
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of:

Schedules of Controlled Substances: Placement
of the Five Tryptamines in Schedule I

Docket No. DEA1715

Joint Request for Hearing; 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, 91 Fed. Reg. 60,338 (proposed Sept. 23, 2026).

VIA PHYSICAL DELIVERY

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

October 23, 2026

**Re: JOINT REQUEST FOR HEARING AND WRITTEN STATEMENT OF POSITION
OF MINDSTATE DESIGN LABS, INC., BENJAMIN RYAN CUMMINGS, JANELLE
KATHLEEN LANHAM, AND STUDENTS FOR SENSIBLE DRUG POLICY**

Mindstate Design Labs, Inc. ("Mindstate"), Benjamin Ryan Cummings, Janelle Kathleen Lanham, and Students for Sensible Drug Policy ("SSDP") (collectively, the "Requesting Parties"), through undersigned counsel, jointly request a hearing on the Drug Enforcement Administration's proposal to place 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), including their respective salts, isomers, and salts of isomers, in Schedule I of the Controlled Substances Act (collectively, the "Five Tryptamines"). This request is made pursuant to 21 U.S.C. §§ 811(a) and 812(b)(1) and 21 C.F.R. §§ 1308.44(a)

and 1316.47(a). The Requesting Parties submit this request for physical delivery to the DEA Administrator at the address designated in the notice of proposed rulemaking ("NPRM").

The NPRM requires each hearing request to (1) state with particularity the interest of the person in the proceeding; (2) state with particularity the objections or issues concerning which the person desires to be heard; and (3) state briefly the position of the person regarding those objections or issues. Each requirement is addressed below.

I. PARTICULARIZED INTERESTS OF THE REQUESTING PARTIES

A. The Governing Standard

DEA's regulations define an "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule" issued under 21 U.S.C. § 811. 21 C.F.R. § 1300.01(b). An interested person may request a hearing and participate in the proceeding by timely filing a hearing request that states with particularity the person's interest; the request also constitutes a notice of appearance. *Id.* §§ 1308.44(a)–(b), 1316.47(a). Each Requesting Party makes that showing below on the basis of specific, documented interests. A requester who can demonstrate a substantial interest in the outcome and that it would be adversely affected or aggrieved if the proposed rule were promulgated ordinarily has a right to participate.

B. Mindstate Design Labs, Inc.

Mindstate Design Labs, Inc. ("Mindstate") is a corporation organized under the laws of the State of Delaware, with its principal place of business at 611 Gateway Blvd, Suite 120, South San Francisco, California 94080. Mindstate is engaged in the development of psychedelic drug therapies for intractable mental health conditions and is currently investigating 5-MeO-MiPT as part of a live research and drug-development program.

Mindstate was previously recognized as an interested party in the 2022 DEA proceeding concerning the proposed scheduling of the same five tryptamines. DEA announced that hearing in the Federal Register. See 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; Announcement of Hearing, 87 Fed. Reg. 40,167 (July 6, 2022). Mindstate's prior recognition provides relevant procedural

history supporting its present request. The scientific and commercial interests underlying its 2022 participation continue today and have deepened through several additional years of investment in research and drug development involving 5-MeO-MiPT. Mindstate relies on that continuity and its ongoing investment as further evidence of its direct stake in this proceeding, while independently establishing its present eligibility through its active research program and the concrete adverse effects the proposed rule would have on that work.

Mindstate possesses controlled human data, dose-response data, physiological measures, psychometric data, neuroimaging findings, and preclinical data specific to 5-MeO-MiPT, which constitute a unique record bearing directly on the statutory findings DEA must make. Placement of 5-MeO-MiPT in Schedule I would subject research and other handling of the compound to applicable registration, research-protocol, security, storage, inventory, transfer, and recordkeeping requirements, subject to statutory and regulatory exemptions. See 21 U.S.C. § 822; 21 C.F.R. §§ 1301.18, 1301.22(a), 1301.71–1301.76; *id.* pts. 1304, 1305, 1312. Those requirements would directly burden Mindstate's ability to conduct ongoing and planned research and development, collaborate with outside investigators and institutions, transfer research materials, and pursue its drug-development pipeline for 5-MeO-MiPT.

Mindstate's commercial, scientific, regulatory, and intellectual-property interests would each be adversely affected by finalization of the rule: the proposed classification would eliminate unregistered access to the compound, delay and complicate further human research, increase the cost and administrative burden of studies needed to support drug-development and regulatory pathways, and risk foreclosing or substantially delaying the development of a potential therapeutic agent. Mindstate therefore would be adversely affected or aggrieved by the proposed rule within the meaning of 21 C.F.R. § 1300.01(b) and qualifies as an interested person under 21 C.F.R. § 1308.44(a).

C. Benjamin Ryan Cummings

Dr. Cummings is a post-doctoral researcher. Dr. Cummings conducts research at Louisiana State University Health Sciences Center and participates in research programs at the University of South Florida. Dr. Cummings also serves as Chief Editor of the Intercollegiate Psychedelic Network and on the Science Policy Committee of SSDP.

Dr. Cummings has spent approximately six years characterizing the structural biology of the 5-HT2A receptor, focusing on the functional selectivity of tryptamine and phenethylamine psychedelics. His research has specifically examined how molecular features bias receptor signaling toward or away from anti-inflammatory and therapeutic outcomes versus hallucinogenic effects. DiPT and 4-OH-DiPT are central to this work: his research has shown that the hydroxyl group at the 4-position differentiates anti-inflammatory outcomes such that 4-OH-DiPT exhibits anti-inflammatory activity while DiPT does not, and that the diisopropyltryptamine scaffold anchors these compounds in the receptor in a manner that allows direct and consistent engagement of the 4-OH position. This work has direct implications for medicinal drug development targeting the 5-HT2A receptor, which is implicated in numerous mental health disorders. Executive Order 14401 establishes a broader policy favoring accelerated research and appropriate approvals for psychedelic treatments. Exec. Order No. 14,401, §§ 1, 4–6, 91 Fed. Reg. 21,709 (Apr. 22, 2026). Research into DiPT and 4-OH-DiPT may advance that policy, although the order does not specifically identify either compound or alter the CSA’s scheduling criteria.

Placement of DiPT and 4-OH-DiPT in Schedule I would adversely affect Dr. Cummings in the following concrete respects. First, continued access to these compounds for purposes of his structural-biology research would require appropriate Schedule I research authorization and compliance with applicable security, storage, protocol, recordkeeping, and transfer requirements. Depending on his employment and institutional arrangements, Dr. Cummings may work under an authorized registrant’s registration rather than obtain a separate personal registration. See 21 C.F.R. § 1301.22(a). These are requirements he does not currently face. Second, the time and cost of obtaining and maintaining such a registration, and, if no institution is willing to sponsor his research, the practical unavailability of a Schedule I research infrastructure to an independent researcher could delay or prevent continuation of his current research. Third, Dr. Cummings is actively seeking a position at an academic institution on the basis of his prior research into these compounds and is proposing a next research project built on this foundation. Schedule I placement would narrow the pool of institutions willing and equipped to support that research, complicate grant and fellowship applications that require guaranteed compound access, and impair his ability to propose and execute the work on which his near-term career development depends. Fourth, Dr. Cummings has manuscripts under peer review or in preparation involving

DiPT and 4-OH-DiPT. The Requesting Parties do not assert that scheduling necessarily ends Dr. Cummings's career or prohibits any publication, but the concrete causal pathway from scheduling to registration burden, access restriction, institutional barrier, grant constraint, and career-development impairment will adversely impact Dr. Cummings. Dr. Cummings is therefore adversely affected or aggrieved by the proposed rule within the meaning of 21 C.F.R. § 1300.01(b).

Dr. Cummings participates in his individual professional capacity. Any institutional affiliation is stated for identification only and does not imply institutional endorsement. He requires no institutional approval to participate as an individual.

D. Janelle Kathleen Lanham

Dr. Lanham requests a hearing and participation in this proceeding as an interested person under 21 C.F.R. §§ 1300.01(b), 1308.44(a)–(b), and 1316.47(a). She has direct scientific and professional interests in the proposed scheduling action because four of the substances at issue are integral to research she has personally conducted and to an unpublished manuscript representing a substantial portion of her doctoral work.

Dr. Lanham is a postdoctoral researcher in the Department of Cell Biology, Neurobiology and Anatomy at the Medical College of Wisconsin, working in the laboratory of Dr. John McCorvy. She earned her doctorate there in December 2025. Her research examines the effects of psychedelic and antipsychotic compounds across serotonin, dopamine, muscarinic, adrenergic, and histamine G protein-coupled receptors. She studies how differences in chemical structure affect activity across multiple receptors, aiming to inform drug design, mechanisms of action of psychoactive substances, identify off-target effects, and investigate understudied receptors with potential therapeutic relevance.

In pursuing this research, Dr. Lanham has personally worked with 4-OH-DiPT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. These four compounds were essential to her graduate research and are included in a manuscript she anticipates submitting for publication before the end of 2026. Publication of that work is particularly important at this early stage of her career because it represents the majority of her research efforts as a graduate student and would contribute materially to her record of scientific accomplishment and future professional opportunities.

Placement of these compounds in Schedule I would subject further research involving them to additional regulatory requirements, including applicable Schedule I research-protocol requirements. See 21 C.F.R. § 1301.18(a). Those requirements create a risk of delay or disruption if additional experiments involving these compounds are needed to complete the manuscript, respond to peer-review requests, validate findings, or pursue related research. To the extent scheduling impedes such work, it could delay publication, limit the scientific development of her findings, and impair the timely dissemination of research on which her professional advancement depends.

Dr. Lanham's asserted injury therefore concerns the practical consequences of restricting access to compounds underlying an identifiable research project and forthcoming manuscript. Any resulting interruption or curtailment of that research could materially impair her publication record and future research opportunities. Her interest extends beyond a generalized disagreement with drug-control policy: she seeks to protect the completion, validation, and continued development of research she has personally undertaken.

Dr. Lanham seeks to present testimony concerning her work with these compounds, their role in her research, and the potential effects of Schedule I controls on that work and her professional development. Dr. Lanham would be adversely affected or aggrieved by the proposed rule within the meaning of 21 C.F.R. § 1300.01(b). Dr. Lanham participates in her individual professional capacity; institutional affiliation is stated for identification only. Dr. Lanham also serves on the Science Policy Committee of SSDP.

E. Students for Sensible Drug Policy

Students for Sensible Drug Policy ("SSDP") is a national nonprofit, youth-led organization that advances evidence-based drug education, harm reduction, and drug policies grounded in health, safety, science, and human rights. Its membership and broader network include students and early-career professionals engaged in scientific research, academic training, public-health work, and peer education. SSDP seeks participation both in its own organizational capacity and in a representative capacity on behalf of members who would be adversely affected by the proposed scheduling of the Five Tryptamines.

Direct organizational interest and injury. SSDP independently seeks participation based on the proposed rule's adverse effects on its existing educational, scientific-policy, and harm-reduction activities and the organizational resources required to carry them out. SSDP serves students and early-career researchers whose work and training depend on access to scientific information and research opportunities involving psychoactive substances. Placement of the Five Tryptamines in Schedule I would require SSDP to devote additional staff time and financial resources to educating its network about the resulting research barriers, the consequences for ongoing and planned studies, and the effects of those restrictions on scientific knowledge and public health.

That work would include developing and updating educational materials, distributing revised guidance to members and campus chapters, and providing additional education concerning research access and the harms caused by interruptions or delays in scientific work. These demands would consume resources otherwise available for SSDP's existing educational and harm-reduction activities, adversely affecting its budget and its capacity to serve its constituency. SSDP's asserted injury thus concerns identifiable consequences for its ongoing work and resource allocation arising from the proposed rule.

This basis for administrative participation is consistent with Chief Administrative Law Judge Mulrooney's treatment of Smart Approaches to Marijuana ("SAM") in the marijuana-rescheduling proceeding. Although SAM had not established associational standing, the ALJ credited its showing that rescheduling would adversely affect its training and advocacy expenditures, budget, and mission, and concluded that it had established standing to participate. Order Regarding Standing, Scope, and Prehearing Procedures at 37–38, *In re Schedules of Controlled Substances: Proposed Rescheduling of Marijuana*, Hearing Docket No. 24-44, DEA Docket No. 1362 (DEA Nov. 19, 2024). SSDP presents an analogous organizational interest: the proposed scheduling action would increase the demands on its established educational work and require the commitment of additional organizational resources to address research restrictions and their consequences. SSDP therefore asserts that it would be adversely affected or aggrieved by the proposed rule within the meaning of 21 C.F.R. § 1300.01(b), independently of its associational grounds for participation.

Associational interest and injury. SSDP independently seeks participation on behalf of its members whose research, training, and professional development would be adversely affected. These include Dr. Cummings and Dr. Lanham, who are both actively studying or pursuing the publication of research on DiPT and 4-OH-DiPT, and 4-OH-DiPT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, respectively. Schedule I placement would subject their work to applicable registration, protocol, security, and institutional compliance requirements, potentially delaying experiments, restricting access to research materials, and impairing completion of research projects and resulting publications. See, e.g., 21 C.F.R. § 1301.18(a).

The effects on each member depend on the member's research and institutional circumstances. For members whose institutions lack the necessary authorizations or are unwilling or unable to undertake the required compliance measures, scheduling could prevent continuation of the affected work. For others, additional approvals and restrictions could delay research during time-limited appointments or training programs. SSDP relies on those particularized consequences, as established by the affected members' statements, rather than a generalized assertion that all students or researchers would suffer identical harm.

These interests satisfy the associational-standing framework. First, the identified members would have standing in their own right based on concrete research and professional injuries attributable to the proposed restrictions and redressable by withholding the proposed scheduling action. Second, protecting their access to scientific research and training is germane to SSDP's purposes. Third, SSDP seeks relief concerning the proposed rule, rather than individualized damages; neither its claims nor its requested relief requires those members to participate as named parties.

Prior participation and requested recognition. SSDP previously received party status and participated in the DOI/DOC scheduling proceeding, presenting factual evidence and expert testimony concerning scientific access and research burdens. DEA Docket No. 1156. That participation provides relevant context for SSDP's established work in this field. SSDP nevertheless bases its present request on the specific organizational and member injuries arising from the proposed scheduling of the Five Tryptamines.

SSDP therefore asserts two independent grounds for participation: direct injury to its existing organizational activities and representative injury through its affected members. On those grounds, SSDP qualifies as an “interested person” adversely affected or aggrieved by the proposed rule under 21 C.F.R. § 1300.01(b) and requests a hearing and participation pursuant to 21 C.F.R. §§ 1308.44(a)–(b) and 1316.47(a).

II. PARTICULARIZED OBJECTIONS AND ISSUES FOR HEARING

The Requesting Parties request a hearing to present factual evidence and expert opinion on the following issues. A hearing is appropriate under 21 C.F.R. § 1308.42 for receiving factual evidence and expert opinion; preserved legal and policy questions will be addressed in pre-hearing and post-hearing submissions. The issues below are stated separately so that the Administrator can identify the disputed facts, the relevant expert disciplines, and the statutory finding to which each relates.

A. Factual Issues Requiring Evidentiary Hearing

1. Whether the 2026 HHS eight-factor analysis for each of the Five Tryptamines satisfies the evidentiary requirements of 21 U.S.C. § 811(c) and 21 U.S.C. § 812(b)(1), or is instead arbitrary, capricious, unsupported by substantial evidence, or otherwise contrary to law.
2. Whether the finding of "high potential for abuse" for each compound is supported by substantial evidence distinguishing "high" potential from any detectable abuse-related effect, by reference to specific, reliable human or animal evidence for each compound individually, and by appropriate comparison to other scheduled substances under 21 U.S.C. § 811(c)(1).
3. Whether DEA adequately identified and applied a coherent, textually defensible legal standard for "potential for abuse" and "high potential for abuse" under 21 U.S.C. § 812(b)(1)(A), or whether the analysis equates psychoactivity, receptor affinity, structural similarity, or analogical inference with a "high" potential for abuse without a limiting principle grounded in the statute.
4. Whether DEA's comparative analysis properly accounts for dose comparability, species translation, assay conditions, reference standards, endpoint selection, pharmacokinetics, route of administration, and the distinction between reinforcing effects and hallucinogenic or

adverse effects in determining actual or relative potential for abuse under 21 U.S.C. § 811(c)(1).

5. Whether the aggregate poison-center data, case reports, and law-enforcement encounter data, as aggregated across the Five Tryptamines, provide a sufficient and compound-specific evidentiary basis for each of the three required Schedule I findings, and whether the record adequately distinguishes single-substance exposures from polysubstance exposures, confirms product identity, and accounts for denominator effects.
6. Whether the finding that each of the Five Tryptamines lacks currently accepted medical use in treatment in the United States is premised on a legally defensible and textually grounded construction of that phrase under 21 U.S.C. § 812(b)(1)(B), or on an implicit requirement of FDA marketing approval or other standard not found in the statute's text or structure.
7. Whether the finding that each of the Five Tryptamines lacks accepted safety for use under medical supervision is made and supported as a separate, independent inquiry distinct from the absence of FDA approval or the absence of currently accepted medical use, as required by 21 U.S.C. § 812(b)(1)(C).
8. Whether DEA's analysis for DiPT and 4-OH-DiPT adequately addresses the compound-specific differences—including the anti-inflammatory profile associated with 4-OH-DiPT's 4-OH substitution that does not appear to exist in DiPT—or instead treats these compounds as interchangeable based on structural similarity and generalized tryptamine pharmacology.
9. Whether the proposed control of every salt, isomer, and salt of isomers of each compound is supported by a compound-specific, form-specific analysis, or whether the record fails to establish equivalent pharmacology, abuse liability, and risk profile for every covered chemical form.
10. Whether the three conjunctive findings required by 21 U.S.C. § 812(b)(1) have each been separately made and independently supported for each of the Five Tryptamines, or whether any required finding has been derived by inference from another, such as inferring absence of accepted safety from absence of FDA approval or marketing authorization.
11. Whether DEA's Regulatory Flexibility Act certification rests on a supported factual basis sufficient to satisfy 5 U.S.C. § 605(b), in particular whether its assumptions about the

number, current registration status, and incremental burden on affected researchers, students, universities, nonprofit organizations, analytical laboratories, and contract research organizations are adequately supported.

12. Whether the 2026 HHS eight-factor analysis defines, or applies consistently, the term "potential for abuse," including high potential for abuse, given that GAO's reported gaps in DEA and FDA procedures for eight-factor analyses and in FDA's criteria and process for evaluating potential and relative potential for abuse. See GAO-26-108623, at 12–14 (Sept. 2026).
13. Whether the 2026 analysis adequately accounts for the proportionality between demonstrated compound-specific risks for each of the Five Tryptamines and the regulatory consequences of Schedule I placement, including the research and public-health costs of foreclosing legitimate scientific investigation into compounds implicated in mental health research.

III. BRIEF STATEMENT OF POSITION

A. "High Potential for Abuse": Standard and Evidence

Schedule I requires a finding of high potential for abuse. 21 U.S.C. § 812(b)(1)(A). The legislative history describes four criteria relevant to "potential for abuse," but "high" imposes a heightened threshold beyond detectable nonmedical use, structural similarity, or receptor activity. The NPRM's analysis of the Five Tryptamines relies substantially on aggregate exposure data—65 poison-center exposure cases involving one or more of the five compounds—on generalized tryptamine pharmacology, and on comparative reference to other scheduled hallucinogens. That evidence does not, without more, establish that each compound has a high potential for abuse comparable to Schedule I benchmarks, particularly absent dose-response data, reinforcement evidence in controlled human or animal studies, and controlled denominator analysis specific to each compound. The Requesting Parties will present expert testimony and evidence bearing on whether the standard applied is consistent with the best reading of the statute and whether the compound-specific evidence satisfies it.

B. Currently Accepted Medical Use: Statutory Construction

The term currently accepted medical use in treatment in the United States in 21 U.S.C. § 812(b)(1)(B) does not, on its face, require FDA marketing approval. The Requesting Parties preserve the argument that importing an FDA-approval requirement into that phrase substitutes an agency-constructed standard for the one Congress enacted, a construction that courts must now evaluate independently. Whether DEA's applied test accurately reflects the statute's text and structure is a legal question that does not require testimonial evidence, but the hearing should develop the factual record necessary to determine which standard, if correctly applied, the evidence satisfies.

C. "Accepted Safety" as an Independent Inquiry

The third Schedule I finding—lack of accepted safety for use under medical supervision—is a distinct statutory requirement. 21 U.S.C. § 812(b)(1)(C). *Grinspoon v. DEA*, 828 F.2d 881, 891 (1st Cir. 1987), held that the absence of FDA interstate marketing approval cannot conclusively establish either lack of currently accepted medical use or lack of accepted safety under medical supervision. The Requesting Parties contend that DEA must support the accepted-safety finding for each compound rather than treat the absence of FDA approval as dispositive. They will present evidence and argument bearing on that finding.

D. Proportionality and Reasoned Decisionmaking

The APA requires an agency to examine relevant evidence and explain its decision, including the connection between its factual findings and the action chosen. *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983). In making scheduling findings, DEA must consider the eight factors identified in 21 U.S.C. § 811(c), including actual or relative potential for abuse, with respect to each substance, and make the findings required by § 812(b)(1). The Requesting Parties contend that DEA must explain how the evidence concerning each of the Five Tryptamines supports those findings and address material contrary evidence. They further contend that documented research-access harms warrant consideration insofar as those harms bear on the statutory factors and legally available alternatives. These objections invoke statutory requirements and arbitrary-and-capricious review, rather than a freestanding constitutional proportionality test.

Constitutional preservation. The Requesting Parties separately preserve for briefing and, if necessary, judicial review, any available arguments under the non-delegation doctrine and the First Amendment as applied to suppression of legitimate scientific inquiry, without asserting that those theories independently require testimonial evidence at this stage.

