



IND 101,825

Multidisciplinary Association for Psychedelic Studies (MAPS)
Attention: Rick Doblin, Ph.D.
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 lysergic acid diethylamide (LSD) Capsules.

We also refer to your amendment of September 9, 2008, which provided a complete response to our letter of April 8, 2008, which cited the reasons for placing this IND on clinical hold and the information needed to resolve the clinical hold issues.

We have completed the review of your submission and have concluded that your clinical trial may be initiated.

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, call LCDR Janet Cliatt, Regulatory Project Manager, at (301) 796-0240.

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

Linked Applications

Sponsor Name

Drug Name

IND 101825

MULTIDISCIPLINARY
ASSN PSYCHEDELIC
STUDIES

LYSERGIC ACID DIETHYLAMIDE (LSD)

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/s/

THOMAS P LAUGHREN
09/26/2008