DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Bellwyck Clinical Services

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 30, 2017. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before October 30, 2017.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his 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, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on June 30, 2017, Bellwyck Clinical Services, 8946 Global Way, West Chester, Ohio 45069 applied to be registered as an importer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Drug code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine ..........</td>
<td>1100</td>
<td>II</td>
</tr>
<tr>
<td>Methylphenidate ......</td>
<td>1724</td>
<td>II</td>
</tr>
<tr>
<td>Oxycodone ..........</td>
<td>9143</td>
<td>II</td>
</tr>
</tbody>
</table>

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. Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.


Demetra Ashley,
Acting Assistant Administrator.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Research Triangle Institute

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 on or before November 28, 2017.

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his 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, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on March 31, 2017, Research Triangle Institute, 3040 East Cornwallis Road, Hermann Building, Room 106, Research Triangle Park, North Carolina 27709–2194 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Drug code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marihuana ............</td>
<td>7360</td>
<td>I</td>
</tr>
<tr>
<td>Tetrahydrocannabinols</td>
<td>7370</td>
<td>I</td>
</tr>
</tbody>
</table>

The company will manufacture marihuana (7360) and tetrahydrocannabinols (7370) for use by their researchers under the above listed controlled substances as Active Pharmaceutical Ingredient (API) for clinical trials.

In reference to drug code (7370) the company plans to bulk manufacture a synthetic tetrahydrocannabinol. No other activities for this drug code are authorized for this registration.


Demetra Ashley,
Acting Assistant Administrator.

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On September 19, 2017, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of South Carolina in the lawsuit entitled United States v. JW Aluminum Company, Civil Action No. 17–cv–02490–DCN.

The United States filed this lawsuit under the Clean Air Act. The United States’ complaint seeks injunctive relief and civil penalties for violations of the regulations that govern secondary aluminum production at the defendant’s facility in Mount Holly, South Carolina. The consent decree requires the defendant to perform injunctive relief and pay a $230,000 civil penalty.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to United States v. JW Aluminum Company, D.J. Ref. No. 90–5–2–1–