

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Cody Laboratories, Inc.

ACTION: Notice of registration.

SUMMARY: Cody Laboratories, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The DEA grants Cody Laboratories, Inc. registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated August 27, 2014, and published in the *Federal Register* on September 4, 2014, 79 FR 52762, Cody Laboratories, Inc., 601 Yellowstone Avenue, Cody, Wyoming 82414-9321, applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted to this notice. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007).

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Cody Laboratories, Inc. 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 listed:

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

The company plans to import narcotic raw materials for manufacturing and further distribution to its customers. The company is registered with the DEA as a manufacturer of several controlled substances that are manufactured from poppy straw concentrate.

The company plans to import an intermediate form of tapentadol (9780) to bulk manufacture tapentadol for distribution to its customers.

Dated: January 9, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Catalent CTS, LLC

ACTION: Notice of registration.

SUMMARY: Catalent CTS, LLC applied to be registered as an importer of certain basic classes of controlled substances. The DEA grants Catalent CTS, LLC registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated June 10, 2014, and published in the *Federal Register* on June 17, 2014, 79 FR 34551, Catalent CTS, LLC, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, applied to be registered as an importer of certain basic classes of controlled substances. One comment of objection was received on this registration and a request for a hearing was received on September 3, 2014. The objection was resolved. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007).

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Catalent CTS, LLC 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 listed:

Controlled substance	Schedule
Marihuana (7360)	I
Poppy Straw Concentrate (9670)	II

The company plans to import a finished pharmaceutical product containing cannabis extracts in dosage form for a clinical trial study.

This compound is listed under drug code 7360. No other activity for this drug code is authorized for this registration.

In addition, the company plans to import an ointment for the treatment of wounds which contain trace amounts of the controlled substances normally found in poppy straw concentrate for packaging and labeling to be used in clinical trials.

Dated: January 9, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: IRIX Manufacturing, 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 March 27, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 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, and dispensers of controlled substances