



NDA 019527/S-032

APPROVAL LETTER

Salix Pharmaceuticals Inc.
Attention: Sunny Bhardwaj
Associate Director, Global Regulatory-CMC
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Sunny Bhardwaj:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 15, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pepcid (famotidine) for Oral Suspension, 40 mg/5mL.

We acknowledge receipt of your amendment dated April 8, 2024, which constituted a complete response to our January 12, 2024, action letter.

This Prior Approval supplemental new drug application provides for:

Reintroduction of Pepcid (famotidine) for oral suspension as an authorized generic, Famotidine for Oral Suspension as this product has not been manufactured, packaged, and distributed since 2016.

Furthermore, this supplement additionally includes associated changes as follows:

1. Addition of [redacted] (b) (4)
2. Addition of [redacted] (b) (4)
3. Addition of [redacted] (b) (4)
4. Removal of [redacted] (b) (4) as the drug substance manufacturer.
5. [redacted] (b) (4)
6. Addition of [redacted] (b) (4)

7. Updates to the drug product container closure system as follows:
- Change in (b) (4) round bottle size from 3 oz to 4 oz
 - Change in the bottle cap and liner

APPROVAL & LABELING

We have completed our review of this supplemental application. 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(l)(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

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA**”

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019527/S-032.” Approval of this submission by FDA is not required before the labeling is used.

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 Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Supervisor
Division of Product Quality Assessment XI
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling



David
Lewis

Digitally signed by David Lewis

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