DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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

APR 25 2007

Dear Mr. Chairman:

Thank you for the letter dated February 16, 2007, co-signed by Ranking Minority Member Joe Barton, and Chairman of the Subcommittee on Oversight and Investigations, Bart Stupak, and Ranking Minority Member Ed Whitfield, 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, March 7, March 29, and April 4, 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 privileged 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 Food and Drug Administration (FDA or the Agency) 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.

The enclosed documents are responsive to your request and are from files of the Center for Drug Evaluation and Research offices including: the Office of the Center Director, Office of New Drugs, Office of Antimicrobial Products, Division of Anti-Infective Drug Products, and the Office of Drug Safety.

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. An identical 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