DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-004

Sankyo Pharma Inc.
Attention: Albert S. Yehaskel
Senior Director, Regulatory Affairs
399 Thornall Street
Edison, New Jersey 08837

Dear Mr. Yehaskel:

Please refer to your supplemental new drug application dated January 29, 2002, received January 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for WelChol (colesevelam hydrochloride) Tablets, 625 mg.

We acknowledge receipt of your submissions dated August 7, 2002, and February 4, 2003.

Your submission of August 7, 2002, constituted a complete response to our July 29, 2002, action letter.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted February 4, 2003).

Please submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – NDAs". Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-176/S-004." 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, HF-2
FDA
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 William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
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/

David Orloff

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