

Company	FR Docket	Published
Sigma Aldrich Research Biochemicals, Inc	81 FR 38217	June 13, 2016.

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 registration as a bulk manufacturer to the above listed persons.

Dated: September 7, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016-22082 Filed 9-13-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Halo Pharmaceutical, 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 November 14, 2016.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her

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 July 27, 2016, Halo Pharmaceutical, Inc., 30 North Jefferson Road, Whippany, New Jersey 07981 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

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

The company plans to manufacture Hydromorphone (9150) for distribution to its customers. Dihydromorphine (9145) is an intermediate in the manufacture of Hydromorphone and is not for commercial distribution.

Dated: September 7, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016-22074 Filed 9-13-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: United States Pharmacopeial 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 October 14, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before October 14, 2016.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her 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 February 26, 2016, 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	Schedule
Cathinone (1235)	I
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I

Controlled substance	Schedule
Tetrahydrocannabinols (7370)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
3,4-Methylenedioxymphetamine (7400)	I
Codeine-N-oxide (9053)	I
Difenoxin (9168)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Norlevorphanol (9634)	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 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: September 7, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016-22079 Filed 9-13-16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Insys Manufacturing 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 November 14, 2016.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her 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 June 29, 2016, Insys Manufacturing LLC, 811 Paloma Drive, Suite C, Round Rock, Texas 78665-2402 applied to be registered as a bulk manufacturer the following basic classes of controlled substances:

Controlled substance	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to manufacture bulk synthetic active pharmaceutical ingredients (APIs) for product development and distribution to its customers. No other activity for these drug codes are authorized for this registration.

Dated: September 7, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

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