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

JUL 16 2007

Dear Mr. Chairman:

Thank you for your letter dated June 15, 2007, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, in which you expressed concerns regarding the proposed closure of Food and Drug Administration (FDA or the Agency) laboratories.

First and foremost, let me assure you that FDA's Office of Regulatory Affairs (ORA) is not reducing or cutting its workforce. As you are aware, ORA is engaged in a transformation process that involves every component of its organizational structure. As part of this endeavor, ORA plans to restructure the Agency's field force to meet today's public health challenges as well as those posed by the future. The restructuring does not reduce the size of the field force. Instead, as the restructuring is implemented over the next few years, ORA will increase its areas of expertise to meet new challenges by training current employees, and by recruiting new employees as vacancies occur in a manner that will best serve ORA in meeting its mission. The size of ORA's workforce will not be reduced unless required due to future appropriations levels.

Regarding the laboratory consolidation aspect of the transformation, all of the analysts from closing laboratories will be reassigned to the laboratory where their program work will be transferred, with full relocation benefits for them and their families. For those who are unable or unwilling to relocate, ORA may have some jobs available, for which they can compete, in other high priority and currently under-resourced areas within the ORA district in which they reside. Since it is likely that some of the analysts will nevertheless leave the Agency, ORA plans to back-fill with new hires to meet program needs.

Through ORA's transformation efforts, the Agency will enhance its capacity to perform its work more efficiently. ORA will also ensure that we maintain our analytical capabilities during the transition process; and hire new analysts if it becomes necessary. ORA plans to stagger its laboratory closures and to maintain some redundancy in operations during the transition. The timing for closing a particular laboratory will be determined by ORA's ability to successfully migrate the work of that facility to a consolidated laboratory. The effect on sample analyses will therefore be limited since ORA will be able to adjust for changes in

workflow and laboratory efficiency as the process moves forward. ORA expects to be able to meet its work plan obligations in terms of the number of samples analyzed, and to continue laboratory operations in a seamless manner.

I understand that your letter was prompted by review of documents provided to you in response to your request of February 6, 2007, particularly a document entitled "New Organization Staffing" dated December 11, 2006. This document was created by the Steering Committee of the Organizational Optimization Group within ORA's Transformation Leadership Team (TLT). The document is one of many planning documents produced both before and since the date of December 11, 2006. It was part of the draft proposal for a new organizational structure of ORA, and is 28 pages in length. Pages 1 and 22 were attached to your letter. I have attached the entire document for your convenience. This document does not support the conclusion that ORA is cutting its laboratory workforce. If it would be helpful, the Agency would welcome the opportunity to have an informal discussion with you about our transformation plans.

We have restated your requests in bold followed by our response.

1. The number and types of samples that FDA currently analyzes but will not be able to analyze due to the reduction in the number of laboratory analysts.

We do not anticipate that we will be unable to analyze any samples since ORA will be staggering the laboratory closures to ensure that we have complete coverage for the analyses that need to be performed.

2. The type of domestic or import inspections that FDA currently performs that involved taking samples that will not be able to rely on FDA laboratory analyses in the future due to the reduction in the number of laboratory analysts; and

Sample collections will not have to be reduced, nor will FDA be unable to perform laboratory analyses on those samples collected.

3. All records reflecting plans, budget analyses, and contracts intended to replicate the work currently performed by the 196 analysts that you plan to eliminate from the Agency.

As stated above, the proposed ORA restructuring does not eliminate 196 analysts from the Agency, but rather reassigns to other laboratories all analysts from the closing laboratories. Therefore we do not have any records reflecting plans, budget analyses and contracts intended to replicate the work such analysts currently perform.

ORA's restructuring does not reduce the size of our field force; it positions the Agency to meet the public health challenges we face today and in the future. We remain dedicated to protecting public health, and ORA's transformation efforts will provide us with the organizational structure and capabilities to do so well into the 21st Century.

Thank you again for your continued interest in this matter. If we can be of further assistance, please let us know. A similar copy of this response, without enclosures, is being sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure