February 17, 2014

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville MD 20705-1266

RE: IND **#110513**

TO: Mr. Paul David, Chief, Project Management Staff, FDA Division of Psychiatry Products, Office of Drug Evaluation I, Center for Drug Evaluation and Research.

Dear Mr. David,

I'm Rick Doblin, Ph.D., Executive Director of MAPS. I am writing in response to your January 27, 2014, Pre-Inactivation letter regarding MAPS' IND #110513. In a 12/15/2010 letter to MAPS, FDA raised no further issues regarding our protocol design for a study of five different potencies of marijuana in 50 veterans with chronic, treatment-resistant PTSD but placed a Clinical Hold on our study pending information regarding the supply of the marijuana. More than three years later, we still do plan on responding to the clinical hold deficiencies but we can't say exactly when we will have located a supply of marijuana for the study.

At present, despite our best efforts over the last 12 ½ years, NIDA still retains a monopoly on the supply of marijuana legal for use in FDA-regulated studies. In June 2001, Prof. Lyle Craker, Director, Medical Plant Program, Dept. Plant Soil and Insect Sciences, UMass Amherst, applied to DEA for a license to grow marijuana under contract to MAPS exclusively for use in federally regulated research. On February 12, 2007, Prof. Craker won a DEA Administrative Law Judge lawsuit and obtained an ALJ recommendation that it would be in the public interest for DEA to issue him a license. However, DEA Administrator Leonhart rejected the recommendation. On April 15, 2013, the US First Circuit Court of Appeals dismissed Prof. Craker's appeal.

Multidisciplinary Association for Psychedelic Studies
MAPS • Rick Doblin, Ph.D. • 3 Francis Street • Belmont, MA. 02478-2218 •
c. 617 276-7806 • www.maps.org • rick@maps.org

The 1999 HHS Guidance for the sale of NIDA marijuana at cost to privately-funded studies calls for a Public Health Service (PHS) protocol review process that exists only for marijuana, not for any other Schedule 1 drug. The Guidance explicitly rejects provision of marijuana to medical marijuana drug development studies intended to develop the marijuana plant into an FDA-approved prescription medicine in smoked form.

Frustratingly, on September 26, 2011, the Public Health Service (PHS) reviewers rejected our protocol. The rejection was in part due to a series of protocol critiques that stemmed from the PHS reviewers' basic science orientation and lack of understanding of drug development research and in part because we had not yet sought IRB approval.

We subsequently obtained IRB approval by submitting our protocol, the PHS critiques and our response to the PHS critiques, to the University of Arizona Phoenix IRB. The IRB approved all of our core design elements of the protocol, rejecting the PHS critiques, and added some additional safety measures and procedures.

On Oct. 24, 2013, we re-submitted our revised protocol for review to the Public Health Service, seeking approval to purchase marijuana at cost from NIDA so that we can conduct our study. There is no time limit for the PHS review process. It's now been over 3 ½ months that we have been waiting to hear from the PHS regarding its review of our protocol. We are also working with Congressional Representatives seeking to have the PHS protocol review process itself ended, but cannot say if our efforts will be successful.

Our protocol submitted under IND 110513 is politically blocked as long as NIDA retains its monopoly, the HHS Guidance creating the PHS protocol review remains in force, and we cannot yet import medical grade marijuana from foreign producers until at least one submits data about their GMP marijuana into an FDA Drug Master File. We are searching for opportunities to import GMP marijuana from either Israel or Canada or another country and anticipate availability within the next one to two years. There is also a reasonable chance that the PHS protocol review process will be ended fairly soon and/or that the current PHS protocol reviewers will approve of our study design.

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As a result of major public support for the medical use of marijuana, 20 states and the District of Columbia have passed medical marijuana laws. As far as I know, MAPS is the only organization in the world still seeking to develop the marijuana plant itself into an FDA-approved prescription medication through the conduct of clinical trials. Should we obtain approval, other sponsors can be anticipated.

We have great respect for the FDA's decision to put science before politics in reviewing our marijuana/PTSD protocol. We request that you do not inactivate our protocol but keep it active while we continue to struggle to obtain the marijuana required for our study.

Sincerely,

Rick Doblin

Rick Doblin, Ph.D.
MAPS Executive Director

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