ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

February 6, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Pursuant to Rules X and XI of the Rules of United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are conducting an investigation into the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply. We are also concerned about the ability and willingness of the FDA to assure that the drugs and medical devices reaching American consumers are safe and effective. In the case of food safety alone, the recent outbreaks of E coli and salmonella have further increased our concern regarding FDA's domestic enforcement efforts.

Of even greater concern is the ability of the Agency to address possible terrorist assaults on our food supply. The ability of the FDA to analyze food samples quickly and accurately is critical to a viable enforcement program that can stop dangerous imports while not unnecessarily obstructing legitimate commerce in perishable goods. Likewise, the ability of FDA to guard the drug supply from counterfeits and other dangerously substandard drugs requires an efficient laboratory system with a meaningful forensic capability. Toxicology is a critical enforcement tool that should not be compromised by a lack of laboratory capacity.

Accordingly, we are dismayed to learn that the FDA is contemplating shutting down seven to nine of the 13 laboratories that the Agency operates, including the Forensic Chemistry Lab. This comes on the heels of a $20 million proposed increase for the labs in FY2007 budget, an indication of the priority that the Administration placed on their operation just a year ago.

Further, FDA should have disclosed its planned lab closures to the Committee in your December 26, 2006, written response to questions posed by then-Committee and Subcommittee Chairmen Barton and Whitfield in an October 14, 2006, letter to the Agency. Instead, the FDA told the Committee that the Office of Regulatory Affairs (ORA) "is currently conducting a

strategic planning process. At this time, the plan has not been finalized; therefore, there are no changes to ORA's current laboratory structure."

Incredibly, the Committee has learned that FDA notified the National Treasury Employees Union (NTEU) representing some of its workforce of the proposed closings in November, weeks before the Agency apparently decided to mislead the Committee. The refusal of FDA to provide Congress with accurate information in response to the request by a Committee Chairman is completely unacceptable. We ask you to inform us of the name of the individual who made this decision.

In order to evaluate the implications for the safety of food, drugs, and devices that Americans consume, we hereby request that you provide all records created on or after January 1, 2005, relating to proposed closure of FDA labs. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional documents and/or staff interviews of FDA personnel.

We further request that you direct that all preparations to close these labs be suspended until after the Committee completes its review. We ask that you supply all requested documents no later than the close of business, Thursday, March 1, 2007.

If you have any questions relating to this request, please have your staff contact David Nelson (Majority staff (202) 225-2927) or Alan Slobodin (Minority staff at (202) 225-3641) with the Committee on Energy and Commerce.

Sincerely,

John D. Dingell
Chairman
Committee on Energy and Commerce

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Joe Barton
Ranking Member
Committee on Energy and Commerce

Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Attachment

Congress of the United States

House of Representatives

Washington, D.C. 20515

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.