



27 April 2021

Sarah Seung, PharmD
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: IND #063384, Serial No. 0177, MT2 Partial Clinical Hold Response

Dear Division of Psychiatry Products,

This letter is in response to the Division's Partial Clinical Hold Letter dated 30 January 2020 regarding the MAPS-sponsored protocol MT2, entitled "*A Phase 1, Open-Label, Multi-Site Study to Assess Psychological Effects of MDMA-Assisted Psychotherapy when Administered to Healthy Volunteers,*" under IND#063384.

In an effort to resolve the outstanding clinical hold issues relating to risk of illness or injury to human subjects (21 CFR 312.42(b)(1)(i)) as well as qualifications of the clinical investigators (21 CFR 312.42(b)(1)(ii)), the Sponsor submitted a Formal Dispute Resolution Request to the Agency on 01 December 2020 (SN 0160). Pursuant to the review conducted by Dr. Eric Bastings with the Office of Neuroscience, the Sponsor is writing to request a lift of the clinical hold placed on protocol MT2 for the reasons outlined by Dr. Bastings in the enclosed Formal Dispute Resolution Appeal Granted Letter, dated 16 April 2021.

The Sponsor appreciates the Agency's time and consideration on this matter. If you have any questions or requests regarding this submission, please do not hesitate to contact Sponsor Designee, Amy Emerson, by email at [REDACTED] or by phone at [REDACTED].

Sincerely,

Amy Emerson Electronically signed by: Amy Emerson
Reason: I am the approver of this document
Date: Apr 27, 2021 09:40 PDT

Amy Emerson
Chief Executive Officer
MAPS Public Benefit Corporation