URGENT NOTICE

TYPE: Drug Recall

Drug Name: **Oral Liquid Docusate Sodium by PharmTech**

Audience: Health Professionals

Date: **07/16/2016**

ISSUE

The FDA is alerting health care professionals that PharmaTech LLC, Davie, Florida, is voluntarily recalling all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories, Livonia, Michigan. The agency confirmed the product has been contaminated with Burkholderia cepacia, a bacteria linked to an outbreak in five states.

In addition, FDA has received several adverse event reports of B. cepacia infections in patients. Some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and the Centers for Disease Control and Prevention continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products.

BACKGROUND

PharmaTech manufactures the oral liquid docusate sodium, which is distributed nationwide by Rugby with a Rugby label in one pint (473 mL) bottles.

RECOMMENDATION

FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. FDA and CDC will provide additional information when it is available.

For additional information please visit https://www.drugs.com/fda/oral-liquid-docusate-sodium-pharmatech-recall-contaminated-b-cepacia-13892.html