



NDA 021179/S-039

APPROVAL LETTER

Genzyme Corporation
Attention: Tiejun Wang
Global Regulatory Affairs CMC
55 Corporate Drive
Bridgewater, NJ 08807

Dear Tiejun Wang:

Please refer to your Supplemental New Drug Application (sNDA) dated June 28, 2023, and received June 29, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Renagel (sevelamer hydrochloride) tablets.

This Prior Approval supplemental new drug application provides for the addition of Sanofi Winthrop Industrie, Ambares et Lagrave (France) as an alternative manufacturing site for all the manufacturing operations of RENAGEL® and Sevelamer Hydrochloride (generic), 800 mg, film-coated tablets.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

We acknowledge your December 8, 2023, submission containing final printed carton and container labeling.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Grafton Adams at grafton.adams@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari Ph.D.
on behalf of
Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari
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