

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 DENYING THE GOVERNMENT'S CONSENT MOTION TO AMEND
PREHEARING SCHEDULE**

This is a scheduling case under 21 U.S.C. § 811. On January 14, 2022, the Drug Enforcement Administration published a Notice of Proposed Rulemaking (NPRM) to schedule five hallucinogenic substances. 87 Fed. Reg. 2376 (2022). That NPRM set February 14, 2022 as the deadline for Requests for Hearing (RFH) to challenge the scheduling of those substances but did not set a date or location for a hearing. *Id.* at 2377. Four Interested Parties (two of whom are joint parties) filed RFHs; two of those Interested Parties are not represented by counsel. This tribunal issued an Order for Prehearing Statements (OPHS) setting deadlines, including a Prehearing Conference. This tribunal amended that OPHS three times, and the Prehearing Conference is currently set for June 7, 2022.

On April 22, 2022, the Government filed its Consent Motion to Amend the Prehearing Schedule (Government's Motion to Amend), requesting to vacate the Prehearing Statement deadlines and Prehearing Conference date. Gov't Mot. to Amend at 2-3. The Government is requesting such relief because the Interested Parties indicated to the Government that the NPRM in this matter did not include a date and time for hearings to commence, as required by 21 C.F.R. § 1308.43(f). *Id.* at 1. The Government maintains that the NPRM complied with the regulatory requirements; however, the Government indicated that it intends to publish a notice of hearing in the Federal Register because "the regulations contemplate" such publication so that additional interested parties may participate. *Id.* at 1-2 (citing 21 C.F.R. §§ 1308.44(b), 1316.53).¹

¹ At the status conference, the Government took the position that the failure to publish a separate notice of hearing was not a fatal defect in the rulemaking.

Specifically, § 1308.44(b) provides that: “Any interested person desiring to participate in a hearing pursuant to § 1308.41 shall, within 30 days after the date of publication of the notice of hearing in the FEDERAL REGISTER, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in § 1316.48 of this chapter.” 21 C.F.R. § 1308.44(b).² The Government set forth a proposed “scheduling framework” as to how the tribunal should adjust the current deadlines to accommodate publication of a notice of hearing. Gov’t Mot. to Amend at 3.

On April 26, 2022, this tribunal held a status conference to discuss the Government’s Motion to Amend. The Government indicated that it is in the process of publishing a notice of hearing in the Federal Register; the Government could not provide an anticipated publication date, but expected to submit the notice for publication in the near future. The Interested Parties took the position that a notice of hearing, including a date for a hearing, must be published in the Federal Register. The Government and Interested Parties asserted that the hearing date published in the notice of hearing should be the Prehearing Conference date, not the merits hearing date, and that the Prehearing Conference should occur 30 days after the date of publication.

Upon consideration of the Government’s Motion to Amend and the status conference with all parties, I find it is unnecessary to delay these proceedings while the Government publishes the notice of hearing. The parties essentially request a stay of these proceedings—the second request for a stay in this case. “A stay is not a matter of right, even if irreparable injury might otherwise result. It is instead an exercise of judicial discretion, and the propriety of its issue is dependent upon the circumstances of the particular case.” *Nken v. Holder*, 556 U.S. 418, 433 (2009). The circumstances identified by the Government and the Interested Parties do not warrant a stay. This tribunal has provided the Government and Interested Parties substantial time in which to prepare for this matter; that time was enlarged to allow the Interested Parties to file a Preliminary Objection and Motion to Stay Rulemaking (which was denied). No current party has been prejudiced by any failure in the NPRM to identify a date of hearing or any failure to publish a separate notice of hearing. Moreover, as to future, potential Interested Parties, there is still considerable time before the June 7, 2022 Prehearing Conference, and there is currently no merits hearing scheduled. As a result, should any additional parties file a request for hearing after publication in the Federal

² Section 1316.48 is entitled “Notice of appearance.”

Register, the tribunal can consider adjusting any deadlines at that time.³ Accordingly, the Government's Motion to Amend is herein **DENIED**.

Dated: April 27, 2022

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TERESA A. WALLBAUM
Administrative Law Judge

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³ And, as indicated in the status conference, once a merits hearing is set at the June 7, 2022 Prehearing Conference, this tribunal can, if necessary, direct the Government to publish a notice of that hearing date in the Federal Register

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on April 27, 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 Jason Wallach and 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 email at amynicholerising@gmail.com.

**ANIAYAH
BECKFORD**
Aniayah S. Beckford
Staff Assistant to Judge Wallbaum

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