DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STNs: BL 103979/5058; BL 103979/5065; BL 103979/5066

Genzyme Corporation
Attention: Darlene Noci
Manager, Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Noci:

Your request to supplement your biologics license application for Fabrazyme to provide for changes to the Clinical Pharmacology, Clinical Trials, Warnings, Precautions, Adverse Reactions, and Dosage and Administration sections of the Package Insert (PI) based on pediatric study AGAL-016-01, Phase 3 Open-label extension study AGAL-005-99, and rechallenge study AGAL-019-01, has been approved.

This fulfills your commitment, as stated in commitment number 4 of the April 24, 2003 approval letter, to complete the European study AGAL-016-01, entitled "A Multicenter, Phase 1/2 Open-Label Study of Fabrazyme (Recombinant Human a-Galactosidase-A) Replacement Therapy in Pediatric Patients with Fabry Disease." This study obtained pharmacodynamic and safety data on the use of Fabrazyme in pediatric patients.

Based upon the review of your data, we have the following additional recommendations:

(b)(4)

(b)(4)

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communication, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by a FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions.

Send all submissions to this application, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

This information will be included in your biologics license application file.

Sincerely,

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

(Enclosed: Package Insert)