

statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.
 Issued: June 7, 2018.

Lisa Barton,
Secretary to the Commission.
 [FR Doc. 2018-12651 Filed 6-12-18; 8:45 am]
BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-392]
Bulk Manufacturer of Controlled Substances Application: Alcami Wisconsin Corporation

ACTION: Notice of application.

² All contract personnel will sign appropriate nondisclosure agreements.
³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

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 13, 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 delegated to the Assistant Administrator of the DEA Diversion Control Division ("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 May 3rd, 2018, Alcami Wisconsin Corporation, W130 N10497 Washington Dr., Germantown, WI 53022 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Alfentanil	9737	II

The company plans to provide bulk active pharmaceutical ingredient to support clinical trials.

Dated: June 6, 2018.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2018-12684 Filed 6-12-18; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
Gazelle A. Craig, D.O.; Decision and Order

On September 20, 2017, the Acting Assistant Administrator, Diversion

Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Gazelle A. Craig, D.O. (hereinafter, Respondent), of Houston, Texas. GX 2 (Order to Show Cause). The Show Cause Order proposed the revocation of Respondent's Certificate of Registration on the ground that she does "not have authority to handle controlled substances in the State of Texas, the [S]tate in which . . . [she is] registered with the DEA." *Id.* at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

As to the Agency's jurisdiction, the Show Cause Order alleged that Respondent holds DEA Certificate of Registration No. FC1384306, which authorizes her to dispense controlled substances in schedules II through V as a practitioner, at the registered address of Gulfton Community Health Center, 6306 Gulfton St., Suite 101, Houston, Texas 77081. *Id.* The Show Cause Order alleged that this registration expires on August 31, 2018. *Id.*

As the substantive ground for the proceeding, the Show Cause Order alleged that Respondent is "without authority to handle controlled substances in the State of Texas, the [S]tate in which . . . [she is] registered . . . with the DEA." *Id.* It further alleged that, on July 28, 2017, the Texas Medical Board temporarily suspended Respondent's medical license and that the Texas Medical Board order remains in effect. *Id.* The Show Cause Order asserted that Respondent is "required to possess authority from a [S]tate in order to obtain or retain a DEA Registration. . . . [and c]onsequently, the DEA must revoke . . . [her registration] based upon [her] lack of authority to handle controlled substances in the State of Texas." *Id.* at 1-2.

The Show Cause Order notified Respondent of her right to request a hearing on the allegations or to submit a written statement while waiving her right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of the opportunity to submit a Corrective Action Plan. *Id.* at 2-3 (citing 21 U.S.C. 824(c)(2)(C)).

According to the Declaration of a DEA Diversion Investigator (hereinafter, DI), on September 20, 2017, he mailed the Show Cause Order to Respondent's "residential address . . . where . . . [he] had previously interacted with . . . [her] in conjunction with a search warrant." GX 3, at 1–2 (DI Declaration, Dec. 5, 2017). Attached to his Declaration was a "copy of the return receipt [card] showing that the certified mail . . . was delivered on October 3, 2017." *Id.* at 2. However, the return receipt card was signed by someone other than Respondent.¹ GX 3, Attachment D, at 1.

On November 21, 2017, the Office of Administrative Law Judges (OALJ) received a Request for Hearing from an attorney representing Respondent.² GX 4, at 1. Therein, Respondent admitted that her "license to practice medicine in the [S]tate of Texas is suspended," but represented that "she maintains an active and unrestricted license to practice medicine in the State of New York." *Id.* at 1. Respondent also represented that, "[o]n or about September 2017, [she] modified her practice address" from Houston, Texas to New York, NY, and that she "has modified her registration to reflect her practice address as the address indicated above to the State of New York." *Id.* Respondent further stated that prior to modifying her practice address to her Houston location, she practiced at the New York address she referenced in her Request. *Id.* Under the heading of "CORRECTIVE ACTION PLAN," the Hearing Request stated that Respondent "submits this modification of her practice address as a corrective action plan to the continuation of her DEA controlled substance registration." *Id.*

