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ONE HUNDRED TENTH CONGRESS

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

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February 16, 2007

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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:

Pursuant to Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are conducting an investigation into the Food and Drug Administration's (FDA) management of drug safety issues. As part of this investigation, the Subcommittee is examining concerns related to the pre-market review and post-market surveillance of the antibiotic telithromycin (Ketek). Documents and information available to the Subcommittee raise questions about the management of drug safety issues in connection with Ketek.

Accordingly, we hereby request that the Department provide to the Subcommittee by no later than Wednesday, February 28, 2007, all records relating to:

1. The integrity of data associated with the planning, coordination, implementation, or review of Study 3014. This does not include Study 3014 itself;
2. Questions or concerns with respect to Study 3014 arising between July 24, 2002, when the study was presented to the FDA, and January 8, 2003, the second meeting of the Advisory Committee;
3. Communications between representatives, including but not limited to independent contractors, of the FDA and Sanofi-Aventis regarding Study 3014;

4. Investigations conducted by the FDA's OCI and DSI relating to Study 3014;
5. Compliance or lack of compliance with Good Clinical Practices (GCP) in association with the Ketek new drug application; and
6. The use of foreign adverse event data to satisfy the safety concerns of the Advisory Committee without even reconvening the Advisory Committee. This does not include the body of any large study or analysis of the data supplied by Sanofi-Aventis to the NDA file except for any executive summary of such study or analysis.

In addition, please provide the following information in writing no later than Wednesday, February 28, 2007:

1. Identify all persons who worked on any aspect or matter related to the review or investigation of Study 3014;
2. Has the FDA ever withheld data integrity problems from an Advisory Committee in association with the review of other drugs?

If the Department elects to assert a privilege or objection to the production of the foregoing documents, please provide a privilege log fully identifying each document withheld and the legal basis for withholding that document from a Congressional committee of competent jurisdiction.

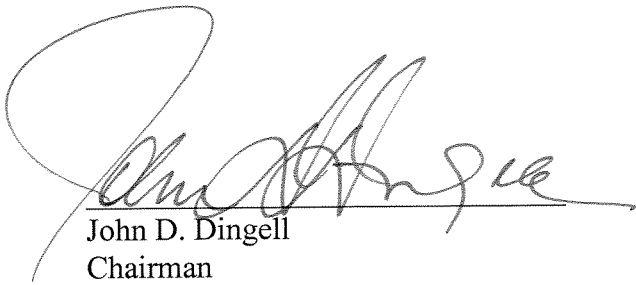
We also request that any and all FDA employees involved in the review and approval of Ketek, as well as the investigators of sites that produced data for Study 3014, be given a copy of this letter and specifically advised of their right to speak and cooperate with this Committee during this important investigation.

In responding to this request for documents please be advised that the terms "records" and "relating to" are defined in the attachment to this letter. Also when complying with this request we expect that you will search the relevant files within FDA, the Office of General Counsel and the Office of Legislative Affairs at the Department. In addition, all records submitted to the Committee must be produced unredacted except that you may redact patient identifiers from any document. Any other redactions that the Department feels are important require the concurrence of the majority and minority staff.

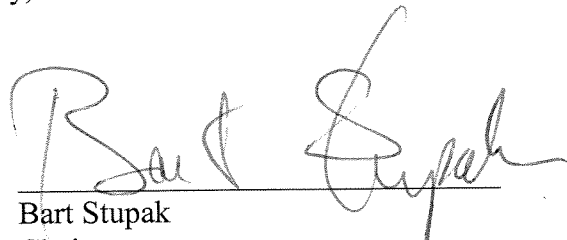
The Honorable Michael O. Leavitt
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Thank you in advance for your cooperation in this critical matter. If you have any questions regarding these requests, please do not hesitate to have your staff contact David Nelson of the Committee Majority staff at (202) 225-2927 or Alan Slobodin of the Committee Minority staff at (202) 225-3641.


Sincerely,



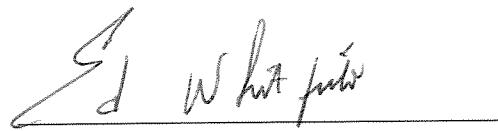
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Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations



Joe Barton
Ranking Member
Committee on Energy and Commerce



Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations

Attachment

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.