DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-367/S-066

Genzyme Corporation
Attention: Douglas Owen
Associate Director, Regulatory Affairs
500 Kendall Street
Cambridge MA 02142

Dear Mr. Owen:

Please refer to your supplemental new drug application dated September 20, 2004, received September 21, 2004, 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 January 31, 2005. This submission constituted a complete response to our January 18, 2005 action letter.

This supplemental new drug application provides for replacement of the (b)(4) (b)(4), with a (b)(4). In addition, the supplement proposes slight changes in the concentrations of the (b)(4) used in the (b)(4).

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-367/S-066**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html.

All communications regarding this application that contain electronic media or a combination of electronic and paper media should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

Paper communications regarding this application that **DO NOT** contain electronic media should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 8B45
5600 Fishers Lane
Rockville, Maryland 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 Pat Madara, Regulatory Project Manager, at (301) 827-6416.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, for the
Division of Metabolic and Endocrine Drug Products (HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure: draft package insert

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

/s/

Stephen Moore
3/3/05 10:16:27 AM