DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 19 2007

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for the letter dated February 16, 2007, co-signed by Joe Barton, Ranking Member, Committee on Energy and Commerce, Bart Stupak, Chairman of the Subcommittee on Oversight and Investigations, and Ed Whitfield, Ranking Member, to Michael O. Leavitt, Secretary of Health and Human Services, requesting information and documents related to telithromycin (Ketek). Secretary Leavitt asked that the Food and Drug Administration (FDA or the Agency) respond on his behalf. On March 1, 7, 29, April 4, 25, May 17, and July 3, 2007 we sent partial responses. This is a further partial response.

Information contained in the enclosures includes information that is trade secret, commercial confidential or other information protected from disclosure to the public under the Freedom of Information Act (Title 5, *United States Code* [U.S.C.] 552), the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), and FDA regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information. As you instructed in your letter, we have redacted the documents to remove patient identifiers.

As has been discussed with Committee staff, we had previously asked for a broader set of Ketek-related documents from the FDA Centers, Office of Commissioner, and the Office of Regulatory Affairs field operations in connection with a similar congressional request. To expedite our response to your request, we are reviewing that set of documents for documents responsive to your request. In cases where there were large numbers of documents containing patient privacy identifiers, we redacted an example of those particular documents and have indicated how much more of that same type of document we have in our files that would be responsive to your request.

The enclosed documents are responsive to your request. Tab A includes documents that are related to Questions 1, 2, and 3 of your letter. Tab B includes documents from FDA's Office of Criminal Investigations that are responsive to Question 4 of your letter. We have determined that these documents are no longer part of an ongoing investigation or a matter pending before the Agency.

We will continue to work with Committee staff on this request, and may provide additional responsive materials to these and other questions if they are identified. A similar letter has been sent to your co-signers without enclosures. Thank you for your interest in this matter. If you have further questions, please let us know.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures