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 February 8, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/OD/D, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearing should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her 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, including the authority to issue, revoke, amend, suspend, or deny registrations, has been delegated to the Deputy Assistant Administrator.

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 the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Schedule</th>
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<tbody>
<tr>
<td>Phenylacetone (8501)</td>
<td>II</td>
</tr>
<tr>
<td>Poppy Straw Concentrate (9670)</td>
<td>II</td>
</tr>
<tr>
<td>Tapentadol (9780)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to import narcotic raw materials for manufacturing and further distribution to its customers. The company is registered with the DEA as a manufacturer of several controlled substances that are manufactured from poppy straw concentrate.

The company plans to import an intermediate form of tapentadol (9780), to bulk manufacturer tapentadol for distribution to its customers.

Dated: November 30, 2015.

Louis J. Milione,
Deputy Assistant Administrator.

[FR Doc. 2015–30812 Filed 12–7–15; 8:45 am]

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