



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

MAY 15 2008

Dear Mr. Chairman:

Thank you for your letter of April 25, 2008, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting all records relating to any print or Internet advertisements for Vytorin (ezetimibe/simvastatin) since January 16, 2008.

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 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.

In your letter you request that the records include, but not be limited to, any records relating to the review or monitoring of said advertisements, complaints received relating to these advertisements, and any comments or consultations that the FDA's Division of Drug Marketing, Advertising, and Communications has provided relating to these advertisements. We are sending one box of documents and six disks.

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", is written over a horizontal line.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure

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

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce