DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-010

Sankyo Pharma
Attention: Jean Lyons
Associate Director, Promotion and Advertising
399 Thornall Street, 10th Floor
Edison, NJ 08837

Dear Ms. Lyons:

Please refer to your supplemental new drug application dated June 11, 2003, received June 12, 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 October 29, 2003.

Your submission of October 29, 2003, constituted a complete response to our October 9, 2003, action letter.

This supplemental new drug application provides for the addition of a 540-count bottle presentation.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted October 29, 2003, and immediate container labeling submitted June 11, 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 (package insert and container label) as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 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-010." 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, HFD-410
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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
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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