

Genzyme moves drug vial filling business overseas

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(AP:CAMBRIDGE, Mass.) Genzyme Corp. said Wednesday all operations for filling vials of its key products have been moved to a facility in Waterford, Ireland, fulfilling part of a deal with the Food and Drug Administration stemming from manufacturing problems at a plant in the Boston area.

The company had already been making products at the Ireland facility and through a contract with an external manufacturer. The move, which has been ongoing, is part of a previously disclosed deal with the FDA following issues at the company's facility in the Boston neighborhood of Allston last year.

In June of 2009, the company shut down its Allston plant for about three months to clean up viral contamination that had been slowing production of the drugs Cerezyme and Fabrazyme. The virus was not harmful to people, but the shutdown was costly. Then, in November of 2009, the FDA said it found tiny particles of steel, rubber and fiber in drugs made by Genzyme. The drugs included Cerezyme, Fabrazyme, Myozyme and Thyrogen.

Genzyme's best-seller 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. Other drugs include Myozyme, which treats Pompe disease, which interferes with muscle development and Thyrogen, which is used to diagnose thyroid cancer.

In May, Genzyme agreed to pay a \$175 million penalty to federal regulators in connection with the manufacturing problems that had already cost the company millions. The payment was the return of "unlawful profits" from the sale of products made at the plant, according to the FDA.

The FDA also said the company signed a legal agreement to fix problems at the Allston biotech drug plant.

Under terms of the consent decree, Genzyme mapped out a plan for overhauling the plant.

The decree requires Genzyme to move operations for filling drug vials to a new plant by Nov. 28 for U.S.-sold products, and by Aug. 31, 2011 for those sold internationally. The company has now met the requirement for U.S. products and said it is working with international regulators to meet the additional requirements.

Since the beginning of 2010, Genzyme has restructured its manufacturing operations, naming a new president of global manufacturing and corporate operations, along with a senior vice president of global product quality. It also contracted manufacturing for some of its key products to Hospira Inc.