



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

MAR 25 2008

Dear Mr. Chairman:

Thank you for the letter of November 26, 2007, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, requesting information and documents related to Trasylol, a drug used to control bleeding during heart surgery. We provided a partial response on February 6, 2008. This is our final response.

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), and Food and Drug Administration (FDA) regulations. Further, information contained in these enclosures includes information that was received from a Canadian government counterpart, Health Canada, with whom FDA has a confidentiality arrangement to not further disclose the information. 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 restated your request in bold, followed by our response:

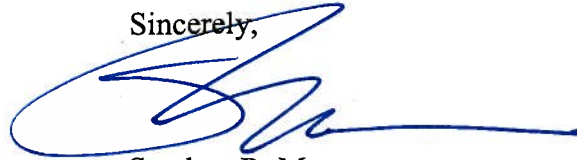
**2) Any and all records reflecting communications between FDA and Health Canada relating to the decision by the BART safety-monitoring board to stop enrolling patients into the BART study;**

Responsive documents are enclosed.

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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

cc: The Honorable Joe Barton, Ranking Member  
Committee on Energy and Commerce  
The Honorable John Shimkus, Ranking Member  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce