



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-985/S-006

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 December 7, 2007, received December 7, 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 new text related to P glycoprotein (Pgp) substrate inhibitors, new aliskiren pharmacokinetic data following concomitant administration with cyclosporine in the **CLINICAL PHARMACOLOGY** section, a recommendation against co-administration of aliskiren and cyclosporine in the **PRECAUTIONS** section, and revisions to the **PATIENT PACKAGE INFORMATION** section of the 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 December 7, 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
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/s/

Norman Stockbridge
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