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Application Number:NDA 20665/S004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-665/S-004

NOV 27 1998

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

Dear Ms. Price:

Please refer to your supplemental new drug application dated October 16, 1998, received October 21, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diovan (valsartan) 80 and 160 mg Capsules.

This supplemental new drug application provides for final printed labeling revised as follows:

"Novartis" and "Rx only" have been added to the top of the package insert. "Diovan" now has "®" instead of "™" next to it.

ADVERSE REACTIONS: a new subsection has been added:

"**Post-Marketing Experience**
The following additional adverse reactions have been reported in post-marketing experience:
Hypersensitivity: There are rare reports of angioedema;
Digestive: Elevated liver enzymes and very rare reports of hepatitis."

At the end of the package insert,

NOVARTIS
Distributed by
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

replaces the information on Ciba.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in the October 16, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

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:

Ms. Kathleen Bongiovanni
Regulatory Health Project Manager
(301) 594-5334

Sincerely yours,

/S/ 11/27/98

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Archival NDA 20-665
HFD-110/Div. Files
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-101/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-95/DDMS (with labeling)
HFD-810/DNDC Division Director
DISTRICT OFFICE
HFD-110/K.Bongiovanni
sb/11/20/98;11/27/98
Initialed by: C Berninger/11/23/98
K Srinivasachar/11/23/98
A Proakis/11/23/98
C Resnick/11/23/98
C Ganley/11/25/98
N Morgenstern/11/25/98
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APPROVAL (AP)