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 06 2008

Dear Mr. Chairman:

Thank you for the letter of November 26, 2007, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, requesting specific information and documents related to Trasylol, a drug used to control bleeding during heart surgery. This is a partial response to your request.

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) and Food and Drug Administration (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.

Enclosed are documents responsive to your questions reprinted below:

> **1) Any and all records reflecting communications between FDA and Bayer relating to the decision by the BART [Blood conservation using antifibrinolytics: A randomized trial on a cardiac surgery population] safety-monitoring board to stop enrolling patients into the Bart Study;**

Responsive documents are located at tab A.

> **2) Any and all records reflecting communications between FDA and Health Canada relating to the decision by the BART safety-monitoring board to stop enrolling patients into the BART study;**

Responsive documents are located at tab B.

3) Any and all records reflecting communications between FDA and the German drug regulatory-the Federal Institute for Drugs and Medical Devices—relating to the decision by the BART safety–monitoring board to stop enrolling patients into the BART study.

Responsive documents are located at tab C.

In addition, you asked when FDA will complete a revised analysis of the BART study data. The BART study investigators are Canadian physicians and are unaffiliated with Bayer. Bayer, as well as FDA, must await release of the study data by the BART study investigators. The release of these data is at the discretion of the BART study investigators and the investigators have not provided a specific timeline for disclosure of their data. A conversation with the principal investigator of the BART study indicated that data analyses by the BART study investigators will take many weeks. FDA has requested that the BART study investigators release their data as soon as possible. FDA anticipates completing its review of the BART study data within weeks following receipt of the data. We will be happy to schedule a briefing with your staff following our review.

We will continue to work with Committee staff on this document request and may provide additional responsive materials if they are identified.

Thank you again for your interest in this matter. If you have any further questions, 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