

June 1, 2007

**CONFIDENTIAL**

**By Hand**

David Nelson  
Investigator/Economist  
Committee on Energy and Commerce  
United States House of Representatives  
316 Ford House Office Building  
Washington, DC 20515

Re: Fourth Response to March 9, 2007 Document Request to sanofi-aventis U.S.

Dear Mr. Nelson:

On behalf of sanofi-aventis U.S., we are providing a fourth response to the Committee's March 9, 2007 letter to Mr. Timothy Rothwell, Chairman, sanofi-aventis U.S., requesting certain information relating to Ketek<sup>®</sup> (telithromycin) Study 3014 conducted by Aventis Pharmaceuticals Inc. ("Aventis").

This fourth response follows:

- Our initial response, dated March 27, 2007, in which sanofi-aventis U.S. produced Aventis' response to Question 1.A.1 in the Food and Drug Administration's January 24, 2003 Approvable Letter for Ketek<sup>®</sup>, submitted as part of NDA 21-144 Amendment 3 on October 17, 2003 (Bates number range 0000001 - 0133187);
- Our second response, dated April 25, 2007, in which sanofi-aventis U.S. produced materials in response to the proposed, interim production categories outlined in "Sanofi-aventis U.S.' Proposed Timeline and Initial Scope of Response to the Energy & Commerce Committee's March 9, 2007 Document Request," which was sent to the Committee by email on March 28, 2007 (Bates number range 0133188 - 0134751); and
- Our third response, dated May 17, 2007, in which sanofi-aventis U.S. produced a first installment of emails and hard-copy communications between Aventis and PPD, Copernicus, and FDA pertaining to Study 3014, between December 1, 2001 and March 30, 2004, also in response to a proposed, interim production category outlined

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in "Sanofi-aventis U.S.' Proposed Timeline and Initial Scope of Response to the Energy & Commerce Committee's March 9, 2007 Document Request."

Today's production is a second installment of responsive communications between Aventis and PPD, Copernicus, and FDA pertaining to Study 3014, between December 1, 2001 and March 30, 2004. As we have discussed, at this time we are producing responsive communications without their attachments, except where the attachment itself is a responsive communication.

With respect to Aventis-Copernicus communications, since the last production dated May 17, 2007, we have not identified additional responsive communications between the two parties. Thus, today's production does not include any responsive Aventis-Copernicus communications.

With respect to Aventis-PPD communications (S-A 3/07 O&I 0137813-0140466) and Aventis-FDA communications (S-A 3/07 O&I 0140467- 0141236), we have identified additional documents that are being produced today.

We are providing the materials referenced above on one (1) disc. As requested, the disc has been converted to a searchable format. The documents are Bates-labeled S-A 3/07 O&I 0137813 - S-A 3/07 O&I 0141236, and are marked "Confidential." Sanofi-aventis U.S. understands that this request is continuing in nature, and to the extent sanofi-aventis U.S. identifies additional materials in the above categories it will produce such documents immediately.

In addition, in response to a request from Ms. Joanne Royce of the Committee staff by telephone on May 23, 2007, we are providing another copy of a disc that sanofi-aventis U.S. initially produced on March 27, 2007 (disc 1 of 9) (Bates number range 0000001 - 0016764) that presented technical problems upon the Committee's review. The Committee should be able to view all of the documents contained on this disc, and we apologize for any inconvenience. Please let us know if you encounter additional technical difficulties.

The documents in this production contain confidential and/or commercially valuable and proprietary business information and trade secrets of sanofi-aventis U.S., and sanofi-aventis U.S. therefore respectfully requests that the Committee keep this material confidential and limit access to Members and staff involved in this inquiry. Sanofi-aventis U.S. also requests return of the material when the Committee has completed its review.

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We appreciate the Committee's willingness to work with us to achieve efficient compliance with this document request. Sanofi-aventis U.S. is committed to cooperating with the Committee and we would be pleased to discuss further requests based upon the materials produced to date.

If you or your staff have any questions, please do not hesitate to contact me at (202) 942-5120.

Respectfully submitted,



Daniel A. Kracov

Counsel to sanofi-aventis U.S.

cc: Alan Slobodin

Enclosures