From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Product Recall - Raritan Pharmaceuticals
Date: Monday, November 28, 2016 2:50:18 PM

Products Containing Belladonna Extract by Raritan Pharmaceuticals: Recall - Possible Belladonna Alkaloids

AUDIENCE: Consumer, Pharmacy, Pain management, Family Practice, Pediatrics, Pharmacy

ISSUE: Raritan Pharmaceuticals, a contract manufacturer for Homeolab USA, is voluntarily recalling homeopathic products containing belladonna extract (see products below) due to the potential for variation in the content of belladonna extract in the products. The FDA has tested some products and recovered varying levels of belladonna extract content from what is declared on the label.

BACKGROUND: Raritan Pharmaceuticals is a contract manufacturer of these products for Homeolab USA that supplies the belladonna blends to Raritan Pharmaceuticals. These products were distributed Nationwide: 1) Product: CVS Homeopathic Infants' Teething Tablet 135 tablets, UPC: 050428424162, Lots: 41116 and 43436; 2) Product: Kids Relief Homeopathic Ear Relief Oral Liquid 0.85 fl. oz., UPC: 778159090639, Lot: 35254 3) Product: CVS Homeopathic Kids' Ear Relief Liquid 0.85 fl. oz., UPC: 050428441633, Lot: 33149.

RECOMMENDATION: Consumers with any product being recalled should stop using the product. Consumers with questions regarding this recall can contact Raritan Pharmaceuticals by phone at 1-866-467-2748 (Monday-Friday from 8am to 5:30pm EST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

Read the MedWatch safety alert, including links to the Recall notice at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm530642.htm