DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-100/S-002

Daiichi Sankyo Pharma Development
Attention: Yoshihiro (Yoshi) Emura
Manager Regulatory Affairs
399 Thornall Street
Edison, NJ 08837

Dear Mr. Emura:

Please refer to your supplemental new drug application dated July 11, 2008, received July 11, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Azor (amlodipine and olmesartan medoxomil) 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg Tablets.

We acknowledge receipt of your submissions dated November 20 and 26, and December 31, 2008.

This supplemental new drug application provides for the use of Azor (amlodipine/olmesartan medoxomil) 5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg Tablets as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-100/S-002."

PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

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

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

Enclosure: Agreed-upon labeling text

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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