



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-985/S-004

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 September 13, 2007, received September 13, 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 revisions to the PRECAUTIONS, Hyperkalemia subsection and the establishment under PRECAUTIONS, of a Renal Artery Stenosis subsection.

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 September 13, 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

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/s/

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Norman Stockbridge  
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