



IND 063384

**REMOVE PARTIAL CLINICAL HOLD**

Multidisciplinary Association for Psychedelic Studies (MAPS)  
Attention: Amy Emerson  
Chief Executive Officer  
3141 Stevens Creek Blvd #40563  
San Jose, CA 95117

Dear Ms. Emerson:

Please refer to your investigational new drug application (IND) submitted October 1, 2001, under section 505(i) of the Federal Food, Drug, and Cosmetic Act for 3,4-methylenedioxymethamphetamine (MDMA).

We also refer to your amendment dated April 27, 2021, which provides a complete response to our January 30, 2020, letter which cited the reasons for placing Protocol MT2, titled "A Phase 1, Open-Label, Multi-Site Study to Assess Psychological Effects of MDMA-Assisted Psychotherapy when Administered to Healthy Volunteers," on continued clinical hold, and the information needed to resolve the clinical hold issues.

We have completed the review of your submission, and have concluded that you may proceed with the proposed study.

If you have any questions, contact CDR Sarah Seung, Regulatory Project Manager, at [REDACTED] or [REDACTED]

Sincerely,

*{See appended electronic signature page}*

Tiffany R. Farchione, MD  
Director  
Division of Psychiatry  
Office of Neuroscience  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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TIFFANY R FARCHIONE  
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