Upon receipt of Respondent's Hearing Request, the matter was assigned to Administrative Law Judge (ALJ) Charles Wm. Dorman, who issued an order captioned as "Briefing Schedule for Lack of State Authority Allegations." GX 6, at 1. In this order, the ALJ noted the respective dates of the Show Cause Order and the receipt of the Hearing Request and further directed the Government to "submit evidence of the

date of service of the" Show Cause Order "by December 5, 2017." *Id.* The ALJ also ordered that if the Government moved to terminate the proceeding, it must file its motion "by the same date" and that Respondent's response was due "by 2:00 p.m. Eastern Standard Time . . . on December 12, 2017." *Id.*

According to the ALJ's Termination Order (Dec. 14, 2017), on December 5, 2017, "[t]he Government timely filed" its Termination Request wherein "it argued that . . . Respondent filed her Hearing Request more than 30 days after the date of service of the" Show Cause Order. *Id.* The ALJ further noted that, "[as] of the date of" his Termination Order, "Respondent had not filed a response to the Government's Termination Request." *Id.* at 2.

As grounds for finding waiver, the ALJ noted that "[a]lthough there is no evidence of when the Respondent received the" Show Cause Order that was sent by regular mail to her registered location, "the fact that [it] was not returned as undeliverable establishes the presumption of receipt." *Id.* (citing *Net Wholesale*, 70 FR 24626 (2005)). The ALJ then noted that "given that it was mailed on September 20, [2017,] it is highly likely that it was delivered before October 15, 2017." *Id.* at 2. The ALJ further noted, that "[n]otwithstanding this uncertainty, there is evidence that the Respondent received the [Show Cause Order] at her residential address on October 3, 2017." *Id.* The ALJ explained that, "[b]ased on this date, the Hearing Request should have been filed by November 3, 2017, in order to be timely," but "[t]he Hearing Request . . . was not received by the OALJ, and therefore not filed, until November 21, 2017." *Id.* The ALJ thus found that "Respondent's hearing Request was filed more than 30 days after the [Show Cause Order] was served." *Id.*

The ALJ then noted that "[f]ailing to show good cause for an untimely hearing request constitutes a waiver of the right to a hearing." *Id.* (citing *Shannon L. Gallentine*, 76 FR 45864, 45864 (2011); *Gilbert E. Johnson*, 75 FR 65663, 65663–64 (2010)). Because Respondent did not file a response to the Government's Termination Request, the ALJ found that Respondent failed to show good cause to excuse the untimely filing of her Hearing Request and had waived her right to a hearing. *Id.* The ALJ thus granted the Government's motion and terminated the proceedings before his Office. *Id.*

On December 22, 2017, the Government filed its Request for Final Agency (RFAA) along with an investigative record in support of its

proposed action. RFAA, at 6. Therein, the Government seeks revocation of Respondent's Certificate of Registration on the ground that she is registered in the State of Texas, where she no longer has authority to dispense controlled substances. *Id.* at 4–6. While the Government further notes that Respondent attempted to change the address of her registration to a location in New York State, it argues that her "attempt to change addresses . . . was made only after being served with the [Show Cause Order and] should not serve as a basis to prevent revocation of her" Registration. *Id.* at 4. The Government further argues that "pursuant to 21 CFR 1301.51(c), this attempted modification is to be treated as an application for a registration." *Id.*

Having considered the record in its entirety, I grant the Government's Request to revoke Respondent's Certificate of Registration. While I agree with the Government that Respondent's attempt to modify her registered location to an address in the State of New York is to be treated as a new application, I find that this application remains pending before the Agency. I also conclude that because the Government seeks revocation of her existing registration solely on the basis that Respondent lacks authority to dispense controlled substances in Texas, her application for registration in New York must be the subject of separate proceedings.

The Waiver Finding

As discussed above, the ALJ found that "there is evidence that the Respondent received the [Show Cause Order] at her residential address on October 3, 2017," and "[b]ased on this date, the Hearing Request should have been filed by November 3, 2017, in order to be timely." GX 6, at 2 (citing 21 CFR 1301.43(a)). The ALJ also found that Respondent's Hearing Request was untimely based on the fact that it was not received by his Office until November 21, 2017. *Id.* Notwithstanding that the return receipt card is signed by someone other than Respondent and that under the Agency's regulations, the timeliness of a hearing request is based on the request being filed "within 30 days after the date of receipt of the order to show cause," 21 CFR 1301.43(a), I agree with each of the ALJ's findings.

