



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

MAY 15 2008

Dear Mr. Chairman:

Thank you for your letter of February 21, 2008, 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) pre-approval inspection policy for drugs. We provided a partial response on April 17, 2008. This is a further partial response.

Information contained in the enclosures may include information that is protected from disclosure to the public under the Freedom of Information Act (Title 5, *United States Code* 552) 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.

We are enclosing the following documents responsive to your request.

Tab A: Contains Center for Drug Evaluation and Research Standard Operating Procedures for facility reviews, import alerts, international compliance team, issuing warning and untitled letters to foreign facilities, and for maintaining foreign inspection files.

Tab B: Contains Section 5.5.1 of the 2008 Investigations Operations Manual that addresses drug inspections.

Tab C: Contains the Office of Regulatory Affairs (ORA) Field Management Directive No. 86 that addresses inspection reports.

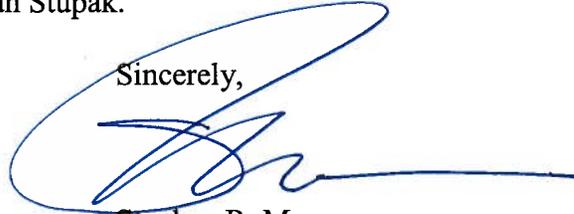
Tab D: Contains ORA Field Bulletin #2 and #4 that addresses pre-approval inspections.

Tab E: Contains two ORA PowerPoint presentations on pre-approval inspections.

Tab F: Contains an ORA pre-approval inspection training manual.

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

Sincerely,

A handwritten signature in blue ink, appearing to read "Stephen R. Mason", with a long horizontal flourish extending to the right.

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