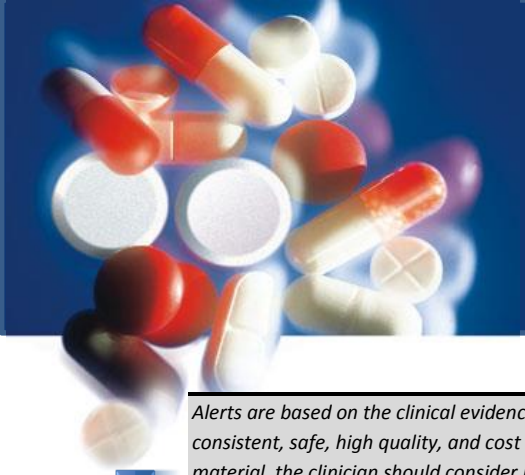

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

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 **AUGUST 15, 2017**

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 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). 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 ADERS 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, or by mail).

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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).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
      - 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

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA

REFERENCE(S): FDA Recalls, Market Withdrawals, & Safety Alerts. Voluntary Nationwide Recall of all Liquid Products Manufactured by Pharmatech LLC and Distributed by Leader Brand, Major Pharmaceuticals, and Rugby Laboratories Due to Possible Product Contamination. https://www.fda.gov/Safety/Recalls/ucm571001.htm . Accessed August 10, 2017.

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	00904-5023-09	ALL LOTS
Poly-Vita Drops	50ML	00904-5099-50	ALL LOTS
Poly-Vita Drops W/Iron	50ML	00904-5100-50;	ALL LOTS
Ferrous Drops Iron Supp	50ML	00904-6060-50	ALL LOTS
D-Vita Drops	50ML	00904-6273-50	ALL LOTS
Tri-Vita Drops	50ML	00904-6274-50	ALL LOTS
Senna Syrup	237ML	00904-6289-09	ALL LOTS
RUGBY LABORATORIES			
C Liquid 500mg	118ML	00536-0160-97	ALL LOTS
Diocto Liquid 50mg/5ml	473ML	00536-0590-85	ALL LOTS
Ferrous Sulfate Elixir	473ML	00536-0650-85	ALL LOTS
Fer Iron Liquid 50ML	50ML	00536-0710-80	ALL LOTS
Senexon Liquid	237ML	00536-1000-59	ALL LOTS
Diocto Syrup 60MG/15ML	473ML	00536-1001-85	ALL LOTS
Aller Chlor Syrup	120ML	00536-1025-47	ALL LOTS
Calcionate Syrup	16OZ	00536-2770-85	ALL LOTS
Cerovite Liquid	236ML	00536-2790-59	ALL LOTS
D3 400iu Liquid	50ML	00536-8400-80	ALL LOTS
Poly-Vitamin Liquid	50ML	00536-8450-80	ALL LOTS
Tri-Vitamin Liquid	50ML	00536-8501-80	ALL LOTS
Poly-Vitamin W/Iron Liquid	50ML	00536-8530-80	ALL LOTS