

GAO Critical of FDA Foreign Drug Oversight

By Lisa Richwine April 21, 2008

WASHINGTON, April 21 (Reuters) - U.S. authorities increased inspections of foreign drug plants last year but still checked only a fraction of sites that supply medicine ingredients to the U.S. market, a government watchdog is set to tell Congress on Tuesday.

Concern about Food and Drug Administration oversight of foreign drug manufacturers has risen since the finding of a contaminant in some batches of blood-thinner heparin that were made with raw ingredients from China.

The Government Accountability Office will testify that the FDA increased inspections of foreign manufacturing sites to about 11 percent last year and took other steps in recent months, but made limited progress overall.

"FDA's plans represent a step forward in filling the large gaps in FDA's foreign drug inspection program, but do little to accomplish short-term change," said Marcia Crosse, health care director for the GAO, the investigative arm of Congress.

A copy of Crosse's testimony was provided to Reuters.

The FDA said on Monday it had determined the contaminant in heparin could trigger the types of sometimes-fatal allergic reactions reported in some patients treated with Baxter International Inc's (BAX.N: [Quote](#), [Profile](#), [Research](#)) brand of the product.

A House of Representatives subcommittee is set to question FDA Commissioner Andrew von Eschenbach about foreign drug inspections at a hearing on Tuesday where the GAO's Crosse and others also will appear.

FDA spokeswoman Julie Zawisza said officials "look forward to speaking with the committee about the challenges of globalization and potential solutions." The agency had no comment on the GAO testimony, she said.

More than 80 percent of active ingredients in U.S. drugs come from abroad, with more than half from India and China, lawmakers have said.

The GAO told Congress in 1998, and in November 2007, that the FDA was inspecting few foreign drugmakers.

The latest review found the agency checked 11 percent of more than 3,200 foreign ingredient makers registered with the FDA in fiscal 2007, which ended in September. Nineteen of more than 700 sites in China were among those inspections.

"FDA has made progress in conducting more foreign inspections, but it still inspects relatively few establishments," Crosse said.

The GAO estimated it would cost between \$67 million and \$71 million to inspect all 3,200 foreign sites every two years. The FDA has proposed spending about \$11 million on foreign inspections in fiscal 2008, the GAO said.

"FDA will need to devote considerable resources to this area if it is to increase the rate of inspections. However, FDA's plans currently call for incremental increases that will have little impact in the near future," Crosse said.

Congress is considering legislation meant to strengthen the FDA's oversight and increase funding for inspections.

"It's clear that FDA does not have the ability to protect the American people from unsafe food and drugs," House Energy and Commerce Committee Chairman John Dingell, a Michigan Democrat, said in a statement issued on Monday.