E. Loper Bright and Independent Statutory Interpretation

Under *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2273 (2024), courts independently interpret statutes rather than defer merely because statutory language is ambiguous. The Requesting Parties preserve challenges to DEA’s construction of the Schedule I criteria. *Loper Bright* does not displace statutory delegations of discretion or judicial review of scientific factfinding under the applicable evidentiary standard. Nor does it automatically reopen earlier decisions: prior holdings upholding specific agency actions remain subject to statutory *stare decisis*. *Id.* at 2273. The Requesting Parties seek application of the governing statutory text to this rulemaking, subject to those limits.

F. GAO Report: Policy Gaps in the Eight-Factor Process

The Government Accountability Office identified gaps in DEA and FDA procedures for conducting scheduling evaluations and in FDA’s criteria and process for evaluating potential and relative potential for abuse. U.S. Gov’t Accountability Off., GAO-26-108623, *Drug Scheduling: While DEA Decisions Have Aligned with Recent HHS Recommendations, Both Need Comprehensive Policies* 12–14 (Sept. 2026). DOJ and HHS concurred with GAO’s recommendations. *Id.* at 18–19. Those findings support scrutiny of the standards and methods used here; they do not themselves establish that this particular scheduling analysis was arbitrary or scientifically invalid. The Requesting Parties seek a record permitting that assessment.

G. Regulatory Flexibility Act

DEA’s certification that the proposed rule would not have a significant economic impact on a substantial number of small entities rests on the empirical assumption that researchers who work with the Five Tryptamines are likely already registered with DEA to handle other controlled substances. That assumption is not self-evident and has not been supported with factual data about the actual population of affected researchers, students, universities, and nonprofit organizations. A 5 U.S.C. § 605(b) certification must include a statement providing the factual

basis for the certification. The Requesting Parties will present evidence that Schedule I registration, security, storage, institutional, and compliance requirements impose incremental burdens on researchers who are not currently Schedule I registrants, and that the affected population includes students and early-career researchers for whom these barriers may be project- or career-determinative.

The Requesting Parties request initial and final regulatory flexibility analyses under 5 U.S.C. §§ 603–604 if DEA cannot substantiate its § 605(b) certification. Such analyses would include a description of the reasons why action by the agency is being considered and alternatives to the proposed rule which accomplish the stated objectives of applicable statute and which minimize any significant economic impact of the proposed rule on small entities. The Requesting Parties specifically request the agency consider two alternatives aligned with the objectives of the CSA that would permit DEA to control abuse and diversion while minimizing the economic impact the proposed rule would have on small entities conducting legitimate research, including qualifying Requesting Parties:

1. Whether enforcement of the Federal Analogue Act, where its statutory elements are satisfied, could address unlawful human-consumption markets while avoiding unnecessary restrictions on legitimate research. See 21 U.S.C. §§ 802(32), 813(a). Structural or pharmacological similarity alone does not establish that every compound or transaction satisfies those requirements. The Requesting Parties ask DEA to evaluate this alternative without conceding that any particular compound or research activity is subject to analogue liability.
2. Whether a less restrictive schedule is legally and factually available for any compound under 21 U.S.C. § 812(b). The Requesting Parties preserve their proposed interpretation of “currently accepted medical use with severe restrictions,” the language applicable to Schedule II under § 812(b)(2)(B), including its possible application to appropriate medical research. They recognize that research use alone does not establish that criterion and that each alternative schedule requires its own statutory findings. Executive Order 14401’s research policy supports considering lawful alternatives but does not dispense with those findings. Exec. Order No. 14,401, §§ 1, 4–6, 91 Fed. Reg. 21,709 (Apr. 22, 2026).

IV. EVIDENCE AND TESTIMONY TO BE PRESENTED

The Requesting Parties expect to present the following categories of factual evidence and expert opinion, subject to the notice of hearing, the presiding officer's scheduling orders, and ordinary evidentiary procedures.

1. Expert testimony from qualified pharmacologists and clinical pharmacologists concerning the pharmacology of each of the Five Tryptamines, including receptor binding, functional selectivity, dose-response relationships, species translation, comparison to scheduled reference compounds, and the adequacy of the agency's abuse-potential findings for each compound.
2. Expert testimony concerning the structural biology of the 5-HT_{2A} receptor and compound-specific differences between DiPT and 4-OH-DiPT, including the functional significance of the 4-OH substitution for anti-inflammatory versus hallucinogenic outcomes, and the limitations of treating these compounds as interchangeable for abuse-liability purposes.
3. Mindstate's controlled human data, dose-response observations, physiological measures, psychometrics, and neuroimaging data for 5-MeO-MiPT, and expert testimony explaining what those data demonstrate about the compound's pharmacology and the adequacy or inadequacy of the agency's factual findings.
4. Expert testimony concerning the interpretation of poison-center data, case reports, law-enforcement encounter data, and adverse-event reports, including denominator effects, polysubstance exposure rates, product-identity confirmation, causal attribution, and the distinction between evidence of some adverse events and evidence establishing a high potential for abuse.
5. Evidence and testimony concerning the practical burdens of Schedule I registration on researchers, students, universities, nonprofit organizations, and other small entities, including testimony from Drs. Cummings and Lanham about the specific effects scheduling would have on their current and planned research programs, career development, institutional relationships, and grant prospects.
6. SSDP organizational testimony and evidence concerning the effects of Schedule I placement on student researchers and campus-based programs within SSDP's network, the operational

demands the rule would impose on SSDP's educational and harm-reduction work, and the compound-specific access barriers that network members would face.

7. Expert or lay testimony concerning available research accommodations, alternative scheduling approaches, and transition measures that would address legitimate law-enforcement concerns while minimizing unnecessary disruption to ongoing scientific research.
8. Agency witnesses and records concerning the methodology, data sources, compound-specific analyses, and inferential steps underlying the 2026 HHS eight-factor evaluation and DEA's own analysis, including the searches conducted, databases consulted, and how contradictory or omitted evidence was treated.
9. A supplemental independent scientific analysis organized around the eight factors of 21 U.S.C. § 811(c) and the Schedule I findings required by 21 U.S.C. § 812(b)(1), together with supporting literature, data, declarations, and expert materials, to be submitted consistent with the presiding officer's scheduling orders.

V. REQUESTED RELIEF

For the foregoing reasons, the Requesting Parties respectfully request that the Administrator:

1. Grant this joint request and convene a formal evidentiary hearing on whether each of the Five Tryptamines meets the conjunctive statutory criteria for Schedule I placement under 21 U.S.C. § 812(b)(1).
2. Recognize Mindstate Design Labs, Inc., Benjamin Ryan Cummings, Janelle Kathleen Lanham, and SSDP as parties to the hearing, with this joint request deemed a notice of appearance under 21 C.F.R. § 1308.44(b).
3. Direct DEA to identify, supplement, and docket the portions of the scientific analyses, receptor-pharmacology reports, compound-specific data, and other materials relied upon in the 2026 HHS evaluation and DEA's eight-factor analysis, and to make such materials available for meaningful adversarial review prior to hearing.
4. Determine that the proposed rule may not be finalized unless each of the three conjunctive findings required by 21 U.S.C. § 812(b)(1) is independently supported, for each compound, on the complete record.

5. In the alternative, withdraw or defer the proposed rule as to any compound or chemical form for which the compound-specific, form-specific evidence does not independently satisfy each required statutory finding, pending supplemental analysis.
6. Reevaluate the Regulatory Flexibility Act certification; if its factual assumptions cannot be substantiated, prepare the initial regulatory flexibility analysis required by 5 U.S.C. § 603 and, if the rule proceeds, the final analysis required by 5 U.S.C. § 604, including consideration of alternatives that minimize burdens on affected small entities while achieving the CSA's objectives.
7. Adopt procedures sufficient to protect confidential research data, proprietary scientific information, and other legitimately confidential material while permitting meaningful adversarial testing of the evidence relied upon by the agencies.
8. If DEA proceeds toward control, evaluate and state on the record appropriate research accommodations, transition measures, and effective-date provisions that avoid needless interruption of ongoing research programs.
9. Grant such other relief as is necessary and appropriate to produce a complete, transparent, and scientifically reliable record.

The Requesting Parties reserve the right to refine or modify the issues identified herein, name additional witnesses, and supplement the evidentiary record consistent with the notice of hearing and the presiding officer's orders.

VI. PRESERVATION OF ADDITIONAL LEGAL OBJECTIONS

The Requesting Parties preserve for briefing, proposed findings, exceptions, and, if necessary, judicial review, the following legal objections, which are stated here to ensure they appear in the administrative record:

1. Statutory construction (APA / Loper Bright). The Requesting Parties preserve the argument that DEA's construction of each Schedule I criterion fails to reflect the best reading of the CSA. *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2273 (2024), requires independent judicial interpretation, subject to statutory delegations and the continued stare decisis effect of prior holdings. This objection includes any treatment of FDA approval as an indispensable condition of currently accepted medical use.

