

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

ORDER MODIFYING ORDER FOR PREHEARING STATEMENTS

On January 14, 2022, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM), with the docket number DEA-623, titled “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.” 87 Fed. Reg. 2376 (2022). The NPRM proposes to place the five tryptamine hallucinogens (4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT) in Schedule I of the Controlled Substances Act. *Id.* The NPRM provided a February 14, 2022 deadline for comments and requests for a hearing but did not fix a location for any hearings. *Id.* at 2377.

I am the Administrative Law Judge assigned to hear the above-captioned matter.

On January 31, 2022, Panacea Plant Sciences (Panacea), filed a document titled “Regarding Docket No. DEA-623” regarding the proposed placement of the five tryptamine hallucinogens in Schedule I. In its filing, Panacea: (1) indicated that it is a “Washington State biotech company;” (2) set forth its reasons why it opposes DEA’s proposed action; and (3) stated that its filing serves as both a comment and a Request for Hearing (RFH).¹ Panacea RFH at 1, 5.² Panacea did not serve its RFH on the DEA Office of the Chief Counsel (Government) but requested that the RFH be shared with: “(1) Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: Hearing

¹ Panacea’s RFH is herein provided to the parties as Attachment A.

² Panacea’s written submission did not contain page numbers.

Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (3) Drug Enforcement Administration, Attn: DEA FR Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.” *Id.* at 5-6.

On February 1, 2022, I issued an Order for Prehearing Statements setting **March 2, 2022 at 2:00 p.m. Eastern Time (ET)** as the deadline for the Government’s Prehearing Statement and **March 30, 2022 at 2:00 p.m. ET** as Panacea’s deadline to file a Prehearing Statement. Additionally, I scheduled a Prehearing Conference to be conducted by video teleconference (VTC) for **April 5, 2022, at 1:00 p.m. ET.**

On February 14, 2022, Dr. Jason Wallach and Mr. Hamilton Morris jointly filed correspondence under the subject line: “Request for Hearing in the matter of Docket No. DEA-623.”³ Dr. Wallach and Mr. Morris, through counsel, indicated that they are academic scientists who have been studying DiPT and other hallucinogenic compounds. Wallach & Morris RFH at 1. They oppose DEA’s proposed scheduling of DiPT in Schedule I and set forth their reasons in their RFH. *Id.* Dr. Wallach and Mr. Morris served their RFH on the Government.

On February 14, 2022, Kykeon Biotechnologies Inc. (Kykeon) and Tactogen Inc. (Tactogen) jointly filed correspondence, dated as February 10, 2022, under the subject line: “Docket No. DEA-623.”⁴ Kykeon and Tactogen, through counsel, indicated that they are also requesting a hearing regarding the NPRM. Kykeon and Tactogen RFH at 1. Both companies are investigating one or more of the five tryptamines and listed five objections as to why the tryptamines should not be added to Schedule I. *Id.* at 2-8. Kykeon and Tactogen did not indicate whether they served the RFH on the Government.

On February 14, 2022, Amy Rising filed correspondence, dated as February 11, 2022, under the subject line: “Request for Hearing.”⁵ Ms. Rising indicated that she is requesting a hearing because she believes that putting the five tryptamines in Schedule I would “result in barriers to research and the denial to life-saving healthcare to US patients.” Rising RFH at 1. Ms. Rising did not indicate whether she served the RFH on the Government.

Upon consideration of each RFH, it is hereby **ORDERED** that the deadlines set forth in the February 1, 2022 Order for Prehearing Statements are **VACATED** and the Prehearing

³ Dr. Wallach and Mr. Morris’ RFH is herein provided to the parties as Attachment B.

⁴ Kykeon and Tactogen’s RFH is herein provided to the parties as Attachment C.

⁵ Ms. Rising’s RFH is herein provided to the parties as Attachment D.

Conference scheduled for **April 5, 2022** is **CANCELED**. It is further **ORDERED** that the Government file a Prehearing Statement no later than **2:00 p.m. ET on March 28, 2022**. It is further **ORDERED** that each party requesting a hearing file a Prehearing Statements no later than **2:00 p.m. ET on April 27, 2022**.

