ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

August 1, 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:

Americans depend on the Food and Drug Administration (FDA) to ensure the safety of our pharmaceutical drug supply. FDA enforces standards that govern the safety, effectiveness, and manufacture of pharmaceutical products, including those that are imported into the United States.

China and India have increasingly become major suppliers of both drugs and drug ingredients that reach American consumers. It is estimated that as much as 20 percent of generic and over-the-counter drugs and 40 percent of active ingredients for pills manufactured in the U.S. come from China and India. The U.S. Department of Commerce reported that China and India sold $675 and $800 million worth of drugs and drug ingredients, respectively, in the United States in 2006. In the next 15 years, analysts expect that up to 80 percent of the key ingredients used in drugs will come from these two countries.

Yet, FDA's inspections of facilities—a cornerstone of ensuring safety—in these countries have not kept pace with this emerging trend. FDA, however, conducted fewer than 50 inspections between the 2 countries in 2006. The recent detection of tainted food products from China, including toothpaste, pet food, and farmed fish, has caused FDA to ban these products to protect our citizens. In addition, a Chinese company has been cited as the source of medicine contaminated with diethylene glycol, a chemical commonly found in antifreeze, which was exported to Panama and is associated with at least 94 deaths there. In 1999, an FDA investigation linked severe reactions in 155 patients in the United States to problems in a bulk ingredient provided by a Chinese supplier. During the 1990s, at least 66 adverse event reports involving deaths and gentamicin were filed with the FDA.

In 1998, GAO reported that FDA needed to improve its foreign drug inspection program and recommended, among other things, that FDA conduct more frequent inspections of foreign manufacturers that have been identified as having serious manufacturing deficiencies. Given our increasing reliance on imported drugs, we request that you follow up on this vitally important topic.

Although, ultimately, we anticipate your review to encompass global FDA inspection operations, initially, we would appreciate it if you concentrated your efforts on exports from China and India. Specifically, we would like GAO to review how FDA oversees the safety of imported drugs and drug ingredients. For example, we are interested in learning how many foreign manufacturers are registered to import drugs and drug ingredients into the United States, how often inspections are conducted, whether FDA's data collection and tracking systems are adequate to support foreign inspection decision-making, and the level of resources FDA devotes to inspection-related activities. Please also examine how FDA identifies high-risk foreign products and whether risk-based criteria are used to select facilities for inspection In addition, we would like you to obtain information on FDA's efforts to ensure that identified deficiencies are corrected by foreign facilities, including whether appropriate enforcement actions are taken in a timely manner.

We would appreciate your undertaking this effort at your earliest convenience. If you or your staff have any questions, please do not hesitate to contact Chris Knauer, Paul Jung, or Joanne Royce with the Majority Committee staff at (202) 226-2424 or Peter Spencer with the Minority Committee staff at (202) 225-3641.

Sincerely,

John D. Dingell
Chairman

Joe Barton
Ranking Member

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations