

Act on September 4, 2018 (83 FR 44903).

Suzanne Morris,

*Chief, Premerger and Division Statistics Unit,
Antitrust Division.*

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, 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 January 22, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 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 September 26, 2018, Patheon API Manufacturing, Inc., 309 Delaware St., Greenville, South Carolina 29605 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Noroxymorphone	9668	II

The company plans to manufacture the above-listed controlled substances

as an Active Pharmaceutical Ingredient (API) for supply to its customers.

Dated: November 2, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–25228 Filed 11–19–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–36]

Eldor Brish, M.D.; Decision and Order

On June 25, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Eldor Brish, M.D. (Respondent), of Houston, Texas. The Show Cause Order proposed the revocation of Respondent’s DEA Certificate of Registration No. FB2033049 on the ground that he has “no state authority to handle controlled substances.” Order to Show Cause, at 1 (citing 21 U.S.C. 824(a)(3)). For the same reason, the Order also proposed the denial of any of Respondent’s “applications for renewal or modification of such registration and any applications for any other DEA registrations.” *Id.*

With respect to the Agency’s jurisdiction, the Show Cause Order alleged that Respondent is the holder of Certificate of Registration No. FB2033049, pursuant to which he is authorized to dispense controlled substances as a practitioner in schedules II through V, at the registered address of 5400 Pinemont Drive, #108, Houston, Texas. *Id.* The Order also alleged that this registration does not expire until July 31, 2019. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on May 18, 2018, the Texas Medical Board (TMB) “issued an Order of Temporary Suspension suspending” Respondent’s Texas medical license, and Respondent is therefore “without authority to practice medicine or handle controlled substances in Texas, the [S]tate in which [he is] registered with DEA.” *Id.* at 2. Based on his “lack of authority to [dispense] controlled substances in . . . Texas,” the Order asserted that “DEA must revoke” Respondent’s registration. *Id.* (citing 21 U.S.C. 824(a)(3); 21 CFR 1301.37(b)).

The Show Cause Order notified Respondent of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either

option, and (3) the consequence for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The Order also notified Respondent of his right to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

On July 23, 2018, Respondent, through counsel, filed a letter requesting a hearing on the allegations. July 23, 2018 Letter from Respondent’s Counsel to Hearing Clerk (hereinafter, Hearing Request). In his Hearing Request, Respondent “requests a hearing be conducted to contest all of the legal issues and factual allegations raised in the DEA’s Order in support of its proposed revocation.” *Id.* at 1. Respondent specifically requested a hearing “to determine whether the DEA is authorized to revoke” Respondent’s registration and, “even if the DEA has authority to revoke, whether a revocation in the instant case represents an abuse of power and/or a failure to exercise appropriate discretion.” *Id.* at 1–2.

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Mark M. Dowd (hereinafter, ALJ). On July 31, 2018, the ALJ ordered the Government to “file evidence to support the allegation that the Respondent lacks state authority to handle controlled substances” and file “any motion for summary disposition” no later than August 3, 2018. Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1. The ALJ also directed Respondent to file his response to any summary disposition motion no later than August 8, 2018. *Id.* at 2.

On August 3, 2018, the Government filed its Motion for Summary Disposition. In its Motion, the Government argued that Respondent lacks authority to handle controlled substances in Texas because the TMB “suspended Respondent’s Texas Medical License” on May 18, 2018. Government’s Motion for Summary Disposition (hereinafter Government’s Motion or Govt. Mot.) at 3; Government Exhibit (GX) 2 to Govt. Mot. The Government also noted that the TMB conducted a hearing on June 25, 2018 and then “issued a second suspension order” on June 27, 2018. Govt. Mot. at 3 (citing GX 3 to Govt. Mot.). The Government further argued that, “[a]bsent authority by the State of Texas to dispense controlled substances, Respondent is not authorized to possess a DEA registration in that state.” *Id.* Lastly, the Government argued that under Agency precedent, revocation is warranted even where a State has