

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals, Inc.**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic class, 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 April 18, 2016.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: 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 1301.33(a), this is notice that on November 4, 2015, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024 applied to be registered as a bulk manufacturer of nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to manufacturer bulk active pharmaceutical ingredients (API) for distribution to its customers.

Dated: February 10, 2016.

**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: Euticals, Inc.**

**ACTION:** Notice of registration.

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

**SUPPLEMENTARY INFORMATION:** By notice dated September 16, 2015, and published in the **Federal Register** on September 23, 2015, 80 FR 57391, Euticals, Inc., 2460 W. Bennett Street, Springfield, Missouri 65807-1229 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 Euticals, 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 following basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Amphetamine (1100) .....	II
Lisdexamfetamine (1205) .....	II
Methylphenidate (1724) .....	II
Phenylacetone (8501) .....	II
Methadone (9250) .....	II
Methadone intermediate (9254) ...	II
Oripavine (9330) .....	II
Tapentadol (9780) .....	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers.

In reference to oripavine (9330), the company plans to acquire the listed

controlled substance in bulk from a domestic source in order to manufacture other controlled substances in bulk for distribution to its customers.

Dated: February 10, 2016.

**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: Catalent Pharma Solutions, LLC**

**ACTION:** Notice of registration.

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

**SUPPLEMENTARY INFORMATION:** By notice dated August 21, 2015, and published in the **Federal Register** on August 31, 2015, 80 FR 52510, Catalent Pharma Solutions, LLC, 3031 Red Lion Road, Philadelphia, Pennsylvania 19114 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 Catalent Pharma Solutions, 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 hydromorphone (9150), a basic class of controlled substance listed in schedule II.

The company plans to import the above listed controlled substance for a clinical trial study. Approval of permit applications will occur only when the