DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-019

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 application dated April 5, 2007, received April 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for WelChol (colesevelam HCl) Tablets, 625 mg.

This supplemental new drug application provides for revised graphics on the following labeling: 8-count physician sample bottle, 180-count commercial bottle and tray for physician sample bottles.

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

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved supplemental NDA 21-176/S-019**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: 18-count sample label
180-count bottle label
Tray for 18-count sample bottles

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
8/27/2007 10:24:32 AM
Eric Colman for Mary Parks