NDA 021027/S-038

**SUPPLEMENT APPROVAL**

Genzyme Corporation
Attention: Praveena Deenumsetti
Manager, Global Regulatory Affairs
55 Corporate Drive, Mail Stop: 55C-300
Bridgewater, NJ 08807

Dear Ms. Deenumsetti:

Please refer to your supplemental new drug application (sNDA) dated and received, March 28, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hectorol (doxercalciferol) injection.

This "Changes Being Effected" sNDA provides for addition of the National Drug Code (NDC) in its 3-segment format to the Hectorol container labeling for all available presentations, consistent with our February 4, 2022, Supplement Request letter.

## APPROVAL & LABELING

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

## CONTAINER LABELING

Submit final printed container labeling that are identical to the enclosed container labeling submitted on March 28, 2022, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 021027/S-038**." Approval of this submission by FDA is not required before the labeling is used.

## REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

**ADDITIONAL COMMENT**

We note the 2 mcg/mL vial presentation is not currently on the market; however, if the presentation re-enters the market, please include the NDC on the container label.

**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 Meghna M. Jairath, Pharm.D., Senior Regulatory Project Manager, at (301) 796-4267.

Sincerely,

*{See appended electronic signature page}*

Theresa E. Kehoe, MD
Director
Division of General Endocrinology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE:

- Container Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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