

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

**THE GOVERNMENT’S CONSENT MOTION TO
AMEND THE PREHEARING SCHEDULE**

The Objectors indicated to the Government in early April a belief that the Notice of Proposed Rulemaking (NPRM) in these rulemakings may not have fully complied with 21 C.F.R. § 1308.43(f) because the NPRM did not include a specific date and time for the hearings in this matter to commence. *Id.* (“Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to § 1308.44.”); *see also*, *e.g.*, 38 Fed. Reg. 9,170 (April 11, 1973). The Objectors also identified that since the NPRM, there has not been such notice published in the Federal Register. *See, e.g.*, 49 Fed. Reg. 50,732 (Dec. 31, 1984). The Objectors have asked the Government to publish an additional Notice of Hearing indicating that hearings on the proposed rulemakings will be held in order to allow any additional Interested Persons to participate in these proceedings.

While the Government believes that the NPRM complied with the regulatory requirements, the Government acknowledges that the regulations contemplate the publication of a notice of hearing, *see* 21 C.F.R. § 1316.53, and that additional

interested parties are likely permitted to enter a notice of intent to participate within 30 days following that notice. *See* 21 C.F.R. § 1308.44(b). Accordingly, the Government intends to cause to be published in the Federal Register an Announcement of Hearing (Announcement) as soon as practicable. The Government believes that this will remove any doubt over the adequacy of the notice of these rulemakings as well as promote the orderly disposition of this matter by bringing all parties wishing to participate before the Tribunal prior to extensive prehearing procedures.¹ The Government also understands that this approach is consistent with recent past practice in contested scheduling proceedings. *See Placement of Carisoprodol into Schedule IV; Announcement of Hearing*, 75 Fed. Reg. 14,538 (2010).

While the Government is diligently working to prepare the Announcement, the publication of the Announcement in the Federal Register requires a comprehensive review and approval process and the Government cannot be certain, at this point, when the publication will occur.² Accordingly, the Government respectfully moves that the Tribunal enter an order vacating the current prehearing deadlines.

¹ Such notice would also conclusively establish that any party that does not thereafter enter a timely notice of intent to participate has waived their right to participate. *See* 21 C.F.R. § 1308.44(d).

² If the Tribunal desires, the Government will provide bi-weekly status updates to the Tribunal.

In order to minimize delay, while also granting any new parties adequate time to respond to the Announcement, the Government respectfully suggests the following scheduling framework:

- The Government will inform the Tribunal of the publication of the Announcement within two business days of the date of publication in the Federal Register (Publication Date).
- The Announcement will set a date for hearing to commence approximately 60 days after the Publication Date.³
- New parties may file a notice of intent to participate within 30 days of the Publication Date. *See* 21 C.F.R. § 1308.44(b).
- The Government's Prehearing Statement will be due 14 days after the later of the Publication Date or the Tribunal's ruling on the Government's Motion to Dismiss in Part.
- The Objectors' Prehearing Statements will be due 30 days after the Government's Prehearing Statement.

To the extent helpful to the Tribunal's evaluation of the above issues, the Government is available for a status conference on these issues.

The Government also recognizes that the above deadlines may need to be adjusted in the event that any new parties file a notice of intent to participate. For example, any new parties may need additional time to file their prehearing

³ That hearing will serve as the prehearing conference pursuant to 21 C.F.R. § 1316.54.

statements. The Government believes that any deadlines may properly be amended following the deadline to enter a notice of intent to participate.

The Government has conferred with the current Objectors who all consent to the relief sought in this motion.

Dated: April 22, 2022

Respectfully submitted,

/s/ John E. Beerbower
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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2022, I electronically submitted the foregoing to the DEA Office of the Administrative Law Judges via the DEA Judicial Mailbox, at ECF-DEA@dea.gov, and simultaneously to the Objectors at:

- Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Mindstate Design Labs, via email at mzorn@yettercoleman.com;
- Graham Pechenik, Esq., Counsel for Tactogen Inc. and Mindstate Design Labs, via email at graham@calyxlaw.com;
- David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
- John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at John@hljdefense.com; and
- Amy Rising, via email at amynicholerising@gmail.com.

/s/ John E. Beerbower

John E. Beerbower