

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 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: June 25, 2015.

**Joseph T. Rannazzisi,**  
*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 January 9, 2015, and published in the **Federal Register** on January 26, 2015, 80 FR 3978, 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 to 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 basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Amphetamine (1100) .....	II
Lisexamfetamine (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 Amphetamine (1100), 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: June 25, 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: Navinta, 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 in accordance with 21 CFR 1301.33(a) on or before September 4, 2015.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODXL, 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, 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 February 4, 2015, Navinta, LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414 applied to be registered 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: June 25, 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: Mylan Pharmaceuticals, Inc.

**ACTION:** Notice of registration.

**SUMMARY:** Mylan Pharmaceuticals, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mylan Pharmaceuticals, Inc. registration as an importer of those controlled substances.

**SUPPLEMENTARY INFORMATION:** By notice dated March 20, 2015, and published in the **Federal Register** on March 27, 2015, 80 FR 16436, Mylan Pharmaceuticals, Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505 applied to be registered as an importer