



June 22, 2009

Thomas Laughren, M.D.
FDA/CDER/ODE1/DPP
White Oak CDER Office Building 22 Rm 4114
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: IND 63,384; Forms 1571, Serial No. 0018 and Serial No, 0019

Dear Director Laughren,

I'm submitting for your review two Forms 1571, each associated with a different set of documents.

The first Form 1571, serial number 0018, is for the submission of preliminary data from Protocol MP-1 (63,384), "Phase II clinical trial testing the safety and efficacy of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy in subjects with chronic posttraumatic stress disorder," conducted by Dr. Michael Mithoefer, in Charleston, South Carolina. The preliminary data includes safety data and outcome measures of PTSD. All experimental session data has been collected, and the study is currently in long-term follow-up.

The Final Report will be completed several months after the long-term follow-up phase is completed in July 2009. When the Final Report is submitted, MAPS will also be submitting for review a protocol for another US MDMA/PTSD pilot study, with subjects being exclusively US veterans with PTSD, primarily from the Iraq and/or Afghanistan wars.

The second Form 1571, serial number 0019, is for the submission of a new protocol entitled "MDMA Administration in a Therapeutic Setting in People Who have Completed the MAPS Training Program for Therapists Learning to Conduct MDMA-Assisted Psychotherapy Research in Subjects with PTSD" (Protocol Number M-T1).

The MT-1 protocol is seeking permission for the administration of a single session of MDMA-assisted psychotherapy to up to 20 therapists/researchers who have completed an initial sponsor-developed training program designed to teach how to perform MDMA-assisted psychotherapy in people with PTSD. Both the training program and the MT-1 protocol will assist the sponsor in improving therapeutic skills in the male/female co-therapist teams conducting MAPS' Phase 2 MDMA/PTSD studies and possible future Phase 3 multi-site studies.

Multidisciplinary Association for Psychedelic Studies
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From June 25 to July 1, 2009, near Salzburg, Austria, MAPS will be conducting its first therapist training program. Therapists/Researchers will be attending from 7 different countries: US, Canada, Switzerland, Israel, Jordan, Germany. The program will primarily focus on lectures and discussions about MAPS' MDMA/PTSD treatment manual, watching and discussing videotapes of prior MDMA/PTSD therapy sessions from the US, Swiss and Israeli studies, and discussions of protocols and results from the US, Swiss and Israeli studies. Only researchers who have completed this program, or others in the future like it, and who MAPS has already hired or are considering hiring to conduct MDMA-assisted psychotherapy, will be eligible to participate in the MT-1 protocol.

You'll find along with this letter:

FDA form 1571, serial number 0018

Three copies of the following:

Preliminary data

FDA form 1571, serial number 0019

FDA form 1572

Three copies of the following

Protocol

Most recent revision of the Investigator's Brochure

Curriculum vitae for both investigators

Letter of support from William Richards, PhD

Letter of support from Daniel Helminiak, PhD, PhD LPC

If you have any questions or would like additional information, I would be delighted to be of assistance.

Sincerely,

Rick Doblin, PhD
President, MAPS

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