

development and preparation of stability batches.

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

Drug Enforcement Administration

[Docket No. DEA-392]

**Importer of Controlled Substances
Application: ALMAC Clinical Services
Incorp (ACSI)**

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 September 15, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 15, 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 June 29, 2016, ALMAC Clinical Services Incorp (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Oxycodone (9143)	II
Hydromorphone (9150)	II
Morphine (9300)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in dosage form for clinical trial only. Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under 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.

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

Drug Enforcement Administration

[Docket No. DEA-392]

**Importer of Controlled Substances
Application: Cody Laboratories, Inc.**

ACTION: Notice of application.

SUMMARY: 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 September 15, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 15, 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 May 18, 2016, Cody Laboratories, Inc., 601 Yellowstone Avenue, Barry Baldwin, Controlled Substances Manager, Cody, Wyoming 82414-9321 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Phenylacetone (8501)	II
Poppy Straw Concentrate (9670)	II
Tapentadol (9780)	II

The company plans to import narcotic raw materials to manufacture bulk controlled substances for distribution to its customers. The company plans to import an intermediate form of tapentadol (9780), to bulk manufacture tapentadol for distribution to its customers.

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

Drug Enforcement Administration

[Docket No. DEA-392]

**Importer of Controlled Substances
Application: Actavis Laboratories FL.,
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 1301.34(a) on or before September 15, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 15, 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 June 2, 2016, Actavis Laboratories FL., Inc., 4955 Orange Drive, Davie, Florida 33314 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Fentanyl (9801)	II

The company plans to import the above-listed controlled substances for

clinical trials, research and analytical purposes.

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

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Bellwyck Clinical Services

ACTION: Notice of application.

SUMMARY: 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 September 15, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 15, 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 April 18, 2016, Bellwyck Clinical Services, 8946 Global Way, West Chester, Ohio 45069 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Methylphenidate (1724)	II
Oxycodone (9143)	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. Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

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

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: AMRI Rensselaer, Inc.

ACTION: Notice of application.

SUMMARY: 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 September 15, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 15, 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,