



NDA 021283/S-062

**APPROVAL LETTER**

Novartis Pharmaceuticals Corporation  
Attention: May Abd  
RA CMC Associate Director, RA GDD  
One Health Plaza, Bldg. 337  
East Hanover, NJ 07936

Dear May Abd:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 26, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diovan (valsartan) Tablets.

This Prior Approval supplemental new drug application provides for:

- Addition of (b) (4) (b) (4)  
(b) (4) with the following associated updates. (b) (4)
- Addition of (b) (4) (b) (4) (b) (4)
- Withdrawal of (b) (4) (b) (4)
- Deregistration of (b) (4) (b) (4)
- Addition of (b) (4) (b) (4)
- Deletion of (b) (4) (b) (4)
- (b) (4) (b) (4)

## **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.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to carton and container labels submitted on July 3, 2025, 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-062.**” Approval of this submission by FDA is not required before the labeling is used.

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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 Rajani Ranga, Regulatory Business Process Manager, at [Rajani.Ranga@fda.hhs.gov](mailto:Rajani.Ranga@fda.hhs.gov) or 2404025041.

Sincerely,

*{See appended electronic signature page}*

Vilayat Sayeed, Ph.D.  
Director, Division of Product Quality Assessment II  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality

Enclosure(s):

Content of Labeling

Carton and Container Labeling



Vilayat  
Sayeed

Digitally signed by Vilayat Sayeed

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