DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-127 **NDA APPROVAL**

Genzyme Corporation
Attention: Ms. Mary Beth Clarke
153 Second Avenue
Waltham, MA 02451

Dear Ms. Clarke:

Please refer to your new drug application (NDA) dated December 20, 2006, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Renvela™ (sevelamer carbonate) 800 mg Tablets.

We acknowledge receipt of your submissions dated March 2, April 9 and 17, May 17, June 13, July 31, August 9, September 13 and 28 and October 16, 2007.

This new drug application provides for the use of Renvela™ (sevelamer carbonate) Tablets for the control of serum phosphorus in patients with Chronic Kidney Disease (CKD) on dialysis.

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 enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-127."

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 13 and August 9, 2007 submissions containing electronic draft printed carton and container labels.

A. GENERAL COMMENTS

1. In order to minimize the potential for medication errors between Renagel and Renvela , DMETS recommends that you launch an educational campaign aimed at healthcare professionals informing them of the differences between the products with respect to the differences in the salts, indications of use, and different monitoring parameters, etc.

2. Ensure that the established name is at least ½ the size of the proprietary name in accordance with 21 CFR 201.10(g)(2).

3. The dosage form statement ("tablets") is placed next to the statement of strength ("800 mg"). Please relocate the dosage form statement so that it immediately follows the established name so as to maximize the visibility and prominence of the statement of strength. Additionally, increase the size of the statement of strength so that it is commensurate in size with the proprietary name in order to increase its prominence on the label. See the example below.

Example of placement:

Renvela
(sevelamer carbonate) tablets
800 mg

4. The letter "v" in Renvela is printed in a and detracts from the readability of the name. Please print the letter "v" in the same type, font and size as the other letters in the proprietary name.

5. If the container is a unit-of-use bottle to be dispensed on an outpatient basis, ensure that the container has a Child Resistant Closure in accordance with the Poison Prevention Act.

B. CONTAINER LABEL (270-count)

1. See General Comments A-2 through A-5.

2. Relocate the net quantity statement to the principal display panel. However, ensure that it is not in close proximity to the statement of strength.

C. CONTAINER LABEL (PROFESSIONAL SAMPLE, 30-count)

1. See General Comments A-2 through A-5.

2. Decrease the size and prominence of the net quantity statement (as currently presented, it is more prominent than the strength) and relocate it so that it is not in close proximity to the statement of strength. This will help to minimize the potential to confuse the strength and net quantity with each another.

3. Relocate the "Sample: Not To Be Sold" wording to the principal display panel for better prominence.

D. CARTON LABELING (PROFESSIONAL SAMPLE, 30 count)

See General Comments A-2, A-3, and A-4 and Comment C-2.

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-127**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages < 1 month to 16 years of age until October 20, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of the control of serum phosphorus in patients with Chronic Kidney Disease (CKD) on dialysis in pediatric patients ages < 1 month to 16 years old.

Final Report Submission: October 20, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

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(s), 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 Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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, 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: Agreed upon labeling text

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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