Ranbaxy recalls generic Lipitor doses

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(AP)—Ranbaxy Pharmaceuticals Inc. has recalled dozens of lots of its generic version of cholesterol drug Lipitor because some may contain tiny glass particles, the latest in a string of manufacturing deficiencies that once led U.S. regulators to bar imports of the Indian company's medicines.

Ranbaxy, a subsidiary of Ranbaxy Laboratories Ltd., India's biggest drugmaker, is operating under increased scrutiny from the U.S. Food and Drug Administration because of quality lapses at multiple Ranbaxy factories over the past several years. The FDA also has alleged the company lied about test results for more than two dozen of its generic drugs several years ago.

On Friday, Ranbaxy posted a notice on its U.S. website, saying it's recalling 10-, 20- and 40-milligram doses of tablets of atorvastatin calcium. That's generic Lipitor, the cholesterol fighter that reigned for years as the world's top-selling drug.

The recall includes 41 lots of the drug, nearly all with 90 pills per bottle, but three lots contain 500 pills per bottle. It's unclear how many bottles are in each lot, but medicine batches typically contain many thousands of pills. The 80-milligram strength tablets are not affected.

Ranbaxy spokesman Chuck Caprariello did not answer questions or provide any additional information beyond the statement on the company's website.

"Ranbaxy is proactively recalling the drug product lots out of an abundance of caution," the website statement read. "This recall is being conducted with the full knowledge of the U.S. FDA."

The company also filed a two-sentence statement with the Bombay Stock Exchange stating Ranbaxy's investigation would be completed within two weeks, but that after that temporary disruption to the U.S. supply, the company expected to resume shipments here.

Patients who've filled a prescription can contact their pharmacy to determine whether it was made by Ranbaxy or another generic drugmaker and, if it's from Ranbaxy, whether it came from a recalled lot.

Ranbaxy's manufacturing deficiencies, dating to 2006, led to a lengthy investigation and sanctions by the FDA. During the probe, federal investigators found Ranbaxy didn't properly test the shelf life and other safety factors of its drugs and then lied about the results.

In mid-2008, the FDA barred Ranbaxy from shipping into the U.S more than 30 different drugs made at factories in India. Meanwhile, the U.S. Department of Justice demanded Ranbaxy turn over internal documents, alleging the company lied about ingredients and formulations of some medications.

In early 2009, the FDA said it would not consider any new applications from Ranbaxy to sell in the U.S. any products made at the troubled factories.

As FDA discussions with Ranbaxy continued, it appeared Ranbaxy would lose its shot at a revenue windfall when Lipitor's generic U.S. patent expired last Nov. 30. At the time, Lipitor brought in almost $8 billion a year in U.S. sales.

As often happens when patents first expire, for the first six months only one generic rival could compete with brand-name Lipitor. Ranbaxy had that right, although an authorized generic from Lipitor maker Pfizer Inc. and partner Watson Pharmaceuticals Inc. went on sale on Dec. 1. With competition so limited, the generic prices only declined a bit from brand-name drug's price of about $115 a month—until several other generics entered the market six months later.

The FDA finally ended the suspense, deciding just before midnight on Nov. 30 to let Ranbaxy sell generic Lipitor made at the company's Ohm Laboratories factory in central New Jersey. It was unclear Friday whether the recalled Ranbaxy pills were made there or elsewhere.

Meanwhile, Ranbaxy is operating under a settlement with the FDA, called a consent decree, signed on Dec. 20, 2011. It requires Ranbaxy to improve manufacturing procedures, ensure data on its products is accurate and undergo extra oversight and review by an independent third party for five years. Ranbaxy at the time set aside $500 million to cover potential criminal and civil liability stemming from the Justice Department investigation.