DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022362/S-024

SUPPLEMENT APPROVAL

Daiichi-Sankyo
Attention: Pinku Raval
Manager, Regulatory Affairs
211 Mount Airy Road
Basking Ridge, NJ 07920-2311

Dear Ms. Raval:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 29, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Welchol (colesevelam hydrochloride) Powder for Oral Suspension.

This Prior Approval supplemental new drug application provides for revisions to the carton/container labeling for the 3.75 gram strength product to delete that it can be reconstituted with one half cup of liquid, and retain the language that 1 cup of liquid should be used.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2018, Revision 5).* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 22362/S-024**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an

assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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 Kati Johnson, Senior Regulatory Project Manager, at 301-796-1234.

Sincerely,

{See appended electronic signature page}

William Chong, MD
Deputy Director (Acting)
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

WILLIAM H CHONG
04/10/2019 12:55:25 PM