



NDA 22362/S-007  
NDA 21176/S-028

**SUPPLEMENT APPROVAL**

Daiichi Sankyo, Inc  
Attention: Zoya Borodanski  
Director., Regulatory Affairs-CMC  
399 Thornall Street  
Edison, NJ 08837

Dear Ms. Borodanski:

Please refer to the following Supplemental New Drug Application (sNDAs):

Welchol (colesevelam) for Oral Suspension:  
NDA 22362/S-007, submitted January 28, 2011, amended July 1, 2011  
Welchol (colesevelam) Tablets:  
NDA 21176/S-028, submitted July 8, 2011

These "Prior Approval" supplements provide for revisions to the common package insert and to the carton and container labeling of the Oral Suspension formulation to state that the product can also be mixed with fruit juice or diet soft drinks (in addition to the currently approved water) prior to ingestion.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

At the next printing of the trade cartons, please revise the caption for picture #1 on the inside flap to state, "**Empty entire contents of the packet into an empty glass or cup**" to be consistent with the wording in the package insert.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effectuated" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 22362/S-007.**” Approval of this submission by FDA is not required before the labeling is used.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of

promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

**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, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

*{See appended electronic signature page}*

Eric Colman, MD  
Deputy Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

**ENCLOSURES:**

Content of Labeling

Carton and Container Labeling (Oral Suspension)

- Trade 30-count pouch (3.75 g)
- Sample 3-count pouch (3.75 g)
- Trade 30 packet carton (3.75 g) plus inside top flap
- Sample 3-count carton (3.75 g)
- Trade 60-count pouch (1.87 g)
- Sample 6-count pouch (1.87 g)
- Trade 60-count carton (1.87 g) plus inside top flap
- Sample 6-count carton (1.87 g)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ERIC C COLMAN  
07/18/2011