



NDA 20-926/S-006
NDA 21-179/S-002

Genzyme Corporation
Attention: Mary Beth Clark
Associate Director, Regulatory Affairs
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Clark:

Please refer to your supplemental new drug applications dated May 3, 2002, received May 6, 2002 (NDA 21-179/S-002), and May 20, 2002, received May 31, 2002 (NDA 20-926/S-006), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renagel (sevelamer hydrochloride) Tablets (NDA 21-179) and Capsules (NDA 20-926).

We acknowledge receipt of your submissions dated March 13, May 20, July 1, August 7, and October 3, 2003, and January 23, 2004. Your submission of August 7, 2003, constituted a complete response to our March 6, 2003, action letter.

These supplemental new drug applications provide for revisions to the following sections of the package insert: "Clinical Pharmacology," "Indications and Usage," "Precautions," "Adverse Reactions," "Overdosage," and "Dosage and Administration."

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted draft labeling (text for the package insert). Accordingly, the supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert submitted January 23, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar

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material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-926/S-006 and 21-179/S-002." Approval of this submission by FDA is not required before the labeling is used.

If 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug 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
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/s/

David Orloff
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