DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-851/S-037
20-033/S-037

Novartis Pharmaceuticals Corporation
Attention: Ms. Donna Vivelo
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Vivelo:

Please refer to your supplemental new drug applications dated August 11, 2008 (NDA 19-851/S-037) and August 8, 2008 (NDA 20-033/S-037) 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 and Lotensin HCT (benazepril/hydrochlorothiazide) 5/6.25, 10/12.5, 20/12.5 and 20/25mg Tablets respectively.

We also acknowledge receipt of your submission dated August 12, 2008 (NDA 20-033/S-037).

These supplemental applications provide for additional information in the **PRECAUTIONS**/**Drug Interactions** section of the package insert as requested in our letter dated March 3, 2008.

These supplemental new drug applications provide for electronic draft labeling with the following revisions:

1. Under the **PRECAUTIONS**/***Drug Interactions*** subsection, the following interaction has been added:

   Gold: Nitritoid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy.

We also note the last revised labeling date has been updated to June 2008 for both Lotensin and Lotensin HCT.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the electronic draft labeling text. Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted electronic labeling dated August 8 and 11, 2008. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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:

Alisea Crowley, Pharm.D., RAC
Senior Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

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

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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