



National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

June 3, 2015

Drug Master File Staff
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Re: DMF authorization letter for IND #110513

Authorization is hereby provided for the FDA to review the NIDA Drug Master File (DMF) # 1631; Vol. 18.1, Type II on Production and Analysis of Cannabis Plant Material and Marijuana Cigarettes for a Colorado State-funded study by the Multidisciplinary Association for Psychedelic Studies (MAPS), titled "Placebo controlled Triple Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment Resistant Posttraumatic Stress Disorder (PTSD)" - Protocol MJP-1, IND # 110513.

Please send a copy of the LOA on behalf of MAPS to the following:

Rick Doblin, Ph.D.
Executive Director
Multidisciplinary Association for
Psychedelic Studies
1215 Mission Street
Santa Cruz, CA 95060
E-Mail: Rick@maps.org

Rebecca Matthews
Clinical Trial Leader
MAPS Public Benefit Corporation
1115 Mission Street
Santa Cruz, CA 95060
E-Mail: Rebecca@mapsbcorp.com

We request that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61, and that no information from this file be provided to any unauthorized persons without our written consent. NIDA states that DMF #1631 is current and was originally filed on January 5, 1971. NIDA will comply with the statements made within it.

If you have any further questions or need more information, please contact Dr. Hari H. Singh at 301-435-1310 or Hari.Singh@nih.gov.

Sincerely,



Nora D. Volkow, M.D.
Director