

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 20, 2020, GE Healthcare, 3350 North Ridge Avenue, Arlington Heights, Illinois 60004-1412, applied to be registered as an importer of the following basic class(es) of a controlled substance:

| Controlled substance | Drug code | Schedule |
|----------------------|-----------|----------|
| Cocaine | 9041 | II |

The company plans to import small quantities of Ioflupane, in the form of three separate analogues of cocaine, to validate production and quality control systems, for a reference standard, and for producing material for a future investigational new drug submission. Supplies of this particular controlled substances are not available in the form needed within the current domestic supply of the United States.

William T. McDermott,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-696]

Importer of Controlled Substances Application: Catalent CTS, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Catalent, CTS LLC applied to be registered as an importer of the following basic class(es) of controlled substances: Gamma Hydroxybutyric Acid, Marihuana Extract, Marihuana, and Tetrahydrocannabinols.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 10, 2020. Such persons may also file a written request for a hearing on the application on or before September 10, 2020.

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 a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a 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: In accordance with 21 CFR 1301.34(a), this is notice that on July 17, 2020, Catalent, CTS LLC, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, applied to be registered as an importer of the following basic class(es) 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.

William T. McDermott,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mark D. Beale, M.D.; Decision and Order

On May 14, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Mark D. Beale, M.D. (hereinafter, Registrant) of Las Cruces, New Mexico. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FB0178194. *Id.* It alleged that Registrant has "no state authority to handle controlled substances." *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that, "[o]n April 17, 2019, the New Mexico

Medical Board (hereinafter, NMMB) summarily suspended . . . [Registrant's] medical license." OSC, at 2. The OSC concluded that "DEA must revoke . . . [Registrant's] registration based on . . . [his] lack of authority to handle controlled substances in the State of New Mexico." *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the 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 notified Registrant of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a sworn Declaration dated January 17, 2020, a DEA Diversion Investigator assigned to the El Paso Division (hereinafter, EPDI) stated that she attempted personal service of the OSC on Registrant at his medical practice and at his residence on multiple occasions. Request for Final Agency Action, dated January 17, 2020 (hereinafter, RFAA), Exhibit (hereinafter, EX) 5 (Declaration of Attempted Service of Order to Show Cause, dated January 17, 2020), at 1-3. For the last attempt, EPDI was accompanied by two DEA Special Agents. *Id.* at 3. None of the attempts was successful. *Id.*

EPDI's Declaration also describes her attempts to reach Registrant by telephone. *Id.* at 2. Due to these attempts, EPDI succeeded in speaking with Registrant's wife. *Id.* Registrant's wife told EPDI that their attorney was handling the matter. *Id.* EPDI contacted the attorney whose name Registrant's wife gave her. *Id.* This attorney, however, stated that "he is only handling Registrant's criminal matter." *Id.*

EPDI's Declaration details multiple instances of her transmitting the OSC to Registrant by mail. *Id.* at 2-3. Two of the mailings, one to Registrant's registered address and one to his residential address, were transmitted through the United States Postal Service (hereinafter, USPS) by prepaid postage and return receipt requested. *Id.* at 2. The mailing to Registrant's registered address was returned "with a label stating 'RETURN TO SENDER UNCLAIMED UNABLE TO FORWARD.'" *Id.* Neither the mailing to Registrant's residence, nor the return receipt request attached to it, was returned. *Id.*

EPDI's Declaration states that she attempted to serve the OSC on