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APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-364/S-008

Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 16 1999

NDA 20-364/S-008

Novartis Pharmaceuticals Corporation
Attention: Mr. Carl Schlotfeldt
59 Route 10
East Hanover, NJ 07936-1080

Dear Mr. Schlotfeldt :

Please refer to your supplemental new drug application dated April 29, 1998, received May 4, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrel (amlodipine besylate/benazepril hydrochloride) Capsules.

This supplemental new drug application provides for final printed labeling revised under **ADVERSE REACTIONS** as follows:

"Alopecia" was added to the list of adverse reactions seen infrequently in clinical trials or postmarketing experience in patients receiving Lotrel.

"Pancreatitis," "hemolytic anemia" and "pemphigus" were moved to a paragraph where they were included in a list of adverse reactions that occurred in postmarketing experience with benazepril.

"Gynecomastia" was moved to the list of adverse reactions that have occurred in other calcium channel blockers, and "eosinophilic pneumonitis" was added as an adverse reaction attributed to other ACE Inhibitors.

In addition, the corporate name and address were changed to the following:

Novartis

Distributed by
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

We have completed the review of this supplemental application, as amended, 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 submitted final printed labeling (package insert submitted May 4, 1998). 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:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

/S/ 6/16/99

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 20-364
HFD-110/Div. Files
HFD-110/D.Roeder
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

Drafted by: dlr/May 27, 1999
Initialed by: R Mittal
K Srinivasachar/5/27/99
K Knudsen/6/10/99
N Stockbridge/6/14/99
N Morgenstern/6/14/99
final:

DR 6-15-99

APPROVAL (AP)