While DEA has not specifically addressed the issue of when the clock starts to run for purposes of assessing the timeliness of a hearing request where someone other than the subject of a Show Cause Order signs the return receipt card, the federal courts have long recognized that "a 'strong

¹ In proceedings before the Administrative Law Judge, the Government submitted evidence that it also mailed the Show Cause Order by regular first class mail to Respondent's registered address on September 20, 2017 and that this mailing was not returned as undeliverable. GX 6, at 2.

² While the hearing request was dated November 15, 2017, under DEA's regulation, "[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk." 21 CFR 1316.45. The Show Cause Order also notified Respondent that "[m]atters are deemed filed upon receipt by the Hearing Clerk." GX 2, at 2.

presumption' of receipt applies when notice is sent by certified mail, because it creates actual evidence of delivery in the form of a receipt." *Lupyan v. Corinthian Colleges Inc.*, 761 F.3d 14 (3d Cir. 2014) (quoting *Santana Gonzales v. Att'y Gen.*, 506 F.3d 274, 279 (3d Cir. 2007). To similar effect, the Fifth Circuit has explained that "[p]roof that a letter properly directed was placed in a U.S. post office mail receptacle creates a presumption that it reached its destination in the usual time and was actually received by the person to whom it was addressed." *Beck v. Somerset Technologies, Inc.*, 882 F.2d 993, 996 (5th Cir. 1989). As the Fifth Circuit further explained in discussing the evidence of delivery in *Beck*:

The record contains a copy of the properly addressed letter, a certified mail receipt and signed return post cards. Accordingly, we hold there was sufficient evidence to create a presumption that the letter was received . . . in the due course of the mail. Thus, the burden of producing evidence of non-delivery shifted to Beck.

Id.

To be sure, this rule "'is not a conclusive presumption of law.'" *Lupyan*, 761 F.3d at 319 (quoting *Rosenthal v. Walker*, 111 U.S. 185, 193 (1884)). "Rather, it is a rebuttable 'inference of fact.'" *Id.*; see also *Beck*, 882 F.2d at 996;³ *Cf. Morgan v. Potter*,

489 F.3d 195, 197 n.1 (5th Cir. 2005) (noting that while "the presumption can certainly be overcome," plaintiff provided no evidence to establish the date she claimed to have received right to sue letter and "never made such a claim or presented such evidence to the district court").

In this matter, while the ALJ provided Respondent with the opportunity to respond to the Government's Termination Request, she has entirely failed to respond, let alone provide evidence to rebut the presumption that she received the Show Cause Order on the date the mailing was signed for. Because I find that the mailing was properly addressed to Respondent's residence and delivered on October 3, 2017, and Respondent produced no evidence to rebut the presumption that she received the mailing on this date, I find that Respondent received the Show Cause Order on October 3, 2017. I further find that more than 30 days have since passed since the date of service of the Show Cause Order, and that Respondent has waived both her right to a hearing as well as her right to submit a written statement of position on the matters of fact and law asserted in the Show Cause Order while waiving her right to a hearing. 21 CFR 1301.43(a), (c), (d).⁴ I make the following additional finding of fact.

Findings of Fact

Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. FC1384306, pursuant to which she is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of Gulfton Community Health Center, 6306 Gulfton St., Suite 101, Houston, TX 77081. GX 1. This registration does not expire until August 31, 2018. *Id.*

According to the Acting Unit Chief of the Agency's Registration and Program Support Section, on three different occasions following service of the Show Cause Order, Respondent attempted to change her registered location from the above address to an address in New York, NY. GX 5. According to the Acting Unit Chief, Respondent was unable to change her registered location and remains registered at the Houston, Texas location. *Id.* I further find, however, that Respondent's attempts to modify her registered location are deemed applications for a new registration in the

State of New York. 21 CFR 1301.51(c) ("The request for modification shall be handled in the same manner as an application for registration.").

The Status of Respondent's Texas License

On July 28, 2017, a Disciplinary Panel of the Texas Medical Board entered an Order of Temporary Suspension (hereinafter, Board's Order) of Respondent's Texas Medical License. GX 3, at Attachment A. The Board's Order "remain[s] in effect until it is superseded by a subsequent Order of the Texas Medical Board." *Id.* at 5.

