washingtonpost.com

FDA's Foreign Inspection Budget Lean

By Marc Kaufman
Washington Post Staff Writer
Thursday, November 1, 2007; A02

Although the volume of prescription drugs and drug ingredients coming into the country from foreign manufacturers in developing nations such as India and China has exploded in recent years, the Food and Drug Administration's budget for foreign inspections has not kept pace and will be lower in 2008 than it was in 2002, according to congressional investigators.

As a result, foreign drug and drug ingredient makers are inspected on average once every eight to 12 years, while American-based manufacturers must be inspected at least once every two years.

In addition, the investigators reported, FDA officials generally do not bring their own translators, and so in countries such as China they rely on company-supplied translators to conduct inspections. They also have to tell foreign manufacturers in advance that they are coming, while FDA inspectors can go into American plants at any time unannounced.

"Given the high level of foreign imports, this lack of oversight puts American consumers at considerable risk," said Rep. John D. Dingell (D-Mich.), chairman of the House Energy and Commerce Committee, which has scheduled a hearing for today on the subject.

"China alone has more than 700 firms making drug products for the U.S., yet the FDA has resources to conduct only about 20 inspections a year in China," he said. "This is dangerously inadequate."

A bipartisan group of inspectors from the committee's oversight and investigations subcommittee accompanied FDA inspectors on an August trip to India and China -- two nations that have become major players in supplying the U.S. drug market. Neither country has a strong drug regulatory agency, and the committee inspectors concluded that setting up permanent FDA offices could solve many inspection problems. They reported that Indian officials supported the idea, while the Chinese officials' position was unclear.

According to the committee investigators, the FDA spent $16.7 million on foreign inspections in 2002 and will have an estimated $16 million for 2008. FDA officials told the investigators that this occurred although the volume of FDA-regulated imports doubles every five years -- and that this is especially true for drugs and ingredients manufactured in India and China.

The FDA has generally defended its oversight of foreign drug manufacturers, saying that it inspects plants when troubles become known. By law, foreign drugmakers must be inspected before their products can come into the United States, but there are no requirements to have continuing quality inspections every two years, as there is for firms manufacturing in the United States.

FDA Commissioner Andrew von Eschenbach is scheduled to testify on the subject today, along with critics and defenders of current foreign drug inspection policies.

According to the committee report, the FDA database of foreign companies that supply U.S. markets is limited -- with some senior FDA officials reporting numbers as low as 2,100 companies and others saying there are 4,400. The Government Accountability Office reports that while 3,000 companies are registered to import drugs into the United States, nearly 7,000 foreign companies actually supplied the U.S. market in 2007.