DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-818/S-027

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

Dear Ms. Price:

Please refer to your supplemental new drug application dated 28 June 2005, received 30 June 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan HCT® (valsartan hydrochlorothiazide) 80/12.5, 160/12.5, 160/25, 320/12.5, and 320/25 mg Tablets.

We acknowledge receipt of your submissions dated 28 June (two), 15, 16 and 31 August, 15 September, 31 October, 14 December 2005, 23 and 31 January, 3, 10, and 17 February, 16, 17 and 22 March, and 14 April 2006.

This supplemental new drug application provides for the addition of two new dose strengths (320/12.5 and 320/25 mg) of Diovan HCT (valsartan hydrochlorothiazide) Tablets for the treatment of hypertension.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the electronically submitted labeling text for the package insert submitted 14 April 2006, patient package insert submitted 14 April 2006, and the immediate container and carton labels submitted 16 March 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-818/S-027**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardiovascular and Renal Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

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:

Cheryl Ann Borden, MSN, RN, CCRN, CCNS
Regulatory Health Project Manager
(301) 796 1046.

Sincerely,
{See appended electronic signature page}
Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Package Insert, Patient Package Insert