



NDA 21-286/S-006

NDA 21-532/S-001

Sankyo Pharma Inc.  
Attention: Ms. Jean Lyons  
399 Thornall Street, 11<sup>th</sup> Floor  
Edison, New Jersey 08837

Dear Ms. Lyons:

Please refer to your supplemental new drug applications dated November 6, 2003, received November 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benicar (olmesartan medoxomil) 5, 20, and 40 mg Tablets (NDA 21-286), and Benicar HCT (olmesartan medoxomil/hydrochlorothiazide) 20/12.5, 40/12.5 and 40/25 mg Tablets (NDA 21-532).

We acknowledge receipt of your submissions dated May 14, 2004 which constituted a complete response to our April 22, 2004 approvable letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provides for electronic final printed labeling revised as follows:

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1. Under **DESCRIPTION**, 2<sup>nd</sup> paragraph, the letter "H" has been italicized to be consistent with the Benicar HCT package insert.
2. Under **ADVERSE REACTIONS**, 6<sup>th</sup> paragraph, the sentence that reads "Angioedema has been reported with other angiotensin II antagonists" has been changed to:

Angioedema has been reported with angiotensin II antagonists.

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Under **PRECAUTIONS, Drug Interactions**, *Hydrochlorothiazide*, the word "*Corticosteriods*" has been corrected for spelling.

Under **ADVERSE REACTIONS**, 6<sup>th</sup> paragraph, the sentence that reads "Angioedema has not been reported with olmesartan medoxomil or olmesartan medoxomil-hydrochlorothiazide, but has been reported with other angiotensin II receptor antagonists" has been revised to:

Angioedema has been reported with angiotensin II antagonists.

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Under **ADVERSE REACTIONS**, *Post-Marketing Experience*, the statement “Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers” has been replaced with the following:

Rare cases of angioedema and rhabdomyolysis have been reported in patients receiving olmesartan medoxomil.

Minor administrative changes were noted as follows:

- Copyright statement was added
- Part number was revised
- Date was revised

We completed our review of these supplemental new drug applications, they are approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on May 14, 2004.

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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 call:

Cheryl Ann Borden, MSN, R.N., CCRN, CCNS  
Regulatory Health Project Manager  
(301) 594 5312.

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, M.D., PhD  
Acting Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation and Research  
Center for Drug Evaluation and Research

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/s/

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Norman Stockbridge  
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