CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-100

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA APPROVAL

NDA 22-100

Daiichi Sankyo, Inc.
Attention: Mr. Tetsuya Kaiso
399 Thornall Street
Edison, NJ 08837

Dear Mr. Kaiso:

Please refer to your November 27, 2006 new drug application (NDA) submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for AZOR (amlodipine and olmesartan medoxomil) 5/20, 5/40, 10/20, and 10/40 mg Tablets.

We also acknowledge receipt of your submissions dated December 8, 2006, February 12, March 16, 21 and 27, April 9, May 15, June 1 and 8, July 30 and 31, August 2 (two), 15 (two), and 30 (two), and September 5, 7, and 13, 2007.

This new drug application provides for the use of AZOR indicated for the treatment of hypertension, alone or with other antihypertensive agents.

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

A waiver for performing additional bioequivalence studies with the intermediate strengths of 5/20, 10/20 and 5/40 mg AML/OLM is granted.

An expiration date of 24 months is granted for AZOR (amlodipine and olmesartan medoxomil) 5/20, 5/40, 10/20, and 10/40 mg Tablets.

Based upon the provided information, the following dissolution method is approved for this application.

Apparatus:	USP 2
Media:	900 mL, phosphate buffer, pH 6.8 at 37° C
Speed:	50 RPM
Q value at 30 minutes:	☐ for olmesartan medoxomil ☐ for amlodipine besylate

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your September 13, 2007 submission containing final printed carton and container labels.

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 agreed-upon labeling text. 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." You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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.

PROMOTIONAL MATERIALS

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 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Denise Hinton, Regulatory Project Manager, at (301) 796-1090.

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
9/26/2007 05:44:19 PM