PharmaTech/Rugby – Recall of Diocto Liquid

- On July 15, 2016, the FDA announced a voluntary, consumer-level recall of all lots of Rugby's Diocto Liquid (docusate sodium) due to a risk of product contamination with *Burkholderia cepacia*.
    - Rugby is working with PharmaTech, the manufacturer of Rugby-branded Diocto, to notify customers who may be in possession of Diocto Liquid for all lots within the expiration period.
- Diocto Liquid, an over-the-counter product, is a stool softener used to relieve occasional constipation. Diocto Liquid was distributed nationwide to wholesale and retail facilities including hospitals and pharmacies.

Product Description	NDC #
Diocto Liquid (docusate sodium) 50 mg/5 mL, 473 mL	0536-0590-85

- 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.
- The company learned of the potential issue through the receipt of two isolated complaints regarding this product. The FDA has informed PharmaTech and Rugby that they 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.
- The extent of this recall remains under investigation. Therefore, the FDA and Centers for Disease Control and Prevention (CDC) recommend that healthcare providers and patients not use ***any*** liquid docusate sodium product as a stool softener or for any other medical purpose. If an oral liquid docusate stool softener is medically necessary, alternative medicines should be used.
- Background:
    - The CDC and FDA have been investigating a multi-state outbreak of infections caused by *B. cepacia*. As of July 14, 2016, the CDC has confirmed 53 cases from healthcare facilities in 5 states.
    - The CDC has confirmed bacterial contamination of samples of unused liquid docusate sodium product.
- The CDC and FDA are working together to continue to identify potential contamination of other liquid docusate sodium products.
- Consumers with questions regarding this recall should contact Rugby's Customer Support Department at **1-800-645-2158**. Consumers can contact their healthcare provider if they have additional medical questions about the recalled product.

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- 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 the recalled product should stop using and dispensing them immediately.

Action Plan

- Clinical Services will continue to provide updates as new safety information regarding liquid docusate products becomes available.
- Clinical Services will conduct mailings to member(s) that may be affected by the Diocto Liquid recall, and to providers who prescribed for the drug recently.
- Information regarding the Diocto Liquid recall will be posted on the optumrx.com portals.