



IND 110513

ADVICE/INFORMATION REQUEST

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 amendment dated November 24, 2010.

We have the following comments and requests for additional information. Please note that these requests are not clinical hold issues. However, we request that you provide a response to them prior to initiation of the study:

1. As currently proposed, the study would not be conducted in a manner to assure the safe and secure storage of marijuana, a Schedule I substance under the U.S. Controlled Substances Act. The drug will be self administered on a non-supervised outpatient basis. There are no provisions for maintaining the security and safety of the marijuana outside the investigator's direct control, including providing relevant training to the research subjects so as to prevent misuse, abuse, and diversion of the marijuana.
2. You have not adequately described the proposed process by which the investigator would return any unused marijuana product to a particular research subject [upon request] for use outside of the proposed treatment arms in the protocol. You must demonstrate that this proposed activity is legal and consistent with DEA's administration of the Controlled Substances Act.
3. As currently written, the protocol and consent do not adequately state the legal status of marijuana under current federal regulations.
4. The protocol and consent do not adequately address the subjects' potential legal risks of using marijuana and how these risks can be mitigated.

5. The proposed schedule for clinical monitoring is not adequate. We request that investigators conduct at least weekly face-to-face visits. We recommend that assessments at these visits should include vital signs, serum cannabinoid levels, urine drug screen, CAPS, GAF, BDI-II, and C-SSRS. We also request that you propose an instrument to monitor for general psychiatric symptoms, including psychotic symptoms, dissociative symptoms, depersonalization, and derealization. One example is the Brief Symptom Inventory, which is a broad survey of potential psychiatric symptoms.

6. The subject information and consent form states: “Whenever possible, make sure that you are not going to be driving up to three hours after your last time of marijuana use.” We request that you strengthen the caution by the removing the phrase “whenever possible.”

7. Provide the current Clinical Investigator’s Brochure, which should be available from NIDA.

We remind you that Protocol MFP-1 is on Clinical Hold. Until you have submitted the required information described in our letter dated December 15, 2010, and we notify you that you may initiate the study, you may not legally conduct the study under this IND. Please submit your response to the clinical hold issues as described in the December 15, 2010 letter.

As sponsor of this IND, you are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the implementing regulations (Title 21 of the Code of Federal Regulations). Those responsibilities include: (1) reporting any unexpected fatal or life-threatening adverse experience associated with use of the drug by telephone or fax no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)]; (2) reporting any adverse experience associated with use of the drug that is both serious and unexpected in writing no later than 15 calendar days after initial receipt of the information [21 CFR 312.32(c)(1)]; and (3) submitting annual progress reports (21 CFR 312.33).

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
02/03/2011