NDA 021849/S-017

APPROVAL LETTER

Salix Pharmaceuticals Inc
Attention: Yen Nguyen
Sr. Manager, Global Regulatory Affairs, Cmc
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Mr. Nguyen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 25, 2020, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zegerid (omeprazole) Capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for addition of (b) (4) [FEI # (b) (4)] located in (b) (4) (b) (4) (b) (4) as an alternate facility for manufacturing, packaging, labeling, and testing of Zegerid (omeprazole / sodium bicarbonate) 40mg/1100mg capsules and addition of (b) (4). [FEI # (b) (4)] located in (b) (4) as an alternate analytical facility for determining (b) (4) and for determining the (b) (4)

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.

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 021849/S-017.**" 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, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis,PhD.
Branch Chief, B2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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