DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Akorn, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on May 31, 2013, Akorn, Inc., 1222 W. Grand Avenue, Decatur, Illinois 62522, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Remifentanil (9739), a basic class of controlled substance listed in schedule II.

The company plans to import Remifentanil in bulk for use in dosage-form manufacturing.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act [21 U.S.C. 952(a)(2)(B)] may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than July 31, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: June 18, 2013.

Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.


DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Application, Boehringer Ingelheim Chemicals

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on May 31, 2013, Boehringer Ingelheim Chemicals, 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to bulk manufacture amphetamine.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act [21 U.S.C. 952(a)(2)(B)] may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than July 31, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substances in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. § 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: June 18, 2013.

Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.


DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice Of Registration; Mallinckrodt, LLC.

By Notice dated February 8, 2013, and published in the Federal Register on February 21, 2013, 78 FR 12101, Mallinckrodt, LLC., 3600 North Second Street, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:
The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk for distribution to its customers.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate, 72 FR 3417 (2007). Regarding Phenyacetone (8501), a basic class of controlled substance, no comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and § 952(a), and determined that the registration of Mallinckrodt, LLC., to import 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. DEA has investigated Mallinckrodt, LLC., to ensure that the company’s registration is consistent with the public interest. The investigation has included inspection and testing of the company’s physical security systems, verification of the company’s compliance with state and local laws, and a review of 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 basic classes of controlled substances listed.

Dated: June 18, 2013.

Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.
[FR Doc. 2013–15589 Filed 6–28–13; 8:45 am]
BILLING CODE 4410–09–P

<table>
<thead>
<tr>
<th>Drug</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenyacetone (8501)</td>
<td>II</td>
</tr>
<tr>
<td>Coca Leaves (9040)</td>
<td>II</td>
</tr>
<tr>
<td>Opium, raw (9600)</td>
<td>II</td>
</tr>
<tr>
<td>Poppy Straw Concentrate (9670)</td>
<td>II</td>
</tr>
</tbody>
</table>

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Catalent CTS., Inc.

By Notice dated April 10, 2013, and published in the Federal Register on April 19, 2013, 78 FR 23594, Catalent CTS., Inc., 10245 Hickman Mills Drive, Kansas City, Missouri 64137, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marihuana (7360)</td>
<td>I</td>
</tr>
<tr>
<td>Poppy Straw Concentrate (9670)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to import the listed controlled substance for analytical research and testing.

The import of the above listed basic class of controlled substance would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and § 952(a), and determined that the registration of Mallinckrodt, 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.

DEA has investigated Alkermes Gainesville, LLC, to ensure that the company’s registration is consistent with the public interest. The investigation has included inspection and testing of the company’s physical security systems, verification of the company’s compliance with state and local laws, and a review of 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 basic class of controlled substance listed.

Dated: June 18, 2013.

Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.
[FR Doc. 2013–15589 Filed 6–28–13; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Lipomed, One Broadway, Cambridge, Massachusetts 02142, made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>JWH–250 (6250)</td>
<td>I</td>
</tr>
</tbody>
</table>