UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

Docket No. 22-15

Administrative Law Judge

TERESA A. WALLBAUM

GOVERNMENT'S RESPONSE IN OPPOSITION TO PANACEA PLANT SCIENCES' MOTION FOR INJUNCTION AND STAY IN PROCEEDINGS AND NOTICE REGARDING WITHDRAWAL OF PROPOSED RULE AND HEARING

The United States Department of Justice, Drug Enforcement Administration (DEA or the Government), by and through the undersigned counsel, hereby responds to Panacea Plant Sciences' (Panacea) Motion for Injunction and Stay in Proceedings (Panacea's Motion). Panacea's Motion is meritless and moot.

It is moot because the Agency filed with the Federal Register today a Withdrawal of Proposed Rule and Notice of Hearing, and the Federal Register accepted the filing. An electronic version of that Withdrawal of Proposed Rule and Notice of Hearing sent to the Federal Register is attached hereto as *Appendix A*. Accordingly, Panacea's requested remedy seeking an "injunction" staying these proceedings for three years is now moot as these proceedings will be terminated imminently.¹

Additionally, Panacea's Motion is meritless. It is based on misstatements of the record in this case, and on mere allegations made in an unrelated proceeding. Panacea's selective quotation from the transcript of the July 11, 2022 status conference creates a false picture of the record in this matter. As made clear during the conference, counsel had no improper discussions

¹ Due to the imminent termination of the proceedings, the Government did not file several of its remaining motions that were due today under the schedule set by this Tribunal.

or *ex parte* contact with the Administrator. *See* July 11, 2022 Conference Tr. 15-19. Panacea's submission of a motion for this Tribunal's consideration that blatantly omits essential portions of the conference regarding the nature of discussions within DEA is inappropriate. It also is concerning in light of the requirement that "participants in any hearing and their representatives, whether or not members of the bar, shall conduct themselves in accordance with judicial standards of practice and ethics and the directions of the presiding officer." 21 C.F.R. § 1316.51(b). Finally, to the extent Panacea's Motion makes any claims regarding the merits of the action filed in *AIMS Institute, PLLC et al v. Garland*, No. 4:22-cv-02396 (S.D. Tex.), such claims are not appropriate for this forum, as they are instead to be resolved in the forum where that action was filed.

Panacea's Motion is therefore meritless and moot.

Dated: July 22, 2022

Respectfully submitted,

/s/ David M. Locher David M. Locher Andrew T. Winkler Attorneys Drug Enforcement Administration Office of Chief Counsel 8701 Morrissette Drive Springfield, Virginia 22152 Office: (571) 362-7906 Emails: David.M.Locher@dea.gov Andrew.T.Winkler@dea.gov

CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2022, I electronically submitted the foregoing, and all attachments thereto, to the DEA Office of the Administrative Law Judges via the DEA Judicial Mailbox, at ECF-DEA@dea.gov, and simultaneously to the following via the email addresses listed below:

- Matthew C. Zorn, Esq., <u>mzorn@yettercoleman.com</u> Graham Pechenik, Esq., <u>graham@calyxlaw.com</u> Counsel for Tactogen Inc. and Mindstate Design Labs
- John T. Hunter, Esq. John@HLJDefense.com Counsel for Jason Wallace and Hamilton Morris
- David Heldreth <u>davidh@panaceaplantsciences.net</u> CEO of Panacea Plant Sciences

/s/ David M. Locher

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-623]

Schedules of Controlled Substances: Placement of 4-hydroxy-N,N-

diisopropyltryptamine (4-OH-DiPT), 5-methoxy-alpha-methyltryptamine (5-MeO-

AMT), 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-

N,*N*-diethyltryptamine (5-MeO-DET), and *N*,*N*-diisopropyltryptamine (DiPT) in

Schedule I; Withdrawal of Proposed Rule and Notice of Hearing

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Withdrawal of proposed rule and withdrawal of notice of hearing.

SUMMARY: The Drug Enforcement Administration (DEA) is withdrawing a proposed rule that was published in the Federal Register on January 14, 2022, which proposed to place five tryptamine hallucinogens in schedule I of the Controlled Substances Act. Upon further consideration, DEA has determined that it is appropriate to submit a new request to the Department of Health and Human Services (HHS) for an updated scientific and medical evaluation and scheduling recommendation for these substances. Accordingly, DEA is withdrawing the proposed rule and notice of hearing that was published in the Federal Register on July 6, 2022, and is canceling the public hearing and terminating the pending hearing proceedings. DEA may issue a new proposed rule in the future regarding these substances if warranted.

DATES: The proposed rule that was published in the Federal Register on January 14, 2022 (87 FR 2376) is withdrawn as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. The notice of hearing on the proposed rule that was published in the Federal Register on July 6, 2022 (87 FR 40167) is withdrawn as of [INSERT

DATE OF PUBLICATION IN FEDERAL REGISTER]. The public hearing, originally scheduled to commence on August 22, 2022, is cancelled, and all proceedings related thereto are terminated.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Chief, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

On January 14, 2022, DEA published a Notice of Proposed Rulemaking (NPRM) in the Federal Register (87 FR 2376) to place five tryptamine hallucinogens specifically, 4-hydroxy-*N*,*N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N*,*N*-diethyltryptamine (5-MeO-DET), and *N*,*N*-diisopropyltryptamine (DiPT)—in schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801, *et seq*.). The proposed placement of these substances in schedule I was based on the scientific and medical evaluations and recommendations that the HHS provided to DEA.

In response to the NPRM, DEA received numerous comments and four requests for a hearing on the proposed rule, as provided in 21 U.S.C. 811(a). DEA scheduled a hearing on the proposed rule and published a notice to that effect in the Federal Register on July 6, 2022 (87 FR 40167). The public hearing was scheduled to commence on August 22, 2022.

Upon further consideration, DEA has determined that it is appropriate to submit a new request to HHS for an updated scientific and medical evaluation and scheduling

recommendation for these substances in accordance with 21 U.S.C. 811(b) and 21 CFR 1308.43(d).

Accordingly, DEA's proposed rule published in the Federal Register on January 14, 2022 (87 FR 2376), and the notice of hearing on the proposed rule published in the Federal Register on July 6, 2022 (87 FR 40167), are withdrawn. The public hearing scheduled to commence on August 22, 2022 is canceled, and all proceedings related thereto are hereby terminated. DEA may issue a new proposed rule in the future regarding the five tryptamine hallucinogens if warranted.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 22, 2022, 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.

Scott Brinks Federal Register Liaison Officer, Drug Enforcement Administration