U.S. FOOD & DRUG ADMINISTRATION

Ne[illegible]e Devenot, Ph.D.
(b) (6) [redacted]

May 30, 2024

Re: Docket No. FDA-2024-P-2148

Dear Dr. Devenot:

This letter responds to your citizen petition dated April 28, 2024 (Petition). In the Petition, you request that the Food and Drug Administration (FDA or the Agency) "Convene an advisory committee meeting on MDMA-Assisted Therapy with an extended open public hearing (OPH) that prioritizes input from stakeholders who are concerned about the Lykos Therapeutics new drug application's shortcomings and risks" (Petition at 1)[1]. FDA has considered the Petition and, for the reasons that follow, your Petition is granted in part.

FDA advisory committees play an essential role in FDA's activities to protect and promote public health through the regulation of human and animal drugs, biological products, medical devices, foods, and tobacco products. FDA's advisory committees provide independent expert advice and recommendations to the Agency on scientific, technical, and policy matters related to FDA-regulated products. Advisory committees enhance FDA's ability to protect and promote public health by ensuring FDA has access to such advice through the public hearing process as provided in existing laws and regulations.

Your petition is granted insofar as FDA is convening a public meeting of the Psychopharmacologic Drugs Advisory Committee (the Committee) on June 4, 2024, from 8:30 am to 5:15 pm to discuss new drug application 215455, for midomafetamine (MDMA) capsules, submitted by Lykos Therapeutics, for the proposed indication of treatment of post-traumatic stress disorder. The Committee will be asked to discuss the overall benefit-risk profile of MDMA, including the potential public health impact.[2]

Every advisory committee meeting includes an OPH session, during which interested persons may present relevant information or views orally or in writing (21 CFR 14.25(a)). FDA's regulation, 21 CFR 14.29, requires that a minimum of one hour per meeting be dedicated to an OPH session for oral presentations, unless public participation does not last that long. If a large number of people have requested to address the committee, FDA may reduce the time allotment for each speaker pursuant to 21 CFR 14.29(b)(2) and/or extend the time of the OPH session.

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[1] Your petition also describes concerns about the product and the data supporting the application. Those concerns are framed as reasons to convene an advisory committee meeting and because that request is being granted, we do not address such concerns substantively here.

[2] See 89 FR 38903 (May 8, 2024) (available at https://www.federalregister.gov/documents/2024/05/08/2024-10053/psychopharmacologic-drugs-advisory-committee-notice-of-meeting-establishment-of-a-public-docket).

The *Federal Register* notice announcing the June 4, 2024, meeting of the Committee set aside one hour for the OPH portion of the meeting. Due to the number of individuals who have requested to speak, however, FDA will extend the OPH to one hour and 45 minutes. Your request for an extended OPH is therefore granted in part. However, the Agency does not "prioritize" any one perspective or group of stakeholders in scheduling speakers for the OPH. Thus, your request that the Agency "prioritize[] input from stakeholders who are concerned about the Lykos Therapeutics new drug application's shortcomings and risks" is denied. As noted in the meeting announcement published in the Federal Register on May 8, 2024, interested members of the public also may submit comments and information to the public docket (docket no. FDA-2024-N-1938); all information submitted by June 4, 2024, will be considered by the Agency.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2024.05.30 08:37:02 -04'00'

Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research