

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 classes, and applicants therefore, 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 its 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) as described in 84 FR 44920, published on August 27, 2019.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on May 30, 2019, Irvine Labs, Inc., 1864 Swan Circle, Costa Mesa, California 92626-4739 applied to be registered as a bulk manufacturer of the following basic class of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract ..	7350	I
Marihuana	7360	I
Tetrahydrocannabinols.	7370	I

The applicant noticed above applied to become registered with DEA to grow marihuana as bulk manufacturer subsequent to a 2016 DEA policy statement that provided information on how it intended to expand the number of registrations, and described in general terms the way it would oversee those additional growers. Before DEA completes the evaluation and registration process for applicants to grow marihuana, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law, as described in 84 FR 44920.

Dated: February 3, 2020.

William T. McDermott,
Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-585]

Bulk Manufacturer of Controlled Substances Application: Patheon Pharmaceuticals, Inc.

ACTION: Notice of application.

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 April 24, 2020.

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 December 23, 2019, Patheon Pharmaceuticals, Inc., 2100 E Galbraith Road, Cincinnati, Ohio 45237-1625 applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I

The Gamma Hydroxybutyric Acid will be produced during the process of converting gamma-butyrolactone into a new product for development. The company plans to manufacture the above-listed controlled substance as Active Pharmaceutical Ingredient (API) that will be further synthesized into dosage forms of a new product. No other activities for this drug code are authorized for this registration.

Dated: January 31, 2020.

William T. McDermott,
Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-595]

Bulk Manufacturer of Controlled Substances Application: Chemtos, 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 April 24, 2020.

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 January 9, 2020, Chemtos, LLC, 16713 Picadilly Court, Round Rock, Texas 78664-8544 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
3-Fluoro-N-methylcathinone (3-FMC)	1233	I
Cathinone	1235	I
Methcathinone	1237	I
4-Fluoro-N-methylcathinone (4-FMC)	1238	I
Pentedrone (α -methylaminovalerophenone)	1246	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
4-Methyl-N-ethylcathinone (4-MEC)	1249	I