DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-364/S-039

Novartis Pharmaceuticals Corporation
Attention: Nancy Landzert
Associate Director, Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Landzert:

Please refer to your supplemental new drug application dated February 27, 2007, received February 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotrel® (benazepril hydrochloride/amlodipine besylate) Capsules, 5/40 mg and 10/40 mg.

This "Changes Being Effected" supplemental new drug application provides for the deletion of desiccant in trade bottles of Lotrel 5/40 mg and 10/40 mg. This supplement also provides for revised labeling as a result of the removal of desiccant.

We completed our review of this supplemental new drug application and it is approved.

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

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Jim Vidra

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