DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-107/S-001

Novartis Pharmaceuticals Corporation
Attention: Kimberly D. Dickerson, Pharm.D.
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Dickerson:

Please refer to your supplemental new drug application dated January 31, 2008, received January 31, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Tekturna HCT (aliskiren/hydrochlorothiazide) 150/12.5 mg, 150/25 mg, 300/12.5 mg, and 300/25 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions of the following sections:

- **DRUG INTERACTIONS (Effects of other Drugs on Aliskiren/P-glycoprotein effects):** text related to P glycoprotein (Pgp) substrate inhibitors
- **DRUG INTERACTIONS (Effects of other Drugs on Aliskiren/Cyclosporine):** aliskiren pharmacokinetic data following concomitant administration with cyclosporine; a recommendation against co-administration of aliskiren and cyclosporine in the precautions section
- **WARNINGS AND PRECAUTIONS (Cyclosporine):** a recommendation against coadministration of aliskiren and cyclosporine in the precautions section
- **WARNINGS AND PRECAUTIONS (Serum Electrolyte Abnormalities):** addition of a statement about the potential risk of hyperkalemia when renin angiotensin system agents are combined with drugs that may increase the serum potassium level
- **WARNINGS AND PRECAUTIONS (Renal Artery Stenosis)**: addition of a statement that no clinical studies were performed in the renal artery stenosis population
- **PATIENT INFORMATION:** elements of the aforementioned revisions reflected in the patient labeling.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format submitted on January 31, 2008.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 contact Mr. John David, Regulatory Project Manager at (301) 796-1059.

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

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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