



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. 20515-2215

MAY 28 2008

Dear Mr. Chairman:

Thank you for your letter of August 13, 2007, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, regarding the circumstances surrounding an April 2004 Food and Drug Administration (FDA) Warning Letter to Cordis Corporation concerning their CYPHER™ Sirolimus-eluting Coronary Stent. Enclosed are four boxes of documents which consist primarily of e-mail communications. This is our fourth and final response to your request. Partial responses were sent on September 25, 2007, November 27, 2007, and January 24, 2008.

The enclosures 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), and 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.

Thank you again for your interest in this matter. If we can be of further assistance, please let us know. A similar letter has been sent to Chairman Stupak, without enclosures.

Sincerely,

A handwritten signature in cursive script, appearing to read "Stephen R. Mason".

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures