PROVIDER ALERT

Rugby Diocto Liquid/Syrup Drug Recall Notification

To:	Alliance Contracted Pharmacies	**Recall Class:**	*Not yet classified*
From:	Alliance Pharmacy Services	**Recall Issue Date:**	8/2/2017
Date:	8/9/2017	**Recall #:**	*Not yet classified*
Subject:	**DRUG RECALL NOTICE**	**Manufacturer**:	PharmaTech LLC/Rugby
Products:	Medi-Cal, Group Care	**Reason:**	Bacterial Contamination

DRUG AFFECTED	NDC	LOT #	Action to take
Diocto **Liquid** 50 mg/5 mL (docusate sodium)	0536-0590-85	**ALL**	**Remove from Distribution and return to manufacturer**
Diocto **Syrup** 60mg/15mL (docusate sodium)	0536-1001-85	**ALL**	

SOURCE: United States Food & Drug Administration, www.fda.gov/Safety/Recalls/ucm569967.htm

Diocto **Liquid**
50mg/5 mL

Diocto **Syrup**
60mg/15 mL

Images above reflect examples of recalled drugs.

Rugby® Laboratories of Livonia, MI has issued a voluntary nationwide recall of all lots within the expiry of Diocto Liquid and Diocto Syrup, (docusate sodium solutions) manufactured by **PharmaTech**, **LLC** of Davie, FL due to a risk of product contamination with *Burkholderia cepacia*. 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 with the at-risk patient population.

Questions? Call Alliance Pharmacy Services Department
Monday – Friday, 8 am – 5 pm
Phone Number: 510.747.4541 | www.alamedaalliance.org

As part of its commitment to patient safety, Rugby® Laboratories is partnering with the Food and Drug Administration to notify customers who may be in possession of **Diocto Liquid 50 mg/5 mL NDC 00536-0590-85; or Diocto Syrup 60mg/15mL NDC 00536-1001-85 for all lots within the expiration period.**

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. Rugby® Laboratories learned of the potential issue through recent communication with the FDA. The FDA has informed Rugby® Laboratories 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**.

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 the recalled product should stop using and dispensing immediately.**

Consumers with questions regarding this recall should contact Rugby® Laboratories' Customer Support Department at 1.800.645.2158, available Monday through Friday 8 am – 8 pm (EST). Consumers can contact their physician or healthcare provider if they have additional questions about this product.

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

- Online: Complete and submit the report 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. Complete and return to the address on the pre-addressed form, or submit by fax to **1.800.FDA.0178 (1.800.332.0178)**.