



NDA 21-179/S-021

Genzyme Corporation
Attention: Mr. Timothy W. Belt
500 Kendall Street
Cambridge, MA 02142

Dear Mr. Belt:

Please refer to your supplemental new drug application dated February 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renagel® (sevelamer hydrochloride) 400 and 800 mg Tablets.

This “Changes Being Effected in 30 days” supplemental new drug application provides for changes to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of labeling with additional safety information derived from an assessment of world wide post-marketing adverse event reports.

This supplemental new drug application provides for electronic draft labeling with the following underlined additions:

1. Under the **PRECAUTIONS/General** subsection the following underlined text has been added:

General: The safety and efficacy of Renagel in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery have not been established. Consequently, caution should be exercised when Renagel is used in patients with these GI disorders.

2. Under the **ADVERSE REACTIONS** section the following underlined language has been added:

In the parallel design study, the major reason for drop out in the Renagel group was gastrointestinal adverse events. In a long-term, open-label extension trial, adverse events possibly related to Renagel Capsules and which were not dose-related, included nausea (7%), constipation (2%), diarrhea (4%), flatulence (4%), and dyspepsia (5%). During post-marketing experience, the following adverse events have been reported in patients receiving Renagel although no direct relationship to Renagel could be established: pruritis, rash, abdominal pain and in very rare cases, intestinal obstruction and ileus.

We have completed our review of this application, and 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 February 22, 2007.

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

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, please call:

Alisea Crowley, Pharm.D.
Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Drug
Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Norman Stockbridge
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