The Board's Order was based on fact findings related to Respondent's operation of an unregistered pain management clinic. *Id.* at 2. These findings included that, on August 31, 2016, the Board filed a Complaint with the Texas Office of Administrative Hearings alleging that Respondent and her prescriptive delegates "prescribed controlled medications to ten patients in a manner inconsistent with public health [and] welfare, failed to meet the standard of care in the care and treatment of the patients, . . . failed to keep adequate medical records for the patients," and "failed to supervise her prescriptive delegates adequately." *Id.* The Board's Order also found that the Board's expert had reviewed ten patient cases and concluded that "Respondent's prescriptions for controlled substances were not provided for a legitimate medical purpose." *Id.*

Next, the Board's Order found that, on July 6, 2017, Respondent was indicted in the United District Court for the Southern District of Texas on felony charges of conspiracy to distribute and dispense controlled substances unlawfully, as well as aiding and abetting the unlawful distribution and dispensing of controlled substances at her pain clinic. *Id.* The Board's Order also found that following her arrest, Respondent signed an Order Setting Conditions of Release, which "restricts [her] from employment in a pain management clinic[] [and] from writing prescriptions for any schedule II or IV drug, and from writing prescriptions for any opioid in schedule II." *Id.* Based on a Prescriber Activity Report obtained from the State's Prescription Monitoring Program, the Board's Order found that since her release from custody on July 10, 2017, "eight prescriptions for schedule IV controlled substances (Carisoprodol and Alprazolam) and 21 prescriptions for Promethazine/Codeine syrup were issued under her DEA registration number." *Id.* at 3. Based on the Prescriber Activity Report, the Board's Order also found that from

³In *Vincent G. Colosimo*, an applicant for registration was issued a Show Cause Order which was served by Certified Mail addressed to his proposed registered location. 79 FR 20911, 20912 (2014). The applicant filed a hearing request which was received by the OALJ one day late and therefore deemed untimely by the ALJ, who ordered the parties to address whether there was good cause to excuse the late filing. *Id.*

Thereafter, the Government argued that the respondent's Hearing Request was untimely and that he had not shown good cause. *Id.* The respondent filed a statement wherein he asserted that the mailing containing the Show Cause Order had been signed for by another person at his office, that because it appeared to be of a legal nature, the mailing was sent to his employer's administrative office, and that he had only received it shortly before the due date of his hearing request. *Id.*; see also *Vincent G. Colosimo*, ALJ Termination Order, at 4. The ALJ nonetheless terminated the proceeding finding that the respondent had failed to show good cause for the untimely filing of his hearing request. *Colosimo*, 79 FR at 20912.

The Government then submitted a Request for Final Agency Action. *Id.* On review, the Administrator vacated the ALJ's termination order and rejected the Government's Request for Final Agency Action. The Administrator explained that while the respondent had not supported by affidavit the various factual assertions he had made in response to the ALJ's order directing the parties to address the timeliness of the hearing request, she further "held that if those assertions were supported, [respondent would] demonstrate good cause." *Id.* Of note, the Agency did not hold that the date of receipt commenced on the date on which the respondent actually received the Show Cause Order rather than the date on which the certified mail was received at the respondent's proposed registration location. *Id.*

⁴I also agree with the ALJ's finding that Respondent has failed to show good cause to excuse the untimely filing of her Hearing Request and has therefore waived her right to a hearing for this reason as well.

April 26, 2016 through July 26, 2017, Respondent issued over 10,300 prescriptions for Hydrocodone/Acetaminophen 10/325 mg and over 10,400 prescriptions for Carisoprodol 350 mg. *Id.* at 2.

The Board thus found that “Respondent’s continuation in the practice of medicine poses a continuing threat to public welfare.” *Id.* at 3. Based on these findings, the Panel found “an imminent peril to the public health, safety, or welfare that requires immediate effect of” its Order, *id.*, and temporarily suspended Respondent’s medical license. *Id.* at 5.

I take official notice of the online records of the Texas Medical Board. *See* 5 U.S.C. 556(e). According to the Board’s records, the temporary suspension of Respondent’s medical license remains in effect as of the date of this Decision and Order.⁵

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, 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 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 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 [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 . . . [she] 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 held repeatedly 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., Hooper, supra*, 76 FR at 71371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988); *Blanton, supra*, 43 FR at 27617.

