



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

JUL 12 2006

Assistant Secretary for Health  
Office of Public Health and Science  
Washington D.C. 20201

Mr. Joseph D. Elford  
Staff Attorney  
Americans for Safe Access  
P.O. Box 427112  
San Francisco, CA 94142

Dear Mr. Elford:

This letter constitutes a response to the May 19, 2005 Request for Reconsideration (RFR) that you submitted on behalf of the Americans for Safe Access (ASA). Your reconsideration request was filed pursuant to the Information Quality Act of 2000 (Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Public Law No. 106-554, 114 Stat. 2763A-153). The RFR concerns the review by the Department of Health and Human Services (HHS) of the 1995 Marijuana Rescheduling Petition that was published by the United States Drug Enforcement Administration (DEA) in the Federal Register, Vol. 66, p. 20038, April 18, 2001.<sup>1</sup>

Your RFR claims that the statements made in the response to the 1995 Marijuana Rescheduling Petition lack "objectivity, utility, transparency, peer review, and public participation and that a prompt HHS response would expedite DEA consideration of the October 2002 petition filed by the Coalition for Rescheduling Cannabis, an association of public interest groups and medical cannabis patients that includes the ASA. Your request urges HHS to respond in a prompt and timely manner.

We understand your concerns and would like to thank you for your comments on the marijuana rescheduling process. As HHS explained in the response to your Request for Correction, the United States Congress has established a process to address rescheduling issues. The congressionally mandated Controlled Substances Act (CSA) in section 201(a) establishes a mechanism by which interested parties may petition the DEA to change the schedule of a given substance. Under the CSA, the Secretary of HHS has the responsibility to make recommendations concerning whether a specific substance or drug should be controlled.

In the preamble to the Office of Management and Budget (OMB) Information Quality Guidelines, OMB recognizes that many agencies already have processes in place to respond to public concerns and states that it is not the intent of OMB to require these agencies to establish new processes (67 F.R. at 8458). Similarly the HHS Part I and (Part II agency-specific) FDA Information Quality Guidelines provide that federal agencies may use existing processes that are in place to address information quality requests.

<sup>1</sup> The HHS review of the 1995 Marijuana Rescheduling Petition also is at [http://www.access.gpo.gov/su\\_docs/fedreg/a010418c.html](http://www.access.gpo.gov/su_docs/fedreg/a010418c.html) and [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001\\_register&docid=01-9306-filed.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01-9306-filed.pdf)

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In response to the October 2002 Marijuana Petition, HHS currently is in the process of concluding its comprehensive review of the publicly available peer reviewed literature on marijuana in order to make a recommendation to the DEA as to whether marijuana should continue to be controlled under the CSA. Your appeal request states that the CSA process should not be utilized because of the length of time it involves.

However, a comprehensive review is essential to ensure that our recommendation is accurate. To address whether or not marijuana has a currently accepted medical use in the United States prior to completing our comprehensive review would prejudice the outcome of this process. We estimate that we will complete the analysis and transmit it to DEA in September 2006. We plan to send the DEA a copy of this response to your Request for Reconsideration. We hope that the information that we are providing you helps to clarify both the HHS information quality guidelines and the role of the Department of Health and Human Services in the marijuana rescheduling process.

Sincerely yours,



John O. Agwunobi  
Assistant Secretary for Health

cc: Karen P. Tandy, Administrator  
Drug Enforcement Administration