued by the division in accordance with rules and regulations promulgated by it.”)

New Jersey statute defines “practitioner” as a “physician.” N.J. Stat. Ann. § 24:21–2 (West, current with laws through L. 2020, c. 109 and J.R. No. 2). It defines “physician” as “a physician authorized by law to practice medicine in this or any other state.” *Id.*

Here, the weight of the evidence in the record is that Registrant’s license to practice medicine is currently suspended and that her CDS registration is inactive. In New Jersey, as already discussed, a “practitioner” must be a physician authorized by law to practice medicine. *Id.* As such, she is not a “physician” or a “practitioner” as New Jersey statute defines those terms. *Id.* Thus, since Registrant lacks authority to practice medicine in New Jersey and does not have an active New Jersey CDS registration, she is not eligible to dispense controlled substances in that state. N.J. Stat. Ann. § 24:21–11(c). As such, based on the overwhelming record evidence and the law in New Jersey, I find that Registrant is not authorized to dispense controlled substances in New Jersey. 21 U.S.C. 824(a)(3). Accordingly, I will order that Registrant’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. FN5040136 issued to Anindita Nandi, M.D. This Order is effective January 11, 2021.

**Timothy J. Shea,**

*Acting Administrator.*

[FR Doc. 2020–27235 Filed 12–10–20; 8:45 am]

**BILLING CODE 4410–09–P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA–748]

**Bulk Manufacturer of Controlled Substances Application: Sterling Pharma USA, LLC**

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

**ACTION:** Notice of application.

**SUMMARY:** Sterling Pharma USA, LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental 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 February 9, 2021. Such persons may also file a written request for a hearing on the application on or before February 9, 2021.

**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 August 24, 2020, Sterling Pharma USA, LLC, 1001 Sheldon Drive, Suite 101, Cary, North Carolina 27513–2079, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols ..	7370	I

The company plans to manufacture in bulk drug code 7370 (Tetrahydrocannabinols) exclusively from hemp extract, for distribution and sale to its customers. No other activities for this drug code is authorized for this registration.

**William T. McDermott,**

*Assistant Administrator.*

[FR Doc. 2020–27240 Filed 12–10–20; 8:45 am]

**BILLING CODE 4410–09–P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA–752]

**Bulk Manufacturer of Controlled Substances Application: Johnson Matthey, Inc.**

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

**ACTION:** Notice of application.

**SUMMARY:** Johnson Matthey, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental 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 February 9, 2021. Such persons may also file a written request

for a hearing on the application on or before February 9, 2021.

**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 November 2, 2020, Johnson Matthey, Inc., 2003 Nolte Drive West Deptford, New Jersey 08066–1742, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana .....	7360	I
Tetrahydrocannabinols ..	7370	I
Dihyromorphine .....	9145	I
Difenoxin .....	9168	I
Amphetamine .....	1100	II
Methamphetamine .....	1105	II
Lisdexamfetamine .....	1205	II
Methylphenidate .....	1724	II
Nabilone .....	7379	II
Norfentanyl .....	8366	II
Cocaine .....	9041	II
Codeine .....	9050	II
Dihydrocodeine .....	9120	II
Oxycodone .....	9143	II
Hydromorphone .....	9150	II
Diphenoxylate .....	9170	II
Ecgonine .....	9180	II
Hydrocodone .....	9193	II
Levorphanol .....	9220	II
Meperidine .....	9230	II
Methadone .....	9250	II
Methadone intermediate	9254	II
Morphine .....	9300	II
Thebaine .....	9333	II
Opium tincture .....	9630	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 bulk manufacture the listed controlled substances for the internal use intermediates or for sale to its customers. In reference to drug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

**William T. McDermott,**

*Assistant Administrator.*

[FR Doc. 2020–27241 Filed 12–10–20; 8:45 am]

**BILLING CODE 4410–09–P**