DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-862/S-024 **SUPPLEMENT APPROVAL**

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

Dear Ms. Matthew:

Please refer to your supplemental new drug application dated October 9, 2008, received October 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hectorol (doxercalciferol capsules) 0.5 mcg and 2.5 mcg.

Your submission of March 13, 2009, constituted a complete response to our February 10, 2009, action letter.

This "Prior Approval Supplemental" new drug application provides for the development of an additional 1.0 mcg strength capsule. The additional strength capsule shell colorant and the amount of drug substance used to formulate the 1.0 mcg strength are reflected in the package insert, carton and container labels.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.501(1) in structured product labeling (SPL) format for the package insert (PI) submitted October 9, 2008, and final printed labeling (FPL) submitted for the carton and container labels submitted October 9, 2008.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communication (DDMAC), see www.fda.gov/cder/ddmac.

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
Suite 12B05
5600 Fishers Lane
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

Enclosures:
Package insert
Carton 1 mcg (50 capsules)
1 mcg (7 capsules)
Container 1 mcg (50 capsules)
1 mcg (7 capsules)

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

7/13/2009 04:38:12 PM