DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-014

Daiichi Sankyo, Inc.
Attention: Sandra Smith, RPh, MBA
Director, Regulatory Affairs
399 Thornall Street 10th Floor
Edison, NJ 08837

Dear Ms. Smith:

Please refer to your supplemental new drug application dated November 7, 2005, received November 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for WelChol (colesevelam HCL) Tablets, 625 mg.

We acknowledge receipt of your submissions dated December 30, 2005 and February 13, April 4, May 3, June 14, August 4, and 14, 2006 (email).

This supplemental new drug application provides for changes to the **CLINICAL STUDIES, Combination Therapy** subsection of the package insert to add efficacy data for the effect on lipid parameters of WelChol when added to fenofibrate. This supplement additionally provides for clarification to the **PRECAUTIONS, Drug Interactions** subsection regarding administration of other drugs with WelChol.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. Submit 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 in content to the enclosed labeling text which you submitted by email on August 14, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed draft labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-176/S-014**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

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

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Margaret Simoneau, M.S., R.Ph., Regulatory Project Manager, at (301) 796-1295.

Sincerely,

{See appended electronic signature page}

Mary Parks, MD
Division Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Eric Colman
9/6/2006 08:45:00 PM
Eric Colman for Mary Parks