U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

September 23, 2022

Dr. Sunil Aggarwal
Advanced Medical Science Institute
2825 Eastlake Avenue East, #115
Seattle, WA 98102

Dear Dr. Aggarwal:

This letter responds to your letter dated February 2, 2022, requesting that the Drug Enforcement Administration (DEA) initiate rulemaking proceedings pursuant to the Controlled Substances Act (CSA) to reclassify psilocybin from schedule I to schedule II of the CSA.

A prerequisite to transferring a substance from schedule I to schedule II under the CSA is for the Food and Drug Administration (FDA) to determine that a substance has a currently accepted medical use in treatment in the United States. *See, e.g., Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013) (describing five-part test for demonstrating that); *see also* 21 U.S.C. § 812(b)(1). To date, the FDA has not articulated any accepted medical use for psilocybin in treatment. Accordingly, the CSA requires that psilocybin remain in schedule I.

Sincerely,

Kristi O'Malley Digitally signed by KRISTI O'MALLEY
Date: 2022.09.23 14:58:23 -04'00'

Kristi O'Malley
Assistant Administrator
Diversion Control Division

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
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Kathryn L. Tucker, Esq.
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Dear Kathryn Tucker:

This is in response to your June 29, 2022 letter to the Drug Enforcement Administration (DEA) regarding DEA's June 28, 2022 response to your February 10, 2022 letter. Your February 10, 2022 letter addressed the Right to Try Act (RTT), 21 U.S.C. 360bbb-0a, and requested that your clients—Advanced Integrative Medical Science Institute (AIMS) and its co-director, Dr. Sunil Aggarwal—receive authorization to obtain psilocybin, a schedule I controlled substance, for therapeutic use for terminally ill patients suffering anxiety and/or depression, and immunity from prosecution under the Controlled Substances Act (CSA). Your June 29, 2022 letter sought confirmation on whether DEA's June 28, 2022 letter was "a final decision of the agency and therefore subject to judicial review under 21 U.S.C. § 877." DEA appreciates the opportunity to address your June 29, 2022 letter, and this response constitutes DEA's final decision to deny the requests made in your February 10, 2022 letter. We do so for the following reasons.

DEA's prior two letters to you, dated February 12, 2021, and June 28, 2022, explained why your proposal was not legally feasible under the CSA. We begin with a brief summary of the considerations set forth in DEA's February 12, 2021 letter. As indicated therein, practitioners who seek to dispense or possess schedule I controlled substances must be properly registered as an approved researcher in accordance with the CSA and its implementing regulations. 21 U.S.C. 823(f); 21 CFR 1301.18, 1301.32. As DEA further explained in its prior correspondence, with respect to your request for immunity under 21 CFR 1316.24, that provision only applies to persons who are already registered with DEA to engage in research in controlled substances and are acting within the scope of that registration. Dr. Aggarwal has not requested or obtained a schedule I researcher registration from DEA; therefore, he is not authorized to dispense or possess psilocybin and is not eligible to seek such an exemption from prosecution at this time.

Insofar as it contends that the RTT and CSA grant such authorization and immunity, your letter reflects a fundamental misunderstanding of the relationship between the RTT and the CSA. In enacting the RTT, Congress expressly amended the Federal Food, Drug, and Cosmetic Act (FDCA) and provided exemptions from certain FDCA requirements governing the labeling, approval, and clinical trials of drugs. 21 U.S.C. 360bbb-0a(b). The RTT did not, however, provide any exemptions from the CSA or its implementing regulations. As the Ninth Circuit observed in *AIMS, PLLC v. Garland*, 24 F.4th 1249, 1261 (9th Cir. 2022), the RTT "did not give the DEA authority to waive CSA requirements." Because "Congress has not yet made an exception to the CSA to allow for the legal use of psilocybin for therapeutic purposes," *id*. at 1262, the CSA's requirements to handle psilocybin for research purposes remain in effect.

Your February 10, 2022 letter also asked DEA to "waive or make an exception" to "any registration requirement in the CSA or in DEA's implementing regulations" that would apply to your request for access to psilocybin. Specifically, your letter asked DEA to waive, "at least temporarily," the registration requirement under section 823(f). This request included a citation to 21 U.S.C. 822(d), which provides that DEA "may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if [DEA] finds it consistent with the public health and safety." To the extent that your reference to section 822(d) was intended as a request for DEA to initiate rulemaking to accommodate your clients' requested access to psilocybin, DEA declines to do so. As a preliminary matter, because you did not provide DEA with the proposed text, or even the scope, of the regulation you purportedly seek pursuant to section 822(d), the Agency is unable to fully assess your proposal.

In any event, DEA concludes that any purported request to initiate rulemaking to accommodate your clients' requested access to psilocybin is not consistent with public health and safety. By placing psilocybin in schedule I, Congress determined that the drug has "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use . . . under medical supervision." 21 U.S.C. 812(b)(1). Congress further set forth in 21 U.S.C. 823(f) explicit conditions for practitioners seeking to dispense schedule I controlled substances to research subjects. DEA believes that your general proposal to abandon altogether these findings and limitations when it comes to your proposed activity would be too great a departure from current law and inconsistent with public health and safety.

Although your February 10, 2022 letter did not reference 21 CFR 1307.03, any purported request for an exception to DEA regulations is denied for similar reasons. Among other things, under section 1307.03, DEA may only waive regulatory requirements, not statutory requirements. Thus, this section may not be utilized to waive the statutory requirement of registration under the CSA.

The historical scenarios involving schedule I controlled substances that you cited in your February 10, 2022 letter, which were consistent with this 21 U.S.C. 823(f) framework, do not support your request. For example, you referred to expanded access to the investigational cannabidiol drug, now known as Epidiolex (which was at the time a schedule I controlled substance), to children with seizure disorders. When that dispensing activity occurred, it was carried out by practitioners who, unlike Dr. Aggarwal, were registered with DEA to conduct research with schedule I controlled substances—not practitioners who were only authorized to handle schedule II-V controlled substances. *See* Cannabidiol: Barriers to Research and Potential Medical Benefits: Hearing Before the Caucus on Int'l Narcotics Control of the U.S. Senate (2015) (Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Administration), available at https://www.dea.gov/sites/default/files/pr/speeches-testimony/2015t/062415t.pdf.

As DEA previously indicated, the agency welcomes applications for registration by practitioners seeking to conduct bona fide research with schedule I controlled substances, including psilocybin. *See* 21 U.S.C. 823(f); 21 CFR 1301.18 and 1301.32.

I trust this letter adequately addresses your inquiry. For additional information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

THOMAS PREVOZNIK Digitally signed by THOMAS PREVOZNIK Date: 2022.08.19 12:21:03 -04'00'

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division