

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1202]

Bulk Manufacturer of Controlled Substances Application: Royal Emerald Pharmaceuticals

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Royal Emerald Pharmaceuticals has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 24, 2023. Such persons may also file a written request for a hearing on the application on or before July 24, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 27, 2023, Royal Emerald Pharmaceuticals, 14011 Palm Drive, Building B, Desert Hot Springs, California 92240-6845, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to bulk manufacture the listed controlled substances to provide Marihuana

(Cannabis) as botanical raw material and/or active pharmaceutical ingredients (API) to DEA research registrants and manufacturers. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2023-11177 Filed 5-24-23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1200]

Bulk Manufacturer of Controlled Substances Application: Promega Corporation

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Promega Corporation has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 24, 2023. Such persons may also file a written request for a hearing on the application on or before July 24, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on April 5, 2023, Promega Corporation, 3075 Sub Zero Parkway, Fitchburg, Wisconsin 53719, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to bulk manufacture the listed controlled substances as Active Pharmaceutical Ingredients (API) for sale to its customers. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2023-11175 Filed 5-24-23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1192]

Importer of Controlled Substances Application: Unither Manufacturing LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Unither Manufacturing LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 26, 2023. Such persons may also file a written request for a hearing on the application on or before June 26, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must 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. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 7, 2023, Unither Manufacturing LLC, 331 Clay Road, Rochester, New York 14623-3226, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Methylphenidate	1724	II

The company plans to import the listed controlled substance solely for updated analytical testing purposes to meet European Union requirements for their finished dosage form product. This analysis is required to allow the company to export domestically-manufactured finished dosage forms to foreign markets. No other activities for this drug code is authorized for this registration.

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 Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew Strait,
Deputy Assistant Administrator.
[FR Doc. 2023-11167 Filed 5-24-23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1190]

Importer of Controlled Substances Application: United States Pharmacopeial Convention

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: United States Pharmacopeial has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before June 26, 2023. Such persons may also file a written request for a hearing on the application on or before June 26, 2023.

ADDRESSES: The Drug Enforcement Administration requires that all

comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must 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. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 23, 2023, United States Pharmacopeial Convention, 7135 English Muffin Way, Frederick, Maryland 21704, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Methcathinone	1237	I
Methaqualone	2565	I
Lysergic acid diethylamide	7315	I
4-Methyl-2,5-dimethoxyamphetamine	7395	I
3,4-Methylenedioxyamphetamine	7400	I
4-Methoxyamphetamine	7411	I
Codeine-N-oxide	9053	I
Difenoxin	9168	I
Heroin	9200	I
Morphine-N-oxide	9307	I
Norlevorphanol	9634	I
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Phencyclidine	7471	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Phenylacetone	8501	II
Alphaprodine	9010	II
Anileridine	9020	II
Cocaine	9041	II
Dihydrocodeine	9120	II