

Directorate for the quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM for use as reference standards.

Dated: December 2, 2019.

William T. McDermott, Assistant Administrator.

[FR Doc. 2019-27093 Filed 12-13-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-560]

Importer of Controlled Substances Application: Novitium Pharma 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 January 15, 2020. Such persons may also file a written request for a hearing on the application on or before January 15, 2020.

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 July 18, 2018, Novitium Pharma, LLC., 70 Lake Drive, East Windsor, New Jersey 08520 applied to be registered as an importer of the following basic class of controlled substance:

Table with 3 columns: Controlled substance, Drug code, Schedule. Row 1: Levorphanol, 9220, II

The company plans to import the controlled substance 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.

Dated: December 3, 2019.

William T. McDermott, Assistant Administrator.

[FR Doc. 2019-27095 Filed 12-13-19; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-553]

Importer of Controlled Substances Application: Mylan Pharmaceuticals Inc.

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 January 15, 2020. Such persons may also file a written request for a hearing on the application on or before January 15, 2020

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 October 17, 2019, Mylan Pharmaceuticals Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505 applied to be registered as an importer of the following basic classes of controlled substances:

Table with 3 columns: Controlled substance, Drug code, Schedule. Rows include Amphetamine, Methyphenidate, Oxycodone, Hydromorphone, Methadone, Morphine, Fentanyl.

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Authorization will not extend to the import of Food and Drug Administration approved or non-approved finished dosage forms for commercial sale.

Dated: November 14, 2019.

William T. McDermott, Assistant Administrator.

[FR Doc. 2019-27094 Filed 12-13-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jeffrey D. Olsen, M.D.; Decision and Order

On August 2, 2016, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (OSC) and Immediate Suspension of Registration (ISO) to Jeffrey D. Olsen, M.D. (hereinafter, Registrant), of Newport Beach, CA. Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC 2)), at 1; see also Government Exhibit (hereinafter, GX) 26, at 1-6. OSC 2 informed Registrant of the immediate suspension of his DEA Certificate of Registration (hereinafter, COR) FO6043638 pursuant to 21 U.S.C. 824(d) "because . . . [his] continued registration constitute[d] an imminent danger to the public health and safety." Id.

The substantive ground for the proceeding, as alleged in OSC 2, was that Registrant's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." Id. (citing 21 U.S.C. 824(a)(4)). Specifically, the OSC alleged that Registrant issued numerous prescriptions outside the usual course of the professional practice of medicine in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a) and in violation of California law and the minimum standards of medical practice in California. Id. at 2-4. The OSC stated that "[Registrant's] conduct, viewed as a whole, 'completely betrayed any semblance of legitimate medical treatment.'" Id. at 4 (citing Jack A. Danton, D.O., 76 FR 60900, 60904