



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 under section 505(i) of the Federal Food, Drug, and Cosmetic Act for 3,4-methylenedioxy-methamphetamine (MDMA).

We also refer to your amendment dated May 23, 2022, which provides a complete response to our April 15, 2022, letter which cited the reasons for placing Protocol MPG1, titled "An Open-Label Feasibility and Safety Study of MDMA-Assisted Group Therapy for the Treatment of Posttraumatic Stress Disorder in Veterans," 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]

Sincerely,

{See appended electronic signature page}

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

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.

/s/

TIFFANY R FARCHIONE
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