



NDA 20033/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 applications dated August 6, 2009 submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Lotensin HCT (benazepril/hydrochlorothiazide) 5/6.25, 10/12.5, 20/12.5 and 20/25mg Tablets respectively.

This “Changes Being Effected” supplemental new drug application provides for changes to the **CONTRAINDICATIONS** and **ADVERSE REACTIONS** sections of the package insert.

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 August 6, 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-20033

SUPPL-38

NOVARTIS
PHARMACEUTICA
LS CORP

LOTENSIN HCT

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