

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 5, 2015. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before August 5, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 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 Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy 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 March 3, 2015, United States Pharmacoepial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Cathinone (1235)	I
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

Controlled substance	Schedule
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
3,4-Methylenedioxyamphetamine (7400).	I
Codeine-N-oxide (9053)	I
Difenoxin (9168)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
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
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	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 to 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: June 25, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.
[FR Doc. 2015-16445 Filed 7-2-15; 8:45 am]
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Manufacturer of Controlled Substances Registration: Halo Pharmaceutical, Inc.

ACTION: Notice of registration.

SUMMARY: Halo Pharmaceutical, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Halo Pharmaceutical, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated January 9, 2015, and published in the **Federal Register** on January 26, 2015, 80 FR 3979, Halo Pharmaceutical, Inc., 30 North Jefferson Road, Whippany, New Jersey 07981 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted to this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Halo Pharmaceutical, Inc. to manufacture the 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 the company’s physical security systems, verifying the 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 above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances:

Controlled substance	Schedule
Dihydromorphone (9145)	I
Hydromorphone (9150)	II

The company plans to manufacture Hydromorphone HCL for sale to other manufacturers and to manufacture other controlled substances for distribution to its customers. Dihydromorphone is an intermediate in the manufacture of Hydromorphone and is not for commercial distribution.

Dated: June 25, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015-16456 Filed 7-2-15; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: Kremers Urban Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class, 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 5, 2015. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before August 5, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL/8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 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 Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy 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 January 12, 2015, Kremers Urban Pharmaceuticals, Inc., 1101 C Avenue West, Seymour, Indiana 47274 applied to be registered as an importer of methylphenidate (1724), a basic class of controlled substance listed in schedule II.

The company plans to import the listed substances in finished dosage

form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company’s own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Dated: June 25, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: AMPAC Fine Chemicals 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 in accordance with 21 CFR 1301.33(a) on or before September 4, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 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 Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy 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 20, 2015, AMPAC Fine Chemicals LLC, Highway 50 and Hazel Avenue, Building 05001, Rancho Cordova,

California 95670 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Methylphenidate (1724)	II
Thebaine (9333)	II
Poppy Straw Concentrate (9670)	II
Tapentadol (9780)	II

The company is a contract manufacturer. In reference to Poppy Straw Concentrate the company will manufacture thebaine intermediates for sale to its customers for further manufacture. No other activity for this drug code is authorized for this registration.

Dated: June 25, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015-16443 Filed 7-2-15; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Manufacturer of Controlled Substances Registration: Rhodes Technologies

ACTION: Notice of registration.

SUMMARY: Rhodes Technologies applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Rhodes Technologies registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated January 21, 2015, and published in the **Federal Register** on January 28, 2015, 80 FR 4593, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816 applied to be registered as a manufacturer of certain basic classes of controlled substances. One objection was received on March 27, 2015. However, after a thorough review of this matter, the Drug Enforcement Administration has concluded that the issues raised in the objection do not warrant the denial of this application.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Rhodes Technologies to manufacture the 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