**U.S. Food and Drug Administration**
Protecting and Promoting *Your* Health

### Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

# PharmaTech LLC Issues Voluntary Nationwide Recall of Diocto Liquid Distributed by Rugby Laboratories Due to Product Contamination

### For Immediate Release

July 15, 2016

### Contact

#### Consumers

Rugby®'s Customer Support Department
1-800-645-2158

#### Media

Brett Ludwig
(215) 970-0153

### Announcement

**View Product Photos**

PharmaTech LLC of Davie, FL, the manufacturer of the Rugby® - branded product, is voluntarily recalling all lots within the expiry of Diocto Liquid, a docusate sodium solution due to a risk of product contamination with Burkholderia cepacia. Use of docusate sodium liquid contaminated with B. cepacia may result in serious infections that could be life-threatening in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis.

As part of its commitment to patient safety, Rugby® Laboratories is working with PharmaTech LLC to notify customers who may be in possession of Diocto Liquid NDC 0536-0590-85; 50 mg/5 mL for all lots within the expiration period.

Diocto Liquid is used as a stool softener and is packaged in one pint (473 mL) bottles. All lots with NDC 0536-0590-85 are included in the recall. Diocto Liquid was distributed nationwide to **wholesale and retail facilities including hospitals and pharmacies**. The company learned of the potential issue through the receipt of two isolated complaints regarding this product. FDA has informed PharmaTech and Rugby that it received several adverse event reports of B. cepacia infections in patients. Additionally, some of these reports identify liquid docusate products manufactured by companies other than PharmaTech.

PharmaTech 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 them immediately.

Consumers with questions regarding this recall should contact Rugby®'s Customer Support Department at 1-800-645-2158, available Monday through Friday 8a – 8p 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:

- 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 full knowledge of the U.S. Food and Drug Administration.

###

**Follow FDA**

**Follow @US_FDA (https://twitter.com/US_FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

**Follow FDA (https://www.facebook.com/FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

**Follow @FDArecalls (https://twitter.com/fdarecalls) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

**Recent Recalled Product Photos on FDA's Flickr Photostream (https://www.flickr.com/photos/fdaphotos/sets/72157663245186459/) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

**Product Photos**


COMPARE TO ACTIVE INGREDIENT IN COLACE®*
Rugby®
NDC 0536-0590-85
NEW FORMULA
Drug Facts
Directions
mix with milk or fruit
adults and children 12
children 2 to under 12
children under 2 years
Other information
each teaspoonful
store at room


**More in Recalls, Market Withdrawals, & Safety Alerts (/Safety/Recalls/default.htm)**

Archive for Recalls, Market Withdrawals & Safety Alerts (/Safety/Recalls/ArchiveRecalls/default.htm)

Enforcement Reports (/Safety/Recalls/EnforcementReports/default.htm)

**Industry Guidance (/Safety/Recalls/IndustryGuidance/default.htm)**

Major Product Recalls (/Safety/Recalls/MajorProductRecalls/default.htm)