



**Genzyme Corporation**

500 Kendall Street  
Cambridge, MA 02142  
Tel 617-252-7500

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To the Gaucher community,

We are writing to update you on progress we have made in restoring and improving manufacturing operations at our facility in Allston, Massachusetts, where we produce Cerezyme<sup>®</sup> (imiglucerase for injection) and other products. We also wish to address recent FDA reports and media attention in connection with the operation of this facility.

We understand our responsibility to ensure a safe and adequate supply of this critical therapy, and we are acutely aware of the impact that any interruption or concern about quality has on your confidence in us. We are committed to establishing the highest possible quality standards at this facility and across our global manufacturing operations.

Last week, the US Food and Drug Administration (FDA) completed a five-week inspection of Allston facility, which represented one of the most comprehensive inspections since the FDA Warning Letter issued in February 2009. In its report to us, the FDA expressed over-arching concerns about the quality and rigor of our investigation into problems in the plant, as well as about the documentation and training around these processes. They also noted that equipment used in the fill/finish area where Cerezyme is placed into vials for shipment needs to be modernized.

These factors contributed to the FDA notice last week regarding the presence of tiny foreign particles in some vials of Cerezyme and other products filled at the Allston facility. We understand that these developments have raised questions and led to concern among the Gaucher community, particularly at a time when many are experiencing an interruption in supply.

First and foremost, we want to assure you that the safety and efficacy of Cerezyme has not changed. We have not discovered any evidence of adverse events in our global database to suggest safety concerns for Cerezyme related to foreign particles. Following discussions with the FDA we issued a letter to health care professionals last week to reinforce the existing recommendation in the label for Cerezyme to visually inspect all vials before administration and to also use a commonly available in-line filter to screen out tiny particles that may not be apparent to the naked eye.

Because foreign particles can sometimes be introduced into vials in the normal operation of the fill/finish process, Genzyme routinely inspects every single vial prior to shipping. Approximately 1 percent of vials are removed due to this quality control step. Our review of data from the past two and a half years for Cerezyme and for other products revealed that approximately 0.02 percent of all vials shipped to customers globally were returned to Genzyme due to the presence of foreign particles.



Although it is impossible to eliminate all particulate matter from any fill/finish operation, we recognize that our current level, despite the absence of any documented safety reports, could be improved. Any deviation from truly world-class manufacturing operations is not acceptable to Genzyme, and correcting these issues is one of our highest priorities as a company.

To implement these corrections we have worked to decrease the load on the Allston fill/finish facility by increasingly moving material from Allston to our state-of-the-art facility in Waterford, Ireland, as additional space becomes available. This facility was built in 2005, and successfully passed inspection by the FDA and European authorities. We are approved to fill our 400 unit Cerezyme at that facility and as of this date can confirm that all future Cerezyme 400 unit vials will be filled in Waterford. Furthermore, we have implemented an immediate temporary shut down of fill/finish operations at Allston in order to replace several pieces of equipment and to put additional controls in place.

We wish to assure you that these issues do not impact the schedule we have previously described related to restarting shipments of Cerezyme. We remain on track to ship newly produced Cerezyme later this month to patients currently on treatment. You will receive a letter with further details regarding the re-supply of Cerezyme by Thanksgiving. We welcome any questions or feedback you may have in the meantime.

We recognize that this has been a challenging time for everyone in the Gaucher community, and we are working diligently to fulfill the rightful expectations you have of us. Our focus is not only to address the current issues at Allston, but to also put in place long-term changes to help enable us to serve the Gaucher community with a world-class manufacturing operation in the years to come.

To help address your questions, Genzyme will host a joint town hall meeting for the Gaucher, Fabry, Pompe, and MPS I communities on Monday, November 23rd, from 6pm-7pm EST. You can join this meeting by calling 1-800-369-3331 or 1-312-470-7363 (Passcode: Townhall). Given the large number of anticipated participants, we also encourage you to submit your questions in advance at [TownHall@genzyme.com](mailto:TownHall@genzyme.com).

Yours sincerely,

A handwritten signature in black ink, appearing to read "D. Meeker".

David Meeker, MD  
Executive Vice President  
Genzyme Corporation