

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of

**Schedules of Controlled Substances:
Proposed Rescheduling of Marijuana**

**DEA Docket No. 1362
Hearing Docket No. 24-44**

**ORDER REGARDING THE GOVERNMENT’S SUBPOENA REQUESTS AND
MATTERS RAISED IN ITS SUPPLEMENTAL PREHEARING STATEMENT**

On December 13, 2024, the Government submitted four (4) subpoena requests (the Subpoena Requests or SRs) in accordance with the deadline fixed in a prehearing ruling (the Prehearing Ruling or PHR) issued on December 4, 2024. PHR at 7. In a cover letter accompanying the Subpoena Requests, the Government lists four (4) individuals from the Food and Drug Administration (FDA) it seeks to call as witnesses to testify at the hearing on the merits in this case. SR at 1-2. Despite that representation its cover letter and another filing submitted on December 13, 2024, the Government has listed the same person/subpoena recipient on each of its four (4) subpoena request forms. *Id.* at 5-12. That is, the Subpoena Requests appear to be four (4) identical copies of a subpoena request targeted to a single FDA official rather than four distinct requests to four separate recipients. *Id.* Submitting four (4) copies of a subpoena with the same name is apparently an error borne of inattention or inadvertence. To be sure, a blunder of this nature on a case that has garnered a significant level of national attention is an unexpected development, particularly in light of the unique dynamic of one agency of the United States Government seeking process to compel the attendance of multiple employees from another agency of the United States Government.

All parties to this ongoing litigation were cautioned that any subpoena request that fails to comply with the instructions set forth in the Prehearing Ruling would “be returned to the requestor without further action.” PHR at 8. Accordingly, only the Government’s request for issuance of a draft subpoena which seeks to compel the attendance of Patrizia Cavazzoni (the

Cavazzoni Subpoena) is **GRANTED**.¹ The remainder of the Government's (identical) Subpoena Requests are herein **REJECTED WITHOUT PREJUDICE**.²

Filed simultaneously with its Subpoena Requests was a supplement to its previously-filed, incomplete prehearing statement (Supplemental Prehearing Statement or SPHS). Contained within the SPHS were multiple motions for appropriate relief.³

The Government's SPHS requests that it be excused⁴ from that provision in the PHR (applicable to all parties) that directs that "in addition to the electronic evidentiary submission on JEFS, each party must also timely provide three (3) complete sets of hard copies of all proposed exhibits to the Hearing Clerk." PHR at 4 (emphasis in original). No good cause of any kind beyond the Government's convenience is averred or supported in its motion. The Government is a party in this matter. It must be and will be afforded the same rights and obligations as the other parties. Although allowances have been made (and may be made in the future) to accommodate the reality that, as the proponent of the rule, the Government bears the burden of proof,⁵ this request to be treated more favorably than the other parties stands unrelated to its burden.⁶

¹ The single executed subpoena is attached to this order. Naturally, the Government, as the requesting party, will be responsible for proper service on the witness and compliance with any applicable FDA service requirements.

² To the extent the Government submits draft subpoenas that accurately seek the attendance of the witnesses from FDA that it actually intends to call as witnesses, those requests will be considered, **PROVIDED** that they are filed no later than **2:00 p.m. Eastern Time (ET) on December 20, 2024**. **FURTHER**, to the extent the Government intends to request a stay of these proceedings to seek enforcement of the Cavazzoni Subpoena (or any other subpoena ultimately granted in this matter) in the United States District Court (21 U.S.C. § 876(c); 5 U.S.C. § 555), it should make that request expeditiously, but in no event later than **2:00 p.m. ET on January 3, 2025**.

³ Although the Prehearing Ruling indicated that the time for motion practice had expired and that future "motions must be accompanied by a request to file out of time and supported by a demonstration of good cause that is likely to be narrowly construed" (PHR at 8), no such request accompanied these motions.

⁴ SPHS at 6-7.

⁵ 5 U.S.C. § 556(d).

⁶ Inasmuch as the hearing in this matter has not yet commenced, no evidence has been offered or received. Thus, it would be premature to render a decision on whether the comments filed in response to the notice of proposed rulemaking (the NPRM) will be received into the record. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44597 (2024). It is vital to emphasize here that before any rule can be promulgated, the Agency is duty bound to consider those comments, even if it is not convenient for it to do so. One troubling aspect of the Government's motion in this regard is that it has tendered an incomplete (and arguably misleading) parenthetical quote from the NPRM. The Government, citing the NPRM, supplies the following phrase, complete with quotation marks and a period at its conclusion: "Comments on or objections to the proposed rule submitted under 21 CFR 1308.43(g) will be offered as evidence at the hearing." SPHS at 6 (punctuation as in the SPHS). Regrettably, the actual language in the NPRM is punctuated, not with a period, but with a comma, with the remainder of the sentence reading as follows: "but the [Administrative Law Judge (ALJ)] shall admit only evidence that is competent, relevant, material, and not unduly repetitive." 89 Fed. Reg. at 44598 (citing 21 C.F.R. § 1316.59(a)). Consistent with not only the NPRM, but also the unequivocal language set forth in the regulations, the ALJ is only authorized to admit and consider evidence that is "competent, relevant, material and not unduly repetitious" at the hearing. 21 C.F.R. § 1316.59(a). This is the case, the Government's incomplete rendition of the NPRM notwithstanding. The NPRM authorizes the Government to submit comments, but directs the ALJ to receive

The Government's request to present testimony *via* video teleconference is **GRANTED**.

Dated: December 16, 2024

JOHN J. MULROONEY, II
Chief Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on December 17, 2024, caused a copy of the foregoing to be delivered to the following recipients: (1) Julie L. Hamilton, Esq., Counsel for the Government, via email at julie.l.hamilton@dea.gov; James J. Schwartz, Esq., Counsel for the Government, via email at james.j.schwartz@dea.gov; Jarrett T. Lonich, Esq., Counsel for the Government, via email at jarrett.t.lonich@dea.gov; and S. Taylor Johnston, Esq., Counsel for the Government, via email at stephen.t.johnston@dea.gov; (2) the DEA Government Mailbox, via email at dea.registration.litigation@dea.gov; (3) Shane Pennington, Esq., Counsel for Village Farms International, via email at spennington@porterwright.com; and Tristan Cavanaugh, Esq., Counsel for Village Farms International, via email at tcavanaugh@porterwright.com; (4) Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com; William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com; and Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com; (5) Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net; (6) Andrew J. Kline, Esq., Counsel for Hemp for Victory, via email at AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com; (7) Timothy Swain, Esq., Counsel for Veterans Initiative 22, via email at t.swain@vicentellp.com; Shawn Hauser, Esq., Counsel for Veterans Initiative 22, via email at s.hauser@vicentellp.com; and Scheril Murray Powell, Esq., Counsel for Veteran's Initiative 22, via email at smpesquire@outlook.com; (8) Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com; Joanne Caceres, Esq., Counsel for The Commonwealth Project, via email at joanne.caceres@dentons.com; and Lauren M. Estevez, Esq., Counsel for The Commonwealth Project, via email at lauren.estevez@dentons.com; (9) Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hkllaw.com; (10) David G. Evans, Esq., Counsel for Cannabis Industry Victims Educating Litigators, Community Anti-Drug Coalitions of America, Kenneth Finn, International Academy on the Science and Impacts of Cannabis, and National Drug and Alcohol Screening Association, via email at thinkon908@aol.com; (11) Patrick Philbin, Esq., Counsel for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; and Chase Harrington, Esq., Counsel for Smart Approaches to Marijuana, via email at charrington@torridonlaw.com; (12) Eric Hamilton, Esq.,

into the record and consider only that which constitutes evidence under the regulation. Any party seeking to admit any comment as evidence must be prepared to establish a foundation that complies with the regulations and the NPRM. This applies with equal force to each comment. To repeat here for emphasis, no ruling has been issued regarding this aspect of the Government's noticed exhibits, and the Government (like all the parties) will be permitted to lay a foundation for this proposed evidence and all of its proposed evidence. Further, although the Government noticed the NPRM as a proposed exhibit, that document is jurisdictional, not evidentiary, and will be included in the record as a procedural exhibit (ALJ Exhibit), not evidence.

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Quinn Fox
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