



PharmaTech – Recall update

- On August 10, 2017, as a precautionary measure, the distribution firms [Leader Brand, Major Pharmaceuticals, and Rugby Laboratories](#) are voluntarily recalling all lots within expiry of all liquid products manufactured by PharmaTech due to possible product contamination.
 - Consumers, pharmacies, and healthcare facilities that have product being recalled should stop using and dispensing the product immediately.
 - A complete list of recalled products can be located [here](#).
- On August 8, 2017, the [FDA announced](#) that patients, pharmacies and healthcare facilities should immediately stop using and dispensing **all** liquid products manufactured by PharmaTech due to *Burkholderia cepacia* contamination and the potential for severe patient infection.
- The Centers for Disease Control and Prevention (CDC) laboratory testing of PharmaTech's oral liquid docusate detected a strain of *B. cepacia* bacteria linked to recent patient infections. Therefore, the FDA recommends healthcare professionals and patients not use PharmaTech's liquid drug products.
- The FDA advises healthcare facilities and pharmacies that think they might have liquid PharmaTech drug products, especially oral liquid docusate drug products, to check with their supplier to determine the identity of the manufacturer.
- Patients who are using liquid drug products and who have concerns should contact their healthcare professional.
- Any company that purchased liquid products manufactured by PharmaTech should immediately quarantine material under their control and contact the local FDA pharmaceutical recall coordinator.
- Consumers with questions regarding this recall should contact Rugby Laboratories/Major Pharmaceuticals Customer Support at **1-800-645-2158** or Leader Customer Support at **1-800-200-6313**.
- In 2016, the FDA advised health care professionals and patients not to use liquid docusate drug products manufactured at PharmaTech's facility after being implicated in the CDC's public health investigation. These products were labeled and distributed by multiple companies, including Rugby.
 - An FDA investigation associated with a 2016 multistate outbreak identified *B. cepacia* in more than 10 lots of oral liquid docusate sodium manufactured by PharmaTech, which was linked to patient infections that required intensive medical treatment. The 2016 investigation also detected *B. cepacia* in the water system used to manufacture the product.



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