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