



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 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.

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 2, 2018, Myoderm, 48 East Main Street, Norristown, Pennsylvania 19401-4915 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled Substance	Drug Code	Schedule
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 for clinical trials, research, and analytical purposes.

Approval of permit applications will occur only when the registrant’s activity is consistent with what is authorized under to 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.

Dated: December 8, 2018

John J. Martin,

Assistant Administrator.

Billing Code 4410-09-P

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