DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-057/S-034

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

Dear Mr. Owen:

Please refer to your supplemental new drug application dated October 26, 2005, received October 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceredase® (alglucerase injection).

Your submission of October 26, 2005, constituted a complete response to our December 20, 2002, action letter.

This "Changes Being Effected" supplemental new drug application provides for a complete response to our December 20, 2002, letter and includes the recommended revisions outlined in the referenced letter.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Ryan Barraco, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

Ceredase®

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

/s/

Joyce Korvick
2/9/2006 01:06:02 PM
for Dr. Brian E Harvey