



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

JAN 28 2008

Dear Mr. Chairman:

Thank you for the letter of November 21, 2007, regarding protecting human subjects in biomedical research. Your letter requests data on inspections of Institutional Review Boards by the Food and Drug Administration (FDA or the Agency).

Please be advised that these documents contain trade secret, commercial confidential or other information protected from public disclosure under the Freedom of Information Act (Title 5, *United States Code* [U.S.C.], §552), the Trade Secrets Act (Title 18, U.S.C., §1905), and/or FDA regulations. The Committee should not publish or otherwise make public such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

We have repeated your question in bold, followed by FDA's response.

- 1. All Inspectional Observations Reports (FDA-483), Establishment Inspection Reports (EIRs), from both surveillance and directed inspections, for Western Institutional Review Board and Chesapeake Research Review, Inc.**

Enclosed at Tab A is a partial response to your request.

- 2. All communications between FDA and Western Institutional Review Board, and between FDA and Chesapeake Research Review, Inc.**

Enclosed at Tab B is a partial response to your request.

- 3. Final Center determinations made for each EIR noted above (i.e., No Action Indicated, Voluntary Action Indicated, or Official Action Indicated).**

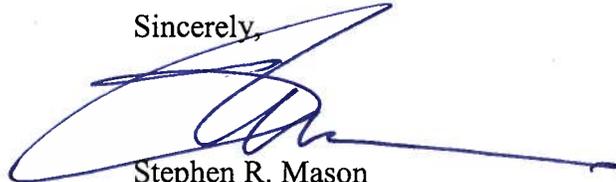
Enclosed at Tab B is a partial response to your request.

4. All warning letters that resulted from the above mentioned inspection reports.

Enclosed at Tab B is a partial response to your request.

Thank you again for your interest in FDA matters. We will provide additional records as soon as possible.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

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

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield
House of Representatives
Washington, D.C. 20515-1701