



NDA 21-176/S-005

Sankyo Pharma Inc.  
Attention: Naushad Islam  
Associate Director, Regulatory Affairs CMC  
399 Thornall Street  
Edison, New Jersey 08837

Dear Mr. Islam:

Please refer to your supplemental new drug application dated April 19, 2002, received April 19, 2002, 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 28, 2002.

This supplemental new drug application provides for an 18-count physician sample presentation in a 60 cc HDPE bottle.

We have completed the review of this supplemental 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 final printed labeling (FPL) submitted on April 19, 2002. Accordingly, this supplemental application is approved effective on the date of this letter.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. 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-005." Approval of this submission by FDA is not required before the labeling is used.

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 William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

*{See appended electronic signature page}*

Sheldon Markofsky, Ph.D.  
Acting 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

ENCLOSURE

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/s/

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Sheldon Markofsky  
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