



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 5 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. This is a partial response.

We have reprinted the questions to which we are now responding in bold.

- 5. All records relating to all Operator Manuals and Reader Manuals for the ENHANCE trial, including but not limited to, the initial Manuals provided to FDA by Merck/Schering-Plough, as well as the final Manuals agreed to by FDA.**

The Food and Drug Administration (FDA) has no responsive documents. There is no requirement for the company to submit Operator Manuals or Reader Manuals to FDA.

- 6. All records relating to any and all amendments to the ENHANCE Operator Manuals and Reader Manuals.**

FDA has no responsive documents. There is no requirement for the company to submit Operator Manuals or Reader Manuals to FDA.

- 7. All records relating to the analysis, assessment, and approval of the ENHANCE protocol, SAP, Operator Manuals, and Reader Manuals, by FDA officials.**

FDA has no responsive documents. There is no requirement for the company to submit Operator Manuals or Reader Manuals to FDA.

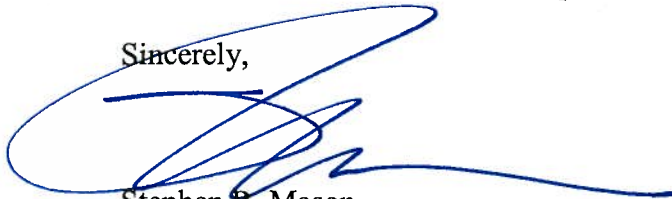
- 9. All Adverse Event Reports related to either Vytorin or Zetia.**

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We are enclosing a disk containing the responsive documents. The documents have been redacted for personal privacy information.

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,

A handwritten signature in blue ink, appearing to read "Stephen R. Mason", with a large, sweeping flourish extending to the right.

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