

Caraco Pharmaceutical to lay off 350 employees

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Crain Communications, Inc.

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Detroit-based **Caraco Pharmaceutical Laboratories** (NYSE:CPD) said today it will lay off 350 employees — more than half of its 650 workers — for an indefinite time after the **Food and Drug Administration** ordered the seizure of more than 30 generic drugs and related ingredients because of unresolved manufacturing problems.

In a statement, Caraco also said **JPMorgan Chase Bank** has frozen the company's \$10 million line of credit, which has a zero balance, until the company satisfies the FDA's concerns.

Officials for Caraco were unavailable for comment Monday morning.

After the FDA action last month, Caraco issued a statement that said profits from its other distributed products would cover its estimated expenses.

"The timing of the resumption of manufacturing operations, in whole or in part, depends on the outcome of discussions with the FDA," Caraco said. "This should have no effect on distributed product sales that we market in the U.S."

In fiscal 2009, sales of manufactured products totaled \$112 million. Distributed products, which include about 52 drugs, totaled \$225 million.

"We anticipate working with the FDA for resolution as expeditiously and effectively as possible," Caraco said.

On Monday, Caraco's stock price dropped to about \$3.03. Caraco's high-water mark was \$18.50 on March 31, 2008.

Caraco operates plants in Detroit, Farmington Hills, and Wixom.

Since January, 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 errors.

The company makes a wide variety of generic drugs, including the popular diabetes medicine, metformin and the pain reliever tramadol.

The seized drug products amounted to inventory of \$15 million to \$20 million, Caraco said.

In May, the FDA completed its last inspection that found unresolved violations of good manufacturing practices that led to the seizures.

But Caraco's quality problems go back to 2005, when the FDA began noting violations. In June 2008 the FDA notified Caraco of a variety of quality control problems with some of Caraco's drugs and processes at its Detroit manufacturing plant.