



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Registration: Unither Manufacturing, LLC

[Docket No. DEA-392]

ACTION: Notice of registration.

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

SUPPLEMENTARY INFORMATION:

By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22552, Unither Manufacturing, LLC, 331 Clay Road, Rochester, New York 14623 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 Unither Manufacturing, 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 methylphenidate (1724), a basic class of controlled substance listed in schedule II.

The company plans to import the listed substance as a raw material for updated testing purposes for EU customer requirements.

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Dated: October 2, 2015.

Louis J. Milione,
Deputy Assistant Administrator.

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