DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-532/S-008

Daichi Sankyo, Inc.
Attn: Tetsuya Kaiso
399 Thornall Street
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 HCT (olmesartan medoxomil/hydrochlorothiazide) 20/12.5, 40/12.5, and 40/25 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following:

> Under **ADVERSE REACTIONS**, *Post-Marketing Experience*, a new sub-heading entitled "*Metabolic and Nutritional Disorders*" has been added with the following item: Hyperkalemia.

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 final electronic printed labeling (FPL) submitted on November 6, 2006.

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 call:

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 1
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

11/16/2007 09:14:52 AM