2. APA arbitrary-and-capricious review. Any final rule is subject to arbitrary-and-capricious review under 5 U.S.C. § 706(2)(A). An agency acts arbitrarily and capriciously when it fails to consider an important aspect of the problem, relies on factors Congress did not intend it to consider, offers an explanation for its decision that runs counter to the evidence before it, or gives an explanation so implausible that it cannot be attributed to a difference in view or agency expertise. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Requesting Parties preserve each of these theories as applied to: the aggregate treatment of the Five Tryptamines without compound-specific findings; the equation of structural similarity or receptor activity with "high potential for abuse"; the failure to independently support the accepted-safety finding; and the omission from the record of contrary evidence bearing on abuse liability, dependence, and research utility.
3. **Statutory ultra vires.** To the extent DEA's construction of the scheduling criteria effectively requires a finding it lacks statutory authority to make—or omits a finding the statute independently requires—the resulting rule exceeds the agency's delegated authority and is ultra vires. The three Schedule I findings are conjunctive and mandatory. A rule that infers one finding from another, or that dispenses with the independent accepted-safety inquiry, does not comply with 21 U.S.C. § 812(b)(1) regardless of the level of deference a court applies.
4. Substantial-evidence review. Because this proceeding is a formal rulemaking conducted on the record under 5 U.S.C. §§ 556 and 557, the agency's factual findings are subject to substantial-evidence review under 5 U.S.C. § 706(2)(E) and 21 U.S.C. § 877. The Requesting Parties preserve the argument that the record, as developed in this proceeding, does not contain substantial evidence for the "high potential for abuse" finding for each of the Five Tryptamines individually, particularly in the absence of compound-specific dose-response, reinforcement, and denominator-controlled data.
5. Regulatory Flexibility Act. The Requesting Parties preserve the argument that DEA's 5 U.S.C. § 605(b) certification lacks the required factual basis, and that DEA was therefore required to conduct and publish an initial regulatory flexibility analysis under 5 U.S.C. § 603 at the time of publication of the proposed rule and a final regulatory flexibility analysis under 5 U.S.C. § 604 when promulgating a final rule.

6. Constitutional preservation (non-delegation and First Amendment). The Requesting Parties separately preserve, without asserting that these theories require testimonial evidence at the hearing stage, the following constitutional objections: (a) that the CSA's delegation of scheduling authority, if construed to permit Schedule I placement without a workable and applied standard for high potential for abuse, raises concerns under the non-delegation doctrine; and (b) that the imposition of Schedule I controls on legitimate scientific inquiry, publications, and educational activities may raise First Amendment questions that become ripe if the final rule forecloses ongoing research without adequate evidentiary justification.

VII. NOTICES OF CORRESPONDENCE; ADDRESSES FOR SERVICE

All notices, orders, correspondence, and communications in this proceeding relating to each Requesting Party should be directed as follows:

Counsel for All Requesting Parties:

Robert T. Rush, Esq.
Law Office of Robert T. Rush
600 17th Street, Suite 2800 South
Denver, Colorado 80202
(201)759-1493
rrush@rrushlaw.com

Brett Phelps, Esq
Phelps Law Office
P.O. Box 1777
Las Vegas, NM 87701
(505) 425-5129
(505) 454-8936
brett@brettphelpsllaw.com

Mindstate Design Labs, Inc.:
611 Gateway Blvd, Suite 120
South San Francisco, California 94080

Benjamin Ryan Cummings PhD:
2618 St. Anthony St.
New Orleans, Louisiana 70119

Janelle Kathleen Lanham, PhD:
839 North Marshall
Apt 2
Milwaukee, WI 53202

Students for Sensible Drug Policy:
1800 M St. NW
FRNT 1 #33051
Washington, DC 20036

Respectfully submitted,



Robert T. Rush, Esq.

Law Office of Robert T. Rush
600 17th Street, Suite 2800 South
Denver, Colorado 80202
(201) 759-1493

rrush@rrushlaw.com

*Counsel for Mindstate Design Labs, Inc., Benjamin Ryan Cummings, Janelle Kathleen Lanham,
and Students for Sensible Drug Policy*



Brett Phelps, Esq.
Phelps Law Office

P.O. Box 1777
Las Vegas, NM 87701
(505) 425-5129
(505) 454-8936

brett@brettphelpslaw.com

Counsel for Students for Sensible Drug Policy

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