DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-008

Sankyo Pharma Inc.
Attention: Nashad Islam
Associate Director, Regulatory Affairs, CMC
399 Thornall Street, 10th Floor
Edison, NJ 08837

Dear Mr. Islam:

Please refer to your supplemental new drug application dated April 14, 2003, received April 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Welchol (colesevelam hydrochloride) Tablets.

We acknowledge receipt of your submission dated August 6, 2003, which contained final printed labeling (FPL).

This supplemental new drug application provides for the addition of a 6-count, 625-mg tablet physicians sample bottle.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 6, 2003.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

Mamta Gautam-Basak, Ph.D.
Chemistry Team Leader II for the
Division of Metabolic and Endocrine Drug Products, HFD-510
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

ENCLOSURES:
Bottle Label
Carton Label

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

/s/

Sheldon Markofsky
8/21/03 01:25:26 PM
Signed for Mamta Gautam-Basak by S. Markofsky (Acting Team Leader)