



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 4330 EAST WEST HIGHWAY
 BETHESDA, MD 20814

Memorandum

Date: **DEC - 8 2009**

TO : The Commission
 Todd Stevenson, Secretary

FROM : Cheryl A. Falvey, General Counsel *CAF*
 Philip L. Chao, Assistant General Counsel *PLC*
 Patricia M. Pollitzer, Attorney *PMP*

SUBJECT : Petition Requesting Exemption for Welchol® (colesevelam hydrochloride)
 Powder for Oral Suspension

DEC 14 2009

BALLOT VOTE due: _____

The Office of the General Counsel has determined that correspondence from Daiichi Sankyo, Inc. ("DSI") requesting that the Commission issue an exemption from special packaging requirements for its prescription drug, Welchol® (colesevelam hydrochloride) Powder for Oral Suspension, should be docketed as a petition.

In accordance with the Commission's directive on procedures for petitions (0605), the Office of the General Counsel has drafted a notice for publication in the Federal Register inviting comments on the petition for a period of 60 days. The draft notice is attached. The Office of Hazard Identification and Reduction recommends that the Commission NOT issue the notice. This recommendation is consistent with agency past practice with regard to petitions for exemption from the Poison Prevention Packing Act (PPPA) based on the fact that the product has only recently been approved by the Food and Drug Administration, and all available information necessary for making the staff's technical decision under the PPPA has been provided with the petition. The staff has concluded that publication in the Federal Register is not necessary.

Please indicate your vote on the following options.

- I. Approve the draft Federal Register notice without change.

 Signature

 Date

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Note: This document has not been reviewed or accepted by the Commission.
 Initials RH Date 12/8/09

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: <http://www.cpsc.gov>

CPSA 600(1) CLEARED for PUBLIC
12/8/09
 NO MFRS PRVT LBLRS OR PRODUCTS IDENTIFIED
 EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG
 WITH PORTIONS REMOVED

II. Approve the draft Federal Register notice with the following changes (please specify):

Signature

Date

III. Do not approve the draft Federal Register notice.

Signature

Date

IV. Take other action (please specify):

Signature

Date

CONSUMER PRODUCT SAFETY COMMISSION

Petition Requesting Exemption from Special Packaging Requirements for Prescription Drug Welchol® (Colesevelam Hydrochloride) Powder for Oral Suspension

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission

(Commission) has received a petition requesting an exemption from special packaging requirements for the prescription drug Welchol® (colesevelam hydrochloride) Powder for Oral Suspension. The Commission invites written comments concerning the petition.

DATES: Written comments on the petition must be received by [insert date 60 days after publication in the **Federal Register**].

ADDRESSES: You may submit comments, identified by Docket No. [insert CPSC docket number], by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Adrienne Layton,
Directorate for Health Sciences, Consumer Product Safety

Commission, 4330 East-West Highway, Bethesda, MD 20814;
telephone (301)504-7576; alayton@cpsc.gov .

SUPPLEMENTARY INFORMATION: The Commission has received correspondence from Daiichi Sankyo, Inc. ("DSI") requesting that the Commission issue an exemption from special packaging requirements for DSI's prescription drug, Welchol® (colesevelam hydrochloride) powder for oral suspension. Commission regulations pursuant to the Poison Prevention Packaging Act ("PPPA") requires special packaging, sometimes called child-resistant packaging, for prescription drugs in a dosage form intended for oral administration. 16 CFR 1700.14(a)(10).

Welchol® (colesevelam hydrochloride) is a bile acid sequestrant indicated to reduce elevated low density lipoprotein cholesterol ("LDL-C") and improve glycemic control in adults with type 2 diabetes mellitus. Welchol® was marketed in tablet form. The Food and Drug Administration ("FDA") recently approved Welchol® in the form of a powder for oral suspension. DSI is requesting this exemption only for the powder dosage form.

Interested parties may obtain a copy of the petition by writing or calling the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923

Dated:

Todd A. Stevenson, Secretary
Consumer Product Safety Commission