DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-176/S-009

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

Dear Ms. Lyons:

Please refer to your supplemental new drug application dated April 22, 2003, received April 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Welchol® (cholesevelam hydrochloride) Tablets.

This supplemental new drug application provides for the addition of "fenofibrate" to the PRECAUTIONS section, Drug Interactions subsection, second sentence and for administrative editorial changes throughout the package insert.

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

1. (b)(4)---------- has been deleted from the header.

2. "Proposed Revision April 8, 2003" has been added in the footer.

3. Under the **Drug Interactions** section, "fenofibrate" was added to the list of drugs (page 8) whose bioavailability is not significantly affected by co-administration with Welchol®.

4. "Manufactured for" city, state, and zip code was changed to Parsippany, New Jersey 07054 (b)(4)----------

5. **Rx Only** was added.

6. Version was changed from 5 to 7.

The final printed labeling (FPL) must be identical, to the enclosed labeling (package insert submitted April 22, 2003).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA's*. 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 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-009." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this application and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation 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

10/10/03 09:25:56 AM