March 8, 2013

Dr. Margaret A. Hamburg, Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted by First-Class mail and by www.regulations.gov

Re: Support for Citizen Petition Regarding FOIA Deletions Policy, Docket # FDA-2012-P-1007-0001/CP

Dear Commissioner Hamburg:

On behalf of the undersigned organizations concerned with government openness and accountability, we write to support in full the citizen petition filed by Public Citizen and designated above. Specifically, we urge that you revoke the Food and Drug Administration's (FDA) Freedom of Information Act (FOIA) "deletions policy" embodied in 21 C.F.R. § 20.49(d) and in FDA's Staff Manual. The policy violates both the letter and spirit of FOIA and casts serious doubt on the accuracy of FOIA performance data that FDA provides to Congress and the public. Public Citizen's citizen petition on this matter has been pending for more than five months and alleges a serious violation of the law; it is high time for the agency to respond to it.

Under 21 C.F.R. § 20.49(d), FDA does not consider "minor deletions"—which we understand may in fact be substantial—to constitute a denial of a FOIA request. Instead, as the Staff Manual provides, the agency makes so-called "minor deletions" to otherwise releasable records and directs FOIA requesters who wish to challenge those deletions to file another request, this time for reconsideration. Only after filing such a request for reconsideration may a FOIA requester receive a formal denial and notice of administrative appeal rights. If the requester does not file a request for reconsideration, the agency closes the request without ever providing the requester a final determination on the deleted portion of the records.

The agency's deletions policy is at odds with the letter and spirit of FOIA. FOIA requires agencies to make a final determination on a request within 20 working days and apprise the requester of his right to appeal an adverse determination in whole or in part. The law simply does not permit the agency to make deletions, minor or otherwise, from documents without giving a requester a final determination and notice of the immediate right to appeal. And it is impossible to square the deletions policy with the President's stated commitment to transparency. As Attorney General Holder's 2009 transparency memorandum to agencies indicated,

"[u]nnecessary bureaucratic hurdles have no place in the 'new era of open Government' that the President has proclaimed." FDA's deletions policy is precisely the kind of bureaucratic hurdle that should be eliminated.

We are also particularly troubled by the impact that FDA's deletions policy may have on its FOIA performance data. Congress and the public depend on accurate, reliable FOIA statistics to gauge agencies' compliance with the law. Yet the citizen petition indicates that FDA may be counting releases with "minor deletions" as releases in full, which would produce misleading data about the agency's FOIA performance.

We support the citizen petition in urging you to revoke 21 C.F.R. § 20.49(d) and to rescind portions of the Staff Manual implementing that regulation. We look forward to working with FDA to craft new policies that are consistent with FOIA and the administration's commitment to transparency. If you would like to discuss these issues further, please contact me at (202) 332-6736 or pmcdermott@openthegovernment.org.

Sincerely,

Patrice McDermott
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OpenTheGovernment.org

Dan Epstein
Executive Director
Cause of Action

Jeff Ruch
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Public Employees for Environmental Responsibility – PEER