



## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **Importer of Controlled Substances Application: Myoderm**

**[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 in accordance with 21 CFR 1301.34(a) 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 pursuant to 21 CFR 1301.43 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/DRW, 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/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

#### **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 11, 2016, Myoderm, 48 East Main Street, Norristown, Pennsylvania 19401 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              |
| Lisdexamfetamine            | 1205             | II              |
| Methylphenidate             | 1724             | II              |
| Nabilone                    | 7379             | II              |
| Oxycodone                   | 9143             | II              |
| Hydromorphone               | 9150             | II              |
| Hydrocodone                 | 9193             | II              |
| Morphine                    | 9300             | II              |
| Oxymorphone                 | 9652             | II              |
| Fentanyl                    | 9801             | II              |

The company plans to import the listed controlled substances in finished dosage form for clinical trials, research, and analytical purposes.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing, research, and clinical trials. This authorization does not

extend to the import of a finished FDA approved or non-approved dosage form for commercial sale.

Louis J. Milione,  
*Assistant Administrator.*

Billing Code 4410-09-P

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