



NDA 20-818/S-012

Novartis Pharmaceuticals Corporation
Attention: Nancy Price
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Price:

Please refer to your supplemental new drug application dated September 14, 2001, received September 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan HCT (valsartan/hydrochlorothiazide) Tablets, 80/12.5 mg and 160/12.5 mg.

We acknowledge receipt of your submission dated January 10, 2002.

This supplemental new drug application provides for a new 160/25 mg strength tablet of Diovan HCT.

We have completed the review of this supplemental application, and it is approved with the understanding that a 2 year expiration dating period will apply to this strength of Diovan HCT packaged in trade bottles whereas blisters and physician samples will have an expiration dating period of 18 months.

Please provide final printed labeling in the next annual report.

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, call Edward Fromm, Regulatory Project Manager, at (301) 594-5313.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D
Chemistry Team Leader, DNDC I for
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar
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