The company plans to import the listed substances for analytical research, testing, and clinical trials. This authorization does not extend to the import of finished FDA approved or non-approved dosage form for commercial distribution in the United States.

The company plans to import an intermediate form of tapentadrol (9780) to bulk manufacture tapentadrol for distribution to its customers. Placement of this drug code 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.

Louis J. Milione,
Deputy Assistant Administrator.

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

Louis J. Milione,
Deputy Assistant Administrator.
DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Unither Manufacturing, 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 1301.34(a) on or before October 6, 2016. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before October 6, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

The company plans to manufacture small quantities of the listed controlled substances to make reference standards which will be distributed to their customers.

Louis J. Milione,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: AMRI Rensselaer, Inc.

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 November 7, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

The company plans to import the listed substance solely for updated analytical testing purposes for EU customer requirements.

This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Louis J. Milione,
Deputy Assistant Administrator.

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