

DEPARTMENT OF JUSTICE**Drug Enforcement Administration**

[Docket No. DEA-392]

**Importer of Controlled Substances
Application: United States
Pharmacoepial Convention****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 in accordance with 21 CFR 1301.34(a) on or before August 25, 2017. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before August 25, 2017.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 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 request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 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 February 15, 2017, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Methaqualone	2565	I
Lysergic acid diethylamide	7315	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
3,4-Methylenedioxyamphetamine	7400	I
4-Methoxyamphetamine	7411	I
Codeine-N-oxide	9053	I
Difenoxin	9168	I
Heroin	9200	I
Morphine-N-oxide	9307	I
Normethadone	9635	I
Methamphetamine	1105	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Phencyclidine	7471	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Phenylacetone	8501	II
Alphaprodine	9010	II
Anileridine	9020	II
Cocaine	9041	II
Dihydrocodeine	9120	II
Diphenoxylate	9170	II
Levomethorphan	9210	II
Levorphanol	9220	II
Meperidine	9230	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Thebaine	9333	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Sufentanil	9740	II

The company plans to import the listed controlled substances in bulk powder form from foreign sources for the manufacture of analytical reference standards for sale to their customers.

The company plans to import analytical reference standards for

distribution to its customers for research and analytical purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances. 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: July 20, 2017.

Demetra Ashley,

Acting Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: AMRI Rensselaer, 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 in accordance with 21 CFR 1301.33(a) on or before September 25, 2017.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 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 1301.33(a), this is notice that on March 30, 2017, AMRI Rensselaer, Inc., 33 Riverside Avenue, Rensselaer, New York 12144 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Pentobarbital	2270	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Meperidine	9230	II
Morphine	9300	II
Fentanyl	9801	II

The company plans to manufacture bulk controlled substances for use in product development and for distribution to its customers.

In reference to drug codes 7360 (marihuana) and 7370 (THC), the company plans to bulk manufacture these drugs as synthetics. No other activities for these drug codes are authorized for this registration.

Dated: July 19, 2017.

Demetra Ashley,

Acting Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as bulk manufacturers of various classes of controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as manufacturers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted for these notices.

Company	FR docket	Published
Cedarburg Pharmaceuticals	82 FR 19083	April 25, 2017.
Siegfried USA, LLC	82 FR 19084	April 25, 2017.
Sigma Aldrich Research Biochemicals, Inc	82 FR 19085	April 25, 2017.

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 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. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a