DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-532/S-004

Howard Hoffman, M.D.
Executive Director, Regulatory Affairs
Sankyo Pharma, Inc.
399 Thornall Street, 11th Floor
Edison, NJ 08837

Dear Dr. Hoffman:

Please refer to your supplemental new drug application dated January 19, 2005, received January 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benicar HCT (olmesartan medoxomil-hydrochlorothiazide) 20/12.5, 40/12.5 and 40/25 mg Tablets.

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

1. Under **ADVERSE REACTIONS,** *Post-Marketing Experience,* section was changed from, "Rare cases of angioedema and rhabdomyolysis have been reported in patients receiving olmesartan medoxomil."

   To read as follows:

   Post-Marketing Experience: The following adverse reactions have been reported in postmarketing experience:

   Body as a Whole: Asthenia, angioedema
   Gastrointestinal: Vomiting
   Musculoskeletal: Rhabdomyolysis
   Urogenital System: Acute renal failure, increased blood creatinine levels
   Skin and Appendages: Alopecia, pruritus, urticaria

2. The symbol ™ was replaced with ® after all Benicar HCT throughout the package insert.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 19, 2005.

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

Sincerely,

{See appended electronic signature page}

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

Attached: label

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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