Company	FR docket	Published
Eli-Elsohly Laboratories	84 FR 27661	June 13, 2019.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of these registrants to manufacture the applicable basic classes of 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 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 the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed companies.

Dated: October 18, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–23501 Filed 10–25–19; 8:45 am]

BILLING CODE 4410–09–P

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 27, 2019. Such persons may also file a written request for a hearing on the application on or before November 27, 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: In accordance with 21 CFR 1301.34(a), this is notice that on July 16, 2019, 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-hydroxybutryic 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 18, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–23502 Filed 10–25–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Euticals 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 December 27, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on June 27, 2019, Euticals Inc., 2460 W Bennett Street, Springfield, Missouri 65807–1229 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Phenylacetone	8501	II
Methadone	9250	II
Methadone intermediate	9254	II
Oripavine	9330	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers.

Dated: October 18, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–23499 Filed 10–25–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

[Bulk Manufacturer 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 bulk manufacturers of various classes of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as a bulk manufacturers of various classes of scheduled I and II controlled substances. Information on previously published notices is listed below. No comments or objections were submitted for these notices.

Company	FR Docket	Published
SpecGx LLC	84 FR 26447	June 6, 2019.
Sigma Aldrich Research	84 FR 27659	June 13, 2019.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of these registrants to manufacture the applicable basic classes of 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 the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed companies.

Dated: October 16, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–23500 Filed 10–25–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–21]

Lesly Pompy, M.D.; Decision and Order

On March 2, 2017, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registrations to Lesly Pompy, M.D. (hereinafter, Respondent), of Monroe, Michigan. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause and Immediate Suspension of Registrations (hereinafter collectively, OSC)), at 1. The OSC informed Respondent of the immediate suspension of his DEA Certificates of Registration BP2527058 and FP2665478 pursuant to 21 U.S.C. 824(d) ''because . . . [his] continued registration constitute[d] an imminent danger to the public health and safety.'' *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Respondent ''committed such acts as would render . . . [his] registrations under 21 U.S.C. 823(f) inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4).'' *Id.* at 2. Specifically, the OSC alleges that Respondent issued numerous prescriptions, including to an undercover investigator, outside the usual course of the professional practice of medicine in violation of 21 CFR 1306.04(a) and in violation of the minimal standards of medical practice in Michigan. *Id.* at 2–3. The OSC also alleges that, at one of his registered locations and at his (unregistered) residence, Respondent unlawfully possessed numerous controlled substances including, but not limited to, varying quantities of Schedule II controlled substances that had been dispensed to patients. *Id.* at 4 (citing 21 CFR 1301.12, 1317.30, and 1317.40; Mich. Comp. Laws § 333.7403). Finally, the OSC alleges that Respondent was unable to provide any of the records that DEA requested concerning his two registrations—an inventory at both registered locations and records for each controlled substance received, sold, and delivered. OSC, at 4 (citing 21 CFR 1304.11 and 1304.21).

On March 2, 2017, based on his preliminary findings that Respondent prescribed controlled substances outside the usual course of the professional practice, unlawfully possessed controlled substances at both his home and his office, and committed numerous recordkeeping violations, the former Acting Administrator concluded that Respondent's ''continued registration . . . [was] inconsistent with the public interest.'' OSC, at 5. Citing 21 U.S.C. 824(d), he also made the preliminary finding that Respondent's continued registration during the pendency of proceedings ''would constitute an imminent danger to the public health or safety because of the substantial likelihood that . . . [Respondent] will continue to prescribe controlled substances in a manner that . . . creates a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur.'' *Id.* Pursuant to 21 U.S.C. 824(f) and 21 CFR 1301.36(f), the former Acting Administrator authorized the DEA Special Agents and Diversion Investigators serving the OSC on Respondent to place under seal or to remove for safekeeping all controlled substances Respondent possessed pursuant to the immediately suspended registrations. *Id.* The former Acting Administrator also directed those DEA employees to take possession of Respondent's Certificates of Registration BP2527058 and FP2665478 and any unused prescription forms. *Id.*

The OSC notified Respondent 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.* at 5–6 (citing 21 CFR 1301.43). According to the Government's Notice of Service, a member of the DEA Detroit Field Division personally served the OSC on Respondent on March 3, 2017. ALJX 2 (Government's Notice of Service of OSC/ISO), at 1.

By letter dated March 16, 2017, Respondent timely requested a hearing. ALJX 3, at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ). On March 16, 2017, he established a schedule for the filing of prehearing statements. ALJX 4 (Order for Prehearing Statements), at 1. On April 20, 2017, the Chief ALJ issued a Prehearing Ruling that, among other things, set out the six Stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements. ALJX 11 (Prehearing Ruling) at 1–2.[1]

The Government filed its Prehearing Statement on March 29, 2017, and its Supplemental Prehearing Statement on June 8, 2017. ALJX 9 and 17, respectively. Respondent filed his Prehearing Statement on April 19, 2017, and his Supplemental Prehearing Statement on June 7, 2017. ALJX 10 and 20, respectively.

The hearing in this matter spanned seven days and took place at multiple locations.[2] On August 4, 2017, after the sixth day of hearings, the Government filed a Notice of Respondent's Lack of State Authority. ALJX 29 (hereinafter,

[1] The parties agreed to an additional 26 stipulations. ALJX 26 and ALJX 30. The first 31 stipulations are set out on pages 3 to 5 of the Chief ALJ's recommendations. The last stipulation is: ''On August 4, 2017, Dr. Pompy was served with a copy of an Order of Summary Suspension by the State of Michigan Department of Licensing and Regulatory Affairs. This order became effective upon service and summarily suspended Dr. Pompy's medical license.'' ALJX 30.

[2] Hearings were held in Detroit, Michigan on July 11, 12, 13, and 14, 2017 and in Arlington, Virginia on July 31, August 1, and August 21, 2017.