DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-862/S-019
NDA 21-027/S-013

Genzyme Corporation
Attn: Chandra Mathew, J.D.
Senior Associate, Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Mathew:

Please refer to your supplemental new drug applications dated January 26, 2006, received January 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hectorol (doxercalciferol) Capsules and Injection.

We acknowledge receipt of your submissions dated April 20, May 15, and July 18, 2006 (email).

These "Changes Being Effected" supplemental new drug applications provide for the following:

- Elimination of "trailing zeros" related to dosage or strength in the package inserts, immediate container labels, and cartons.

- Replacing "µg" with "mcg" in all labeling.

- Relocating and decreasing the prominence of the net quantity statement on all container labels and cartons.

- For the Hectorol Injection package insert only, changing the **Dose Titration** table in the **DOSAGE AND ADMINISTRATION** section to add the statement: "Decreased by > 50% and above 300 pg/ml --- maintain".

- For all Hectorol Injection labeling, inclusion of the statement: "For intravenous use only".

- Changing the name presentation from "Hectorol (doxercalciferol) Capsules" to "Hectorol (doxercalciferol capsules)" and from "Hectorol (doxercalciferol) Injection" to "Hectorol (doxercalciferol injection)".

- Changing the owner name and address on all labeling to reflect Genzyme Corporation as the new owner.

We completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 26, 2006.

We remind you of your commitment to eliminate the “trailing zero” in the **Clinical Studies** (results) subsection of the **CLINICAL PHARMACOLOGY** section in the Hectorol Capsule package insert. You have agreed to make this minor labeling change at the next printing revision.

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 Pat Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

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

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