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

SEP 0 6 2007

Dear Mr. Chairman:

Thank you for the letter of July 31, 2007, co-signed by Chairman Bart T. Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce. The letter expresses your concern about a pilot proposal created by the National Coalition of Food Importing Associations (NCFIA) that would have private laboratories collect and analyze samples of imported food on behalf of the Food and Drug Administration (FDA or the Agency). You also requested documents related to the outsourcing of laboratory testing, including the pilot proposal.

FDA did not solicit or participate in developing the proposal that NCFIA sent to the Agency on July 2, 2007. That proposal has no bearing on, or connection to, FDA's initiative to realign resources within FDA's Office of Regulatory Affairs (ORA). As NCFIA's proposal notes, they conducted a similar pilot in New York in 1994, and the current proposal appears to be based on that experience.

ORA have only recently begun to review NCFIA's current proposal. Over the years, FDA has considered the feasibility of using private laboratories to supplement the surveillance work that our laboratories do, but not as *an alternative* to doing regulatory laboratory work ourselves. ORA generally distinguishes surveillance samples, which are analyzed in the absence of any pending regulatory action primarily for information gathering or research purposes, from regulatory samples, which are analyzed to support regulatory action. On July 2, 2007, NCFIA sent their proposal via email to ORA headquarters and to the laboratory directors in New York and Los Angeles, who forwarded it shortly thereafter to some of their employees for comment. Although some of our employees have begun to share their initial impressions of the proposal, other priorities have prevented the Agency from initiating a formal review process. Consequently, the Agency has not yet responded to NCFIA.

Finally, accompanying documents indicate that some ORA employees mistakenly believed the Agency had either negotiated the pilot with NCFIA or that ORA did not intend to seek a broad comment on it. Neither of these views is true. First, we believe the language of the NCFIA proposal itself may have created the incorrect impression that it was a *fait accompli*.

For example, the NCFIA proposal outlines what FDA "intends" to accomplish and states that FDA "will" do certain things. Additionally, NCFIA proposed that the pilot begin October 1, 2007, the same date that ORA proposed to institute its revitalization plan, creating the impression that the two were linked. They are not. Second, accompanying documents show that, even before initiating a formal review process, ORA management circulated the proposal widely among ORA field employees and asked for their input. These documents also show that employees felt free to offer their supervisors a frank assessment of the proposal.

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

1. **Is this proposal the FDA's plan to replace the work currently being performed by the Office of Regulatory Affairs laboratories that are slated for closure?**

No. ORA's transformation initiative, including the laboratory component, was never intended to reduce the size of ORA's workforce or its budget. Rather, the initiative was designed to realign certain resources to increase ORA's effectiveness. The ORA transformation initiative did not include a plan to outsource regulatory work that is currently performed by ORA laboratories.

2. **Is this proposal part of the Administration's plan to contract out vital Government work functions such as currently being done under the Detention Without Physical Examination Import Alert rules?**

No. As explained above, FDA has no plans to contract out regulatory work that is currently performed by our laboratories. FDA is required to consider evidence submitted (including private laboratory test results) that is relevant to whether there is an appearance of a violation that justifies refusal of the import entry. Some Import Alerts permit importers to secure release of an individual shipment if the importer can show that the particular shipment does not appear to be violative. In these cases, an importer may have an independent laboratory test representative samples of an individual shipment. Those test results are reviewed by FDA to determine whether they overcome the apparent violation in that shipment. If FDA determines that test results do not overcome the apparent violation, FDA does not release the shipment. FDA requires that independent laboratories, rather than the importer itself, conduct these analyses as a means of assuring the integrity of data submitted to the Agency. Under certain circumstances, FDA also collects audit samples – samples of the same entry that the private lab had tested – for analysis in FDA laboratories to ensure the integrity of the process.

3. **Was anyone in the Department of Health and Human Services, the Office of Management and Budget, or elsewhere in the Administration involved in suggesting or directing that FDA consider the pilot program or any other plan involving the contracting out of laboratory functions?**

No. FDA has no plans to contract out regulatory work that is currently performed by FDA laboratories. FDA has not received any direction or suggestion from anyone in the Department of Health and Human Services, the Office of Management and Budget, or from anyone else in the Administration, to consider the proposal.

Thank you again for contacting us about this matter. If we can answer further questions or provide additional information, 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