DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 110513

FULL CLINICAL HOLD

Multidisciplinary Association for Psychedelic Studies
Attention: Rick Doblin, Ph.D.
President
3 Francis Street
Belmont, MA 02478-2216

Dear Dr. Doblin:

Please refer to your Investigational New Drug Application (IND) submitted November 5, 2010, received November 15, 2010, under section 505(i) of the Federal Food, Drug, and Cosmetic Act for smoked or vaporized marijuana containing active ingredients delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). We also refer to your email communication dated November 24, 2010.

Ann Sohn, Regulatory Project Manager, notified you through the December 15, 2010 email to Dr. Rick Doblin that the study you proposed is on clinical hold and may not be initiated. The following are the specific deficiencies and the information needed to resolve the deficiencies.

21 CFR 312.42(b)(2)(i): Insufficient information to assess risks to human subjects

A. Marijuana 'Active' Cigarettes:

1. Provide the name and address of the manufacturer.
2. Provide:
    a. The complete composition of each strength and technical grade of each excipient (e.g. USP, NF).
    b. Information regarding how the specific concentration of THC and CBD in the marijuana plant is achieved.
3. Provide the method of manufacture of the cigarettes.
4. Provide specification for each strength and description of the analytical procedures.
5. Provide Certificate of Analysis for each strength to be used in the clinical study and the date of manufacture.
6. Provide stability data of the drug products.
7. Provide appropriate reference, i.e. Letter of Authorization to NIDA's Drug Master File for Marijuana Cigarettes to this IND.

B. Placebo Cigarettes:

Provide above items A-1, 2a, 3, 4 & 5 for the placebo cigarettes.

Until you have submitted the required information and we notify you that you may initiate the clinical study, you may not legally initiate or resume clinical studies under this IND.

Please identify your response to the clinical hold issues as a "**CLINICAL HOLD COMPLETE RESPONSE**". An incomplete response will not start the review clock. Your complete response submission should reference, by date, any information previously submitted necessary to fully respond to these clinical hold issues. To facilitate a response to your submission, submit this information in triplicate to the IND. In addition, send a copy of the cover letter to Ann Sohn.

Following receipt of your complete response to these issues, we will notify you of our decision within 30 days.

If we have additional comments or information requests not related to this clinical hold, we will notify you. Your responses to any non-hold issues should be addressed in a separate amendment to the IND.

Please cite the IND number listed above at the top of the first page of any communications concerning this application. Each submission to this IND must be provided in triplicate, an original and two copies. Please include three originals of all illustrations which do not reproduce well. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Psychiatry Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, email Ann Sohn, Regulatory Project Manager, at ann.sohn@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
12/15/2010