NDA 022314/S-038

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Lu Wu
Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Lu Wu:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 18, 2021, and your amendments, pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Exforge HCT (amlodipine/valsartan/hydrochlorothiazide) 5/160/12.5, 10/160/12.5, 5/160/25, 10/160/25, 10/320/25 mg Film-coated tablets.

We acknowledge receipt of your amendment dated June 2, 2022, which constituted a complete response to our March 18, 2022, action letter.

This Prior Approval supplemental new drug application provides for:

- Addition of Novartis Farma S.p.A in Torre Annunziata, Italy as an alternate drug product manufacturing and analytical testing site for Exforge HCT Film-coated tablets (all strengths)
- Addition of the following changes related to the drug substance valsartan, USP:
  - Addition of (b) (4) as drug substance manufacturer, (b) (4)
  - Addition of (b) (4) and (b) (4) as drug substance quality control sites.
  - Name change of the approved quality control testing site located in (b) (4)
  - Change to the specification parameters and/ or limits for valsartan supplied from (b) (4) including (b) (4) (b) (4)
  - Addition of specifications parameters and/ or limits for (b) (4) impurities:
    - Addition of an (b) (4) specification (not more than (b) (4) ppm) for (b) (4) (b) (4) valsartan

- Addition of an [redacted] specification (not more than [redacted] ppm) for [redacted] valsartan
- Addition of an [redacted] specification (not more than [redacted] ppm) for [redacted] valsartan only
- Addition of an [redacted] specification (not more than [redacted] ppm) for [redacted] valsartan only

- Minor update of the microbial enumeration tests (MET) procedure
- Editorial changes

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 022314/S-038.**" 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 Elizabeth Markovich, MPH, Regulatory Business Process Manager, at (301) 796 - 5071.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, PhD
Branch Chief, Branch 3
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

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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