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**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 21-283/S011**

**Approval Letter(s)**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

NDA 21-283/S-011

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

Dear Ms. Price:

Please refer to your supplemental new drug application dated December 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan (valsartan) 40, 80, 160, and 320 mg Tablets.

We acknowledge receipt of your submissions dated January 18, and 24, February 2 and 11, March 3, April 28, and June 29, 2005. Your submission of June 29, 2005 constituted a complete response to our January 13, 2005 approvable letter.

This supplemental new drug application provides for the use of Diovan (valsartan) 40, 80, 160, and 320 mg Tablets in the treatment of patients post-myocardial infarction. In clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction, Diovan is indicated to reduce cardiovascular mortality. We also note revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, and HOW SUPPLIED** sections of the labeling.

We have completed our review of this application, as amended, and it 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 enclosed labeling (text for the package insert and patient package insert).

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 21-283/S-011.**" 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 reference our letter dated January 13, 2004 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 Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
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 contact:

Mr. Edward Fromm  
Regulatory Health Project Manager  
(301) 594-5328

Sincerely,

*{See appended electronic signature page}*

Robert Temple, M.D.  
Director  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure

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