



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 1 2004

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

Dear Mr. Elford:

This letter is an interim response to your October 4, 2004, complaint and request for correction pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000), hereinafter referred to as the "Federal Data Quality Act," concerning the Department of Health and Human Services (HHS) Review of the Marijuana Rescheduling Petition of 1995. Your complaint has been referred to the Food and Drug Administration (FDA) for response. We will be consulting with the National Institute on Drug Abuse and the Drug Enforcement Administration in preparing our response.

Your complaint alleges that statements made by HHS in its review of the 1995 Marijuana Rescheduling Petition, which is published on federal government websites (http://www.access.gpo.gov/su_docs/fedreg/a010418c.html, http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.htm) and in the Federal Register, 66 Fed.Reg. 20038, 20052 (April 18, 2001) lack "objectivity, utility, transparency, peer review, and public participation" and need to be corrected. Your complaint requests that HHS replace each of the statement(s) within the HHS review with alternative statements.

FDA's data quality guidance, which is part of the Department of Health and Human Services *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, September 30, 2002, states that FDA will respond to a data quality complaint within 60 days, either by issuing a decision or by informing you that more time is required to respond to the complaint, and providing you with an estimated decision date.

We have not yet completed our response to your complaint because of other agency priorities and the need to coordinate agency review of the response. We hope to provide you with a response within 60 days from the date of this letter.

If you have any questions, you may contact Terry Martin, Regulatory Health Project Manager, at 301-443-5591.

Sincerely,



/s/

Steven Galson, M.D., M.P.H
Acting Director, Center for Drug Evaluation
and Research