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 0 1 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.

Information contained in the enclosures 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.

We are sending two boxes of documents responsive to this request. Also, in the boxes are eight 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 enclosures has been sent to Chairman Stupak.

Sincerely

Stephen R. Mason

Acting Assistant Commissioner

for Legislation

Enclosures