NDA 20-898

Genzyme Corporation
Attention: Ms. Allison Lawton
Vice President, Regulatory Affairs
One Kendall Square
CAMBRIDGE, MA 02139-1562

Dear Ms. Lawton:

Please refer to your new drug application dated December 12, 1997, received December 15, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyrogen® (thyrotropin alfa for injection).

We acknowledge receipt of your submissions dated September 3, October 7 and 28, and November 16, 18, 24 and 30, 1998. The October 7, 1998, submission responded to our approvable letter dated September 15, 1998.

The user fee goal date for this application is April 8, 1999.

This new drug application for Thyrogen® provides for its use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with thyroid cancer.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling (package insert submitted November 30, 1998, immediate container and carton label November 30, 1998). Accordingly, the application is approved effective on the date of this letter.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-898." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submissions dated June 2 and October 10, 1998, and during a meeting held in the Agency September 9, 1998. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted as prior approval supplements to this NDA as soon as they are completed. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, contact Steve McCort, Project Manager, at (301) 827-6415.

Sincerely,

Florence Houn, M.D.
Deputy Office Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES