



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 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) for treatment resistant posttraumatic stress disorder in veterans. We also refer to our February 3, 2011 letter, and your March 10, 2011 amendment.

The IND will remain on hold, because you have not submitted adequate CMC information. With this amended protocol, you have adequately addressed the division's safety concerns. We agree with you that this would serve as an exploratory pilot study and not as a pivotal efficacy and safety study.

We remind you that this application 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.

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
04/28/2011