



NDA 21-283/S-027

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

Dear Ms. Price:

Please refer to your supplemental new drug application dated December 8, 2008, received December 10, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Diovan (valsartan) 40 mg, 80 mg, 160 mg, and 320 mg Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to the **HIGHLIGHTS OF PRESCRIBING INFORMATION, ADVERSE REACTIONS, USE IN SPECIFIC POPULATIONS** and **HOW SUPPLIED/STORAGE AND HANDLING** sections of the label. The following changes were proposed:

1. In **HIGHLIGHTS OF PRESCRIBING INFORMATION/RECENT MAJOR CHANGES**, in accordance with 201.57(a)(5) and subsequent to the expiration of the one-year inclusion period, Use in pediatric hypertension 6-16 years (2.2) and Use in pregnancy (5.1) have been deleted.
2. In **ADVERSE REACTIONS/Post-Marketing Experience**, "**Vascular**: Vasculitis" has been added to the list of reported adverse reactions.
3. In **USE IN SPECIFIC POPULATIONS/Pregnancy**, the following sentence has been removed from the third paragraph: "These adverse effects do not appear to have resulted from intrauterine drug exposure that has been limited to the first trimester."
4. In **HOW SUPPLIED/STORAGE AND HANDLING**, "Packages of 100" has been added to the table under the heading of "Blister."
5. The heading for **13.2 Animal Toxicity and/or Pharmacology** has been deleted, and replaced with:

13.3 Developmental Toxicity

6. Minor editorial changes have been made throughout.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling (SPL) submitted on December 10, 2008.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 call:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager
(301) 796 3975

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: Approved labeling text

**This is a representation of an electronic record that was signed electronically and
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/s/

Norman Stockbridge
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