DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-818/S-032

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

Dear Ms. Price:

Please refer to your supplemental new drug application dated March 14, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan HCT (valsartan/hydrochlorothiazide) 80/12.5 mg, 160/12.5 mg, and 160/25 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for electronic final printed labeling revised as follows:

1. Under the "**WARNINGS/Fetal/Neonatal Morbidity and Mortality"** subsection, the following was added as the third sentence of the first paragraph:

   There have been reports of spontaneous abortion, oligohydramnios and newborn renal dysfunction when pregnant women have inadvertently taken valsartan.

2. Under the "**OVERDOSAGE**" section, the following was added as the third sentence of the first paragraph:

   Depressed level of consciousness, circulatory collapse and shock have been reported.

In addition, the following editorial changes were noted:

1. The "**HOW SUPPLIED**" section was updated to replace the 100-count trade bottles listing with the 90-count trade bottles listing along with the corresponding NDC code numbers as follows:

   a) The last sentence of the first paragraph has been changed to:

      All strengths are packaged in bottles of 90 tablets and unit dose blister packages.

   b) The trade bottles listing and NDC codes have been changed to:

      "Bottles of 90……NDC 0078-0314-34" for the 80/12.5 mg Tablet

      "Bottles of 90……NDC 0078-0315-34" for the 160/12.5 mg Tablet

      "Bottles of 90……NDC 0078-0383-34" for the 160/25 mg Tablet

2. The issue date at the end of the package insert has been updated so that it now reads:

   REV: MARCH 2006

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling submitted on March 14, 2006.

At the time of your next printing, please make the following minor editorial correction:

Under the "**WARNINGS/Fetal/Neonatal Morbidity and Mortality"** subsection, delete the word "inadvertently" from the third sentence of the first paragraph so that it reads:

> There have been reports of spontaneous abortion, oligohydramnios and newborn renal dysfunction when pregnant women have taken valsartan.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health 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

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

/s/

Norman Stockbridge

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