DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-100/S-003

Daiichi Sankyo Inc.
Attention Mr. Rich Cuprys
Regulatory Affairs
399 Thornall Street
Edison, NJ 08837

Dear Mr. Cuprys:

Please refer to your supplemental new drug application dated July 15, 2008, received July 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azor (amlodipine and olmesartan medoxomil), Tablets 5/20 mg, 5/40 mg, 10/20 mg, and 10/40 mg.

This supplemental new drug application provides for a labeling supplement to revise the wording within the **DOSAGE AND ADMINISTRATION** subsection.

Currently, the approved Prescribing Information for AZOR contains the following statement in section "**2. DOSAGE ADMINISTRATION**":

> ***Add-on Therapy for Patients with Hypertension Not Adequately Controlled on Amlodipine or Olmesartan Medoxomil Alone***
>
> AZOR may be used as add-on therapy for patients not adequately controlled on amlodipine or olmesartan medoxomil.

The following revision has been made to the **DOSAGE AND ADMINISTRATION** subsection:

> ***Add-on Therapy***
>
> AZOR may be used to provide additional blood pressure lowering for patients not adequately controlled with amlodipine (or another dihydropyridine calcium channel blocker) alone or with olmesartan medoxomil (or another angiotensin receptor blocker) alone.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the Structured Product Labeling (SPL) submitted on July 15, 2008.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Lori Wachter, RN, BSN
Regulatory Project Manager
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., PhD.
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

8/7/2008 09:58:31 AM