DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D. C. 20515-6115

OCT 31 2007

Dear Mr. Chairman:

Thank you for the letter of August 24, 2007, co-signed by Bart Stupak, Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. The Food and Drug Administration (FDA or Agency) appreciates the opportunity to discuss its ongoing competitive sourcing efforts and to allay your concerns regarding our commitment to protecting the public health. FDA's competitive sourcing program is conducted in accordance with the Office of Management and Budget (OMB) Circular No. A-76, "Performance of Commercial Activities."

FDA is committed fully to maintaining a strong in-house expertise and institutional knowledge base. FDA has completed seven competitive sourcing studies to date under OMB Circular No. A-76. The focus of these efforts has always been on administrative support functions and not mission-direct activities. The savings from these studies ($14.3M) have been redirected to augment mission-critical activities within the Agency, including food safety inspections and drug safety reviews.

FDA currently is conducting several streamlined competitive sourcing studies of a variety of administrative support functions at headquarters and in the field. Similar to prior studies, these reviews do not include any activities or positions that are involved directly in conducting inspections, enforcement, laboratory or other scientific activities. The economies gained from these studies will be utilized to support these mission-direct activities. Your specific questions are restated in bold, followed by our response.

1. List each of the 332 positions identified by you as commercial in nature and provide position descriptions and job responsibilities for each position.

Please see Tab A for a current summary table and complete listing of the positions identified as commercial in nature. Tab B describes the different "rounds" under which the planned studies will occur and illustrates the current functions, definitions and responsibilities of the positions being studied.

2. Provide any and all studies that FDA has conducted in connection with the identification of the 332 positions being considered for outsourcing.

All of the positions currently being studied were identified from an analysis of the Federal Activities Inventory Reform (FAIR) Act Inventory for FDA. The most recent inventory approved by Congress is the 2006 version available at: *http://www.hhs.gov/ogam/oam/fair.* No separate studies, budget analyses, or policy analyses have been conducted in connection with identifying commercial positions for study. FDA utilizes an integrated decision-making model to select competitive sourcing efforts regarding its commercial functions. Before commercial activities are selected for competitive sourcing at FDA, an A-76 Steering Committee of Center executive officers and directors of real property and acquisition, human resources, information technology, facilities, and equal employment opportunity meet to discuss competing commercial activities currently identified in FDA's FAIR Inventory. Final steering committee approval must be obtained before a competition study is initiated.

3. Provide all records reflecting the plans, budget analyses, and policy analyses developed in connection with the FDA's decision to consider replacing the work currently performed by the 332 employees that you plan to eliminate from the Agency.

The focus of FDA's competitive sourcing efforts is to ensure that the administrative support services FDA provides are efficient, cost effective, and utilized to best support FDA mission requirements. Enclosed at Tab C is the preliminary planning report for the studies under consideration. This document contains the budget and policy analysis incidental to FDA's decision to study 349 support positions initially identified. Of those, 32 positions have been excluded resulting in a total of 317. Please note that the type and number of positions that were identified in the preliminary plan, as well as the cost and savings information and schedule of events, have evolved in response to the normal analysis and review conducted during any study effort. Tab A provides the most current information concerning the type and number of positions identified for study.

4. Provide a list of all FDA employees or consultants involved in the planning or designing of the outsourcing of the 332 employees.

Tab D lists the members of the A-76 Steering Committee. Support consultants also are listed.

5. Provide a description of the involvement of Margaret Glavin, Associate Commissioner of Regulatory Affairs, in the outsourcing of the 332 employees.

Margaret Glavin, Associate Commissioner for Regulatory Affairs, is not a member of the A-76 Steering Committee, nor has she been involved with the decision making processes concerning the competitive sourcing efforts at FDA. FDA's Office of Management Programs (OMP) is the lead office that considers and manages activities associated with competitive sourcing positions.

6. Provide a description of the involvement of the Office of the Administrator in the outsourcing of the 332 employees.

OMP, which is part of the Office of the Commissioner, is responsible for managing and providing updates, analysis, and recommendations for competitive sourcing efforts conducted in accordance with OMB Circular No. A-76. OMP is a directorate under the Office of Management which reports to the Chief Operating Officer (COO). The COO, in turn, reports directly to the Commissioner. Though the Commissioner has ultimate responsibility for A-76 activities, the responsibility for making decisions concerning competitive sourcing selection and/or routine study decisions has been delegated to the A-76 Steering Committee.

Please note that some of the information contained in this letter and enclosures is considered internal executive pre-decisional information. Some of the documents are procurement sensitive and protected under Federal Acquisition Regulations, the Freedom of Information Act (Title 5, *United States Code* [U.S.C.] 552) and FDA regulations. In particular, Tab C, the Preliminary Planning Report: OMB Circular A-76, is an internal published document which could jeopardize the competitive procurement process if the information were to be made public. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

Thank you again for your interest in this matter. If you have further questions, please let us know. A similar response is being sent to Chairman Stupak, without enclosures.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures:

A: Summary tables and detailed study listings of positions being studied
B: Function definitions and associated responsibilities.
C: FDA A-76 Preliminary Planning Report
D: A-76 Steering Committee membership