

Dated: October 11, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–23684 Filed 10–29–18; 8:45 am]

BILLING CODE 4410–09–P

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 schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as bulk 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 |
|---|--------------|----------------|
| Johnson Matthey Pharmaceutical Materials Inc. | 83 FR 27632. | June 13, 2018. |
| Alcami Wisconsin Corporation. | 83 FR 27628. | June 13, 2018. |

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 registration as a bulk manufacturer to the above listed companies.

Dated: October 22, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–23698 Filed 10–29–18; 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 on or before December 31, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 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 August 22, 2018, Insys Manufacturing, LLC, 2700 Oakmont Drive, Round Rock, Texas 78665–1019 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 |

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: October 22, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–23696 Filed 10–29–18; 8:45 am]

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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 on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 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/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 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 August 17, 2018, United States Pharmacopeial

Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852-1717, applied to be registered as an importer of the following basic class of the controlled substance:

| Controlled substance | Drug code | Schedule |
|----------------------|-----------|----------|
| Oxymorphone | 9652 | II |

The company plans to import the bulk controlled substance for distribution of analytical reference standards to its customers for research and analytical purposes.

Dated: October 22, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018-23701 Filed 10-29-18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

**Importer of Controlled Substances
Application: Sharp (Bethlehem), 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 on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 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/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 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 August 30, 2018, Sharp (Bethlehem), LLC, 2400 Baglyos Circle, Bethlehem, Pennsylvania 18020, applied to be registered as an importer of the following basic class of controlled substances:

| Controlled substance | Drug code | Schedule |
|----------------------------|-----------|----------|
| Gamma Hydroxybutyric Acid. | 2010 | I |

The company plans to import dosage forms of the listed controlled substances to conduct clinical trials.

Approval of permit applications will occur only when the registrant’s 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: October 22, 2018.

John J. Martin,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

**Importer of Controlled Substances
Application: Fisher Clinical Services, 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 on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement

Administration, Attention: DEA Federal Register Representative/DPW, 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/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 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 August 17, 2018, Fisher Clinical Services Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106, applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|----------------------|-----------|----------|
| Psilocybin | 7437 | I |
| Methylphenidate | 1724 | II |
| Levorphanol | 9220 | II |
| Noroxymorphone. | 9668 | II |
| Tapentadol | 9780 | II |

The company plans to import the listed controlled substances for clinical trials.

Dated: October 22, 2018.

John J. Martin,

Assistant Administrator.

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