



NDA 20-665/S-016
NDA 21-283/S-001

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 applications dated April 27 (NDA 20-665) and July 23, 2001 (NDA 21-283), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan (valsartan) Capsules, 80 and 160 mg (NDA 20-665) and Tablets, 40, 80, 160, and 320 mg (NDA 21-283).

We acknowledge receipt of your submissions dated July 25 and 29, 2002. Your submissions of July 29, 2002 constituted a complete response to our July 23, 2002 approvable letter.

These supplemental new drug applications provide for the use of Diovan (valsartan) Capsules and Tablets for the treatment of heart failure (NYHA class II-IV) in patients who are intolerant to an ACE (angiotensin converting enzyme) inhibitor. In addition, NDA 21-283/S-001 provides for a new 40 mg tablet strength.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert included in your submissions of July 29, 2002, immediate container and carton labels included in your submission of June 17, 2002). Accordingly, these supplemental applications are approved effective on the date of this letter.

Please make the following changes to the labeling at your next printing:

1. (NDA 20-665/S-016)-Under **DESCRIPTION**, 5th sentence, please add after iron oxides, in parentheses, the individual color components (yellow, black, brown, and/or red).
2. (NDA 21-283/S-001)-Under **DESCRIPTION**, 5th sentence, please insert the word "brown" after the word "black" in the parentheses (yellow, black and/or red).

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new

Food and Drug Administration
Rockville MD 20857

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 (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies for this indication until September 30, 2007. However, in the interim, please submit your pediatric drug development plans within 180 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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) 594-5332

Sincerely,

{See appended electronic signature page}

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

Enclosures: Final Printed Labeling for NDA's 20-665/S-016 & 21-283/S-001

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

/s/

Robert Temple
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