

FOR IMMEDIATE RELEASE



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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

LIVONIA, MI, August 9, 2017 — As a precautionary measure, the distribution firms Leader Brand, Major Pharmaceuticals, and Rugby Laboratories are jointly issuing a nationwide voluntary recall of all lots within expiry of all liquid products manufactured by PharmaTech LLC at its FDA registered facility in Davie, Fla. due to possible product contamination.

The distribution firms are committed to patient safety and are partnering with the Food and Drug Administration to notify customers who may be in possession of liquid products manufactured by PharmaTech LLC. Please see the below list of affected products.

The products subject to this recall were distributed nationwide to **wholesale and retail facilities, including hospitals and pharmacies**. Through recent communication with FDA, the distribution firm Rugby Laboratories learned of a potential issue with a product manufactured by PharmaTech LLC. The FDA informed Rugby Laboratories that it received several adverse event reports of *B. cepacia* infections in patients, which may be linked to PharmaTech LLC manufactured Diocto Syrup or Diocto Liquid (docusate sodium solutions). In response, Rugby Laboratories issued a voluntary recall on August 3, 2017, of the PharmaTech LLC manufactured Diocto Syrup and Diocto Liquid. As a precautionary measure based on additional information received from the FDA, the three distribution firms are recalling all lots within expiry of all liquid products manufactured by PharmaTech LLC.

The distribution firms are notifying their distributors and customers by recall letter and are arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product being recalled should stop using and dispensing the product immediately.

Consumers with questions regarding this recall should contact Rugby Laboratories/Major Pharmaceuticals Customer Support at 1-800-645-2158, available Monday through Friday 8 a.m. – 8 p.m. EST or Leader Customer Support at 1-800-200-6313 option #1 Monday through Thursday 8 a.m. – 7p.m. and Friday 8 a.m. – 5 p.m EST. Consumers can contact their physician or healthcare provider if they have additional questions about this product.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

This recall is being conducted with the full knowledge of the U.S. Food and Drug Administration.

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

NDC / UPC

Certa-Vite Liquid	236 mL	09045 02309	ALL LOTS
Poly-Vita Drops	50 mL	09045 09950	ALL LOTS
Poly-Vita Drops W/Iron	50 mL	09045 10050	ALL LOTS
Ferrous Drops Iron Supp	50 mL	09046 06050	ALL LOTS
D-Vita Drops	50 mL	09046 27350	ALL LOTS
Tri-Vita Drops	50 mL	09046 27450	ALL LOTS
Senna Syrup	237 mL	0904-6289-09	ALL LOTS

RUGBY LABORATORIES

NDC / UPC

C Liquid 500mg	118 mL	05360 16097	ALL LOTS
Diocto Liquid 50mg/5mL	473 mL	0536-0590-85	ALL LOTS
Ferrous Sulfate Liquid	473 mL	05360 65085	ALL LOTS
Fer Iron Liquid	50 mL	05360 71080	ALL LOTS
Senexon Liquid	237 mL	0536-1000-59	ALL LOTS
Diocto Syrup 60 mg/15 mL	473 mL	0536-1001-85	ALL LOTS
Aller Chlor Syrup	120 mL	0536-1025-47	ALL LOTS
Calcionate Syrup	473 mL	05362 77085	ALL LOTS
Cerovite Liquid	236 mL	05362 79059	ALL LOTS
D3 400 IU / 1 mL Liquid	50 mL	05368 40080	ALL LOTS
Poly-Vitamin Liquid	50 mL	05368 45080	ALL LOTS
Tri-Vitamin Liquid	50 mL	05368 50180	ALL LOTS
Poly-Vitamin W/Iron Liquid	50 mL	05368 53080	ALL LOTS

About Leader™

The Leader™ Brand product line is a broad assortment of quality, healthcare and personal care items available at authorized pharmacies nationwide. A broadly-based distribution network and strong customer loyalty enables Leader™ to offer products with the same active ingredients as nationally-advertised brands, but at significant savings to customers.

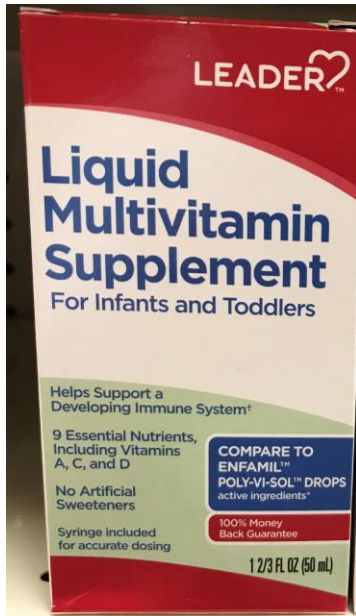
About Major Pharmaceuticals

For more than 30 years, Major® has been offering a broad and expanding portfolio of Rx unit dose, bulk and OTC options focused on supporting patient care efforts and providing economic value.

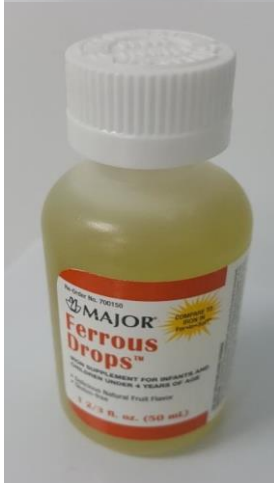
About Rugby® Laboratories

Rugby® Laboratories is a leading provider of high-quality Over the Counter, vitamin, and nutritional supplement products. With more than 40 years of history, Rugby® has been able to build out a comprehensive portfolio of products designed to enhance the quality of life for our consumers while reducing the cost of purchasing their medications.

LEADER BRAND



MAJOR PHARMACEUTICALS



RUGBY LABORATORIES

