



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville MD 20857

The Honorable John D. Dingell  
Chairman  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-0115

APR 11 2007

The Honorable Bart Stupak  
Chairman  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-0115

Dear Chairman Dingell and Chairman Stupak:

I write in follow-up to the Food and Drug Administration's (FDA or the Agency) April 4, 2007, response to your letter dated March 28, 2007, regarding my written testimony at the March 22, 2007, Subcommittee on Oversight and Investigations hearing entitled, "The Adequacy of FDA Efforts to Assure the Safety Efforts of the Drug Supply -- Part II."

A copy of the Agency's response is enclosed. In addition, the following documents are being provided to further support our response:

- December 14-15, 2006, Joint Meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, transcript, pages 301-426;
- 2003 Approvable Letter for Application NDA 21-144;
- Medical Officer Safety Review of NDA 21-144: Telithromycin (Ketek); and
- 2005 Office of Drug Safety evaluation of the safety profile of Telithromycin.

Information contained in the enclosures may include 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 specific information.

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The Honorable Bart Stupak

Please be assured that FDA takes our obligations to Congress very seriously. We appreciate the opportunity to provide further information to you. If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew C. von Eschenbach". The signature is fluid and cursive, with a large initial 'A'.

Andrew C. von Eschenbach, M.D.  
Commissioner of Food and Drugs

Enclosures