DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals, 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 October 5, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 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 Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on July 28, 2014, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marihuana (7360)</td>
<td>I</td>
</tr>
<tr>
<td>Tetrahydrocannabinols (7370)</td>
<td>I</td>
</tr>
</tbody>
</table>

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. In reference to drug code 7360 marihuana, the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic tetrahydrocannabinol 7370. No other activity for this drug code is authorized for this registration.

Dated: July 29, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Cody Laboratories, Inc.

ACTION: Notice of registration.

SUMMARY: Cody Laboratories, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cody Laboratories, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the Federal Register on April 22, 2015, 80 FR 22560, Cody Laboratories, Inc., Steve Hartman-Vice President of Compliance, 601 Yellowstone Avenue, Cody, Wyoming 82414 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cody Laboratories, Inc. 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 basic classes of controlled substances listed:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydromorphine (9145)</td>
<td>I</td>
</tr>
<tr>
<td>Amphetamine (1100)</td>
<td>II</td>
</tr>
<tr>
<td>Methamphetamine (1105)</td>
<td>II</td>
</tr>
<tr>
<td>Amobarbital (2125)</td>
<td>II</td>
</tr>
<tr>
<td>Pentobarbital (2270)</td>
<td>II</td>
</tr>
<tr>
<td>Secobarbital (2315)</td>
<td>II</td>
</tr>
<tr>
<td>4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)</td>
<td>II</td>
</tr>
<tr>
<td>Phencyclidine (8501)</td>
<td>II</td>
</tr>
<tr>
<td>Cocaine (9041)</td>
<td>II</td>
</tr>
<tr>
<td>Codeine (9050)</td>
<td>II</td>
</tr>
<tr>
<td>Dihydrocodeine (9120)</td>
<td>II</td>
</tr>
<tr>
<td>Oxycodone (9143)</td>
<td>II</td>
</tr>
<tr>
<td>Hydromorphone (9150)</td>
<td>II</td>
</tr>
<tr>
<td>Diphenoxylate (9170)</td>
<td>II</td>
</tr>
<tr>
<td>Egcgonine (9180)</td>
<td>II</td>
</tr>
<tr>
<td>Hydrocodone (9193)</td>
<td>II</td>
</tr>
<tr>
<td>Meperidine (9230)</td>
<td>II</td>
</tr>
<tr>
<td>Methadone (9250)</td>
<td>II</td>
</tr>
<tr>
<td>Morphin (9300)</td>
<td>II</td>
</tr>
<tr>
<td>Thebaine (9333)</td>
<td>II</td>
</tr>
<tr>
<td>Oxymorphone (9652)</td>
<td>II</td>
</tr>
<tr>
<td>Al芬tanyl (9737)</td>
<td>II</td>
</tr>
<tr>
<td>Remifentanil (9739)</td>
<td>II</td>
</tr>
<tr>
<td>Sufentanil (9740)</td>
<td>II</td>
</tr>
<tr>
<td>Fentanyl (9801)</td>
<td>II</td>
</tr>
</tbody>
</table>

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

Dated: July 29, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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