



## **Drug Enforcement Administration**

**[Docket No. DEA-911]**

### **Importer 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 an importer of basic class(es) of controlled substance(s). Refer to Supplemental 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 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 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.34(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 an importer of the following basic class(es) of controlled substance(s):

| Controlled Substance | Drug Code | Schedule |
|----------------------|-----------|----------|
| Levorphanol          | 9220      | II       |

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. No other activity for this drug code is authorized for this registration.

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 Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

**Brian S. Besser,**  
*Acting Assistant Administrator.*

[FR Doc. 2021-23032 Filed: 10/21/2021 8:45 am; Publication Date: 10/22/2021]