DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Application: Novitium Pharma LLC

[Docket No. DEA-711]

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Novitium Pharma LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug(s) 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 30 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 30 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. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on August 18, 2020, Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Lisdexamfetamine	1205	II
Levorphanol	9220	II

The company plans to import the listed controlled substance Lisdexamfetamine as a raw Active Pharmaceutical Ingredients (API) material for drug product development and research purposes only. The company may import Lisdexamfetamine API for research purposes only but not for the manufacturing of Food and Drug Administration (FDA)-approved products.

The company plans to import the listed controlled substance Levorphanol to develop the manufacturing process for a drug product that will in turn be used to produce a tablet equivalent to the current brand product.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,
Assistant Administrator.

[FR Doc. 2020-20161 Filed: 9/11/2020 8:45 am; Publication Date: 9/14/2020]