significant factors in determining the appropriate sanction. *Id.* The Agency has also considered the need to deter similar acts by an applicant and by the community of registrants. *Id.*

Applicant posits that the RD ''prejudge[s]'' him and ''misinterprets'' his approach by not ''distinguish[ing] between a person who explains what took place,'' as he argues he did, ''as opposed to someone who seeks to offer an excuse for what took place.'' Applicant Exceptions, at 2; *supra* section II.B. Applicant also argues that he stated, ''truthfully,'' ''how the grow houses became used for marijuana'' and ''admit[ted] his responsibility in same.'' Applicant Exceptions, at 2. Citing his ''remarkable'' CME compliance and re-issued Texas medical license, Applicant also claims that he ''has demonstrated, through his actions since, that he is worthy of any discretion the Court could provide.'' *Id.; but see* RD, at 19.

Even if the Agency were to credit Applicant's arguments, they do not change the fact that he did not unequivocally accept responsibility for the founded violations. *Supra* sections III.B. and III.C. For example, regarding the allegation that he prescribed controlled substances after the 2013 suspension of his registration, Applicant even refused to admit that the signatures on the controlled substance orders were his. *Supra* section II.B. The RD credits the DI's testimony over Applicant's steadfast refusal to acknowledge his signatures, and the Agency agrees. RD, at 14–15; *see also supra* sections II.A., II.B., and II.D.

This record evidence also shows that Applicant, despite his ''remarkable'' CME compliance, does not understand the responsibilities the CSA places on practitioners. Applicant posits that, ''throughout his practice, he has provide[d] medical[ly] necessary assistance with prescribed, controlled substances when the patient's condition(s) suggest that such a treatment would be in the patient's best interest.'' Applicant's Closing Argument, at 2; *see also* Applicant Exceptions, at 2–4. Such statements attempt to minimize, or divert attention from, his unlawful activity, and show Applicant's lack of understanding of the CSA's requirements. Accordingly, the Agency finds that Applicant did not unequivocally accept responsibility for the unlawful acts he committed and has not convinced the Agency that he can be entrusted with a registration.[10]

The interests of specific and general deterrence weigh in favor of denying Applicant's registration application. *See, e.g., Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases) (''The egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction.''). Given the seriousness and extent of Applicant's founded violations, a sanction less than application denial would tell prospective registrants that compliance with the law is not a condition precedent to the issuance of a registration.

Accordingly, the Agency shall order the sanction the Government requested.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the DEA registration application of Keith Ly, M.D. (Control No. W21134341C). Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending application of Keith Ly, M.D., for a DEA Registration in Texas. This Order is effective June 26, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on May 16, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–11131 Filed 5–24–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1181]

Bulk Manufacturer of Controlled Substances Application: Benuvia Operations LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Operations 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 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 9, 2023, Benuvia Operations, LLC., 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):

Controlled substance	Drug code	Schedule
Ibogaine	7260	I
Lysergic Acid Diethylamide	7315	I
Tetrahydrocannabinols	7370	I
Mescaline	7381	I

[10] Remedial measures are insufficient without an unequivocal acceptance of responsibility. *Brenton D. Wynn, M.D.,* 87 FR 24228, 24261 (2022); *see also Michael T. Harris, M.D.,* 87 FR 30276, 30278 (2022) (collecting Agency decisions).

Controlled substance	Drug code	Schedule
3, 4-Methylenedioxyamphetamine	7400	I
3, 4-Methylenedioxymethamphetamine	7405	I
5-Methoxy-N-N-dimethyltryptamine	7431	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N, N-diisopropyltryptamine	7439	I

The company plans to bulk manufacture the listed controlled substances for the internal use intermediates or for sale to its customers. In reference to dug codes 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as synthetic. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2023–11158 Filed 5–24–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1206]

Bulk Manufacturer of Controlled Substances Application: Irvine Labs, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Irvine Labs, 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 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, Irvine Labs, Inc., 7305 Murdy Drive, Hunting Beach, California 92647–3533, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Lysergic acid diethylamide.	7315	I
Mescaline	7381	I
Peyote	7415	I
Diethyltryptamine	7434	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to bulk manufacture the listed controlled substances to support their internal research, clinical trials, and analytical purposes as well as to distribute to their customers. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2023–11178 Filed 5–24–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1191]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API 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 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 31, 2023, Patheon API Manufacturing, Inc., 309 Delaware Street, Greenville, South Carolina 29605–5420, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. No other activities for these