NDA 021014/S-051

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Elizabeth Marchese
Regulatory Affairs, CMC Senior Manager, RA GDD
One Health Plaza
Building 337
East Hanover, NJ 07936-1080

Dear Ms. Marchese:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 8, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trileptal (oxcarbazepine) tablet, film coated.

We acknowledge receipt of your amendment dated September 3, 2024, which constituted a complete response to our July 2, 2024, action letter.

This Prior Approval supplemental new drug application provides for:

- Change in the manufacturing site of the drug product.
  - Replacement o (b) (4) (b) (4)
  - Replacement o (b) (4) (b) (4) (b) (4) (b) (4)
- Minor change in th (b) (4) of the drug product.
  - 150 mg Tablet: (b) (4) (b) (4) (b) (4)
  - 300 mg Tablet (b) (4)
  - 600 mg Tablet (b) (4) (b) (4)
- Change in batch size of the finished product.
  - From (b) (4) for 150 mg tablet
  - From (b) (4) for 300 mg tablet
  - From (b) (4) for 600 mg tablet
- Minor change in the manufacturing process of the finished product.
- Change in th (b) (4)
  - (b) (4)

(b) (4)

- Changes in the specifications of the finished product. s

(b) (4)

  - From (b) (4) closure to (b) (4) (b) (4) closure for 1 0 mg and s 300 mg tablet. s
  - From (b) (4) closure to s (b) (4) closure for 600 mg s tablet. s
- Prs pose (b) (4) for the new container closure system. s

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APPROVAL & LABELING s

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

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CARTON AND CONTAINER LABELS s

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ubmit final printed container labels that are identical to enclosed container labels and s container labels submitted on March 8, 2024, as soon as they are available, but no s more than 30 days after they are printed. lease submit these labels electronically s according to the guidance for industry *Providing Regulatory Submissions in Electronic* s *Format – Certain Human Pharmaceutical Product Applications and Related* s *Submissions Using the eCTD Specifications*. For administrative purposes, designate s this submission "**Product Correspondence – Final Printed Carton and Container** s

Labels for approved NDA 021014/S-051." 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 Erica Keafer, Regulatory Business rocess Manager, at (301) 796 – 143 or erica.keafer@fda.hhs.gov.

incerely,

{See appended electronic signature page}

Richard Matsuoka, h.D.
Chemist

For:
Gurpreet Gill angha, h.D.
upervisor
Division of roduct Quality Assessment II
Office of roduct Quality Assessment I
Office of harmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

- Container Labeling

Richard U
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Digi a ly igned by Richard Ma U a U
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