ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

May 24, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

Since the 110th Congress began, Committee staff have requested briefings, documents, and information regarding a range of problems with the operation of the Food and Drug Administration (FDA). Copies of these letters are attached. With the exception of the January 23, 2007, request regarding the generic drug approval process, and the provision of two food safety briefings, all of the other requests from this Committee have been, at best, only partially answered, and several have been ignored altogether. As the attached spreadsheet indicates, these requests for documents and information have been outstanding for one to three months. In sum, none of the document requests has been fulfilled to the satisfaction of the Committee. Moreover, in some instances FDA has produced redacted records to the Committee, without any prior consultation on such redactions.

The delays and the quality of responses to the Committee's requests concerning FDA are unacceptable. With the exception of patient identifiers in medical records, all documents produced to the Committee are to be unredacted. Please understand the seriousness of our position—all questions must be answered and all outstanding documents must be delivered by no later than close of business on Friday, June 1, 2007. After that date, the Committee will consider other options, including compulsory process, to achieve fulfillment of these requests.

If you have any questions regarding this request, please contact us or have your staff contact John Sopko, Chief Counsel for Oversight with the Committee on Energy and Commerce, at (202) 225-7469.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachments

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner, U.S. Food and Drug Administration

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS – LETTERS				
Date Sent	**Agency**	**Subject**	**Response Due**	**Response Received**
Jan. 22, 2007	FDA/Andrew C. von Eschenbach	Contracting Conflicts of Interest	Jan. 25, 2007	Incomplete response, no letter provided
Jan. 29, 2007	FDA/Andrew C. von Eschenbach	Food Safety	Feb. 7, 2007	Incomplete response; Briefing Feb. 23, 2007 (follow up requested); Apr. 18, 2007; Apr. 20, 2007; May 8, 2007
Feb. 6, 2007	FDA/Andrew C. von Eschenbach	Lab Closures	Mar. 1, 2007	Incomplete response; Mar. 2, 2007; Mar. 16, 2007; May 8, 2007
Feb. 15, 2007	FDA/Andrew C. von Eschenbach	Food Safety	Briefing Feb. 23, 2007	Briefing Feb. 23, 2007 (follow up requested)
Feb. 16, 2007	HHS/Michael O. Leavitt	Ketek Records	Feb. 28, 2007	Incomplete response; Mar. 1, 2007; Mar. 29, 2007; Apr. 4, 2007; Apr. 25, 2007
Mar. 8, 2007	HHS/Michael O. Leavitt	Contracting Conflicts of Interest	Mar. 22, 2007	
Mar. 28, 2007	HHS/Michael O. Leavitt	FDA Testimony Mistatement	April 9, 2007	
Mar. 30, 2007	FDA/Andrew C. von Eschenbach	Pet Food	Apr. 13, 2007	
Apr. 12, 2007	FDA/Andrew C. von Eschenbach	Religious Comp Pay	unspecified	
Apr. 12, 2007	FDA/Andrew C. von Eschenbach	FDA Bonuses	unspecified	
Apr. 13, 2007	FDA/Andrew C. von Eschenbach	3/22 OI FDA Hearing Follow up Questions	Apr. 27, 2007	
Apr. 18, 2007	FDA/Andrew C. von Eschenbach	Animal Antibiotics	May 2, 2007	