Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

**PBM-2017-09**

**ITEM:** Leader Brand, Major Pharmaceuticals, and Rugby Laboratories recall of ALL liquid products manufactured by PharmaTech due to *B. cepacia* contamination risk

**SPECIFIC INCIDENT(S):**
- Earlier this month, Rugby Laboratories issued a voluntary nationwide recall of diocto liquid and diocto syrup manufactured by PharmaTech, LLC due to possible product contamination with *Burkholderia cepacia* (*B. cepacia*).
- FDA currently advises health care professionals and patients not to use any liquid drug products manufactured by PharmaTech and distributed by Rugby Laboratories and other companies due to possible *B. cepacia* contamination.
- On August 8, 2017, FDA provided a list of affected products which were previously addressed in a [National PBM Patient Level Recall Communication](http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html) that was issued last year (in August 2016) but have been re-identified by the FDA because of CDC testing that identified contamination linked to patient infection.
- On August 10, 2017, FDA released new information regarding affected products to recall.

**GENERAL INFORMATION:**
- Contamination with *B. cepacia* may 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 an at-risk patient population.
- Additional product information for **affected oral liquid drug and dietary supplement products is listed on page 3.** Affected products were manufactured in PharmaTech LLC’s Davie, Florida, facility; they are distributed by Leader Brand, Major Pharmaceuticals, and Rugby Laboratories.
- This is an extension of the product sequestration actions in **Product Recall Office Log # 12230** (available at: [http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html](http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html)). Healthcare providers and laboratories should be on alert for *B. cepacia* cases occurring among non-cystic fibrosis patients and should inform infection prevention staff when these infections occur. Cases should be reported to state or local public health authorities.
- Providers should continue to report any adverse reactions with the use of affected oral liquid drug and dietary supplement product(s) by entering the information into CPRS’ Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADRS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at [https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm](https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm), or by mail).
ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., primary care providers, infectious disease specialists, pulmonologists, and pharmacy staff, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D**: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy**: Within 10 business days of issue (due 08/29/2017):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to take the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
      - In the event patients feel ill (such as fevers and chills), they should seek immediate medical care and inform their provider that they had taken affected oral liquid products.
  - Communicate to PBM/VAmedSAFE that all patient notification actions
have been completed via the VHA Alerts and Recalls Website:

SOURCE: FDA


ATTACHMENT(s): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.

DRUG PRODUCTS AND DIETARY SUPPLEMENTS

LEADER BRAND
- Liquid Multivitamin Supplement for Infants and Toddlers 50 mL
- UPC: 096295128611
- ALL LOTS
- Liquid Vitamin D Supplement for Breastfed Infants 400 IU 50 mL
- UPC: 096295128628
- ALL LOTS

MAJOR PHARMACEUTICALS
- Certa-Vite Liquid 236ML
- UPC: 00904-5023-09
- ALL LOTS
- Poly-Vita Drops 50ML
- UPC: 00904-5099-50
- ALL LOTS
- Poly-Vita Drops W/Iron 50ML
- UPC: 00904-5100-50;
- ALL LOTS
- Ferrous Drops Iron Supp 50ML
- UPC: 00904-6060-50
- ALL LOTS
- D-Vita Drops 50ML
- UPC: 00904-6273-50
- ALL LOTS
- Tri-Vita Drops 50ML
- UPC: 00904-6274-50
- ALL LOTS
- Senna Syrup 237ML
- UPC: 00904-6289-09
- ALL LOTS

RUGBY LABORATORIES
- C Liquid 500mg 118ML
- UPC: 00536-0160-97
- ALL LOTS
- Diocto Liquid 50mg/5ml 473ML
- UPC: 00536-0590-85
- ALL LOTS
- Ferrous Sulfate Elixir 473ML
- UPC: 00536-0650-85
- ALL LOTS
- Fer Iron Liquid 50ML 50ML
- UPC: 00536-0710-80
- ALL LOTS
- Senexon Liquid 237ML
- UPC: 00536-1000-59
- ALL LOTS
- Diocto Syrup 60MG/15ML 473ML
- UPC: 00536-1001-85
- ALL LOTS
- Aller Chlor Syrup 120ML
- UPC: 00536-1025-47
- ALL LOTS
- Calcionate Syrup 16OZ
- UPC: 00536-2770-85
- ALL LOTS
- Cerovite Liquid 236ML
- UPC: 00536-2790-59
- ALL LOTS
- D3 400iu Liquid 50ML
- UPC: 00536-8400-80
- ALL LOTS
- Poly-Vitamin Liquid 50ML
- UPC: 00536-8450-80
- ALL LOTS
- Tri-Vitamin Liquid 50ML
- UPC: 00536-8501-80
- ALL LOTS
- Poly-Vitamin W/Iron Liquid 50ML
- UPC: 00536-8530-80
- ALL LOTS