



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

FEB 28 2008

Dear Mr. Chairman:

Thank you for your letter of January 16, 2008, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting documents related to Vytorin. On February 1, 2008, we provided documents responsive to your request. Your letter noted that after review of the documents you might ask for additional records or staff interviews.

Your staff requested a telephone briefing with Food and Drug Administration (FDA or the Agency) staff after reviewing the documents. On February 27, 2008, majority and minority committee staff participated in a telephone briefing with FDA staff. At that time, your staff requested a copy of a further document.

Information contained in the enclosure includes 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 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.

We have repeated your request below followed by our response.

We ask that you provide all records relating to any print, radio, television, or internet advertisements for Vytorin. These records are to include, but not be limited to, any records relating to the review or monitoring of said advertisements, complaints received related to these advertisements, and any comments or consultations that DDMAC provided related to these advertisements.

Enclosed is a copy of the January 23, 2008, letter from FDA to Merck & Co. regarding direct-to-consumer promotional materials for Vytorin.

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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 "S. Mason", with a long horizontal flourish extending to the right.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure