



NDA 20-818/S-024

Novartis Pharmaceuticals Corporation
Attention: Ms. Nancy A. Price
Associate Director, Drug Regulatory Affairs
One Heath Plaza
East Hanover, New Jersey 07936-1080

Dear Ms. Price:

Please refer to your supplemental new drug application dated 24 November 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan HCT® (valsartan/ hydrochlorothiazide) 80/12.5, 160/12.5, and 160/25 mg Tablets.

This supplement new drug application provides for final printed labeling for a patient package insert (PPI) for Diovan HCT® (valsartan/ hydrochlorothiazide) Tablets.

Your submission of 3 June 2005 constituted a complete response to our 24 May 2005 action letter.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on 3 June 2005.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call:

Cheryl Ann Borden, MSN, R.N., CCRN, CCNS
Regulatory Health Project Manager
(301)594.5312.

Sincerely,

{See appended electronic signature page}

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

Enclosure: FPL Patient Package Insert

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

Norman Stockbridge
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