DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21176/S-027
NDA 22362/S-002

SUPPLEMENT APPROVAL

Daiichi Sankyo, Inc.
Attention: Gretchen Golikov
Associate Director, Regulatory Affairs
399 Thornall Street
Edison, NJ 08837

Dear Ms. Golikov:

Please refer to your Supplemental New Drug Applications (sNDAs) dated March 10, 2010, received March 3, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Welchol (colsevelam) Tablets (NDA 21176) and Welchol (colesevelam) for Oral Suspension (NDA 22362).

These "Changes Being Effected" supplemental new drug applications provide for a revision to the shared package insert to include information on the results of a drug-drug interaction study with cyclosporine. These supplements were submitted in response to our letter dated August 14, 2009 (NDA 21176).

We have waived the requirement, under 21 CFR 314.70(c)(6)(iii), that revisions to the HIGHLIGHTS section of the package insert be submitted as a prior approval supplemental application.

We have completed our review of these supplemental applications. They are 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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 pending "Changes Being Effected" (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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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) 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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21176	SUPPL-27	DAIICHI SANKYO INC	WELCHOL TABLETS 625 MG.
NDA-22362	SUPPL-2	DAIICHI SANKYO INC	WELCHOL POWDER FOR ORAL SUSPENSION

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/s/

ERIC C COLMAN
09/14/2010