

FDA mixed up drug plant names

Confusion prevented China factory inspection

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The Chinese factory involved in the production of possibly tainted blood-thinning drugs for export to America was not inspected by the U.S. Food and Drug Administration because of a paperwork error in which Washington regulators confused the factory's name with another that already had U.S. approval, the FDA said Monday.

The FDA's explanation, by Joseph Famulare, deputy director of compliance for the FDA's center for drug evaluation and research, comes amid questions about the safety of different types of goods made in China and the adequacy of the FDA's inspection procedures for drugs entering the U.S. from China.

More than 300 people have reported potentially deadly allergic reactions after taking the blood-thinning drug heparin, which includes a key active ingredient produced in China for Deerfield-based Baxter International Inc. by Scientific Protein Laboratories of Waunakee, Wis.

While the cause of the allergic reactions remains unknown, the FDA said it plans to visit the Chinese plant this week as part of an investigation that the agency on Monday deemed "one of its top priorities."

Famulare portrayed the failure to inspect the Chinese plant as a record-keeping glitch and thus an "isolated incident." But the FDA acknowledged that there is no law requiring that every foreign plant producing pharmaceuticals for the U.S. be inspected.

In China's case the FDA has said the Beijing government does not inspect plants producing solely for export, and the U.S. and China are still working out the details of a new agreement in which they will cooperate more to regulate factories.

The FDA said it "generally" inspects foreign plants as a matter of policy before they begin producing active pharmaceutical ingredients, but the agency "is not specifically required by law to inspect a foreign drug manufacturing facility," FDA spokeswoman Karen Riley said in an e-mailed statement to the Tribune.

The plants are inspected after providing the FDA with necessary documentation indicating that the company has abided by "good manufacturing practices." The FDA didn't specify the frequency of foreign inspections but made clear that they are not routine. When a change in ownership occurs, for example, it is possible that documentation can take the place of another on-site visit.

In the U.S., inspections typically occur when a new product is being approved or production is moving to a new facility.

The FDA said it inspected 250 foreign pharmaceutical ingredient manufacturers last year, 13 of which were in China. There is no firm number available for how many plants ship pharmaceutical ingredients and finished drugs into the U.S., but industry groups and analysts put the number for China alone at

several hundred.

Over the last five years China has experienced an explosion in the production of active pharmaceutical ingredients, the raw materials that make drugs effective in treating disease, with many new companies coming on line.

Senate investigators have found that from 2002 to 2007 the FDA conducted 75 inspections in China. The top three countries on the list for that period were India, with 193 inspections, Germany with 135 and Italy with 122.

Some critics of the FDA question whether the agency truly knows whether all Chinese plants have been inspected.

"I don't think the FDA is intentionally lying," said Dr. Sidney Wolfe, head of Public Citizen's Health Research Group. "On the other hand, I don't think they know enough about the full extent of ingredient-makers and how many there are to really say that it is isolated." In the heparin case the production plant owned in a joint venture by Scientific Protein in Changzhou, China, has been shipping bulk heparin to Baxter for three years.

At the time shipments began, Famulare said, someone at the FDA may have misread the name on an application to begin shipments and thought that the facility previously had been inspected by the FDA.

"The wrong firm was put into the database," Famulare said. The production plant actually making the shipments, Changzhou SPL, co-owned with SPL by Changzhou Techpool Pharmaceutical Co. Ltd., "was not put in for inspection," Famulare said.

The name that Baxter supplied to the FDA in its paperwork to allow for the production of this active ingredient is "Changzhou SPL facility," company spokeswoman Erin Gardiner said. The FDA would not disclose the facility or company with a similar sounding name.

During this week's planned inspection, the FDA said, a Chinese-speaking chemist familiar with heparin will participate. Heparin, which is used before kidney dialysis and heart surgeries, among other uses, is derived from an enzyme found in pig intestines.

Michael Rogers, director of the FDA's division of field investigations, said the inspection in China was one of several taking place related to heparin. SPL's Wisconsin plant and a Baxter-owned plant in Cherry Hill, N.J., also will be visited.

Another heparin-maker trying to increase production in the wake of Baxter's problems is Schaumburg-based APP Inc., which also gets the active pharmaceutical ingredient to make its blood thinner from a Chinese supplier. The FDA said APP's Chinese supplier has been inspected.