



IND 063384

**MEETING DENIED**

Multidisciplinary Association for Psychedelic Studies  
Attention: Amy Emerson  
Executive Director &  
Head of Clinical Development and Regulatory Affairs  
1115 Mission Street  
Santa Cruz, CA 95060

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 April 20, 2020, correspondence requesting a type A meeting to discuss the continued clinical hold on Protocol MT2. We are denying the meeting because the meeting package is not submitted with the meeting request and the meeting request does not propose discussion of new information.

If you have any questions, contact me at [REDACTED] or [REDACTED].

Sincerely,

*{See appended electronic signature page}*

Sarah Seung, PharmD, MS  
CDR, US Public Health Service  
Regulatory Project Manager  
Psychiatry Group  
Division of Regulatory Operations for Neuroscience  
Office of Regulatory Operations  
Center for Drug Evaluation and Research

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/s/

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SARAH H Seung  
04/30/2020 07:44:35 PM