



## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **Manufacturer of Controlled Substances Registration: Mallinckrodt, LLC**

**[Docket No. DEA-392]**

**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:

<b><u>Controlled Substance</u></b>	<b><u>Schedule</u></b>
Gamma Hydroxybutyric Acid (2010)	I
Lisdexamfetamine (1205)	II
Oripavine (9330)	II
Tapentadol (9780)	II

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

Dated: July 10, 2015.

Joseph T. Rannazzisi,  
*Deputy Assistant Administrator.*

