



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 in accordance with 21 CFR 1301.33(a) 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/ODXL, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 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 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 May 15, 2014, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616 applied to be registered as a bulk manufacturer the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
4-Anilino-N-phenethyl-4-piperidine (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, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

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

Dated: April 14, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

OD:_____
ODX:_____
OD/DX:_____
ODXL:_____
ODW:_____
ODW Policy Analyst:_____
ODQ:_____
ODG:_____
ODG/ODGR – M. Herron: _____
ODG/ODGR - S. Powell:_____
ODG/ODGR - M. Brown:_____2/20/2015

NOA – CAMBREX CHARLES CITY
Document#: ODGR-14-063

DFN: 010.02.A1 General Correspondence
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