

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

Form Approved: [REDACTED]
Expiration Date: May 31, 2009
See OMB Statement on Reverse.

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).

1. NAME OF SPONSOR
Multidisciplinary Association for Psychedelic Studies (MAPS)

2. DATE OF SUBMISSION
04/01/2010

3. ADDRESS (Number, Street, City, State and Zip Code)

4. TELEPHONE NUMBER (Include Area Code)

5. NAME(S) OF DRUG (Include all available names: Trade, Generic, Chemical, Code)
+/-3,4-methylenedioxymethamphetamine; N-methyl-3,4-methylenedioxyamphetamine; MDMA; C11H15N02

6. IND NUMBER (If previously assigned)

7. INDICATION(S) (Covered by this submission)
Posttraumatic Stress Disorder

8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED:

PHASE 1 PHASE 2 PHASE 3 OTHER _____
(Specify)

9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), DRUG MASTER FILES (21 CFR Part 314.420), AND PRODUCT LICENSE APPLICATIONS (21 CFR Part 601) REFERRED TO IN THIS APPLICATION.
IND# 63,384, DMF 6293

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.

SERIAL NUMBER

0 0 2 2

11. THIS SUBMISSION CONTAINS THE FOLLOWING: (Check all that apply)

INITIAL INVESTIGATIONAL NEW DRUG APPLICATION (IND)

RESPONSE TO CLINICAL HOLD

PROTOCOL AMENDMENT(S):

INFORMATION AMENDMENT(S):

IND SAFETY REPORT(S):

NEW PROTOCOL

CHEMISTRY/MICROBIOLOGY

INITIAL WRITTEN REPORT

CHANGE IN PROTOCOL

PHARMACOLOGY/TOXICOLOGY

FOLLOW-UP TO A WRITTEN REPORT

NEW INVESTIGATOR

CLINICAL

RESPONSE TO FDA REQUEST FOR INFORMATION

ANNUAL REPORT

GENERAL CORRESPONDENCE

REQUEST FOR REINSTATEMENT OF IND THAT IS WITHDRAWN, INACTIVATED, TERMINATED OR DISCONTINUED

OTHER _____

(Specify)

CHECK ONLY IF APPLICABLE

JUSTIFICATION STATEMENT MUST BE SUBMITTED WITH APPLICATION FOR ANY CHECKED BELOW. REFER TO THE CITED CFR SECTION FOR FURTHER INFORMATION.

TREATMENT IND 21 CFR 312.35(b)

TREATMENT PROTOCOL 21 CFR 312.35(a)

CHARGE REQUEST/NOTIFICATION 21 CFR 312.7(d)

FOR FDA USE ONLY

CDR/DBIND/DGD RECEIPT STAMP

DDR RECEIPT STAMP

DIVISION ASSIGNMENT:

IND NUMBER ASSIGNED: