DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-286/S-012

Daiichi Sankyo, Inc.
Attention: Mr. Tetsuya (Ted) Kaiso
399 Thornall Street
10th floor
Edison, NJ 08837

Dear Mr. Kaiso:

Please refer to your supplemental new drug application dated November 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benicar (olmesartan medoxomil) 5, 20, and 40 mg Tablets.

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

Under the **ADVERSE REACTIONS/***Post-Marketing Experience* subsection, the following line was added after "*Gastrointestinal:* Vomiting":

Metabolic and Nutritional Disorders: Hyperkalemia

In addition, the following minor editorial changes were also noted:

1. Throughout the package insert, the registered trademark symbol has been added so that "Benicar" now reads as "Benicar®."

2. In the **boxed "USE IN PREGNANCY" warning**, the trade name "Benicar" has been changed to "Benicar HCT®".

3. At the end of the labeling,

    a. The phrase "Manufactured by Sankyo Pharma GmbH, Munich, Germany" has been deleted.
    b. The PI part number has been changed from P1800406 to P1800407.
    c. The issue date has been updated from "Revised December 2004" to "Rev. Sept 2006."

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling submitted on November 6, 2006.

At the time of your next printing, please make the following minor editorial correction:

Correct the trade name "Benicar HCT®" to "Benicar®" in the **boxed "USE IN PREGNANCY" warning**.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

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

9/26/2007 04:57:52 PM