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

MAR 2 0 2008

Dear Mr. Chairman:

Thank you for your letter of February 11, 2008, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting specific information and documents related to Vytorin (ezetimibe/simvastatin) and the ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Subjects With Heterozygous Familial Hypercholesterolemia) trial. On March 5, 2008, we provided responses to Questions 5, 6, 7 and 9. This is a further partial response.

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 the Food and Drug Administration (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. The documents have been redacted for personal privacy information.

We have reprinted the questions from your letter in bold. We are sending a total of one box of documents that contains documents that are responsive to these five questions.

1. **All records relating to all protocols for the ENHANCE trial, including but not limited to, the initial ENHANCE trial protocol provided to FDA by Merck/Schering-Plough, as well as the final protocol agreed to by FDA.**

2. **All records relating to any and all amendments to any ENHANCE protocol.**

3. **All records relating to all SAPs for the ENHANCE trial, including but not limited to, the initial SAP provided to FDA by Merck/Schering-Plough, as well as the final SAP agreed to by FDA.**

4. **All records relating to any and all amendments to the ENHANCE SAP.**

Documents responsive to Questions 1 through 4 are enclosed at TAB A.

10. All records relating to the Early Communication briefing on January 25, 2008.

Documents responsive to Question 10 are enclosed at TAB B.

The documents were redacted for personal privacy information that includes: dates of birth, dates of death, and dates of hospital admissions.

Thank you again for your interest in this matter. If you have any further questions, please let us know. A similar letter without the enclosure has been sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigation