



Daiichi-Sankyo

Petition No. PP 10-1

CPSA 6(b)(1) CLEARED for PUBLIC

NO MFRS PRVTLBLRS OR PRODUCTS IDENTIFIED 1/5/10

EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG

WITH PORTIONS REMOVED: *Conf. Submission*

DAIICHI SANKYO PHARMA DEVELOPM
a division of DAIICHI SANKYO, INC.

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February 24, 2009

Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

SUBJECT: Petition for Exemption from Child-Resistant Packaging – Colesevelam Hydrochloride

To Whom It May Concern:

Pursuant to 16 CFR 1702, Daiichi Sankyo, Inc. (DSI) hereby petitions the Consumer Product Safety Commission to exempt Welchol[®] (colesevelam hydrochloride) Powder for Oral Suspension for an exemption from the Poison Packaging Act Requirements detailed in 16 CFR 1700. Special packaging is not required to protect young children from serious injury or illness from colesevelam hydrochloride.

Colesevelam hydrochloride is a bile acid sequestrant indicated as an adjunct to diet and exercise to:

- reduce elevated low density lipoprotein cholesterol (LDL-C) in patients with primary hypercholesterolemia as monotherapy or in combination with an hydroxymethylglutaryl-coenzyme A (HMG CoA) reductase inhibitor; and
- improve glycemic control in adults with type 2 diabetes mellitus.

Currently marketed in tablet form, DSI has recently submitted a New Drug Application for a new dosage form, powder for oral suspension, to the Food and Drug Administration for approval. This new dosage form will provide 1.875 or 3.75 g of colesevelam HCl in unit dose packets, the contents of which are to be mixed with water and taken orally as a suspension. DSI requests this exemption for the powder dosage form only; the tablet will continue to be packaged to meet the requirements of 16 CFR 1700.

Please be advised that the material and data contained in this submission are considered to be confidential. The legal protection of such confidential commercial material is claimed under the applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331 (j) as well as the FDA regulations.



Daiichi-Sankyo

Petition for Exemption from Child-Resistant Packaging
Colesevelam Hydrochloride

Page 2

If there are any questions regarding this submission, please do not hesitate to call me at (732) 590-4986 or e-mail me at ggolikova@dsus.com.

Sincerely,

Gretchen Golikov
Associate Director, Regulatory Affairs