



## Drug Enforcement Administration

[Docket No. 1354]

### **Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Entheogen Pharmaceuticals Inc**

**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 therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.”

**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 submit electronic 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). 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 December 11, 2023, Entheogen Pharmaceuticals Inc, 17349 Muskrat Avenue, Adelanto, California, 92301 applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

<b>Controlled Substance</b>	<b>Drug Code</b>	<b>Schedule</b>
Ibogaine	7260	I

Lysergic Acid Diethylamide	7315	I
Marihuana Extract	7350	I
Marihuana	7360	I
Mescaline	7381	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

In reference to drug codes 7260 (Ibogaine), 7315 (Lysergic Acid Diethylamide), 7381 (Mescaline), 7435 (Dimethyltryptamine), 7437 (Psilocybin), and 7438 (Psilocyn), the company plans to bulk manufacture the listed controlled substances for internal research and analytical development purposes. No other activities for these drug codes are authorized for this registration.

**Marsha Ikner,**

*Acting Deputy Assistant Administrator.*

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