



IND 63384

STUDY MAY PROCEED

Multidisciplinary Association for Psychedelic Studies
Attention: Rick Doblin, Ph.D.
3 Francis Street
Belmont, MA 02478-2238

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 3,4-Methylenedioxymethamphetamine (MDMA).

We have completed our safety review of your application and have concluded that you may proceed with your proposed clinical investigation, "A Phase I Placebo-Controlled, Double-Blind Crossover Study to Assess Psychological Effects of MDMA when Administered to Healthy Volunteers."

As sponsor of this IND, you are responsible for compliance with applicable portions of the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act, and the Code of Federal Regulations (CFR). These 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).

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, 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, please 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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
IND-63384	ORIG-1	MULTIDISCIPLINARY ASSN PSYCHEDELIC STUDIES	3,4-METHYLENEDIOXYMETHAMPHETAMINE
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/s/

THOMAS P LAUGHREN
10/01/2009