DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of Orphan Products Development(HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(301) 827-3667

December 21, 1998

Multidisciplinary Association for Psychedelic Studies, Inc.
2121 Commonwealth Ave., Suite 220-A
Charlotte, NC 28205

Attention: Rick Doblin
President

Dear Mr. Doblin:

Reference is made to the orphan product application of April 24, 1997, submitted pursuant to Section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for the designation of marijuana as an orphan product (application #97-1053). We also refer to your amendments of and September 24, 1997, June 5, 1998, and the supplemental information of August 25, 1998.

We have completed review of your amendment and the supplemental information. We acknowledge your proposed revised definition of HIV-related wasting syndrome from HIV-related wasting to "involuntary weight loss of greater than or equal to 5% of body weight in patients with AIDS." We have concluded that smoked marijuana will be used in a broader population than AIDS patients experiencing involuntary weight loss of greater than 5% after their AIDS diagnosis. Because you have not submitted scientific rationale which provides a medically plausible reason why smoked marijuana is limited to the treatment of AIDS patients experiencing involuntary weight loss of greater than 5% after their AIDS diagnosis, smoked marijuana does not qualify for orphan designation for this indication.

Alternatively, you may wish to consider requesting an orphan drug designation based on evidence that it is unlikely that sales of marijuana in the United States will be adequate to recover the preclinical and clinical development costs within seven years of approval. Congress provided for products that may be "orphans" for reasons other than the size of the population they are intended to treat, by allowing these products to be designated based on their lack of profitability [21 CFR § 316.21(c)]. We are enclosing a copy of the pertinent regulations, and should you have any questions relating to the process of applying for designation because of an expected lack of profitability, you may wish to contact Robert Steeves, J.D. of this office.

Further review of this application is being held in abeyance pending receipt of any new information. A written response to this letter must be received within 90 days from the date of this communication or the file will be considered inactive and withdrawn. Following 90 days, further requests for designation of the same product for the same indication must be made in the form of a new designation application. Information contained in this file may be cross-referenced in support of a new designation request.

Please provide copies of appropriate references used in support of any new submissions. Your cooperation is appreciated.

Sincerely yours,

Marlene E. Haffner, M.D., M.P.H.
Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development

Enclosure

cc:
HF-35/OP File #98-1053
HF-35/Chron