United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

November 29, 2006

Via Electronic Transmission

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

Dear Secretary Leavitt:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage, including prescription drugs, under those programs.

The Food and Drug Administration (FDA), Department of Health and Human Services (Department/HHS) has repeatedly delayed the oversight work of this Committee. Last week, I wrote you and Attorney General Gonzales regarding the failure of the Food and Drug Administration (FDA), Department of Health and Human Services (Department/HHS) to take a number of good faith steps toward fully complying with the Committee's subpoenas to compel the production of information and documents related to the approval and postmarket surveillance of telithromycin (Ketek). Selectively providing documents and access to executive agency officials pursuant to a Congressional subpoena cannot constitute compliance, no matter how voluminous the documents or how many executive agency officials are made available, when relevant documents and information have been "overlooked" or purposefully withheld.

Over the past several months my Committee staff have sought and received assurance from FDA's Office of Legislation, both written and verbal, that all relevant FDA officials who worked on Ketek matters were notified to produce documents responsive to the Committee's subpoenas. As long ago as June 5, 2006, Mr. David Boyer, FDA Assistant Commissioner for Legislation, sent an email to my Committee staff, and copied to Mr. Vincent Ventimiglia, HHS Assistant Secretary for Legislation, which stated that "on May 23, an email requesting Ketek-related documents was sent to the heads of appropriate CDER offices, with clear and direct instructions that it be shared with their employees. Additionally, the email explicitly mentioned emails as documents

to be included in all searches/productions/deliveries." The assurances that FDA/HHS provided the Committee have proven to be less than accurate.

In recent weeks, my Committee staff interviewed a number of FDA officials who referred to extremely relevant documents, which have been withheld from the Committee to date. Further, the Committee is aware that at least three FDA officials, who played integral roles in the FDA's review of Ketek, were never asked to review their files and turn over relevant documents in their possession to the Office of Legislation. For example, most recently, my Committee staff was to interview the Regulatory Project Manager (RPM) for Ketek, pursuant to my request letter, dated October 5, 2006. Last Wednesday, more than six months since the Committee subpoenaed Ketek documents, FDA notified my Committee staff that during interview preparation it was discovered that the RPM was never directed to produce documents responsive to the Committee's subpoenas. It is simply dumbfounding that someone as centrally involved as the RPM in the review of a drug was not directed to produce documents pursuant to the Committee's subpoenas. This latest "oversight" is but one of many that shows the inability of HHS/FDA to comply with the Committee's subpoenas in good faith.

Accordingly, as Chairman of the Committee, I respectfully request that HHS/FDA provide the Committee with a list of all HHS/FDA officials who were involved with the review and post-market surveillance of Ketek, as of May 19, 2006. Second, provide the Committee with a list of all HHS/FDA officials who produced documents responsive to the Committee's subpoenas. Please provide this and additional information in a table according to the following format:

Official /Center/ Office / Division	Date 4/27/06 Chairman's letter distributed to official	Date 5/16/06 Chairman's letter distributed to official	Date 5/19/06 Committee subpoena distributed to official	Date documents delivered to Office of Legislation

As Chairman of the Committee, I respectfully request your response by no later than December 13, 2006. Before any conversation we have to discuss the pending nomination of Dr. von Eschenbach, it would be most helpful if you personally intervened in this and other matters of importance to the Committee. I refer you to my letters addressed to you, Senator Frist, and Attorney General Gonzales, dated November 15, 16, and 21, 2006, which are attached for your convenience.

If you anticipate any difficulty in complying with this request, please immediately contact my Committee staff. Any questions or concerns should be directed to

All formal correspondence should be sent electronically in PDF format to

or delivered in PDF format on compact disc(s) to the Committee's main office.

Sincerely,

Charles E. Grassley
Chairman

cc: Dr. Andrew von Eschenbach
Acting Commissioner
Food and Drug Administration

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

November 15, 2006

Via Electronic Transmission

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

Dear Secretary Leavitt:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage, including prescription drugs, under those programs.

Pursuant to the Committee's ongoing investigation into the approval and postmarket surveillance of telithromycin (Ketek) by the Food and Drug Administration (FDA), I thank you for making arrangements for my Committee staff to interview officials within the FDA's Division of Scientific Investigations (DSI), including M.D. M.D. M.D., and Ph.D. My Committee staff conducted these interviews in recent weeks and concluded them yesterday. During the course of these interviews, my Committee staff confirmed that numerous documents relevant to the Committee's investigation were not provided pursuant to the Committee's subpoena, dated May 19, 2006 (Committee Subpoena). As Chairman of the Committee, I respectfully request your immediate attention to these matters.

Mr. Secretary, at this late date, more than half a year since the Committee began this investigation, it is beyond troubling that such seminal documents have not been provided pursuant to the Committee Subpoena. As Chairman of the Committee, I request that these documents, and all such responsive documents, be turned over to the Committee immediately. Finally, I call your attention once again to the Committee Subpoena's General Instructions, which instruct that if any document is withheld from the Committee on the basis of privilege, that you provide the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.

