DEPART

Drug Enforcement Administration

[Docket No. DEA-916]

Bulk Manufacturer of Controlled Substances Application: Novitium Pharma LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Novitium Pharma LLC 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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Such persons may also file a written request for a hearing on the application on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on September 8, 2021, Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s)**:**

Controlled Substance	Drug Code	Schedule
Psilocybin	7437	I
Psilocyn	7438	I
Levorphanol	9220	II

The company plans to bulk manufacture drug codes 7438 and 7437 to produce Active Pharmaceutical Ingredient (API) and finished dosage forms for use in clinical trial studies only. In reference to drug code 9220, the company plans to bulk manufacture this drug code to support commercial drug product manufacturing and drug development purposes. No other activities for these drug codes are authorized for this registration.

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2021-23282 Filed: 10/25/2021 8:45 am; Publication Date: 10/26/2021]