ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

July 22, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

As you are aware, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been conducting inquiries into the ability and commitment of the Food and Drug Administration to protect Americans from unsafe food and drugs. As part of the prescription drug safety investigation, we have come into possession of a Motion to Enforce Subpoenas and Points and Authorities filed in the U.S. District Court for the District of Maryland (Southern Division) on July 3, 2008, by the U.S. Attorney for the District of Maryland. The motion involving drugs sold in this country by Ranbaxy, Inc. reads in relevant part:

> Allegations from reliable sources and supporting documents indicate a pattern of systematic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out of specification ("OSS"), and attempts to conceal violations of current Good Manufacturing Practices (cGMPs) regulations from FDA. Specific allegations under investigation include fabricating bioequivalence and stability data to support Abbreviated New Drug Applications ("ANDAs" filed with FDA for generic drugs....

Further, the motion indicates that the Agency was aware of this alleged "pattern of systematic fraudulent conduct" for at least 18 months, yet did nothing to remove the suspect products from the market, or even notify the pharmacists in this country that Ranbaxy may have been distributing products that may have been obtained using fraudulent bioequivalence data and/or manufactured in a manner seriously out of compliance with current Good Manufacturing Practices (cGMPs).

If true, these statements would call into serious question whether the leadership of the Agency, including your office, the Center for Drug Evaluation and Research, and the Office of Regulatory Affairs, have met even the minimum requirements of due diligence with respect to the FDA's primary mission under the Federal Food Drug and Cosmetic Act.

When your predecessors found fraud in generic drug applications, they acted swiftly to remove suspect products from the market. During the so-called generic drug scandal, companies were forced to remove all products from the market and surrender their abbreviated new drug applications whenever they could not prove that the approvals had been lawfully obtained. Although it is not a consideration that should ever interfere with the Agency's primary purpose to protect the public health, we note that no one escaped criminal prosecution because the FDA acted first to protect the public health. In fact, numerous individuals and companies pled or were ultimately found guilty in prosecutions conducted by the same Office of the U.S. Attorney that made the July 3rd Motion.

Unfortunately, the FDA's alleged lack of action to remove these suspect products from the market requires this Committee to review the pre-market approval inspections of all currently marketed Ranbaxy drugs, as well as any "for cause" inspections, to determine if FDA has expended the resources required to justify leaving these suspect drugs on the market. Therefore, we request, for each drug that Ranbaxy has approval to market in the United States:

1. All documents that that convey preapproval inspection assignments;

2. All documents that describe the tasks undertaken and all findings by the investigators during the preapproval inspections, including but not limited to any 483s or Establishment Inspection Reports (EIRS);

3. All documents relating to any "for cause" inspection of Ranbaxy or its active pharmaceutical ingredient (API) suppliers;

4. A list of all API suppliers and any 483s, EIRs, and other documents that describe the tasks undertaken and the findings resulting from inspections of those suppliers;

5. A list of all laboratories performing bioequivalence studies, noting which Ranbaxy drug substances were tested, when they were tested, and the test results;

6. Any 483, EIR, or comparable document that would describe inspections (if any) of the laboratories that performed bioequivalence testing for Ranbaxy; and

7. A list of FDA personnel that conducted and/or reviewed each inspection listed above.

At this time the Committee does not expect you to discuss any ongoing criminal investigations. Therefore, for the purpose of complying with this request, you may remove any Official Action Indicated (OAI) designation from any relevant 483 or EIR. No other redactions, however, are acceptable.

Further, we ask that you inform each of the investigators that performed the inspections or reviews of inspections listed above that the Committee staff may seek to interview each of them in our offices before the end of August. Please provide all requested documents no later than two weeks after the date of this letter.

To arrange for a rolling production of these documents or to answer any questions relating to these requests, please contact David Nelson, Joanne Royce, or Paul Jung with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

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

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