



NDA 21176/S-030
NDA 22362/S-010

SUPPLEMENT APPROVAL

Daiichi Sankyo, Inc.
Attention: Zoya Borodanski
Associate Director, Regulatory Affairs, CMC
399 Thornall Street, 10th floor
Edison, NJ 08837

Dear Ms. Borodanski:

Please refer to your Supplemental New Drug Applications (sNDAs) dated December 21, 2011 (NDA 21176/S-030) and January 20, 2012 (NDA22362/S-010), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Welchol (colesevelam HCl) Tablets and Welchol (colesevelam HCl) for Oral Suspension, respectively.

These "Prior Approval" supplemental new drug applications provide for revisions to the shared package insert. Specifically, the following sections have been revised:

Highlights (Drug Interactions)
Section 7 (Drug Interactions)
Section 12.3 (Pharmacokinetics)
Section 17 (Patient Counseling Information)

This supplement was submitted to fulfill a postmarketing commitment for the approved supplement -017 (NDA 21176). The specific commitment was to conduct drug-drug interaction testing between Welchol and the following drugs:

- A commonly used ACE inhibitor (drug chosen; enalapril)
- A commonly used angiotensin receptor blocker (drug chosen; olmesartan)
- A long-acting beta-blocker (drug chosen; atenolol)
- Aspirin
- Rosiglitazone
- Glimepiride
- Sitagliptin
- Metformin ER
- Phenytoin

We have completed our review of this supplemental application. 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), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Amundson Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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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, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Eric Colman, MD
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:

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/

ERIC C COLMAN
07/09/2012