NDA 021283/S-059

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Albina Taigounov
Regulatory CMC Director - Regulatory Affairs Global Drug Development CMC
One Health Plaza
Bldg. 337 - B08.4C
East Hanover, NJ 07936

Dear Albina Taigounov:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 24, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diovan (valsartan) tablets, 40 mg, 80 mg, 160 mg, and 320 mg.

This Prior Approval supplemental new drug application provides for multiple updates involving the manufacture and testing of the drug substance including the following:

- The addition of (b) (4) (b) (4) as an alternate valsartan drug substance manufacturer and quality control site. This includes changes in the specification parameters and test procedures of the drug substance with a cross reference to Type II DMF (b) (4)
- The addition of specifications and analytical methods for (b) (4) impurities (b) (4) (b) (4) in valsartan drug substance.
- The addition of (b) (4) (b) (4) as an alternate analytical site for (b) (4) impurities testing of valsartan drug substance.
- The addition of (b) (4) (b) (4) as an alternate analytical site for microbial enumeration testing (MET) of valsartan drug substance.

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 021283/S-059.**" 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 Eydelman, 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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