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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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September 19, 2008

The Honorable Condoleezza Rice
Secretary
Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Dear Madame Secretary:

Under rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been conducting a broad investigation into the ability and willingness of the Food and Drug Administration (FDA) to enforce laws protecting the public from unsafe food and drugs. Our investigation involving drugs manufactured by Ranbaxy Laboratories Limited has led us to expand this inquiry to include the safety and effectiveness of drugs supplied to African and other developing countries for the treatment of acquired immune deficiency syndrome (AIDS) that are produced pursuant to "expedited review" by FDA and paid for from the U.S. Treasury under the President's Emergency Plan for AIDS Relief (PEPFAR).

Serious questions have been raised by a Motion filed July 3, 2008, in the U.S. District Court for the District of Maryland, as well as other sources, regarding the safety and efficacy of four AIDS drugs manufactured by Ranbaxy. Lamivudine, zidovudine, nevirapine, and efavirenz were supplied to developing nations under the PEPFAR program according to FDA's Web site and a May 2008 report to Congress by the Global AIDS Coordinator.

As we move forward with FDA reform legislation, the Committee would like to understand what information your Department, and specifically the PEPFAR program, had regarding these drugs of concern. Therefore, we ask that you provide all records relating to the following items within <u>two weeks of the date of this letter</u>:

1. All communications from recipient nations or other sources that question the efficacy or safety of the Ranbaxy drugs supplied to the PEPFAR program;

2. A list of all non-government organizations that have received the Ranbaxy drugs for distribution under the PEPFAR or any related program;

3. All communications with the Department of Health and Human Services or FDA relating to the safety and efficacy of the Ranbaxy Drugs;

4. All communications with the White House relating to the safety and efficacy of the Ranbaxy drugs; and

5. All information regarding substantive safety and health concerns with any PEPFAR drug.

For the purposes of these requests, "Ranbaxy drugs" refer to lamivudine, zidovudine, nevirapine, efavirenz, any of these drugs in combinations or cocktails with each other, or other drugs that Ranbaxy Laboratories Limited, or any of it subsidiaries, has provided or requested authorization to provide to the PEPFAR program. The terms "records" and "relating" are defined in the attachment to this letter. Should you have any questions regarding these requests, please contact David Nelson, Paul Jung, or Joanne Royce of the Committee Majority staff at (202) 226-2424 or Karen Christian of the Committee Minority Staff at (202) 225-3641.

Sincerely,

John D. Dingell
Chairman

Joe Barton
Ranking Member

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.