UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of **Scheduling of Controlled Substances: 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I**	**Docket No. 22-21** ADMINISTRATIVE LAW JUDGE PAUL E. SOEFFING

GOVERNMENT'S PREHEARING STATEMENT

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Dated: June 13, 2022

Pursuant to the Administrative Law Judge's May 18, 2022 Order for Prehearing Statements, the Government submits its Prehearing Statement in the above-captioned matter.

ISSUES

1. Whether 2,5-dimethoxy-4-iodoamphetamine (DOI) should be listed in Schedule I of the Controlled Substances Act (CSA), pursuant to 21 U.S.C. §§ 811 & 812(b)(1).

2. Whether 2,5-dimethoxy-4-chloroamphetamine (DOC) should be listed in Schedule I of the CSA, pursuant to 21 U.S.C. §§ 811 & 812(b)(1).

REQUESTED RELIEF

The Government requests that the Tribunal recommend that 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) both should be listed in Schedule I of the CSA, pursuant to 21 U.S.C. §§ 811 & 812(b)(1).

PROPOSED STIPULATIONS OF FACT

Stipulation No. 1:	DOI belongs to the phenethylamine class of drugs with hallucinogenic properties that is known chemically as 2,5-dimethoxy-4-iodoamphetamine.
Stipulation No. 2:	DOI has been seized by law enforcement in the United States.
Stipulation No. 3:	DOI is not an approved human drug product in the United States.
Stipulation No. 4:	DOI is not an approved human drug product in any other country.
Stipulation No. 5:	There are no approved or pending New Drug Applications for DOI.
Stipulation No. 6:	There are no approved or pending Investigational New Drug Applications for DOI.
Stipulation No. 7:	DOI is not currently marketed anywhere in the world as an approved drug product.
Stipulation No. 8:	DOI has no currently accepted medical use in the United States.
Stipulation No. 9:	DOI has a high potential for abuse.

Stipulation No. 10: The Department of Health and Human Services (HHS) has recommended that DOI and its salts be controlled under Schedule I of the CSA under 21 U.S.C. § 812(b).

Stipulation No. 11: DOC belongs to the phenethylamine class of drugs with hallucinogenic properties that is known chemically as 2,5-dimethoxy-4-chloroamphetamine.

Stipulation No. 12: DOC has been seized by law enforcement in the United States.

Stipulation No. 13: DOC is not an approved human drug product in the United States.

Stipulation No. 14: DOC is not an approved human drug product in any other country.

Stipulation No. 15: There are no approved or pending New Drug Applications for DOC.

Stipulation No. 16: There are no approved or pending Investigational New Drug Applications for DOC.

Stipulation No. 17: DOC is not currently marketed anywhere in the world as an approved drug product.

Stipulation No. 18: DOC has no currently accepted medical use in the United States.

Stipulation No. 19: DOC has a high potential for abuse.

Stipulation No. 20: HHS has recommended that DOC and its salts be controlled under Schedule I of the CSA under 21 U.S.C. § 812(b).

Stipulation No. 21: On March 4, 2020, the United Nations Commission on Narcotic Drugs voted to place DOC in Schedule I of the 1971 Convention on Psychotropic Substances.

Stipulation No. 22: The United States of America is a signatory to the 1971 Convention on Psychotropic Substances.

Stipulation No. 23: *N,N*-dimethyltryptamine (DMT) is a Schedule I controlled substance.

Stipulation No. 24: 4-methyl-2,5-dimethoxy-amphetamine (DOM) is a Schedule I controlled substance.

Stipulation No. 25: 4-bromo-2,5-dimethoxy-amphetamine (DOB) is a Schedule I controlled substance.

Stipulation No. 26: Lysergic acid diethylamide (LSD) is a Schedule I controlled substance.

PROPOSED WITNESSES[1]

1. Scott A. Brinks, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152.

2. Dr. Theresa M. Carbonaro, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152.

SUMMARY OF TESTIMONY

1. Scott A. Brinks

The Government anticipates that Mr. Brinks will testify by declaration, pursuant to 21 C.F.R. § 1316.58(b). The Government anticipates that Mr. Brinks' declaration will be marked as Government Exhibit 1.

Mr. Brinks will testify that he is currently the Section Chief of the Regulatory Drafting and Policy Support Section of the Diversion Control Division at the Drug Enforcement Administration (DEA) Headquarters. He will testify that he oversees the section that is responsible for maintaining the administrative record for all proposed DEA rules and regulations.

Mr. Brinks will testify that, on April 11, 2022, DEA caused to be published in the Federal Register a Notice of Proposed Rulemaking (NPRM), proposing to place two phenethylamine hallucinogen substances (2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC)) into Schedule I of the CSA. He will testify that that NPRM permitted interested persons to file written comments on the proposed rulemaking. Such comments could be submitted electronically through the Federal eRulemaking Portal (www.regulations.gov) or in paper directly to DEA. The deadline to file written comments was June 10, 2022. Mr. Brinks will authenticate a copy of the NPRM.

[1] The Government reserves the right to call rebuttal witnesses as well as any of the witnesses listed by the Objectors on matters identified by the Objectors.

Mr. Brinks will testify that DEA received approximately 96 electronic comments and one paper comment on the proposed rulemaking. Mr. Brinks will authenticate copies of the comments received by DEA in response to the NPRM.

2. Dr. Theresa M. Carbonaro, Ph.D.

Dr. Theresa Carbonaro will testify that she is currently employed as a pharmacologist with the DEA's Drug and Chemical Evaluation Section. Dr. Carbonaro will testify regarding her background and experience. Dr. Carbonaro will testify as an expert in pharmacology. She will authenticate a copy of her C.V.

Dr. Carbonaro will testify that she is the DEA pharmacologist assigned to the proposed scheduling of DOI and DOC. She will testify regarding the history of the proposed scheduling of these substances based on her personal knowledge, as well as her review of DEA's files and information provided to her in the course of her duties.

Dr. Carbonaro will testify that, in response to reports of abuse and trafficking, DEA began investigating DOI and DOC. She will testify that DEA gathered and reviewed available information regarding the pharmacology, chemistry, trafficking, abuse, and dependence of both DOI and DOC. She will testify that DEA conducted a review and analysis of this information and, that in September 2018, DEA sent a data review document to the Assistant Secretary of HHS with a request to provide scientific and medical evaluations and scheduling recommendations for both DOI and DOC. She will authenticate a copy of the request and accompanying documents that were sent to HHS.

Dr. Carbonaro will testify that on September 28, 2020, HHS provided its scientific and medical evaluation and scheduling recommendations for DOI and DOC to DEA. She will testify that the HHS analyses considered the eight statutory factors relevant to a scheduling decision as set forth in 21 U.S.C. § 811(c), and made findings related to each of the substances' abuse

potential, lack of legitimate medical use, and lack of accepted safety for use under medical supervision. She will testify that HHS recommended that DOI and DOC and their respective salts be placed in Schedule I of the CSA. She will authenticate copies of the HHS evaluations received by DEA.

Dr. Carbonaro will testify that DEA received a letter dated May 7, 2020, from the Secretary General of the United Nations advising that, on March 4, 2020, the United Nations Office on Drugs and Crime had voted to place DOC in Schedule I of the 1971 Convention on Psychotropic Substances. She will authenticate of copy of that letter. She will also authenticate copies of the data obtained from the National Forensic Laboratory Information System (NFLIS) showing reported encounters by federal, state, and local forensic laboratories with DOI and DOC between 2005 and 2020.

Dr. Carbonaro will testify that DEA reviewed the HHS findings and scheduling recommendations as well as all other relevant data, and that DEA performed its own eight-factor analysis to determine whether DOI and DOC each should be controlled and, if so, in which schedule each should be placed. She will testify that this analysis was documented in a written report, dated August 2021 (the DEA Eight Factor Analysis). She will testify that she is the primary author of the DEA Eight Factor Analysis. She will authenticate a copy of that analysis, and copies of its accompanying references.

Dr. Carbonaro will adopt the findings contained in the DEA Eight Factor Analysis as her analysis on the application of the eight factors to DOI and DOC. She will testify that her analysis confirmed the 2020 HHS evaluations. She will testify that she concluded that both DOI and DOC each have a high potential for abuse; that neither DOI nor DOC have a currently accepted

medical use for treatment in the United States; and that there is a lack of accepted safety for use of DOI and DOC under medical supervision.

EXHIBITS

Government Exhibit No. 1	Declaration of Scott A. Brinks
Government Exhibit No. 2	Notice of Proposed Rulemaking, published April 11, 2022 (7 pages)
Government Exhibit No. 3	Comments received in response to Notice of Proposed Rulemaking (158 pages)
Government Exhibit No. 4	C.V. of Theresa M. Carbonaro (7 pages)
Government Exhibit No. 5	Letter and attachments from DEA to HHS, dated September 26, 2018: (35 pages)
Government Exhibit No. 6	HHS, Basis for Recommendation to Control DOI and DOC in Schedule I of the CSA, dated September 28, 2020 (14 pages)
Government Exhibit No. 7	Letter from the Secretary General of the United Nations to the United States Secretary of State, dated May 7, 2020 (6 pages)
Government Exhibit No. 8	DEA NFLIS Drug Data for DOI and DOC (queried February 23, 2021) (3 pages)
Government Exhibit No. 9	DEA, Eight Factor Determinative of Control and Findings Pursuant to 21 U.S.C. § 812(b) (16 pages)
Government Exhibit No. 10	References Cited in DEA Eight Factor Analysis (398 pages)

POSITION REGARDING HEARING SITUS

The Government requests to hold the hearing at the DEA Hearing Facility in Arlington, Virginia, provided that it would be safe and practicable.

OTHER MATTERS

The Government reserves the opportunity to amend its Prehearing Statement at a time and date specified by this Tribunal.

It is not clear that the Request for Hearing submitted by Daniel J. Lustberg, Lindsey Galbo, and Elijah Z. Ullman was timely filed, nor does that request establish that all of these

individuals are "interested persons" with standing to request a hearing on this proposed rulemaking. *See* 21 C.F.R. §§ 1308.44(a); 1316.47. Accordingly, the Government reserves the right to seek appropriate relief with respect to any or all of these individuals at an appropriate time.

The Government requests that the hearing commence on a Tuesday.

ESTIMATE OF TIME

The Government estimates that it can present its case-in-chief in one day, exclusive of cross-examination and rebuttal.

Dated: June 13, 2022

Respectfully submitted,

/s/ David M. Locher
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CERTIFICATE OF SERVICE

I hereby certify that on June 13, 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 to the Objectors at:

- David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net

- Daniel J. Lustberg, Lindsey Galbo, and Elijah Z. Ullman, via Federal Express at:
  Elijah Z. Ullman
  1063 Burton Drive, NE
  Atlanta, Georgia 30329

/s/ David M. Locher

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