

FDA NEWS RELEASE

For Immediate Release: May 24, 2010

Media Inquiries: Karen Riley, 301-796-4674; karen.riley@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

Genzyme Corp. Signs Consent Decree to Correct Violations at Allston, Mass., Manufacturing Plant and Give up \$175 Million in Profits

Genzyme Corp. has signed a consent decree agreeing to correct manufacturing quality violations at its Allston, Mass., manufacturing facility and will turn over to the federal government \$175 million in unlawful profits from the sale of products that were made at the plant, the U.S. Food and Drug Administration announced today.

Under the consent decree of permanent injunction, the Cambridge, Mass.-based company agreed to adhere to a strict timetable to bring the plant in line with the regulatory requirements of the FDA.

The payment is known as a disgorgement in which a company must give up profits obtained by improper or illegal acts.

The decree was agreed to by Genzyme, its Chief Executive Officer Henri A. Termeer; its Senior Vice President for Manufacturing Sciences and Technical Operations, W. Blair Okita; and its Senior Vice President for Global Product Quality, Ronald Branning. It was filed in the U.S. District Court for the District of Massachusetts on May 24, 2010, and is subject to court approval.

Genzyme is a sole supplier of several enzyme replacement drugs for injection that are used to treat rare genetic disorders. During an inspection of the Allston plant from Oct. 8, 2009, until Nov. 13, 2009, FDA inspectors found that the company's systems for ensuring manufacturing quality were inadequate resulting in production delays, critical shortages of medically necessary products to consumers and drugs contaminated with metal, fiber, rubber and glass particles. These manufacturing problems violated the FDA's regulations for manufacturing practice. Genzyme also temporarily suspended manufacturing of some products due to a viral contamination in a bioreactor that makes bulk amounts of its drugs. This resulted in additional drug shortages.

"It is critical for the safety of the drug supply that companies comply with basic manufacturing standards. FDA takes these obligations very seriously and expects manufacturers to do the same," said Joshua Sharfstein, M.D., FDA principal deputy commissioner.

Cerezyme, Fabrazyme, Myozyme, and Thyrogen are drug products that undergo all or some stages of manufacture at the Allston plant. Cerezyme treats Gaucher's disease, which causes fatty substances to accumulate in the liver, spleen and other organs. Fabrazyme treats Fabry disease, which prevents the body from breaking down oils and

fats that build up in the eyes and the kidneys. Myozyme treats Pompe disease, a muscular disorder, and Thyrogen is used to diagnose thyroid cancer.

Genzyme has agreed to a work plan for making facility improvements. It begins with selecting, within 10 days of entry of the decree by the court, an independent expert who will inspect the plant and issue recommendations. Genzyme will use the expert's recommendations to create a work plan, subject to FDA approval, that requires specific steps for bringing its Allston plant into compliance within given dates. If Genzyme fails to complete any step specified in the work plan, the company will have to pay a substantial fine. In addition, the consent decree provides a deadline for Genzyme to transfer its operations for filling drug vials from its Allston facility to other manufacturing sites or else it will have to disgorge further profits from the sales of drugs filled at Allston after that specific date.

FDA is working with Genzyme during the company's remediation to ensure availability of the company's medically necessary drugs.