DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-364/S-016

Novartis Pharmaceuticals Corporation
Attention: Carl Schlotfeldt
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Schlotfeldt:

Please refer to your supplemental new drug application dated June 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrel (amlodipine and benazepril HCl) Capsules, 2.5/10mg, 5/10 mg, and 5/20 mg.

We acknowledge receipt of your submissions dated May 2 and 20, 2002. Your submission of May 20, 2002 constituted a complete response to our April 29, 2002 action letter.

This supplemental new drug application provides for a new, higher dosage strength that combines 10 mg of amlodipine with 20 mg of benazepril.

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 20, 2002, and immediate container and carton labels submitted May 2, 2002). 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 call:

Ms. Denise M. Hinton
Regulatory Health Project Manager
(301) 594-5312.

Sincerely yours,

{See appended electronic signature page}

Douglas C.Throckmorton M.D.
Director
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/

Doug Throckmorton

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