



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Chairman Inez M. Tenenbaum
 Commissioner Thomas H. Moore
 Commissioner Nancy A. Nord
 Commissioner Robert S. Adler
 Commissioner Anne M. Northup

ITEM:

Final Rule to Exempt Powder Formulations of Colesevelam Hydrochloride (Welchol®) (PP 10-1) and Sevelamer Carbonate (Renvela®) (PP 10-2) from Special Packaging Requirements of the Poison Prevention Packaging Act
(Briefing package dated July 6, 2011, OS No. 3002)

DECISION:

The Commission voted unanimously (5-0) to approve publication in the *Federal Register* of the draft final rule without change that will exempt two drugs from special packaging requirements under the Poison Prevention Packaging Act ("PPPA"). The rulemaking is based on petitions submitted by: (1) Daiichi Sankyo, Inc., (Petition PP 10-1) requesting an exemption for the powder formulation of colesevelam hydrochloride, which it markets as Welchol®; and (2) Genzyme Corporation (Petition PP 10-2) requesting an exemption for the powder formulation of sevelamer carbonate, which it markets as Renvela®. The Commission previously voted to grant the petitions and publish a notice of proposed rulemaking.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due July 15, 2011