

Dated: December 3, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018-27036 Filed 12-12-18; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Eli-Elsohly Laboratories

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 February 11, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: 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 1301.33(a), this is notice that on November 22, 2017, Eli-Elsohly Laboratories, Mahmoud A. Elsohly Ph.D., 5 Industrial Park Drive, Oxford, Mississippi 38655 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols ..	7370	I
Dihydromorphine	9145	I
Amphetamine	1100	II
Methamphetamine	1105	II

Controlled substance	Drug code	Schedule
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Ecgonine	9180	II
Hydrocodone	9193	II
Morphine	9300	II
Thebaine	9333	II

The company plans to manufacture the listed controlled substances for product development and reference standards. In reference to drug codes 7360 (marihuana) and 7370 (THC), the company plans to isolate these controlled substances from procured 7350 (marihuana extract). In reference to drug code 7360 (marihuana), no cultivation activities are authorized for this registration. No other activities for these drug codes are authorized for this registration.

Dated: December 3, 2018.

John J. Martin,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Cambrex High Point, 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 February 11, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: 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 1301.33(a), this is notice that on July 16, 2018, Cambrex High Point Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substances	Drug code	Schedule
Oxymorphone	9652	II
Noroxymorphone	9668	II

The company plans to manufacture the above listed controlled substances in bulk for distribution to its customers.

Dated: December 3, 2018.

John J. Martin,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: Noramco 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 14, 2019. Such persons may also file a written request for a hearing on the application on or before January 14, 2019.

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 August 14, 2018, Noramco Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801-4417 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols ..	7370	I
Nabilone	7379	II
Phenylacetone	8501	II
Opium, raw	9600	II
Poppy Straw Concentrate.	9670	II
Tapentadol	9780	II

The company plans to import phenylacetone (8501), and poppy straw concentrate (9670) to bulk manufacture other controlled substances for distribution to its customers. In reference to drug codes 7360 (marihuana) and 7370 (THC), the company plans to import a synthetic cannabidiol and a synthetic tetrahydrocannabinol. No other activity for these drug codes is authorized for this registration. Placement of these drug codes onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances.

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

Dated: December 3, 2018.
John J. Martin,
Assistant Administrator.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: Mylan Technologies, 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 14, 2019. Such persons may also file a written request for a hearing on the application on or before January 14, 2019.

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 7, 2018, Mylan Technologies Inc., 110 Lake Street, Saint Albans,

Vermont 05478 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Methylphenidate	1724	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.

Dated: December 3, 2018.
John J. Martin,
Assistant Administrator.
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DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On December 4, 2018, the Department of Justice lodged a proposed consent decree with the United States District Court for the Northern District of New York in the lawsuit entitled *United States of America v. Grimmel Industries, LLC, et al.*, Civil Action No. 1:16-cv-1103 (NAM/CFH).

The United States filed the complaint in this Clean Water Act case against the Defendants on September 9, 2016. The complaint alleged that the Defendants, Grimmel Industries, LLC, Rensselaer Iron & Steel, Inc., and Toby Grimmel, violated the Multi-Sector General Permits issued by the New York Department of Environmental Conservation concurrently under Section 402(b) of the Clean Water Act, 42 U.S.C. 1342(b). The Complaint sought civil penalties and injunctive relief for eleven alleged violations of the permits, including effluent discharges in excess of permitted limits; failure to comply with corrective action requirements; inadequate permit coverage and stormwater pollution prevention plans; improper implementation of stormwater pollution prevention plans; failure to conduct quarterly visual monitoring; failure to timely submit reports; failure to perform annual dry weather flow monitoring; inadequate responses to benchmark exceedances; failure to train employees;