ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

October 30, 2007

The Honorable Kenneth M. Donohue, Sr.
Inspector General
U.S. Department of Housing and Urban Development
451 7th Street, S.W.
Washington, D.C. 20410

Dear Inspector General Donohue:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the Food and Drug Administration's (FDA's) management of drug safety issues. As part of this investigation, on February 16, 2007, the Subcommittee sent the Health and Human Services Secretary, Michael O. Leavitt, a letter requesting production of documents pertaining to the pre-market review and post-market surveillance of the antibiotic telithromycin (Ketek).

A number of the documents produced by FDA, as well as information from third party sources, led us to believe that FDA may have been involved in misconduct in connection with the large safety trial of Ketek, Study 3014. At least one individual clinical investigator, Dr. Anne Kirkman-Campbell, has been convicted of fraud. Other clinical investigators were also suspected of serious misconduct. The Committee has opened investigations into the FDA decision-making process with respect to the approval of Ketek, as well as the conduct of the Independent Review Board (Copernicus), the Contract Research Organization (PPD), and the sponsor itself, Sanofi-Aventis.

The evidence of wrongdoing prompted a recent letter to Secretary Leavitt requesting that arrangements be made for Committee staff to interview FDA Special Agents who participated in FDA's investigation of fraud in Ketek safety trials. One of those Special Agents, Mr. Ekey, currently works in your department.

Consequently, we respectfully request that you instruct your staff to arrange for Committee staff to interview Mr. Ekey. Congress has the authority to obtain deliberative process memoranda as well as the testimony of line attorneys, agents, and other subordinate agency employees regarding the conduct of open or closed cases in the course of investigations of agency wrongdoing.

We appreciate your cooperation in our efforts to investigate allegations and evidence of misconduct at FDA. Please arrange, by close of business within two weeks from the date of this letter, for a convenient time to make Mr. Ekey available to Committee staff. To make arrangements, please have your staff contact David Nelson or Joanne Royce with Committee staff at (202) 226-2424. If further information is needed, please contact us or have your staff contact John Sopko, Chief Counsel for Oversight, 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 Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations