

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Nabilone	7379	II
Phenylacetone	8501	II
Ecgonine	9180	II
Levorphanol	9220	II
Methadone	9250	II
Thebaine	9333	II
Opium, raw	9600	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Noroxymorphone	9668	II
Poppy Straw Concentrate	9670	II
Tapentadol	9780	II

The company plans to import Opium, Raw (9600), Opium, Powdered (9639) and Opium, Granulated (9640) to manufacture an Active Pharmaceutical Ingredient (API) only for distribution to its customers. The company plans to import Phenylacetone (8501) and Poppy Straw Concentrate (9670), to bulk manufacture other controlled substances for distribution to its customers. The company plans to import impurities of buprenorphine that have been determined by DEA to be captured under Thebaine (9333). In reference to Marihuana Extract (7350), Marihuana (7360), and Tetrahydrocannabinols (7370), the company plans to import as synthetic. The company plans to import an isomer of methadone (9250) not currently available domestically to manufacture a non-controlled substance. No other activities for these drug codes are 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. 2025-02600 Filed 2-12-25; 8:45 am]
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1447]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: University of Kentucky Cannabis Center

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

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 April 14, 2025.

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: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), the Drug Enforcement Administration (DEA) is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant

would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on July 1, 2024, University of Kentucky Cannabis Center, 845 Angliana Avenue, Lexington, Kentucky 40508, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I

Matthew Strait,
Deputy Assistant Administrator.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1487]

Bulk Manufacturer of Controlled Substances Application: Maridose LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Maridose LLC 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 April 14, 2025. Such persons may also file a written request for a hearing on the application on or before April 14, 2025.

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 December 30, 2024, Maridose LLC, 74 Orion Street, Unit 7, Brunswick, Maine 04011, 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 supply the Drug Enforcement Administration-registered researchers for their approval studies. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2025-02596 Filed 2-12-25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1486]

Importer of Controlled Substances Application: Mylan Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Mylan Inc. 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 March 17, 2025. Such persons may also file a written request for a hearing on the application on or before March 17, 2025.

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 December 10, 2024, Mylan Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505-2362, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methylphenidate	1724	II
Oxycodone	9143	II
Hydromorphone	9150	II
Methadone	9250	II
Morphine	9300	II
Fentanyl	9801	II

The company plans to import the listed controlled substances as bulk active pharmaceutical ingredients for internal testing purposes only and finished dosage forms for analytical testing and distribution for clinical trials to support foreign market participation. No other activities for these drug codes are 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.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1490]

Importer of Controlled Substances Application: Janssen Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Janssen Pharmaceuticals Inc. 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 March 17, 2025. Such persons may also file a written request for a hearing on the application on or before March 17, 2025.

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