DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-862/S-023

Genzyme Corporation
Attention: Chandra Mathew, Esq.
Principal-Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Mathew:

Please refer to your supplemental new drug application dated January 22, 2008, received January 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hectorol (doxercalciferol capsules) 0.5 mcg & 2.5 mcg.

This supplemental new drug application provides for a change in the capsule shell colorant, change in test methods for the determination of strength, identity and related substances, and the addition of an in-process action limit and removal of several subjective specifications. The changes in capsule colors are reflected in the carton and container labels and the package insert.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 22, 2008 (prescribing information [PI]), in the final printed trade and sample 0.5 mcg and 2.5 mcg container labels submitted on January 22, 2008, the final printed trade and sample 2.5 mcg carton labels submitted on January 22, 2008, and in the January 22, 2008, 0.5 mcg trade and sample carton labels with the following minor editorial revision listed below.

1. The electronic final printed trade and sample carton labels for the 0.5 mcg capsules submitted January 22, 2008, list a concentration of 0.0015% of doxercalciferol under "Contents: Active Ingredient". This must be changed to a concentration of 0.0003% - as in the previously approved 0.5 mcg capsule carton labels.

CARTON AND IMMEDIATE CONTAINER LABELS

We note that your January 22, 2008, submission includes acceptable final printed labeling (FPL) for your trade and sample container labels (0.5 mcg and 2.5 mcg) and your trade and sample 2.5 mcg carton labels.

Submit final printed carton labels for the 0.5 mcg capsules that are identical to the enclosed 0.5 mcg carton labels, except with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton Labels for approved NDA 20-862/S-023**." Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

REPORTING REQUIREMENTS

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 Haley Seymour, Regulatory Project Manager, at (301) 796-2443.

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
Carton labels 0.5 mcg
Carton labels 2.5 mcg
Container labels (blister) 0.5 mcg
Container labels (blister) 2.5 mcg

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

7/10/2008 12:21:57 PM