



IND 63384

**GRANT –
BREAKTHROUGH THERAPY DESIGNATION**

Multidisciplinary Association for Psychedelic Studies
Attention: Amy Emerson
Executive Director and Director of Clinical Research
1115 Mission Street
Santa Cruz, CA 95060

Dear Ms. Emerson:

Please refer to your Investigational New Drug Application (IND) dated October 3, 2001 submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for +/-3,4-methylenedioxymethamphetamine (MDMA).

We also refer to your June 20, 2017 request for Breakthrough Therapy designation. We have reviewed your request and have determined that +/-3,4-methylenedioxymethamphetamine (MDMA) for post-traumatic stress disorder meets the criteria for Breakthrough Therapy designation. Therefore, we are granting your request for Breakthrough Therapy designation. Please note that if the clinical development program does not continue to meet the criteria for Breakthrough Therapy designation, we may rescind the designation.

FDA will work closely with you to provide guidance on subsequent development of +/-3,4-methylenedioxymethamphetamine (MDMA) for post-traumatic stress disorder to help you design and conduct a development program as efficiently as possible. For further information regarding Breakthrough Therapy designation and FDA actions to expedite development of a designated product, please refer to section 902 of the Food and Drug Administration Safety and Innovation Act (FDASIA) and the *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics*.¹

In terms of next steps, please submit a Type B meeting request. This meeting will be for a multidisciplinary comprehensive discussion of your drug development program, including planned clinical trials and plans for expediting the manufacturing development strategy. Please refer to MAPP 6025.6 - *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics*, Attachment 1, for potential topics for discussion at this initial

¹ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>

Breakthrough Therapy meeting². Please refer to the *Guidance for Industry: Formal Meetings between FDA or Sponsors and Applicants*³ for procedures on requesting a meeting. If you feel that submitting a meeting request for such a meeting at this point is pre-mature or if you have recently held a major milestone meeting, please contact the Regulatory Health Project manager noted below to discuss the timing of this meeting.

If the Breakthrough Therapy designation for +/-3,4-methylenedioxymethamphetamine (MDMA) for post-traumatic stress disorder is rescinded, submission of portions of the NDA will not be permitted under this program. However, if you have Fast Track designation you will be able to submit portions of your application under the Fast Track program.

If you have any questions, contact Ann Sohn, Regulatory Project Manager, at

[REDACTED]

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>.

³ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

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/s/

MITCHELL V Mathis
08/15/2017