DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200175/S-026

SUPPLEMENT APPROVAL

Daiichi Sankyo, Inc.
Attention: Kerri 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 June 3, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tribenzor (olmesartan medoxomil/ amlodipine/hydrochlorothiazide) 20 /5 /12.5 mg, 40 /5 /12.5 mg, 40 /5 /25 mg, 40 /10 /12.5 mg, and 40 /10 /25 mg.

This supplemental new drug application provides for revisions to the label as follows (additions are shown as underlined text and deletions are shown as ~~strikethrough text~~):

1. The **HIGHLIGHTS** section was revised to read:

12 Pages of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

13. Under **PATIENT COUNSELING INFORMATION**, the following revisions were made:

> Pregnancy: Tell f(b) (4)emale patients of childbearing age (b) (4) about the consequences of exposure to Azor during pregnancy. Discuss treatment options with women planning to become pregnant. Tell (b) (4)patients (b) (4) to report pregnancies to their physicians as soon as possible.
>
> Symptomatic Hypotension: (b) (4) Advise patients that lightheadedness can occur, especially during the first days of therapy, and that it should be reported to the prescribing physician. Tell patients that if syncope occurs, Tribenzor should be discontinued until the physician has been consulted.
>
> (b) (4) Tell patients that inadequate fluid intake, excessive perspiration, diarrhea, or vomiting can lead to an excessive fall in blood pressure, with the same consequences of lightheadedness and possible syncope (b) (4)

1. In the FDA Approved Patient Labeling (PPI), the following bullet was added to the section entitled Especially tell your doctor if you are taking:

   - tacrolimus and cyclosporine (medicines used to alter the way your immune system works)

2. The revision date and version number were updated.

There are no other changes from the last approved package insert.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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
01/05/2017