(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on May 22, 2025.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (''Inv. No. 337–TA–1398'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 22, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–07170 Filed 4–24–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1523]

Importer of Controlled Substances Application: Royal Emerald Pharmaceuticals

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Royal Emerald Pharmaceuticals has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before May 27, 2025. Such persons may also file a written request for a hearing on the application on or before May 27, 2025.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must 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. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 25, 2025, Royal Emerald Pharmaceuticals, 14011 Palm Drive, Building B, Desert Hot Springs, California 92240–6845, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols ...	7370	I

The company plans to import immature plants to use as starting/raw materials to continue cultivation of Marihuana under their Bulk Manufacturing registration. All products and materials will be developed as botanical raw materials or Active Pharmaceutical Ingredients for Drug Enforcement Administration-approved legitimate medical, scientific, research, and/or industrial purposes. No other activities for these drug codes are 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 Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2025–07155 Filed 4–24–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1520]

Bulk Manufacturer of Controlled Substances Application: SpecGx LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: SpecGx LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled

substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 24, 2025. Such persons may also file a written request for a hearing on the application on or before June 24, 2025.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on February 17, 2025, SpecGx LLC, 3600 North 2nd Street, Saint Louis, Missouri 63147–3457, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I
Psilocybin	7437	I
Codeine-N-oxide	9053	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Alphamethadol	9605	I
Betamethadol	9609	I
Norlevorphanol	9634	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Fentanyl related compounds as defined in 21 CFR 1308.11(h)	9850	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Phenylacetone	8501	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Hydrocodone	9193	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine intermediate-A	9232	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Methadone	9250	II
Methadone intermediate	9254	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to bulk manufacture the listed controlled substances for sale to its customers as Active Pharmaceutical Ingredients and Analytical Research Standards for formulation and analytical development purposes. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug code as synthetic. No other activity for

this drug code is authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2025–07154 Filed 4–24–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Liberty Pharmacy Inc.; Metro Care Pharmacy Inc.; Ritecare Pharmacy Inc.; United Pharmacy Upper Darby Inc.; Decision and Order

I. Introduction

On October 31, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registrations (OSC/ISO) to Liberty Pharmacy Inc., Metro Care Pharmacy Inc., RiteCare Pharmacy Inc., and United Pharmacy Upper Darby Inc., of Philadelphia, Pennsylvania (collectively, Registrants). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 10. The OSC/ISO informed Registrants of the immediate suspension of their DEA Certificates of Registration, Nos. FL2056908, FM2936120, FR5934244, and FU0598790, pursuant to 21 U.S.C. 824(d), alleging that Registrants' continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* at 1–2 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrants' registrations, alleging that Registrants' continued registration is inconsistent with the public interest. *Id.* at 2 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).[1]

Specifically, the OSC/ISO alleged that between February 1, 2019, and August 30, 2023, Registrants failed to maintain accurate records of their purchasing and dispensing of controlled substances, in violation of federal and Pennsylvania state law. *Id.* at 2–3, 5–8 (citing 21 CFR 1304.04(a), 1304.11(a)–(c), 1304.21(a); 35 Pa. Cons. Stat. Ann. secs. 780–112(a)–(c), 780–113(a)(21)).

The OSC/ISO notified Registrants of their right to file with DEA a written request for hearing and that if they failed to file such a request, they would be deemed to have waived their right to a hearing and be in default. RFAAX 2, at 9 (citing 21 CFR 1301.43). Here, Registrants did not request a hearing. RFAA, at 2.[2] ''A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC/ISO].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrants' default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1–2; *see also* 21 CFR 1316.67.

II. Applicable Law

A. The Alleged Statutory and Regulatory Violations

As discussed above, the OSC/ISO alleges that Registrants violated provisions of the CSA and its implementing regulations. As the Supreme Court stated in *Gonzales* v. *Raich,* ''the main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. . . . To effectuate these goals, Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by the CSA.'' 545 U.S. 1, at 12–13 (2005). In maintaining this closed regulatory system, ''[t]he CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping.'' *Id.* at 14.

Here, the OSC/ISO's allegations concern the CSA's ''strict requirements regarding registration . . . drug security, and recordkeeping'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances,'' and ''to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–14, 27.

B. Improper Dispensing, Recordkeeping, and Unaccounted for Controlled Substances

According to DEA's implementing regulations, pharmacies must maintain ''a complete and accurate record of each controlled substance . . . sold . . . .'' 21 CFR 1304.21(a). This includes conducting and maintaining an ''initial inventory . . . of all stocks of controlled substances on hand on the date [the pharmacy] first engages in the . . . dispensing of controlled substances,'' as well as a ''biennial inventory . . . of all stocks of controlled substances on hand.'' 21 CFR 1304.11(a)–(c). Pharmacies must retain these inventories ''for at least 2 years from the date of such inventory or records, for inspection and copying.'' 21 CFR 1304.04.

Pennsylvania law also requires pharmacies to keep accurate records and maintain proper inventories regarding the purchase, sale, or dispensing of any controlled substances. 35 Pa. Cons. Stat. Ann. sec. 780–112(a)–(c). In Pennsylvania, it is unlawful for a pharmacy to fail to ''make, keep or furnish any record, notification, order form, statement, invoice or information'' relating to the purchasing or dispensing of a controlled substance. *Id.* sec. 780–113(a)(21).

III. Findings of Fact

The Agency finds that, in light of Registrants' default, the factual allegations in the OSC/ISO are deemed admitted.[3] Registrants are deemed to

[1] According to Agency records, Metro Care Pharmacy's registration expired on January 31, 2024. The fact that a registrant allows its registration to expire during the pendency of an administrative enforcement proceeding does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC/ISO to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68476–79 (2019).

[2] Based on the Government's submissions in its RFAA dated February 9, 2024, the Agency finds that service of the OSC/ISO on Registrants was adequate. Specifically, the included Declaration from a DEA Special Agent asserts that on November 1, 2023, the OSC/ISO was personally served at all of Registrants' registered addresses during the execution of simultaneous search warrants at each location. RFAAX 3, at 2. The Special Agent noted in the Declaration that an individual who serves in a management role for all four pharmacies was physically present at the location of Liberty Pharmacy, Inc. during the execution of the search warrant and service of the OSC/ISO. *Id.* This individual received a copy of the OSC/ISO as well as instructions from DEA personnel. *Id.*

[3] Registrants are deemed to have admitted and the Agency finds that Registrants share common management and control. RFAAX 2, at 4. The following facts, which illustrate that F.E. exercises management and control over all four entities, are deemed admitted: (1) ''Liberty Pharmacy, Metro Care Pharmacy, and United Pharmacy share common corporate management as reflected in their state corporate filings . . .''; (2) at RiteCare Pharmacy, DEA investigators observed an information sheet displaying proprietary information for Liberty Pharmacy, Metro Care Pharmacy, and United Pharmacy, such as contact information and relevant licensing numbers; (3) regarding their controlled substance ordering, Registrants all ordered almost exclusively large quantities of alprazolam tablets and promethazine with codeine bottles; (4) DEA's search of trash from Liberty Pharmacy revealed controlled substance order invoices for suppliers to RiteCare Pharmacy, Metro Care Pharmacy, and United Pharmacy, as well as cardboard boxes originally shipped to RiteCare Pharmacy, Metro Care Pharmacy, and United Pharmacy; (5) DEA's interview with an employee of a distributor company supplying Registrants revealed the commonality of management between Registrants; (6) DEA's administrative subpoenas issued to Registrants'