The parties' Prehearing Statements must be served on each other and contain the following sections:

1. **Issue(s).** Statement of the perceived issues.
2. **Requested Relief.** Statement of the relief requested.
3. **Stipulations.** Proposed stipulations and admissions of fact. Each party is directed to examine available evidence and determine which facts may be the subject of stipulation to narrow the issues to those that will be and should be the subject of contested litigation.
4. **Witnesses.** Names and *current* addresses of all witnesses whose testimony is to be presented.
5. **Summary of testimony.** Brief summary of the testimony of each witness. *The summaries are to state what the testimony will be, rather than merely list the areas to be covered.* The parties are reminded that testimony not disclosed in the Prehearing Statements or pursuant to subsequent rulings is likely to be excluded at the hearing.
6. **Documents.** A list of all documentary evidence, including affidavits and other exhibits to be offered in evidence, specifying the number of pages in each. Each exhibit is to be numbered or lettered ("For Identification") with the designation to be used at the hearing.
7. **Position regarding hearing situs.** Statement of position regarding the location where the hearing will be conducted.⁶
8. **Other matters.** Any other matters that the parties consider relevant.
9. **Best estimate as to time required for presentation of own case.**

It is further **ORDERED** that a **Prehearing Conference in this matter will be conducted by VTC on May 4, 2022, at 1:00 p.m. ET;**⁷ and it is further **ORDERED** that all proceedings will

⁶ The current COVID-19 pandemic may impact the setting of venue in this case, and may result in the hearing being conducted in whole or in part through the use of videoconference (VTC) technology.

⁷ Logistical issues (including counsel availability) will be coordinated by Law Clerk Anne Cotter, who can be contacted at (571) 362-7930 and Anne.M.Cotter@dea.gov. To access the VTC Prehearing Conference, the respective counsel will receive an evite to the email addresses of record in this case.

be governed by the provisions of 21 C.F.R. §§ 1316.41-1316.68.⁸ Your attention is specifically directed to 21 C.F.R. § 1316.45, which provides, *inter alia*, that “[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk.” Documents (other than proposed exhibits) may be filed electronically, by hard copy, or by facsimile with a hard copy follow-up on all facsimiles. Only one method of document filing may be utilized.

Electronic Filing: The preferred method of filing correspondence in these proceedings is as a PDF attachment via email to the DEA Judicial Mailbox (**ECF-DEA@dea.gov**). The forwarding email on all electronically filed correspondence must indicate that it was simultaneously served on the opposing party via email. The parties requesting a hearing must ensure that all documents filed with the DEA Judicial Mailbox are simultaneously served on the Government Mailbox at (**dea.registration.litigation@dea.gov**). Any request(s) to modify email addresses of a party or counsel must be made on notice to this tribunal and the opposing party. The email receipt date reflected by the DEA Judicial Mailbox server shall conclusively control all issues related to the date of service of all filed correspondence, provided however, that correspondence received after 5:00 p.m., local Washington, D.C. time, will be deemed to have been received on the following business day. Note: While email is utilized as the method to forward documents for filing—as attachments—no substantive matter communicated through the body of a forwarding email will be considered. The parties are directed to refrain from including social security numbers or personally identifiable information in electronically-filed documents. Proposed exhibits will not be accepted via electronic filing.

Hard Copy and Facsimile Filing: Alternatively, correspondence may be filed in hard-copy form. Hard-copy filings must be served in triplicate and addressed to my attention at: **The DEA Office of Administrative Law Judges, 8701 Morrisette Drive, Springfield, VA 22152**. Because the DEA Hearing Facility is not physically collocated with the DEA mailing address, hard copy filings must be posted sufficiently in advance of the due date to assure timely receipt by this office. Documents may also be served via facsimile,⁹ so long as they are followed up by hard copies consistent with the directions above that are simultaneously placed for delivery. Facsimile filings will be deemed timely if received at this office by the date and time

⁸ Additional helpful information regarding DEA administrative proceedings may be found at the OALJ website, <https://www.dea.gov/administrative-law-judges>.

⁹ The facsimile number for this office is (202) 307-8198.

due, and are limited in size to twenty (20) pages, absent prior permission granted by me upon advance request.

It is further **ORDERED** that any requests for extension of time to file must be made by written motion sufficiently in advance of scheduled deadlines to be considered and ruled upon.

Dated: February 15, 2022

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TERESA A. WALLBAUM
Administrative Law Judge

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Date: 2022.02.15
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CERTIFICATE OF SERVICE

This is to certify that the undersigned, on February 15, 2022, caused a copy of the foregoing to be delivered to the following recipients:

- (1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
- (2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
- (3) John T. Hunter, Esq., Counsel for Dr. Jason Wallach and Mr. Hamilton Morris, via email at John@hljdefense.com;
- (4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
- (5) Dillian DiNardo, Kykeon Biotechnologies Inc., via email at dillan@mindstate.design;
- (6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com;
- (7) Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at mzorn@yettercoleman.com; and
- (8) Amy Rising, via First Class mail at 1266 Oates St. NE, Washington, DC 20002.

**ANIAYAH
BECKFORD**

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ANIAYAH BECKFORD
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Aniayah S. Beckford,
Secretary to Judge Wallbaum