

# FDA finds bits of steel, rubber in Genzyme drugs

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WASHINGTON – Federal health regulators have found tiny particles of trash in drugs made by Genzyme, the second time this year the biotechnology company has been cited for contamination issues.

The Food and Drug Administration said Friday that bits of steel, rubber and fiber found in vials of drugs used to treat rare enzyme disorders could cause serious adverse health effects for patients.

Despite those problems, the FDA said the products would remain on the market, because there are few alternative treatments.

FDA regulators say doctors should closely inspect vials for particles before injecting them into patients. Doctors should return the product to Genzyme if they suspect contamination, the agency said. Physicians should also watch for potential allergic reactions, blood clots and other problems in patients.

Shares of Genzyme Corp. dropped \$4.17, or 7.8 percent, to \$49 in afternoon trading.

The FDA announcement is the second case of contamination for the Cambridge, Mass.-based company this year. In June, Genzyme was forced to shut down a key production facility due to viral contamination.

Genzyme did not return repeated calls for comment Friday.

The drugs affected by the latest announcement include: Cerezyme, Fabrazyme, Myozyme, Aldurazyme and Thyrogen. All are manufactured at a biotech plant in Allston Landing, Mass., where FDA regulators are conducting an inspection.

The FDA estimates the contamination only affects about 1 percent of Genzyme's products, and no adverse events have been reported to the government.

The agency said it supports Genzyme's decision to leave the products on the market because the health risks are minor and there are few alternative treatments.

"We have worked continuously with Genzyme to ensure the continued availability of safe and effective products to meet the medical needs of patients with rare medical disorders," said Dr. Jason Woo, FDA's associate director of medical affairs.

Genzyme specializes in biotech drugs to treat rare diseases.

The company's best-selling drug Cerezyme treats Gaucher disease, an enzyme disorder that can result in liver and neurological problems. Its second-best seller Fabrazyme treats an inherited disorder known as Fabry disease, which is caused by the buildup of a particular type of fat in the body's cells.

The two drugs had combined sales of roughly \$1.7 billion last year.