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 the letter of June 26, cosigned by Chairman Bart Stupak, Subcommittee on Oversight and Investigations Subcommittee, regarding the Food and Drug Administration's (FDA or Agency) Winchester Engineering and Analytical Center (WEAC). Your letter requests information and documents related to the plans for this facility as part of the proposed Office of Regulatory Affairs (ORA) transformation.

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

1. **If WEAC is closed, will FDA move WEAC's capabilities to another laboratory?**

   If WEAC is closed, its capabilities will be moved to another laboratory.

2. **If WEAC capabilities are moved, what will be the time interval between closure and movement when the Nation will be unprotected from nuclear threats to the food supply?**

   The proposed laboratory consolidation would not adversely impact ORA's ability to address the regulatory needs of the Agency's public health mission, nor would it leave the nation's food supply unprotected from nuclear threats.

   The timing for closing a particular laboratory, including WEAC, will be determined by the Agency's ability to successfully migrate the work of that facility to a consolidated laboratory. Equipment for each program will be installed in the receiving laboratory, and we will utilize the expertise of staff from both the closing and the receiving laboratories as preparations move forward to implement each move.

   ORA's proposal provides a mechanism by which analysts who receive work from a closing laboratory would be given any needed on-the-job, side-by-side training with analysts from the laboratory from which the work is being transferred. This approach will allow ORA to maintain critical expertise during the transition and into the future. In addition, the enhanced laboratories would continue to provide supporting layers of

expertise with appropriate redundancies to protect against unforeseen operational problems and provide surge capacity to deal with emergencies.

3. **If FDA would move WEAC's capabilities to another laboratory, what laboratory would it move them to? (Enumerated as number 2 in the letter.)**

   If WEAC capabilities are moved, these programs may be transferred to the Northeast Regional Laboratory (NRL). Other locations are also being considered.

4. **How will FDA replace the expertise and experience of those analysts currently working at WEAC who choose not to remain with the Agency?**

   The proposed transfer of WEAC's analytical capabilities to another laboratory will require that the receiving laboratory have both the scientific expertise and equipment to conduct these types of analyses. ORA is in the process of reviewing and identifying the portfolio of equipment that resides at WEAC for the analyses it conducts and which must be present in, or moved to, the receiving laboratory for these programs to continue. The equipment needed for each program will be installed in the receiving laboratory prior to moving that program. In addition, we expect to utilize the WEAC staff in preparing for, and implementing the movement of WEAC's program work.

   All of WEAC's analysts would be reassigned to the laboratory where their program work will be transferred. As stated above, to replicate the analytical capabilities that reside at WEAC, ORA's laboratory consolidation proposal provides for analysts in the receiving laboratory to receive on-the-job, side-by-side training with a closing laboratory's analysts. This approach serves a dual purpose. It allows ORA to maintain the proficiency it needs to conduct those analyses currently being performed in laboratories that would by closed. In addition, it would enhance ORA's capability to conduct these types of analyses in anticipation of future losses due to attrition or in the event of a public health emergency when it would be beneficial to have several analysts with the scientific expertise to perform specialized analyses. If necessary, new analysts with necessary skill sets will be hired, allowing ORA to continue to meet all of the Agency's public health responsibilities.

5. **Does FDA have a plan to contract out the work currently performed by WEAC? If so, to whom?**

   At the present time, FDA does not anticipate contracting out any of the program work currently performed at WEAC.

   Records relating to the plans for the WEAC facility under the proposed ORA transformation have either been provided to the Committee previously, or will be included in a document production pursuant to the Committee's June 20, 2007, letter related to the ORA transformation proposal.

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 is being sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation