



IND 110513

INCOMPLETE RESPONSE TO HOLD

Multidisciplinary Association for Psychedelic Studies (MAPS)
Attention: Amy Emerson
Chief Executive Officer
3141 Stevens Creek Blvd. #40547
San Jose, CA 95117

Dear Amy:

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for marijuana, *Cannabis sativa*, (containing delta-9-tetrahydrocannabinol and cannabidiol).

We also refer to our letter of December 27, 2021, in which you were notified that your IND continued on partial clinical hold and to your August 16, 2022, submission that responded to our continue partial clinical hold letter. Your cover letter identified your submission as a complete response to the issues listed in our letter.

Upon preliminary review of your submission, we have determined that it is not a complete response to all the issues listed in our clinical hold letter. The following issues were not addressed:

Clinical

You did not submit a revised protocol and did not provide the cited literature in your submission.

Until you have satisfactorily addressed all the issues in our clinical hold letter, we cannot complete our review, and the clinical hold cannot be removed.

Please identify your response to the clinical hold issues as a “**CLINICAL HOLD COMPLETE RESPONSE.**”

We remind you that the protocol titled, “Phase 2 Multicenter Randomized Placebo-controlled, Double-blind, Parallel Study to Assess the Safety and Efficacy of Inhaled Cannabis in Veterans for Treatment of Posttraumatic Stress Disorder (PTSD),” is on clinical hold, and you may not initiate this proposed clinical study until we notify you that the clinical hold is removed and your investigation may proceed.

Your response should be submitted through the Electronic Submissions Gateway (ESG), identified by the above IND number.

If you have any questions, contact Iram Baig, Regulatory Project Manager, at Iram.Baig@fda.hhs.gov.

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/

BERNARD A FISCHER on behalf of TIFFANY R FARCHIONE
08/30/2022 11:44:35 AM