



NDA 20-387/S-040

Merck Research Laboratories  
Attention: Kenneth A. Kramer, RPh  
P.O. Box 1000  
UG2CD-48  
North Wales, PA 19454-1099

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated January 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hyzaar (losartan potassium/hydrochlorothiazide) 50-12.5, 100-12.5, and 100-25 mg Tablets.

This supplemental new drug application provides for a new Patient Package Insert (PPI) for Hyzaar (losartan potassium/hydrochlorothiazide) Tablets.

We acknowledge receipt of your submissions dated August 25 and November 16, 2006.

Your submission of November 16, 2006 constituted a complete response to our August 18, 2006 action letter.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling submitted on November 16, 2006.

At the time of your next printing of the PPI, please delete the word "Tablets:" at the beginning of the paragraph under the "**Inactive ingredients**" section.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.  
Regulatory Health Project Manager  
(301) 796-0510

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

Enclosure: Patient Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Norman Stockbridge  
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