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FDA sends in federal marshals to seize tainted heparin

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By Elizabeth Weise, USA TODAY

Frustrated after twice asking a Cincinnati-based manufacturer of medical products to recall contaminated heparin, the Food and Drug Administration took the rare step Thursday of sending U.S. marshals to seize 11 lots of the blood-thinning drug.

The company, Celsus Laboratories, distributes heparin to drug and medical-device manufacturers both in the United States and internationally.

FDA testing in January found that large amounts of Chinese raw heparin imported into the United States were contaminated with the chemical oversulfated chondroitin sulfate. The FDA believes the substance was added to allow the product to pass tests that measure heparin levels.

A major heparin recall ensued. Almost 250 deaths and hundreds of severe allergic reactions were blamed on tainted batches of the blood thinner, which is frequently given to patients having heart surgery and kidney dialysis.

The two Celsus products were heparin sodium and heparin lithium. The sodium form is given directly to patients as a blood thinner. Just over 2 pounds of it was seized.

Heparin lithium is used to coat medical devices, such as blood-collection tubes, to keep blood from clotting on them. About 31 pounds of that was seized.

The seized heparin was worth about \$112,000. That represented only a portion of the full 11 lots, which had already been shipped to other manufacturers.

But because the FDA had warned those companies earlier, the drug was never used and no patients were put at risk, agency spokeswoman Karen Riley says.

The FDA says it inspected Celsus Laboratories in April and found that two of its heparin products were contaminated.

The company had sent a letter to its customers telling them its heparin was contaminated, but FDA wanted the company to physically recall the product because of the danger it presented to patients.

FDA sent a follow-up letter to the company again asking for a recall on May 8.

What the federal marshals did Thursday was to seize the contaminated heparin that remained at the company's facilities, Riley says.

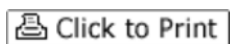
Celsus imported the raw heparin from Changzhou SPL, Riley says.

FDA said in a release that it has also advised manufacturers who might have bought heparin from the company to contact the agency to make sure they don't have any of the contaminated heparin. "The product does not meet acceptable quality standards," the agency said.

In addition, the agency has also notified Japan, Canada, Australia, the European Union and other countries to be on the watch for shipments of contaminated heparin from Celsus.

Find this article at:

http://www.usatoday.com/news/health/2008-11-06-heparin-contaminated_N.htm?csp=34



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FDA seizes contaminated heparin

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WASHINGTON, Nov. 6 (UPI) -- The U.S. Food and Drug Administration announced the Thursday seizure of 11 lots of contaminated heparin from Celsus Laboratories Inc. in Cincinnati.

Officials said the five lots of Heparin Sodium Active Pharmaceutical Ingredient and six lots of Heparin Lithium were seized at the FDA's request by U.S. Marshals.

"These products, which were manufactured from material imported from China, had been found by the agency to be contaminated with over-sulfated chondroitin sulfate, a substance that mimics heparin's anticoagulant activity. This action will help prevent this contaminated heparin from finding its way into the marketplace," said Mike Chappell, the federal agency's acting associate commissioner for regulatory affairs.

The FDA said Celsus has distributed Heparin Sodium and Heparin Lithium to manufacturers in both the United States and abroad. The federal agency said it has notified Australian, Canadian, European Union, Japanese and other international authorities of shipments of contaminated heparin from Celsus.