DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-367/S-055

Genzyme Corporation
Attention: Douglas L. Owen
Director, Regulatory Affairs
One Kendall Square
Cambridge, MA 02139-1562

Dear Mr. Owen:

Please refer to your supplemental new drug application dated May 16, 2002, received May 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cerezyme (imiglucerase for injection).

We acknowledge receipt of your submission, dated August 16, 2002, containing supporting documentation for the proposed changes and a revised package insert and your fax dated November 12, 2002, containing your response to our October 29, 2002 fax.

This "Changes Being Effected" supplemental new drug application provides for revisions in the ADVERSE REACTIONS section of the package insert to reflect the updated incidence of adverse reactions.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-367/S-055." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Samuel Y. Wu, Pharm.D., Regulatory Project Manager, at 301-827-6416.

Sincerely,

{See appended electronic signature page}

David G. Orloff
Director
Division of Metabolic and Endocrine Drug Products

Enclosure

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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David Orloff

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