

as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|-----------------------|-----------|----------|
| Methylphenidate | 1724 | II |
| Levomethorphan | 9210 | II |
| Levorphanol | 9220 | II |
| Thebaine | 9333 | II |
| Remifentanyl | 9739 | II |
| Tapentadol | 9780 | II |

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

Dated: September 20, 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 Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as bulk manufacturers of various classes of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as bulk manufacturers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted for these notices.

| Company | FR docket | Published |
|----------------------------------|-------------|----------------|
| American Radiolabeled Chem | 83 FR 28664 | June 20, 2018. |
| Cerilliant Corporation | 83 FR 28664 | June 20, 2018. |

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of these registrants to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company’s maintenance of effective controls against diversion by inspecting and testing each company’s physical security systems, verifying each company’s compliance with state and local laws, and reviewing each company’s background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed companies.

Dated: September 20, 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 Charles City

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 December 3, 2018.

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 June 8, 2018, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616 applied to be registered as a bulk manufacturer of the basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|--|-----------|----------|
| Gamma Hydroxybutyric Acid. | 2010 | I |
| Amphetamine | 1100 | II |
| Lisdexamfetamine | 1205 | II |
| Methylphenidate | 1724 | II |
| 4-Anilino-N-phenethyl-4-piperidine (ANPP). | 8333 | II |
| Phenylacetone | 8501 | II |
| Cocaine | 9041 | II |

| Controlled substance | Drug code | Schedule |
|---------------------------|-----------|----------|
| Codeine | 9050 | II |
| Oxycodone | 9143 | II |
| Hydromorphone | 9150 | II |
| Hydrocodone | 9193 | II |
| Morphine | 9300 | II |
| Oripavine | 9330 | II |
| Thebaine | 9333 | II |
| Opium extracts | 9610 | II |
| Opium fluid extract | 9620 | II |
| Opium tincture | 9630 | II |
| Opium, powdered | 9639 | II |
| Oxymorphone | 9652 | II |
| Noroxymorphone | 9668 | II |
| Fentanyl | 9801 | II |

The company plans to manufacture the listed controlled substances in bulk for conversion to other controlled substances and sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Dated: September 20, 2018.

John J. Martin,
Assistant Administrator.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of various classes of schedule I or II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices are listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

| Company | FR Docket | Published |
|--------------------------------------|-------------|-----------------|
| AMRI Rensselaer, Inc | 83 FR 15176 | April 9, 2018. |
| S&B Pharma, Inc | 83 FR 31421 | July 5, 2018. |
| Cerilliant Corporation | 83 FR 32906 | July 16, 2018. |
| Shertech Laboratories, LLC | 83 FR 34879 | July 23, 2018. |
| Fresenius Kabi USA, LLC | 83 FR 34878 | July 23, 2018. |
| VHG Labs DBA LGC Standards | 83 FR 34875 | July 23, 2018. |
| Catalent Pharma Solutions, LLC | 83 FR 34874 | July 23, 2018. |
| Fisher Clinical Services, Inc | 83 FR 34879 | July 23, 2018. |
| Anderson Brecon, Inc | 83 FR 37525 | August 1, 2018. |

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

The DEA investigated each company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or II controlled substances to the above listed companies.

Dated: September 20, 2018.

John J. Martin,

Assistant Administrator.

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BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: R & D Systems, 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 November 1, 2018. Such persons may also file a written request for a hearing on the application on or before November 1, 2018.

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 hearings must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearings 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/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 April 9, 2018, R & D Systems, Inc., 614 McKinley Place NE, Minneapolis, Minnesota 55413-5541 applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|--|-----------|----------|
| Mephedrone (4-Methyl-N-methylcathinone) | 1248 | I |
| JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole) | 7118 | I |
| CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol] | 7297 | I |
| Marihuana | 7360 | I |
| Tetrahydrocannabinols | 7370 | I |
| 4-Bromo-2,5-dimethoxyamphetamine | 7391 | I |
| 3,4-Methylenedioxymethamphetamine | 7405 | I |
| Dimethyltryptamine | 7435 | I |
| Psilocyn | 7438 | I |
| Pentobarbital | 2270 | II |
| Phencyclidine | 7471 | II |
| Cocaine | 9041 | II |