DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-364/S-023

Novartis Pharmaceuticals Corporation
Attention: Ms. Donna M. Vivelo
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Vivelo:

Please refer to your supplemental new drug application dated December 20, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrel (amlodipine besylate and benazepril HCl) 2.5/10, 5/10, 5/20 and 10/20 mg Capsules.

We acknowledge receipt of your submissions dated May 21 and June 21, 2004, February 16 (two), November 14, 2005 and March 30, 2006.

Your submission of November 14, 2005 constituted a complete response to our May 19, 2004 action letter.

This supplemental new drug application provides for two higher strengths, 5/40 and 10/40 mg, of Lotrel (amlodipine besylate and benazepril HCL) Capsules for the treatment of hypertension.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling text for the package insert and patient package insert submitted on November 14, 2005 and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-364/S-023**." Approval of this submission by FDA is not required before the labeling is used.

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. We note that the pediatric study requirement for this application has been fulfilled as pediatric data are

available for each of the individual components of Lotrel. Therefore, we are waiving the pediatric study requirements for this application.

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 Project Manager, at (301) 796-1090.

Sincerely,

{See appended electronic signature page}

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

Enclosure (Agreed-upon labeling text)

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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