DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-985/S-002

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 April 20, 2007, received April 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tekturna® (aliskiren) 150 and 300 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes in the **Black Box**, the **WARNINGS/*Fetal/Neonatal Morbidity and Mortality*** and **PRECAUTIONS/*Information for Patients*/Pregnancy** subsections to remove and amend wording regarding the second and third trimesters of pregnancy based on a journal article regarding teratogenicity of a related drug class.

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 April 20, 2007.

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 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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