DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022100/S-030

SUPPLEMENT APPROVAL

Daiichi Sankyo, Inc.
Attention: Kerrie Leigh Nagrod, MSJ
Associate Director, Regulatory Affairs
399 Thornall Street, 10th floor
Edison, NJ 08837

Dear Ms. Nagrod:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 20, 2015, and your amendment dated November 4, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Azor® (amlodipine and olmesartan medoxomil) 5/20mg, 5/40mg, 10/20mg, and 10/40mg Tablets.

This Prior Approval supplemental new drug application provides for revisions to the 7-count sample wallet and sample tray.

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on November 4, 2016, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22100/S-030**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 contact Sabry Soukehal, Regulatory Health Project Manager, at (240) 402 6187.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
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/

MARY R SOUTHWORTH
12/09/2016