

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 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
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.

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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.