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.

Rugby Laboratories Issues Voluntary Nationwide Recall of Diocto Liquid and Diocto Syrup Manufactured By PharmaTech, LLC Due to Possible Product Contamination

For Immediate Release

August 2, 2017

Contact

Consumers

1-800-645-2158

Media

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(614) 757-3383

Announcement

View Product Photos

Rugby® Laboratories of Livonia, MI is voluntarily recalling 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 in the at-risk patient population.

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 0536-0590-85; or Diocto Syrup 60mg/15mL NDC 0536-1001-85 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. All lots with NDC 0536-0590-85 and NDC 0536-1001-85 are included in this recall. 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. FDA has 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.

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.**

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 (www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (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.

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