



## FDA MedWatch

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### **Liquid Drug Products Manufactured by PharmaTech and Distributed by Rugby Laboratories and Possibly Other Companies: FDA Advisory - Not to Use**

**AUDIENCE:** Pharmacy, Patient, Health Professional

**ISSUE:** FDA is advising health care professionals and patients not to use any liquid product manufactured by PharmaTech LLC, Davie, Florida, due to *Burkholderia cepacia* contamination and the potential for severe patient infection. Rugby Laboratories, Livonia, Michigan, announced a voluntary recall on August 3, 2017, of two such products – Diocto Liquid and Diocto Syrup, both oral liquid docusate products – manufactured by PharmaTech.

Additional liquid drug products manufactured by PharmaTech might also be affected. Such products might have been labeled and distributed by Rugby and other companies. Any company that purchased liquid products manufactured by PharmaTech should immediately quarantine material under their control and contact the local FDA pharmaceutical recall coordinator.

Centers for Disease Control and Prevention laboratory testing of PharmaTech's oral liquid docusate detected a strain of *B. cepacia*, bacteria linked to recent patient infections. Therefore, FDA recommends health care professionals and patients not use PharmaTech's liquid drug products.

**BACKGROUND:** In 2016, FDA advised health care professionals and patients not to use liquid docusate drug products manufactured at PharmaTech's Davie, Florida, facility after being implicated in 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.

**RECOMMENDATION:** Patients, pharmacies, and health care facilities should immediately stop using and dispensing all liquid products manufactured by PharmaTech. It might be difficult to determine the manufacturer because these liquid products are not labeled with a PharmaTech label. FDA advises health care 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 health care professional.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report)
- [Download form](#) 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.

[08/08/2017 - [Advisory](#) - FDA]

Previous MedWatch Safety Alert:

[08/03/2017 - [Diocto Liquid and Diocto Syrup by Rugby Laboratories: Recall - Possible Product Contamination](#)]