

April 9, 2018 that it would conduct full reviews (83 FR 18347, April 26, 2018). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on September 14, 2018 (83 FR 46757). Effective February 4, 2019, the Commission revised its schedule due to the lapse in appropriations and ensuing cessation of Commission operations (84 FR 2926, February 8, 2019). The hearing was held in Washington, DC, on February 21, 2019, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on April 24, 2019. The views of the Commission are contained in USITC Publication 4482 (April 2019), entitled *Large Residential Washers from Korea and Mexico: Investigation Nos. 701-TA-488 and 731-TA-1199-1200 (Review)*.

By order of the Commission.

Issued: April 24, 2019.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2019-08671 Filed 4-29-19; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Palafox Pharmacy; Decision and Order

On August 14, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Palafox Pharmacy (hereinafter, Registrant), of Anthony, Texas. Order to Show Cause (hereinafter, OSC), at 1. The Show Cause Order proposes the revocation of Registrant's Certificate of Registration on the ground that it has "no state authority to handle controlled substances." *Id.* (citing 21 U.S.C. 824(a)(3)).

Regarding jurisdiction, the Show Cause Order alleges that Registrant holds DEA Certificate of Registration No. FP1305564 at the registered address of 929 S Main St., Anthony, Texas 79821. OSC, at 1. The Show Cause Order alleges that this registration expires on March 31, 2021. *Id.*

The substantive ground for the proceeding, as alleged in the Show Cause Order, is that Registrant is "currently without authority to handle controlled substances in the State of Texas, the state in which . . . [it] is registered with the DEA." *Id.* at 1-2. Specifically, the Show Cause Order alleges that the Texas State Board of Pharmacy suspended Registrant's pharmacy license on June 18, 2018. *Id.* at 1.

The Show Cause Order notifies Registrant of its right to request a hearing on the allegation or to submit a written statement while waiving its 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 notifies Registrant of the opportunity to submit a corrective action plan. OSC, at 2-3 (citing 21 U.S.C. 824(c)(2)(C)).

#### Adequacy of Service

In a Declaration dated November 2, 2018, a Diversion Investigator (hereinafter, DI), who describes herself as being assigned to the El Paso Field Division, states that she had the OSC delivered to the residential address of Registrant's owner. Government Exhibit (hereinafter, GX) 6 (DI Declaration), at 1-2.<sup>1</sup> See also GX 6, at 8-10 (proof of delivery).

In its Request for Final Agency Action dated November 7, 2018, the Government represents that "[a]t least 30 days have passed since the time the . . . [OSC] was served on Registrant . . . [and] Registrant has not requested a hearing." Request for Final Agency Action (hereinafter, RFAA), at 1.<sup>2</sup> The Government seeks the issuance of "a Final Order revoking Registrant's DEA registration." RFAA, at 4.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service on August 30, 2018.<sup>3</sup> GX 6, at 1-2, 8-10. I also find that more than 30 days have passed since the date the Government served the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to

<sup>1</sup> According to the DI, delivery attempts to Registrant's registered address were not successful. GX 6, at 1.

<sup>2</sup> In its Supplement to Request for Final Agency Action dated March 19, 2019, the Government represents that "Registrant has not otherwise corresponded or communicated with DEA regarding the Order to Show Cause served on it, including the filing of any written statement in lieu of a hearing." Supplement, at 1.

<sup>3</sup> *Nasim F. Khan, M.D.*, 73 FR 4630, 4630 (2008); *Patrick K. Riggs, M.D.*, 72 FR 71,959, 71,959 (2007).

represent him, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived his right to a hearing and his right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

#### Findings of Fact

##### *Registrant's DEA Registration*

Registrant is the holder of DEA Certificate of Registration No. FP1305564 at the registered address of 929 S Main St., Anthony, Texas 79821 under the electronic signature of Samuel Ambrosio Gurrola. GX 1 (Certification of Registration History), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules IV and V as a retail pharmacy. *Id.* Registrant's registration expires on March 31, 2021 and is in an active pending status. *Id.*

##### *The Status of Registrant's State License*

Registrant's Texas pharmacy license (number 26185) was revoked by Order of the Texas State Board of Pharmacy. GX 5 (Texas State Board of Pharmacy certified "Agreed Board Order #J-18-022-B" dated August 7, 2018), at 3. The revocation was effective on the date of entry of the Order. *Id.* The record evidence shows that Registrant's Texas pharmacy license number 26185 is revoked. GX 7 (Texas State Board of Pharmacy website screen print showing Registrant's pharmacy license status as "Revocation"), at 1. Further, according to the online records of the Texas State Board of Pharmacy, of which I take official notice, Registrant's pharmacy license is still revoked.<sup>4</sup> Texas State Board of Pharmacy website, <https://>

<sup>4</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, Registrant 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 Registrant files a motion, the Government shall have 15 calendar days to file a response.

[www.pharmacy.texas.gov/](http://www.pharmacy.texas.gov/) (last visited April 5, 2019).

Accordingly, I find that Registrant currently does not have a license to operate a pharmacy in Texas, 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.” A pharmacy is a “practitioner” under the CSA. 21 U.S.C. 802(21). 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 Fed. Appx. 826 (4th Cir. 2012); *Roots Pharmaceuticals, Inc.*, 76 FR 51,430 (2011); *Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy*, 76 FR 51,415 (2011); *Bourne Pharmacy, Inc.*, 72 FR 18,273 (2007); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a physician, . . . pharmacy, . . . 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, supra*, 76 FR at 71,371–72; *Roots Pharmaceuticals, Inc., supra*, 76 FR at 51,430; *Ideal Pharmacy*

*Care, Inc., d/b/a Esplanade Pharmacy, supra*, 76 FR at 51,416 n.1; *Bourne Pharmacy, Inc., supra*, 72 FR at 18,274; *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, supra*, 43 FR at 27,617.

According to Texas statute, “A person may not operate a pharmacy in this state unless the pharmacy is licensed by the board.” Tex. Occupations Code Ann. § 560.001(a) (West, Westlaw current through the end of the 2017 Regular and First Called Sessions of the 85th Legislature). Further, “a person who is not registered with or exempt from registration with the Federal Drug Enforcement Administration may not manufacture, distribute, prescribe, possess, analyze, or dispense a controlled substance in this state.”<sup>5</sup> Tex. Health and Safety Code Ann. § 481.061(a) (West, Westlaw current through the end of the 2017 Regular and First Called Sessions of the 85th Legislature).

The undisputed evidence in the record before me is that Registrant currently lacks authority to operate a pharmacy in Texas. As such, Registrant is not qualified to dispense controlled substances as a “practitioner.” I will, therefore, 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 order that DEA Certificate of Registration No. FP1305564 issued to Palafox Pharmacy be, and it hereby is, revoked. This Order is effective May 30, 2019.

Dated: April 5, 2019.

**Uttam Dhillon,**

*Acting Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA–392]

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

**ACTION:** Notice of application.

<sup>5</sup> A “dispenser” includes a pharmacy that dispenses a controlled substance. Tex. Health and Safety Code Ann. § 481.002(13) (West, Westlaw current through the end of the 2017 Regular and First Called Sessions of the 85th Legislature).

**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 May 30, 2019. Such persons may also file a written request for a hearing on the application on or before May 30, 2019.

**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 hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for 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. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007).

**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 1301.34(a), this is notice that on November 13, 2018, Mylan Pharmaceuticals Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine .....	1100	II
Methylphenidate .....	1724	II
Oxycodone .....	9143	II
Hydromorphone .....	9150	II
Methadone .....	9250	II
Morphine .....	9300	II