DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-021

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

Dear Ms. Borodanski:

Please refer to your supplemental new drug application dated January 30, 2008, received January 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Welchol (colesevelam HCl) Tablets.

This supplemental new drug application provides for blisters as an alternate packaging system for physician samples and for the addition of alternate primary [redacted] and secondary [redacted]) packaging sites.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling submitted on January 30, 2008 (blister package labeling).

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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}

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

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
5/30/2008 02:47:43 PM
Eric Colman for Mary Parks