



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

APR 17 2008

Dear Mr. Chairman:

Thank you for your letter of February 21, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, to Michael O. Leavitt, Secretary of the Department of Health and Human Services, requesting records relating to the Food and Drug Administration's (FDA or the Agency) preapproval inspection policy for drugs. This is a partial response.

You requested that FDA explain to the Committee its interpretation of the legal status of drugs shipped into the United States commerce by a drug company that knew or should have known that FDA had not performed a preapproval inspection. A drug that is the subject of an FDA-approved new drug application may legally be shipped into the United States unless it appears to be otherwise in violation of U.S. law (e.g., adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act). While FDA is making no statements about what any particular drug company knew or should have known in relation to the heparin matter, the fact that a sponsor knew or should have known that FDA had not performed a preapproval inspection would not by itself render the product in violation of law.

I am enclosing approximately one and one-half inches of documents responsive to your request. Information contained in these 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 (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), and FDA regulations. The Committee should not publish or otherwise make public any such information. FDA would be glad to discuss with the Committee staff the protected status of any specific information.

I am committed to working with you and the Committee staff to respond to your questions and requests for records. Thank you for your interest in this matter. A similar letter has been sent to Chairman Stupak without enclosures.

Sincerely,

A handwritten signature in cursive script, reading "Andrew C. von Eschenbach".

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

Enclosures

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**cc: The Honorable Joe Barton, Ranking Member  
Committee on Energy and Commerce**

**The Honorable John Shimkus, Ranking Member  
Subcommittee on Oversight and Investigations**