



Office of Orphan Products Development (HF-35)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

May 25, 1999

Multidisciplinary Association for Psychedelic Studies, Inc.  
3 Francis Street  
Boston, Massachusetts 02478

Attention: Rick Doblin, President

Dear Mr. Doblin:

Reference is made to your orphan designation application of April 24, 1997, submitted pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act for the designation of marijuana as an orphan drug (application #97-1053). We also refer to your amendments dated September 24, 1997, June 5, 1998, August 25, 1998, November 10, 1998, and February 16, 1999.

We have completed the review of this application and have determined that marijuana qualifies for orphan designation for the treatment of HIV-associated wasting syndrome. Please note that it is marijuana and not its formulation that has received orphan designation.

Please be advised that if marijuana were approved for an indication broader than the orphan designation, your product might not be entitled to exclusive marketing rights pursuant to Section 527 of the FDCA. Therefore, prior to final marketing approval, sponsors of designated orphan drugs are requested to compare the designated orphan indication with the proposed marketing indication and to submit additional data to amend their orphan designation prior to marketing approval if warranted.

Finally, please notify this Office within 30 days of submission of a marketing application for the use of marijuana as designated. Also an annual progress report must be submitted within 14 months after the designation date and annually thereafter until a marketing application is

approved [21 CFR 316.30]. If you need further assistance in the development of your product for marketing, please feel free to contact Lisa Hubbard, RPh at (301) 827-0983.

Please refer to this letter as official notification of designation and congratulations on obtaining your orphan product designation.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Marlene E. Haffner".

Marlene E. Haffner, MD, MPH

Rear Admiral, United States Public Health Service  
Director, Office of Orphan Products Development