DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Almac Clinical Services, Inc. (ACSI)

ACTION: Notice of registration.

SUMMARY: Almac Clinical Services, Inc. (ACSI) applied to be registered as an importer of certain basic classes of narcotic controlled substances. The Drug Enforcement Administration (DEA) grants Almac Clinical Services, Inc. (ACSI) registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated April 21, 2014, and published in the Federal Register on April 28, 2014, 79 FR 23373, Almac Clinical Services, Inc. (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964, applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Almac Clinical Services, Inc., (ACSI) 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. 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 basic classes of controlled substances listed:

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Schedule</th>
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<tbody>
<tr>
<td>Oxycodone (9143)</td>
<td>II</td>
</tr>
<tr>
<td>Hydromorphone (9150)</td>
<td>II</td>
</tr>
<tr>
<td>Tapentadol (9780)</td>
<td>II</td>
</tr>
<tr>
<td>Fentanyl (9801)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to import small quantities of the listed controlled substances in dosage form to conduct clinical trials.

The import of the above listed basic classes of controlled substances is granted only for analytical testing and clinical trials. This authorization does not extend to the import of finished Food and Drug Administration approved or non-approved dosage forms for commercial distribution in the United States.

Dated: July 22, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.