DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: AndersonBrecon Inc. DBA PCI of Illinois

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before June 14, 2019. Such persons may also file a written request for a hearing on the application on or before June 14, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette 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 1301.34(a), this is notice that on March 5, 2019, AndersonBrecon Inc., DBA PCI of Illinois, 5775 Logistics Parkway, Rockford, Illinois 61109 applied to be registered as an importer of the following basic class of controlled substance:

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols ..	7370	I

The company plans to import the listed controlled substance for clinical trials only. Approval of permit application will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: April 27, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019–10006 Filed 5–14–19; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Fred J. Powell, M.D.; Decision and Order

On January 25, 2018, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Fred J. Powell. (hereinafter, Registrant), of St. Augustine, Florida. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposes the revocation of Registrant's Certificate of Registration (hereinafter, COR) on the ground that he is without authority to handle controlled substances in Florida, the State in which he is registered with the DEA. *Id.* at 2. The OSC cites the operative statutory provisions that spell out the requirements for registration upon which the DEA alleges that Registrant is deficient, and the DEA's authority to revoke his registration. *Id.,* at 1–2 (citing 21 U.S.C. 824(a)(3)).

Jurisdiction

This Agency has jurisdiction to decide this case based upon the OSC allegation that Registrant holds a DEA COR (No. AP8271138) at the registered address of 35 Townsend Pl., St. Augustine, FL 32092–3209. OSC, at 1. That registration authorizes Registrant, as a practitioner, to dispense controlled substances in schedules II through V and expires on March 31, 2020. *Id.*

Substantive Ground for Revocation of COR Alleged in OSC

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant agreed to a permanent restriction prohibiting him from prescribing and ordering Schedule I through V controlled substances and thus is ''currently without authority to handle controlled substances in the State of Florida,'' the State in which he is registered with the DEA under DEA COR No. AP8271138. OSC, at 2.

The OSC notified Registrant of his right to request a hearing on the allegations or to submit a written statement if he chooses to waive his right to a hearing, the procedures for electing each option, and the consequences for failing to elect one of those options. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan, the specific procedures for filing a corrective action plan, and the statutory provision that governs such a plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated March 27, 2018, Registrant timely submitted a corrective action plan (hereinafter, CAP). Request for Final Agency Action dated April 10, 2018 (hereinafter, RFAA), Exhibit (hereinafter, Exh.) 5.[1] Registrant's CAP consists of thirteen paragraphs containing assertions. The Assistant Administrator of the Diversion Control Division denied Registrant's CAP by letter dated April 6, 2018. Exh. 6.

In its RFAA, the Government represents that, ''At least 30 days have passed since the time the . . . [OSC] was served on Registrant. Registrant has not requested a hearing.'' RFAA, at 2. The Government requests the issuance of a ''Final Order revoking Registrant's DEA registration.'' *Id.* at 4.

The very existence of the CAP evidences that service of the OSC on Registrant was adequate. In addition, Registrant did not dispute service. Based on the Government's written representations and my review of the record, I find that more than thirty days have now passed since the date the Government served the OSC. I find that Registrant timely submitted a CAP and that the Assistant Administrator of the Diversion Control Division denied Registrant's CAP by letter dated April 6, 2018. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent him, requested a hearing or submitted a written statement while waiving Registrant's right to a hearing. Accordingly, I find that Registrant has waived his right to a hearing and his right to submit a written statement. 21 CFR 1301.43(d). 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).

[1] Also attached to the RFAA is a ''Declaration'' of a DEA Diversion Investigator (hereinafter, DI Declaration). Exh. 4. According to the DI Declaration, two Diversion Investigators personally served the OSC on Registrant on January 26, 2018.

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA COR No. AP8271138, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 35 Townsend Pl., St. Augustine, Florida 32092–3209. Certification of Registration History (Exh. 1), at 1.

On December 15, 2017, the State of Florida, Board of Medicine (hereinafter, Florida Board) issued a Final Order approving and adopting in full the Settlement Agreement that Registrant entered into on October 3, 2017, with the State of Florida, Department of Health. Exh. 3, at 68–70. The Florida Board's Final Order, therefore, adopted each provision of the Settlement Agreement, including Registrant's voluntary permanent restriction from ''prescribing, ordering, and/or delegating the prescribing or ordering of, any substances listed in Schedules I–V, as defined in Section 893.03, Florida Statutes (2016), and may from time-to-time be redefined in Florida Statutes and/or the Florida Administrative Code.'' *Id.* at 63. Thus, Registrant currently lacks authority to handle controlled substances in the State of Florida, the State in which he is licensed to practice medicine and where he is registered with 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 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 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., 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, M.D.,* 53 FR 11919, 11920 (1988); *Blanton, supra,* 43 FR at 27617.

Registrant has voluntarily agreed permanently to stop prescribing and ordering controlled substances, and to stop delegating the prescribing or ordering of controlled substances. Exh. 3, at 63. He has also voluntarily agreed that these permanent restrictions are ''fair, appropriate and acceptable'' to him.[2] *Id.* at 60.

The CSA has consistently been interpreted to mean that the DEA does not have statutory authority to maintain a registration if the registrant is without State authority to handle controlled substances in the State in which he practices. *E.g., Alaaeldin A. Babiker, M.D.,* 81 FR 50723, 50725 (2016); *Yeates, supra,* 71 FR at 39131; *Abraham A. Chaplan, M.D.,* 57 FR 55280, 55280 (1992). Very simply, because Registrant is not authorized to handle controlled substances in Florida, he is not eligible for a DEA registration. As such, I will order that Registrant's COR 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. AP8271138 issued to Fred J. Powell, M.D., be, and it hereby is, revoked. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I further order that any pending application of Fred J. Powell, M.D., to renew or modify this registration (AP8271138), as well as any other pending application by him for registration in the State of Florida, be, and it hereby is, denied. This order is effective June 14 2019.

Dated: April 23, 2019.

Uttam Dhillon,

Acting Administrator.

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[2] Registrant also agreed to support these permanent restrictions before the Florida Board. *Id.* at 65.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of schedule I and schedule 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	84 FR 3246	February 11, 2019.
Stepan Company	84 FR 3250	February 11, 2019.

The 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 and 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 of the 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 schedule II controlled substances to the above listed companies.