DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 16, 2007

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

Dear Chairman Dingell:

Thank you for your letter dated August 13, 2007, cosigned by Chairman Stupak regarding the investigation of the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with products regulated under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. In your letter, which I received on August 13, you requested all records relating to the circumstances surrounding an FDA warning letter to Cordis Corporation regarding their CYPHER Sirolimus-Eluting Coronary Stent in April 2004.

In order to respond to your request in a timely manner, I have asked my staff in the Office of Legislation to immediately begin coordinating the timely collation of information from the relevant components of our Agency. Some of the information you requested may take additional time to produce. Please be assured it is my intention to respond at the soonest possible time. The Office of Legislation will schedule the interview and keep your staff apprised of the status of our response to your request. A similar letter will be sent to Chairman Stupak.

I appreciate your interest in this issue. If you have any questions, please contact our Office of Legislation at 301- 827-3793.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs