

The company plans to import the FDA approved drug product in finished dosage form for distribution to its customers.

Dated: July 10, 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: Mallinckrodt, LLC

**ACTION:** Notice of registration.

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

**SUPPLEMENTARY INFORMATION:** By notice dated January 21, 2015, and published in the **Federal Register** on January 28, 2015, 80 FR 4592, Mallinckrodt LLC, 3600 North Second Street, St. Louis, Missouri 63147 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 Mallinckrodt, LLC 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        |
| Lisdexamfetamine (1205) .....          | II       |
| Oripavine (9330) .....                 | II       |

| Controlled substance    | Schedule |
|-------------------------|----------|
| Tapentadol (9780) ..... | II       |

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

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**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: Navinta LLC

**ACTION:** Notice of registration.

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

**SUPPLEMENTARY INFORMATION:** By notice dated February 11, 2015, and published in the **Federal Register** on February 19, 2015, 80 FR 8901, Navinta LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414 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 Navinta LLC 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 listed:

| Controlled substance       | Schedule |
|----------------------------|----------|
| Pentobarbital (2270) ..... | II       |

| Controlled substance      | Schedule |
|---------------------------|----------|
| Remifentanyl (9739) ..... | II       |

The company plans to initially manufacture API quantities of the listed controlled substances for validation purposes and FDA approval, and then produce commercial size batches for distribution to dosage form manufacturers upon FDA approval.

Dated: July 10, 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: Siegfried USA, LLC

**ACTION:** Notice of registration.

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

**SUPPLEMENTARY INFORMATION:** By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22561, Siegfried USA, LLC, 33 Industrial Park Road, Pennsville, New Jersey 08070 applied to be registered as an importer of certain basic classes of controlled substances. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007).

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Siegfried USA, 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