NDA 021176/S-047
NDA 022362/S-027
NDA 210895/S-001

SUPPLEMENT APPROVAL

Daiichi Sankyo, Inc.
Attention: Pinku Raval, RN, BSN, MS
Manager, Regulatory Affairs
211 Mount Airy Road
Basking Ridge, NJ 07920-2311

Dear Ms. Raval:

Please refer to your supplemental new drug applications (sNDA)s dated and received February 20, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA Number	Product Name
021176	Welchol (colesevelam hydrochrolide) tablets
022362	Welchol (colesevelam hydrochloride) powder for oral suspension
210895	Welchol (colesevelam hydrochloride) chewable tablets

These Prior Approval supplemental new drug applications provide for revisions to correct inconsistencies in Section 6.1, Clinical Studies Experience, Section 8.1, Pregnancy, and other formatting/editorial annual reportable changes throughout the labeling. The reference to non-HDL-C was also removed from Section 2.1, Testing Prior to Initiation of Welchol and Section 5.1, Hypertriglyceridemia and Pancreatitis.

APPROVAL & LABELING

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Arati B. Kamath, Ph.D., Regulatory Project Manager, at (301) 796-3159.

Sincerely,

{See appended electronic signature page}

John Sharretts, M.D.
Deputy Director (Acting)
Division of Diabetes, Lipid Disorders, and Obesity
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOHN M SHARRETTS
05/12/2020 12:25:23 PM