

ACTION: Notice of application.

SUMMARY: Cambrex Charles City has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 23, 2021. Such persons may also file a written request for a hearing on the application on or before August 23, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 6, 2021, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616-3466, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols ...	7370	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Phenylacetone	8501	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Methadone	9250	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 above-listed controlled substances in bulk for conversion to other controlled substances and sales to its customers for dosage form development, clinical trials and use in stability qualification studies. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as synthetic. No other activities for these

drug codes are authorized for this registration.

William T. McDermott,
Assistant Administrator.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-858]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Annac Medical Center LC

AGENCY: Drug Enforcement Administration, Justice.
ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before August 23, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW 8701 Morrisette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No—DEA-858 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or

determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). In addition to seeking to produce marihuana extract, this applicant is separately seeking to cultivate marihuana. See Notice of Application, Bulk Manufacturers of Marihuana, 84 FR 44920, 44922 (Aug. 27, 2019). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on April 14, 2021, Annac Medical Center, LC, 5172 West Patrick Lane, Suite 100, Las Vegas, Nevada 89117-8911, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols ...	7370	I

William T. McDermott,
Assistant Administrator.
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DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Oil Pollution Act

On June 17, 2021, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Louisiana in the lawsuit entitled *United States of America and Louisiana v. CITGO Petroleum Corp.*, Civil Action No. 2:21-cv-1705. The United States is