DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020818/S-060

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Ms. Nancy Price
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Price:

Please refer to your Supplemental New Drug Application (sNDA) dated November 4, 2013, received November 4, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diovan HCT (valsartan/hydrochlorothiazide) Tablets, 80/12.5 mg, 160/12.5 mg, 160/25 mg, 320/12.5 mg, and 320/25 mg.

We acknowledge receipt of your amendments dated November 8 and 22, 2013, February 28 and April 7, 2014.

This "Changes Being Effected" supplemental new drug application provides for 30 count blister packs in a calendarized display and changes to the secondary packaging, including the labeling components listed below for the 160/12.5 mg, 160/25 mg, 320/12.5 mg and 320/25 mg strengths:

Components – Package, 160/12.5 mg:
• Diovan HCT 160/12.5 mg blistercard of 30 Tablets # 5002187
• Shellpak® container (no text)
• Diovan HCT 160/12.5 mg shellpak label of 30 Tablets
• Diovan HCT Package Insert

Components – Package, 160/25 mg:
• Diovan HCT 160/25 mg blistercard of 30 Tablets # 5002190
• Shellpak container (no text)
• Diovan HCT 160/25 mg shellpak label of 30 Tablets
• Diovan HCT Package Insert

Components – Package, 320/12.5 mg:
• Diovan HCT 320/12.5 mg blistercard of 30 Tablets # 5002193
• Shellpak container (no text)
• Diovan HCT 320/12.5 mg shellpak label of 30 Tablets
• Diovan HCT Package Insert

Components – Package, 320/25 mg:
• Diovan HCT 320/25 mg blistercard of 30 Tablets # 5002605
• Shellpak container (no text)
• Diovan HCT 320/25 mg shellpak label of 30 Tablets
• Diovan HCT Package Insert

This supplemental new drug application provides for revisions to the labeling for the Diovan HCT Package Insert as follows:

Under **16 HOW SUPPLIED/STORAGE AND HANDLING**, the "Unit Dose (blister pack of 30)" and NDC numbers were added accordingly for the following strengths: 160/12.5 mg, 160/25 mg, 320/12.5 mg and 320/25 mg.

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 text.

As agreed to in your April 7, 2014 amendment, please add the phrase "[see USP controlled room temperature]" to the Shellpak label at the time of your next printing.

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 package insert, text for the patient package insert,), 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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).

SHELLPAK BLISTERCARD LABEL AND SHELLPAK BLISTERCARD LABELING

Submit final printed labels that are identical to the enclosed Shellpak Blistercard Label for the 30 count unit dose blister and Shellpak Blistercard Labeling for the Shellpak 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed**

Shellpak Blistercard Label and Shellpak Blistercard Labeling for approved NDA 020818/S-060." Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact:

Quynh Nguyen, Pharm.D., RAC
Regulatory Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Shellpak Blistercard Label and Shellpak Blistercard Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
05/30/2014