DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-898/S-038

Genzyme Corporation
Attention: Louisa Caamano
Regulatory Affairs Associate
15 Pleasant Street Connector
Framingham, MA 01701

Dear Ms. Caamano:

Please refer to your supplemental new drug application dated February 15, 2008, received February 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyrogen (thyrotropin alfa) for injection.

This supplemental new drug application provides for the removal of reference to the specific activity of Thyrogen from the package insert and carton labels. This labeling change was proposed in response to a new World Health Organization international thyroid stimulating hormone reference standard.

We have 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (carton labels submitted on February 15, 2008).

Please submit an electronic version of the FPL for the carton labels 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 20-898/S-038**." 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
Food and Drug Administration
Suite 12B05
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 Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Package Insert, 2-Vial and 4-Vial Carton Labels

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

/s/

Mary Parks

8/12/2008 12:51:30 PM