



## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

**[Docket No. DEA-392]**

#### **Bulk Manufacturer of Controlled Substances Application: Cambrex Charles City**

**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 [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette 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 June 8, 2018, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616 applied to be registered as a bulk manufacturer of the basic classes of controlled substances:

<b>Controlled Substance</b>	<b>Drug Code</b>	<b>Schedule</b>
Gamma Hydroxybutyric Acid	2010	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Phenylacetone	8501	II
Cocaine	9041	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for conversion to other controlled substances and sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Dated: September 20, 2018.

**John J. Martin,**

*Assistant Administrator.*

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