If you anticipate any difficulty in complying with these requests, please immediately contact my Committee staff. Any questions or concerns should be directed to at or . All formal correspondence should be sent electronically in PDF format to or delivered in PDF format on compact disc(s) to the Committee's main office.

Sincerely,

Charles E. Grassley
Chairman

cc: Dr. Andrew von Eschenbach
Acting Commissioner
Food and Drug Administration

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

November 16, 2006

The Honorable William H. Frist
Majority Leader
United States Senate
S-230
Washington, DC 205 10
Dear Senator Frist:

I am writing to request that I be consulted prior to entering into any unanimous consent agreement relating to Dr. Andrew von Eschenbach's nomination to be Commissioner of the Food and Drug Administration (FDA). The issues at stake are critically important. Last May the Finance Committee issued two subpoenas to obtain access to FDA documents and an agency employee. As Chairman of the Finance Committee, I am extremely disturbed by the Acting Commissioner's continued failure to comply with the Committee's subpoenas over the past six months. Senator Baucus and I met with Secretary Leavitt to let him know, in no uncertain terms, that failure to comply with the Committee's subpoenas is unacceptable. We also advised Secretary Leavitt that numerous other Committee requests are overdue - on average 101 days late - from both the FDA and the Department of Health and Human Services. The authority and integrity of Senate and Committee processes are being challenged and due concern should be shown to this nomination.

Sincerely,

Chuck Grassley

Charles E. Grassley
Chairman

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

November 21, 2006

Via Electronic Transmission

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

The Honorable Alberto Gonzales
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20535

Dear Secretary Leavitt and Attorney General Gonzales:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage, including prescription drugs, under those programs.

On May 19, 2006, the Committee issued two subpoenas (Subpoenas) – one to Secretary Leavitt and another to Special Agent Robert West – to compel the production of information and documents related to the approval and postmarket surveillance of telithromycin (Ketek) by the Food and Drug Administration (FDA). On November 16, 2006, Mr. David Boyer, FDA Assistant Commissioner for Legislation, forwarded to the Committee "a further partial response, which contains documents from the FDA Office of Criminal Investigations [OCI documents]" pursuant to "subpoenas to compel the production of documents related to Ketek." On November 17, 2006, Ms. Casey Hemard, Counselor on Oversight, Office of the Assistant Secretary for Legislation, Department of Health and Human Services (HHS), contacted the Committee and stated that the Department of Justice (DOJ) reviewed the OCI documents and redacted certain information pursuant to Rule 6(e) of the Federal Rules of Criminal Procedure (Rule 6(e)). As Chairman of the Committee, I respectfully request further information from both HHS/FDA and DOJ regarding the OCI documents and the information redacted from them.

First, I call your attention once again to the Subpoenas' general instructions, which instruct that if any document is withheld from the Committee on the basis of privilege, that you provide the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other. HHS/FDA has not provided such information to the Committee despite numerous, repeated requests to comply fully with the Subpoenas.

Second, HHS, FDA and/or DOJ redacted information from numerous OCI documents without making a notation on the page where information was redacted.

While it is evident on some OCI documents where information was redacted, the extent of redactions is not always clear. Accordingly, as Chairman of the Committee, I request the following information:

1. If HHS/FDA is acting in good faith by "seek[ing] measures of accommodation that respect Congress' need for information, while addressing [its] concerns," state why HHS/FDA has failed to comply with the Subpoenas' instructions to provide information concerning any document withheld on the basis of privilege.

2. On what date did HHS/FDA forward the OCI documents to DOJ for redaction and on what date did DOJ return redacted OCI documents to HHS/FDA?

3. Provide a copy of the OCI documents that indicate where information was redacted on each page.

4. Attached are two pages of emails, dated March 3, 2004, from the OCI documents, which appear identical in all respects except that an entire paragraph appears to have been redacted on one page and not the other page. Provide an explanation for redacting this paragraph pursuant to Rule 6(e).

5. Certify that all information redacted by DOJ was pursuant to Rule 6(e).

Finally, the Committee cannot begin to consider "measures of accommodation that respect Congress' need for information" without good faith steps from HHS/FDA, such as a privilege log, including a specific and detailed showing of the basis for withholding documents or redacting information. As Chairman of the Committee, I respectfully request your responses by no later than December 4, 2006.

If you anticipate any difficulty in complying with these requests, please immediately contact my Committee staff. Any questions or concerns should be directed to or . All formal correspondence should be sent electronically in PDF format to or delivered in PDF format on compact disc(s) to the Committee's main office.

Sincerely,

Charles E. Grassley
Chairman

cc: Dr. Andrew von Eschenbach
Acting Commissioner
Food and Drug Administration