DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 25 2007

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D. C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of August 13, 2007, co-signed by Bart T. Stupak, Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, regarding the circumstances surrounding a Food and Drug Administration (FDA or the Agency) warning letter to Cordis Corporation regarding their CYPHER Sirolimus-Eluting Coronary Stent in April 2004. We are enclosing a partial response to your request that includes two Establishment Inspection Reports (EIR). As discussed with Committee staff, some of the EIR pages are not included with this transmittal. We will send these pages to the Committee as soon as they are available. Additional material is being compiled and will be sent as soon as possible.

Information 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), 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

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures