

## News & Events

### FDA NEWS RELEASE

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### **U.S. Marshals Seize Drug Products Manufactured by Caraco Pharmaceutical Laboratories Ltd.**

#### ***FDA acts to prevent repeated drug quality problems***

U.S. Marshals, at the request of the Food and Drug Administration, today seized drug products manufactured by Caraco Pharmaceutical Laboratories Ltd. (Caraco), at the company's Michigan facilities in Detroit, Farmington Hills, and Wixom. The seizure also includes ingredients held at these same facilities. "The FDA is committed to taking enforcement action against firms that do not manufacture drugs in accordance with our good manufacturing practice requirements," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "Compliance with these standards prevents harm to the public."

This action follows Caraco's continued failure to meet the FDA's current Good Manufacturing Practice (cGMP) requirements, which assure the quality of manufactured drugs. Through this seizure, the FDA seeks to immediately stop the firm from further distributing drugs until there is assurance that the firm complies with good manufacturing requirements.

Since January 2009, Caraco has initiated voluntary recalls of drug products to protect the public from potentially defective medications. The recalls involved manufacturing defects, including oversized tablets and possible formulation error.

The FDA has determined that the seizure of Caraco's drugs may create a shortage of one product, choline magnesium trisalicylate oral tablets, which are commonly used as pain relievers. The FDA recommends in the event of a shortage, that health care providers consider alternative treatments that are safe and effective. Consumers and health care providers who are unable to obtain any of Caraco's products should contact the FDA Drug Shortage Program by e-mail at [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov), or by telephone at 888-463-6332 or 301-796-3400.

The FDA's most recent inspection of Caraco, completed in May 2009, found unresolved violations of cGMP requirements. Today's seizure is intended to lead to major changes at Caraco's facilities.

If the FDA identifies further significant problems, which pose risks to patient safety with any Caraco drug products on the market, the agency will take appropriate additional

regulatory action and immediately notify the public.

"The FDA will continue to take swift, aggressive enforcement action when firms are identified as being in violation of our manufacturing requirements," said Michael Chappell, FDA acting associate commissioner for regulatory affairs.

Seizure of drug products is an effective remedy when there is evidence of continued poor compliance with cGMPs. Following a drug product seizure, companies often agree to a wide range of changes and improvements to their drug manufacturing practices at their facilities.

To view Questions and Answers on Caraco Drugs, Including a List of Effected Drugs:  
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm169095.htm>

To view Facts About Current Good Manufacturing Practices:  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm>

To view the October 31, 2008 FDA Warning Letter to Caraco Pharmaceutical Laboratories, Ltd:  
<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048080.htm>

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June 27, 2009

## FDA confiscates 33 drugs from Caraco

Raw ingredients also removed from 3 sites

*BY PATRICIA ANSTETT  
FREE PRESS MEDICAL WRITER*

The U.S. Food and Drug Administration has confiscated 33 generic drugs and raw ingredients at three Caraco Pharmaceutical Laboratories facilities in metro Detroit.

The seizure, which involved inventory of as much as \$20 million, occurred Thursday at the company's plants in Detroit, Farmington Hills and Wixom.

Caraco, a leading generic drug manufacturer, makes medicines for diabetes, epilepsy, heart treatment, pain, psychiatric problems and muscle spasticity issues. Only one drug the company makes, choline magnesium trisalicylate oral tablets, a pain medicine, may be in short supply because no other company makes a similar generic, the FDA said.

In a news media briefing Thursday and in statements on its Web site, [www.fda.gov](http://www.fda.gov), the FDA said it is "advising consumers not to interrupt their drug therapy" if they take a Caraco drug. If the agency finds Caraco drugs pose risks, it will notify the public and take additional action against the company, the agency said. Consumers should ask a pharmacist for the name of a generic manufacturer if it is not listed on a drug's label, the FDA said.

The FDA statement said it took the action because of Caraco's continued failure to meet federal manufacturing requirements. It has warned the company several times in the last year about its manufacturing practices. Two follow-up inspections of the company's plants this year, found continued problems, including "18 observations of objectionable conditions," the FDA said.

The company's problems include poor control of its raw materials and higher than normal variability of the tablets they make, said Deborah Autor, director of the FDA's office of compliance, drug division, during the briefing Thursday. She said she could not comment on where the company obtains its raw materials for its drugs or whether the company's drugs had been linked to injuries.

Caraco CEO Daniel Movens did not return a call Friday seeking comment. The company released a brief statement saying that its profits from drugs it sells made by other companies will cover ongoing expenses.

The FDA said it hopes the company improves its manufacturing processes. "Our goal is to get Caraco up and running properly," the FDA said.

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