

December 30, 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: MAPS Study MT1; IND 63,384; Forms 1571, Serial No. 0021

Dear Director Laughren,

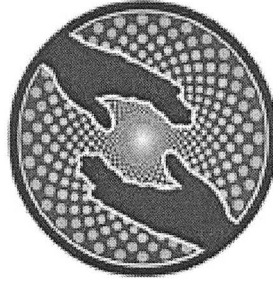
Our study “A Phase 1 Placebo-Controlled, Double-Blind Crossover Study to Assess Psychological Effects of MDMA when Administered to Healthy Volunteers” has been reviewed by an independent IRB and approved on December 28, 2009. No changes were required in the protocol design itself but the IRB required a re-ordering of study objectives, a change in study medical monitor, correction of some typographic errors, and some changes in text describing procedures related to the drug product.

We are now submitting the second amendment of this protocol reflecting the changes required by the IRB. This amendment has no impact on risks to participation. All the same assessments and measures will be used, and the same study population and sequence of events will occur as described in Amendment 1 of the study protocol.

Please find along with this letter the following documents.
Enclosed, please find:

FDA form 1571, serial number 0021, dated December 30, 2009
Revised FDA Form 1572 (revised to reflect IRB address), dated November 18, 2009
Official letter of approval from ~~Openminded Group~~ IRB, dated December 30, 2009
Three copies of the following:
 Amended protocol, including list of changes, dated December 2, 2009
 Approved Informed Consent form, dated December 30, 2009

Multidisciplinary Association for Psychedelic Studies
MAPS • Rick Doblin • 309 Cedar Street # 2323 Santa Cruz, CA 95060•
Tel: 831-429-6362 • Fax: 831-429-6370 • www.maps.org • rick@maps.org



If you have any questions or would like additional information prior to our teleconference, I would be delighted to be of assistance. I can most easily be reached via email or cell phone: [REDACTED]

[REDACTED]

Sincerely,

A handwritten signature in black ink that reads "Rick Doblin". The signature is written in a cursive, flowing style.

Rick Doblin PhD
President, MAPS