

comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before January 4, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before January 4, 2016.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/OD/D, 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 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 October 29, 2015, Mylan Technologies, Inc., 110 Lake Street, Saint Albans, Vermont 05478 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Methylphenidate (1724) .....	II
Fentanyl (9801) .....	II

The company plans to import the listed controlled 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: November 27, 2015.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

[FR Doc. 2015–30555 Filed 12–2–15; 8:45 am]

**BILLING CODE 4410–09–P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA–392]

**Importer of Controlled Substances  
Registration: Fresenius Kabi USA, LLC**

**ACTION:** Notice of registration.

**SUMMARY:** Fresenius Kabi USA, LLC applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Fresenius Kabi USA, LLC registration as an importer of this controlled substance.

**SUPPLEMENTARY INFORMATION:** By notice dated September 16, 2015, and published in the **Federal Register** on September 23, 2015, 80 FR 57389 Fresenius Kabi USA, LLC, 3159 Staley Road, Grand Island, New York 14072 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Fresenius Kabi USA, LLC to import the basic class of controlled substance 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. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of remifentanyl (9739), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for product development and preparation of stability batches.

Dated: November 27, 2015.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA–392]

**Importer of Controlled Substances  
Registration: United States  
Pharmacopeial Convention**

**ACTION:** Notice of registration.

**SUMMARY:** United States Pharmacopeial Convention applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants United States Pharmacopeial Convention registration as an importer of those controlled substances.

**SUPPLEMENTARY INFORMATION:** By notice dated June 25, 2015, and published in the **Federal Register** on July 6, 2015, 80 FR 38466, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of United States Pharmacopeial Convention to import 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. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the 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
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

Controlled substance	Schedule
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: November 23, 2015.

**Louis J. Milione,**  
Deputy Assistant Administrator.  
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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Manufacturer of Controlled Substances Registration: Navinta, LLC**

**ACTION:** Notice of registration.

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

**SUPPLEMENTARY INFORMATION:** By notice dated June 25, 2015, and published in the **Federal Register** on July 6, 2015, 80 FR 38471, Navinta, LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Navinta, LLC 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 following basic classes of controlled substances:

Controlled substance	Schedule
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333) .....	II
Fentanyl (9801) .....	II

The company plans initially to manufacture API quantities of the listed controlled substances for validation purposes and FDA approval, then eventually upon FDA approval to produce commercial size batches for distribution to dosage form manufacturers.

Dated: November 23, 2015.

**Louis J. Milione,**  
Deputy Assistant Administrator.  
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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Importer of Controlled Substances Registration: Akorn, Inc.**

**ACTION:** Notice of registration.

**SUMMARY:** Akorn, Inc. applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Akorn, Inc. registration as an importer of this controlled substance.

**SUPPLEMENTARY INFORMATION:**

By notice dated September 1, 2015, and published in the **Federal Register** on September 9, 2015, 80 FR 54327 Akorn, Inc., 1222 W. Grand Avenue, Decatur, Illinois 62522 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Akorn, Inc. to import the basic class of controlled substance 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. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of remifentanyl (9739), a basic class of controlled substance listed in schedule II.

The company plans to import remifentanyl in dosage form for distribution.

Dated: November 23, 2015.

**Louis J. Milione,**  
Deputy Assistant Administrator.  
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