NDA 021560/S-031

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Neil Costanza
RA CMC Director - Regulatory Affairs Global Drug Development
One Health Plaza
Building 337
East Hanover, NJ 07936

Dear Neil Costanza:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 17, 2022, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zortress tablets (0.25, 0.5, 0.75 and 1 mg).

This "Changes Being Effected in 30 days" supplemental new drug application provides for:

1. Addition of an alternative drug product manufacturing site, Sandoz SRL, Targu Mures, Romania (FEI # 3005587283), with related carton and foil blister label changes.
2. Addition of an alternative testing site, Sandoz SRL, Targu Mures, Romania.
3. Addition of a primary packaging site, Sandoz SRL, Targu Mures, Romania.
4. Addition of a secondary packaging site, Sandoz SRL, Targu Mures, Romania.
5. Addition of (b) (4) as new suppliers of the primary packaging and consequential changes to the foils of the primary packaging.

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.

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 021560/S-031.**" 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}

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):
Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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