DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19851/S-038 **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation
Attention: Donna Vivelo
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-8300

Dear Ms.Vivelo:

Please refer to your supplemental new drug application dated July 7, 2009 submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Lotensin (benazepril hydrochloride) 2.5, 5, 10 and 20 mg.

This "Changes Being Effected" supplemental new drug application provides for changes to the electronic draft labeling with revisions to the **CONTRAINDICATIONS** section of the package insert. The following revision was requested:

> Under **CONTRAINDICATIONS**, a second paragraph, "Lotensin is also contraindicated in patients with a history of angioedema with or without previous ACE inhibitor treatment." was added.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on July 7, 2009.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (*i.e.,* a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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:

Michael Monteleone, M.S.
Regulatory Health Project Manager
(301) 796-1952

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19851	SUPPL-38	NOVARTIS PHARMACEUTICALS CORP	LOTENSIN (BENAZEPRIL HCL) TABLETS

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

/s/

MARY R SOUTHWORTH
11/10/2009