DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-027/S-015

Genzyme Corporation
Attention: Chandra Matthew, JD
Principal Associate Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

SUPPLEMENT APPROVAL

Dear Ms. Matthew:

Please refer to your supplemental new drug application dated April 18, 2008, received April 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hectorol (doxercalciferol) Injection, 4 mcg/2mL (2 mcg/mL).

We acknowledge receipt of your submissions dated May 27, July 25, October 10, and November 18, 2008.

This supplemental new drug application provides for changes in the dosage formulation and packaging configuration from the currently approved Hectorol Injection and also the introduction of another manufacturer. The package insert is revised to include information on the vial presentation, which replaces the ampule, and excipients used in the new formulation. Also, the OVERDOSAGE section is revised.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format for the package insert (PI), final printed labeling (FPL) for the vial submitted November 18, 2008 and for carton labels submitted October 10, 2008.

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 the Division of Metabolism and Endocrinology Products 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
Vial label
Carton label

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

12/8/2008 08:37:48 PM