DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-364/S-024

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

Dear Mr. Schlotfeldt:

Please refer to your supplemental new drug application dated May 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrel (amlodipine and benazepril HCl) 2.5/10, 5/10, 5/20, and 10/20 mg Capsules.

We acknowledge receipt of your submissions dated December 3, 2003, January 21 and April 20, 2004.

This supplemental new application provides for a patient package insert for Lotrel. We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. The established name, benazepril HCL, was changed to benazepril hydrochloride.
2. Amlodipine besylate (Norvasc) was changed to amlodipine besylate (the active ingredient found in Norvasc®.
3. Lotensin was changed to Lotensin®.
4. Manufacturer name and address were added at the bottom of the PPI.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling text for the patient package insert submitted April 20, 2004. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-364/S-024." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Denise M. Hinton, Regulatory Health Project Manager, at (301) 594-5333.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Norman Stockbridge

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