Under the Texas Controlled Substances Act, a “practitioner” includes a “physician” who is licensed “to dispense . . . or administer a controlled substance in the course of professional practice.” Tex. Controlled Substances Act § 481.002(39)(A). Under the Texas Medical Practice Act, a “physician” is “a person licensed to practice medicine,” Tex. Occ. Code § 151.002(a)(12), and “practicing medicine” means the “diagnosis, treatment, or offer to treat a . . . disease . . . by any system or method.” *Id.* § 151.002(a)(13). Moreover, a “person may not practice medicine in [the] state unless the person holds a license issued under” the Medical Practice Act, *id.* § 155.001, and “[a] person commits an offense if the person practices medicine in this state in violation of” the Act. *Id.* § 165.152(a).

As found above, Respondent’s Texas medical license remains temporarily suspended. I therefore find that Respondent is currently without authority to dispense controlled substances under the laws of Texas, the State in which she is registered with the Agency.

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 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 Texas Board has employed summary process in suspending Respondent’s state license. *See Judson J. Somerville, M.D.*, 82 FR 21408, 21410 (2017); *Rezik A. Saqer*, 81 FR 22122, 22126 (2016). What is consequential is that Registrant is no longer currently authorized to dispense controlled substances in Texas, the State in which she is registered. *See Somerville*, 82 FR at 18274; *Saqer*, 81 FR 22126. I will therefore order that her registration be revoked.

While this Order resolves the issue of Respondent’s entitlement to maintain her DEA registration, as found above, Respondent attempted to modify her registered address to a location in the State of New York. As the Government acknowledges, these requests for modification are treated as new applications for registration. RFAA, at 4; *see also* 21 CFR 1301.51(c). The record submitted to my Office provides no indication that the Government sought denial of these applications (which were submitted subsequent to the service of the Show Cause Order) in this proceeding, and in any event, the ground offered by the Government for revoking her Texas registration, which rests exclusively on the summary suspension of her Texas Medical License, does not support denial of her New York applications. Those applications remain pending before the Agency and must be the subject of a separate proceeding if the Government seeks to deny them.⁶

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 No. FC1384306, issued to Gazelle Craig, M.D., be, and it hereby is, revoked. This Order is effective immediately.⁷

⁶ Because Respondent’s Corrective Action Plan is simply to modify her registered location to the New York address, I conclude that consideration of her plan should be considered by the Government in the course of evaluating her New York applications.

⁷ Based on the Texas Board’s finding that Respondent poses “an imminent peril to the public health, safety, or welfare that requires immediate effect of” the suspension order, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

⁵ 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 seven calendar days to file a response.

Dated: June 1, 2018.
Robert W. Patterson,
Acting Administrator.
 [FR Doc. 2018-12686 Filed 6-12-18; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Johnson Matthey Pharmaceutical Materials 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 on or before August 13, 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 Assistant Administrator of the DEA Diversion Control Division (“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 January 1, 2018, Johnson Matthey Pharmaceutical Materials Inc., 25 Patton Road, Devens, MA 01434 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methylphenidate	1724	II
Nabilone	7379	II
Hydrocodone	9193	II
Levorphanol	9220	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II

The company plans to utilize this facility to manufacture small quantities of the listed controlled substances in bulk for distribution to its customers as well as to conduct analytical testing in support of the company’s primary manufacturing facility in West Deptford, New Jersey.

Dated: June 6, 2018.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2018-12685 Filed 6-12-18; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of

various classes of schedule I or II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
PerkinElmer, Inc	83 FR 9337	March 5, 2018.
Stepan Company	83 FR 9337	March 5, 2018.
Noramco, Inc	83 FR 12408	March 21, 2018.
Sanyal Biotechnology	83 FR 12407	March 21, 2018.
S&B Pharma, Inc	83 FR 13523	March 29, 2018.
Siegfried USA, LLC	83 FR 13521	March 29, 2018.
Lannett Company, Inc	83 FR 13520	March 29, 2018.

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II 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 each company’s maintenance of effective controls against diversion by inspecting and testing each company’s physical security systems, verifying each company’s compliance with state and local laws, and reviewing each company’s background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or II controlled substances to the above listed companies.