DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

December 22, 2000

RECEIVED 12/28/00

Michael Kennedy, Esq.
Law Offices of Michael Kennedy
425 Park Avenue, 26th Floor
New York, New York 10022

Dear Mr. Kennedy:

I have been asked to respond to your letter of October 25, 2000 to the General Counsel of the Department of Health and Human Services written on behalf of your clients Jon Gettman and High Times Magazine (Trans-High Corporation). You inquired about the status of their petition regarding the scheduling of marijuana, tetrahydrocannabinols, dronabinol and nabilone under the Controlled Substances Act (CSA). Specifically, you asked a number of questions about the background of the review. You also requested a status report on the review and a timetable for its completion; a means for the petitioners and the public to provide evidence for consideration during the review; and an opportunity for the petitioners to comment on the Department's evaluation and recommendation prior to transmitting it to DEA.

As you know, in December 1997, the Drug Enforcement Administration (DEA) requested that the Department of Health and Human Services (DHHS) develop a scientific and medical evaluation and recommendation as to the proper schedule for the substances at issue, pursuant to 21 U.S.C. 811(b). The Secretary of DHHS has delegated this responsibility to the Assistant Secretary of Health. Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA), as described in the Memorandum of Understanding (MOU) of March 8, 1985 (50 Federal Register 9518-20).

Upon receipt from DEA of Mr. Gettman's petition, FDA began evaluation of the medical and scientific factors raised by the 8 factors determinative of control as set forth in the CSA (21 U.S.C. 811(c)). Once a scheduling request is referred to FDA, FDA's Center for Drug Evaluation and Research (CDER), with assistance from others within the Agency, conducts a review of the substance. This review includes review of the chemical properties, pharmacology studies, and clinical studies and reports related to the substance.

The voluminous petition submitted by Mr. Gettman, coupled with the number of substances at issue, and the complexity of the analysis mandated by the CSA, required a significant amount of time on the part of FDA to ensure that all factors were thoroughly considered. The agency's evaluation is in the final stages. After completion it will be transmitted to the Assistant Secretary of Health who will make the final determination and respond to DEA.

In addition, you requested that the petitioner and the public be provided an opportunity to provide evidence for consideration during review as well as an opportunity to comment on DHHS's evaluation and recommendation prior to transmitting it to DEA. I note that the petitioner had the opportunity to submit any evidence he believed to be relevant when he submitted his petition. He appears to have availed himself of this opportunity since his petition exceeds 275 pages. In addition, the CSA requires that a rule by DEA that adds a substance to a schedule, transfers a substance to a different schedule, or removes a substance from control must be made on the record after an opportunity for a hearing (see 21 U.S.C. 811(a)). Furthermore, FDA is not bound to consider only the evidence contained in the petition, but rather considers all relevant evidence in its medical and scientific evaluation. Thus, in developing a medical and scientific evaluation for the substances identified in Mr. Gettman's petition, the Agency is taking into account studies, reports, and data that have become available since Mr. Gettman filed his petition with the DEA.

We thank you for your patience as we work to conclude our scientific and medical evaluation and recommendation as to the proper schedule for the substances at issue.

Sincerely,

Margaret Jane Porter
Chief Counsel
Food and Drug Administration

cc: Ms. Harriet S. Rabb