### DEPARTMENT OF JUSTICE

**Drug Enforcement Administration**

[Docket No. DEA–392]

**Bulk Manufacturer of Controlled Substances Application: Insys Manufacturing, LLC**

**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 December 31, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 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 1301.33(a), this is notice that on August 22, 2018, Insys Manufacturing, LLC, 2700 Oakmont Drive, Round Rock, Texas 78665–1019 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 plans to manufacture bulk synthetic active pharmaceutical ingredients (APIs) for product development and distribution to its customers. No other activity for these drug codes are authorized for this registration.

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**Summary:** Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as bulk manufacturers of various classes of schedule I and II controlled substances. Information on previously registered as bulk manufacturers of various classes of controlled substances. The DEA has considered the factors in local laws, and reviewing each security systems, verifying each testing each company’s physical registration by the Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 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 persons may also file a written request for a hearing on the application on or before November 29, 2018.

### DEPARTMENT OF JUSTICE

**Drug Enforcement Administration**

[Docket No. DEA–392]

**Importer of Controlled Substances Application: United States Pharmacopeial Convention**

**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 29, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 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 requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 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 August 17, 2018, United States Pharmacopeial...