

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Sigma Aldrich Research

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 December 31, 2018.

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 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 June 14, 2018, Sigma Aldrich Research, 1–3 Strathmore Road, Natick, Massachusetts 01760–2447 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
Lysergic acid diethylamide	7315	I
3,4-Methylenedioxymethamphetamine	7405	I
Dimethyltryptamine	7435	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
MDPV (3,4-Methylenedioxypropylvalerone)	7535	I
Heroin	9200	I
Normorphine	9313	I
Norlevorphanol	9634	I
Amphetamine	1100	II
Nabilone	7379	II
Cocaine	9041	II
Codeine	9050	II
Ecgonine	9180	II
Levorphanol	9220	II
Meperidine	9230	II
Methadone	9250	II
Morphine	9300	II
Thebaine	9333	II
Levo-alphaacetylmethadol	9648	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Fentanyl	9801	II

The company plans to manufacture reference standards.

Dated: October 11, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–23695 Filed 10–29–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: Catalent CTS, LLC

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 November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

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.

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 July 17, 2018, Catalent CTS, LLC, 10245 Hickman Mills Drive, Kansas City,

Missouri 64137–1418 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import finished dosage unit products containing gamma-hydroxybutyric acid and marihuana extracts for clinical trial studies. These marihuana extracts compounds are listed under drug code 7350. No other activity for these drug codes is authorized for this registration. Approval of permit applications 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: October 19, 2018.

John J. Martin,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Eric Lee Knight, M.D.; Decision and Order

On February 6, 2018, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Eric Lee Knight, M.D. (hereinafter, Registrant), of Derry, New Hampshire. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposes the revocation of Registrant's Certificate of Registration on the ground that he does “not have authority to handle controlled substances in the State of New Hampshire, the state in which . . . [he is] registered with the DEA.” *Id.* (citing 21 U.S.C. 823(f) and 824(a)(3)).

Regarding jurisdiction, the OSC alleges that Registrant holds DEA Certificate of Registration No. BK7282940 at the registered address of 93 ½ Walnut Hill Road, Derry, New Hampshire 03038.¹ OSC, at 1. This registration authorizes Registrant to

dispense controlled substances in schedules II through V as a practitioner. *Id.* The OSC alleges that this registration expires on December 31, 2018. *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant is “without authority to handle controlled substances in New Hampshire, the state in which [he is] registered with the DEA.” *Id.* Specifically, the OSC alleges that the State of New Hampshire Board of Medicine (hereinafter, Board) issued an Order of Emergency License Suspension and Notice of Hearing on September 25, 2017. *Id.* at 1–2. On the following day, September 26, 2017, Registrant entered into a written agreement “not to practice medicine [including the writing of] prescriptions . . . until further order of the Board.” *Id.* at 2.

The OSC notifies Registrant of his right to request a hearing on the allegations or to submit a written statement while waiving his 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 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 April 27, 2018, a Diversion Investigator (hereinafter, DI), who describes herself as being assigned to the DEA Boston Field Division-Manchester (New Hampshire) District Office, states that after two unsuccessful attempts at serving the OSC on Registrant, she and two Task Force Officers traveled to the residence of Registrant on February 16, 2018, and “[a]fter displaying our credentials to Dr. Knight, I presented the original copy of the . . . [OSC] to Dr. Knight.” (Government Exhibit (hereinafter, GX) 8 at 2–3 (Declaration of DEA Diversion Investigator)).

In its Request for Final Agency Action dated May 3, 2018, the Government represents that “[m]ore than 30-days have passed since Registrant received the . . . [OSC]; however, Registrant has not submitted to DEA a request for hearing.” Request for Final Agency Action, at 2. In its Request for Final Agency Action—Addendum dated September 26, 2018, the Government represents that Registrant has not “corresponded in writing or otherwise with regard to his position on a hearing before DEA.” Request for Final Agency Action—Addendum, at 2. The Government requests the issuance of a Final Order revoking Registrant's DEA registration. *Id.* at 4.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government personally served the OSC on Registrant on February 16, 2018. I also find that more than 30 days have now 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 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. BK7282940 at the registered address of 93 ½ Walnut Hill Road, Derry, New Hampshire 03038. GX 1 (Certification of Registration), 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 expires on December 31, 2018. *Id.*

The Status of Registrant's State License

In this case, the Board issued an Order of Emergency License Suspension and Notice of Hearing on September 25, 2017. The Board's Order suspended Registrant's New Hampshire medical license until further order of the Board. GX 3 (Order of Emergency License Suspension and Notice of Hearing), at 13. On October 9, 2017, the Board accepted Registrant's agreement “not to practice medicine . . . [including the writing of] prescriptions . . . until further order of the Board.” GX 4 (Preliminary Agreement Not to Practice), at 1.

According to New Hampshire's online records, of which I take official notice, Registrant's license to practice medicine is still suspended.² New Hampshire

¹ The OSC erroneously lists the number of Registrant's address on Walnut Hill Road as 92 ½.

² 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