



NDA 21-176/S-015

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 January 4, 2006, received January 5, 2006, 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 submission dated June 24, 2006, containing a User Fee form 3397.

This “Changes Being Effected” supplemental new drug application provides for the addition of the following Postmarketing Experience subsection to the ADVERSE REACTIONS section of the package insert:

There have been rare reports of elevated thyroid stimulating hormone (TSH) levels in patients who have received WelChol co-administered with thyroid hormone replacement therapy.”

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on January 4, 2006.

(b)(4)

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kati Johnson, Chief, Project Management Staff at 301-796-1234.

Sincerely,

{See appended electronic signature page}

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

Attachment: Package Insert

**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
7/10/2006 12:22:08 PM
Eric Colman for Mary Parks