From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, August 03, 2017 11:02 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Rugby Laboratories

ISSUE: Rugby Laboratories is voluntarily recalling all lots of Diocto Liquid and Diocto Syrup, (docusate sodium solutions) manufactured by PharmaTech, LLC due to a risk of product contamination with Burkholderia cepacia. FDA informed Rugby that it received several adverse event reports of B. cepacia infections in patients which may be linked to Diocto Liquid or Diocto Syrup manufactured by PharmaTech LLC.

If a product contains B. cepacia, its use could result in infections in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. Some of these infections may be serious or even life-threatening in the at-risk patient population.

All lots with NDC 0536-0590-85 and NDC 0536-1001-85 are included in this recall.

BACKGROUND: Diocto Liquid and Diocto Syrup are used as stool softeners and are packaged in one pint (473 mL) bottles. Diocto Liquid was distributed nationwide to wholesale and retail facilities including hospitals and pharmacies.

RECOMMENDATION: Rugby Laboratories is notifying its distributors and customers by recall letter and is arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product which is being recalled should stop using and dispensing the product immediately.

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 a link to the press release, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570014.htm