



# URGENT: PRODUCT RECALL

August 11, 2017

Event # 4974

## PRODUCTS

Product Name	NDC Number	Lot Number / Expiry Date	Size
Rugby Aller-chlor Syrup 2 mg / 5 mL	0536-1025-47	All Unexpired Lots	4 oz (120 mL)
Rugby Diocto Liquid 50 mg /5 mL	0536-0590-85	All Unexpired Lots	One Pint (473 mL)
Rugby Diocto Syrup 60 mg /15 mL	0536-1001-85	All Unexpired Lots	One Pint (473 mL)
Rugby Senexon Liquid	0536-1000-59	All Unexpired Lots	8 oz (237 mL)
Product Name	UPC Number	Lot Number / Expiry Date	Size
Rugby Calcionate Syrup	0 05362 77085 1	All Unexpired Lots	One Pint (473 mL)
Rugby Cerovite Liquid	0 05362 79059 0	All Unexpired Lots	8 oz (236 mL)
Rugby D 3 Vitamin Liquid 400 IU / 1 mL	0 05368 40080 6	All Unexpired Lots	1 ⅔ oz (50 mL)
Rugby Fer-iron Liquid	0 05360 71080 4	All Unexpired Lots	1 ⅔ oz (50 mL)
Rugby Ferrous Sulfate Liquid	0 05360 65085 8	All Unexpired Lots	One Pint (473 mL)
Rugby Liquid Vitamin C Supplement	0 05360 16097 5	All Unexpired Lots	4 oz (118 mL)
Rugby Polyvitamin Liquid	0 05368 45080 1	All Unexpired Lots	1 ⅔ oz (50 mL)
Rugby Polyvitamin Liquid with Iron	0 05368 53080 0	All Unexpired Lots	1 ⅔ oz (50 mL)
Rugby Tri-vitamin Liquid	0 05368 50180 0	All Unexpired Lots	1 ⅔ oz (50 mL)
Product Name	NDC Number	Lot Number / Expiry Date	Size
Major Senna Syrup	0904-6289-09	All Unexpired Lots	8 oz (236 mL)
Product Name	UPC Number	Lot Number / Expiry Date	Size
Major CertaVite Liquid	3 09045 02309 9	All Unexpired Lots	8 oz (236 mL)
Major D-Vita Drops	3 09046 27350 9	All Unexpired Lots	1 ⅔ oz (50 mL)
Major Ferrous Drops	3 09046 06050 5	All Unexpired Lots	1 ⅔ oz (50 mL)
Major Poly-Vita Drops	3 09045 09950 6	All Unexpired Lots	1 ⅔ oz (50 mL)
Major Poly-Vita Drops with Iron	3 09045 10050 9	All Unexpired Lots	1 ⅔ oz (50 mL)
Major Tri-Vita Drops	3 09046 27450 6	All Unexpired Lots	1 ⅔ oz (50 mL)
Product Name	UPC Number	Lot Number / Expiry Date	Size
Leader Liquid Multivitamin Supplement for Infants and Toddlers	0 96295 12861 1	All Unexpired Lots	1 ⅔ oz (50 mL)
Leader Liquid Vitamin D Supplement for Breastfed Infants	0 96295 12862 8	All Unexpired Lots	1 ⅔ oz (50 mL)

Distributed by:  
Rugby Laboratories / Major Pharmaceuticals / Leader

(Over)

<b>REASON</b>	<p>As a precautionary measure, we are voluntarily recalling to the <b>CONSUMER LEVEL</b> the products identified in the table above which were 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 Rugby Laboratories, Major Pharmaceuticals, and Leader Brand are recalling all lots within expiry of all liquid products manufactured by PharmaTech LLC and distributed by said firms.</p>
<b>ACTION</b>	<ol style="list-style-type: none"><li>1. Stop distributing and quarantine these affected lots.</li><li>2. Please carry out a physical count and record this data on the Business Reply Form/Packing Slip which is included with this letter.</li><li>3. Fax the Business Reply Form <b>even if you do not have the recalled product to 1-888-667-1508 or e-mail: <a href="mailto:harvarddrug4974@stericycle.com">harvarddrug4974@stericycle.com</a></b></li><li>4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <p style="text-align: center;">Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 4974</p></li><li>5. If you have further distributed the product, please notify your <b>Wholesale, Retail and consumers</b> customers immediately and have them return the product back to you.</li></ol>
<b>OTHER INFORMATION</b>	<ol style="list-style-type: none"><li>1. This recall is being carried out to the <b>CONSUMER LEVEL</b> and is only for the specific product / lots listed above. No other lots, packages, or formulations are being recalled.</li><li>2. <b>These products were first shipped from our warehouse in December 2016.</b></li><li>3. For questions regarding returns, please contact Stericycle at 1-888-641-9736. For all other questions, please contact Rugby Laboratories at 1-800-645-2158 or Major Pharmaceuticals at 1-800-616-2471 or Leader at 1-800-200-6313.</li><li>4. <b>To ensure proper credit, please return recalled merchandise before December 31, 2017.</b> Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.</li><li>5. This recall is being made with the knowledge of the FDA. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.</li></ol>