ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

November 26, 2007

The Honorable David M. Walker
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

The Food and Drug Administration (FDA) plays a critical role in the health and well-being of Americans by establishing standards that govern the safety and effectiveness of medical products, including pharmaceutical products and medical devices. FDA's responsibility is not limited to overseeing domestic manufacturers, but also extends to foreign establishments whose products are imported for the U.S. market. It is evident that our Nation is receiving increasing numbers of imported goods of all kinds, with pharmaceutical products and medical devices no exception. Given the increasingly global nature of the world's economy, it is vital that FDA's efforts to ensure the safety of such imported products keep pace with these changes.

Earlier this month the Government Accountability Office (GAO) testified before this Committee on FDA's program for inspecting foreign drug manufacturers and provided us with valuable information on FDA's management of this program. That testimony, along with the Committee's own investigation, found a number of significant weaknesses in FDA's system of regulating foreign drug manufacturers, which could significantly affect public health. The following key findings were revealed at that hearing: FDA databases and IT systems used to track foreign manufacturers and schedule inspections are antiquated and seriously inadequate for regulating foreign producers; FDA does not inspect foreign manufacturers with sufficient regularity; and the agency's resources for this program are insufficient given the number of foreign producers now making drug ingredients and products for the U.S. market.

In addition to testimony related to this investigation, GAO issued in January 2007 a related report to the Committee regarding FDA's relatively new program for granting accreditation to "third-party" organizations to conduct inspections of medical device

manufacturers, in lieu of FDA inspectors. Using third-party inspections is one proposal the current Administration has offered as a potential means of addressing the many resource shortcomings that currently affect FDA's foreign drug inspection program. We are interested in learning more about the use of accredited organizations to inspect medical device manufacturers, particularly in foreign countries.

Specifically, we would ask GAO to provide the Committee with the following:

1. Update information contained in your January 2007 report on accredited organizations including providing current data on the number of organizations accredited to conduct inspections of medical device manufacturers and the number of inspections (domestic and foreign) that have been conducted by these organizations;

2. Provide a discussion of the advantages and disadvantages of third-party inspections in the areas of drug and device inspections, including issues relating to cost and the potential conflicts of interest that may arise through such configurations;

3. Provide information on inspections of foreign medical device manufacturers conducted by FDA staff, similar to data it provided in testimony earlier this month on FDA's inspections of foreign drug manufacturers. For example, we are interested in learning how many foreign manufacturers are registered to import medical devices into the United States, how many are currently importing such devices, FDA's criteria for selecting foreign medical device manufacturers for inspection, and how often such inspections are conducted;

4. Assess whether the same database and IT problems uncovered in our recent investigation into FDA's foreign drug manufacturing inspection program also plague the agency's ability to track foreign device manufacturers and prioritize inspections of those facilities; and

5. Conduct an analysis to determine if the foreign medical device program has adequate resources commensurate to the growing number of manufacturers that now reside abroad.

The Committee intends to hold a hearing on this topic in late January or early February 2008 and would like to include GAO testimony on this important issue. We therefore request you initiate this work as soon as possible.

Thank you for your continued efforts on this important public health issue and the previous work already conducted for the Committee. For further information, please contact Mr. Christopher Knauer of the Committee 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 Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations