DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20898/S-051

SUPPLEMENT APPROVAL

Genzyme Corporation
Attention: Melanie Govignon,
Sr. Associate, Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Govignon:

Please refer to your Supplemental New Drug Application (sNDA) dated June 6, 2011, received June 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Thyrogen (thyrotropin alfa for injection).

We acknowledge receipt of your amendments dated July 21, 2011, and January 20, March 27, June 14, and July 23, 2012.

This "Prior Approval" supplemental new drug application provides for additional safety information and revises the PRECAUTIONS and ADVERSE REACTIONS sections of the Thyrogen Package Insert (PI) as follows:

1. Revises the General subsection and adds the following subsections to PRECAUTIONS:

   - Death in Patients Who are not Thyroidectomized or with Distant Metastatic Thyroid Cancer
   - Stroke and Other Neurologic Events
   - Sudden Rapid Tumor Enlargement in Distant Metastatic Thyroid Cancer

2. Adds the following subsections to ADVERSE REACTIONS:

   - Death in Patients Who are not Thyroidectomized or with Distant Metastatic Thyroid Cancer
   - Stroke and Other Neurologic Events
   - Sudden Rapid Tumor Enlargement in Distant Metastatic Thyroid Cancer
   - General

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

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

ENCLOSURE:
Content of Labeling

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

/s/

AMY G EGAN
07/27/2012
Amy Egan for Mary Parks