

approved finished dosage forms for commercial sale.

**Kristi O'Malley,**  
Assistant Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 1038]

#### **Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Morrison Newfound Valley Manufacturing**

**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 December 23, 2022.

**ADDRESSES:** DEA 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), 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 therefore, 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 February 18, 2022, Morrison Newfound Valley Manufacturing, 262 Morrison Road, Bristol, New Hampshire 03222, 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

**Kristi O'Malley,**  
Assistant Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-1087]

#### **Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Rocky Mountain Biotech, LLC**

**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 December 23, 2022.

**ADDRESSES:** DEA 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), 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 therefore, 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 (API) 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 September 1, 2022, Rocky Mountain Biotech, LLC, 4740 Dillon Drive, Pueblo, Colorado 81008-2112, 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

Kristi O'Malley,  
Assistant Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-1104]

#### Importer of Controlled Substances Application: Nexus Pharmaceuticals, Inc.

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of application.

**SUMMARY:** Nexus 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 November 23, 2022. Such persons may also file a written request for a hearing on the application on or before November 23, 2022.

**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 September 19, 2022, 10300 128th Avenue, Pleasant Prairie, Wisconsin 53158-7336, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Remifentanyl .....	9739	II

The company plans to import the listed controlled substance for research and analytical testing purposes. 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.

Kristi O'Malley,

Assistant Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-1105]

#### Bulk Manufacturer of Controlled Substances Application: Benuvia Manufacturing, Inc.

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of application.

**SUMMARY:** Benuvia Manufacturing Inc. 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 December 23, 2022. Such persons may also file a written request for a hearing on the application on or before December 23, 2022.

**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 August 12, 2022, Benuvia Manufacturing Inc., 3950 North Mays Street, Round Rock, Texas 78665, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):