DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-898/S-021

Genzyme Corporation
Attention: Naseem Kabir
Associate Director
One Kendall Square
Cambridge, MA 02139

Dear Ms. Kabir:

Please refer to your supplemental new drug application dated September 10, 2003, received September 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyrogen (thyrotropin alfa for injection).

This "Changes Being Effected" supplemental new drug application provides for labeling changes to your package insert, 4-vial carton label, as well as an introduction of a 2-vial carton package configuration.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 10, 2004.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Oluchi Elekwachi, Pharm.D., M.P.H., Regulatory Project Manager, at (301) 827-6381.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Center for Drug Evaluation and Research

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
3/11/04 05:22:28 PM
for Dr. Orloff