

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 20-665/S-016

NDA 21-283/S-001

Correspondence

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 973 781 7500
Fax 973 781 3590



October 30, 2001

Raymond Lipicky, MD
Director
Food and Drug Administration
Center for Drug Evaluation and Research
Attn: Document Control Room, HFD-110
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-665 / S-016
NDA 21-283 / S-001
Diovan® (valsartan)

Response to FDA request

Dear Dr. Lipicky:

Reference is made to our NDAs 20-665 & 21-283 for Diovan (valsartan), and our pending clinical supplement which provides for a new indication, the treatment of patients with heart failure. Reference is also made to FDA's approvable letter dated October 24, 2001.

We confirm our intent to file an amendment to address the issues raised in the 10/24/01 letter. Should you have any questions or comments, please contact me at (973) 781-3591 (phone) or (973) 781-3590 (FAX).

Sincerely,

A handwritten signature in black ink that reads 'Nancy A. Price'.

Nancy A. Price
Associate Director
Drug Regulatory Affairs

Desk copy, via fax: Edward Fromm, Regulatory Health Project Manager



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Diovan (valsartan) Tablets

NDA Number: 21-283

Supplement number: S-001

Review Priority Classification: Priority (P)

Date of supplement: July 23, 2001

Date of receipt: July 23, 2001

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on September 21, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be January 23, 2002.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
1451 Rockville Pike
Rockville, Maryland 20852

NDA-21-283/S-001

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If you have any questions, please call:

Mr. Edward Fromm
Regulatory Project Manager
(301) 594-5313

Sincerely yours,

/s/

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Natalia Morgenstern
7/31/01 08:54:48 AM



NDA 20-665/S-016

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

Dear Ms. Price:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Diovan (valsartan) 80mg and 160mg Capsules

NDA Number: 20-665

Supplement Number: S-016

Review Priority Classification: Priority (P)

Date of Supplement: April 27, 2001

Date of Receipt: April 27, 2001

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on June 26, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 27, 2001.

Be advised that, as of April 1, 1999, 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 (63 FR 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 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.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit

a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will make a determination whether to grant or deny a request for a waiver of pediatric studies during the review of the application. In no case, however, will the determination be made later than the date action is taken on the application. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products,
HFD-110
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room
1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, please call:

Mr. Edward Fromm
Regulatory Project Manager
(301) 594-5313

Sincerely,

{See appendix  electronic signature page}

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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this page is the manifestation of the electronic signature.**

/s/

Natalia Morgenstern
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