



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**Importer of Controlled Substances Application: Mylan Pharmaceuticals Inc.**

**[Docket No. DEA-392]**

**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 **[INSERT 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Such persons may also file a written request for a hearing on the application on or before **[INSERT 30 DAYS AFTER 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 hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for 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. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007).

## **SUPPLEMENTARY INFORMATION:**

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on November 13, 2018, 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:

| <b>Controlled Substance</b> | <b>Drug Code</b> | <b>Schedule</b> |
|-----------------------------|------------------|-----------------|
| Amphetamine                 | 1100             | II              |
| Methylphenidate             | 1724             | II              |
| Oxycodone                   | 9143             | II              |
| Hydromorphone               | 9150             | II              |
| Methadone                   | 9250             | II              |
| Morphine                    | 9300             | II              |
| Fentanyl                    | 9801             | II              |

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 FDA approved or non-approved finished dosage forms for commercial use.

Dated: January 29, 2019.

**John J. Martin,**

*Assistant Administrator.*

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