From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, April 18, 2017 11:10 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Standard Homeopathic Company Issues Nationwide Recall of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets Due to Mislabeling

Standard Homeopathic Company is recalling all lots of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets sold in retail stores to the consumer level. The U.S. Food & Drug Administration (FDA) has concluded that the medicines have been found to contain inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the products' labels.

FDA believes that belladonna represents a serious health hazard to children and that the effects of belladonna are unpredictable. The Agency has stated to the Company, "There is no known safe dose or toxic dose of belladonna in children because of the many factors that affect it."

The Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets were used to provide temporary relief of teething symptoms in children. The recall includes all products that retailers may have had in stock. The Company stopped making and shipping the medicines nationwide in October 2016. This recall ensures the removal of any possible remaining products that may be on store shelves. No other Standard Homeopathic Company/Hyland's products are affected by this recall.

"We initiated this recall even after discontinuing production last fall because it is appropriate to do what our regulating agency has formally requested," said J.P. Borneman, PhD, chairman and CEO of Standard Homeopathic Company. "We are committed to maintaining and earning the trust consumers have placed in Standard Homeopathic Company. We have worked for 114 years to build relationships with our consumers. We intend to preserve that tradition of trust."

Standard Homeopathic Company is notifying its distributors and retailers by mail and is arranging for the return of all recalled products. Consumers who have products which are being recalled should discard the product.

Consumers with questions regarding this recall can contact Standard Homeopathic Company by calling 1-800-991-3376 (Monday-Friday 6 a.m. to 4 p.m. Pacific Time). Consumers should contact their physician or healthcare provider if they believe they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.