



URGENT: DRUG / PRODUCT RECALL

August 4, 2017
Event # 4974

PRODUCT	<table border="1"><thead><tr><th>Product</th><th>NDC Number</th><th>Lot Number</th><th>Expiry Date</th><th>Size</th></tr></thead><tbody><tr><td>Rugby Diocto Liquid 50 mg/5 mL</td><td>0536-0590-85</td><td>20351701</td><td>03/2019</td><td>One Pint (473 mL)</td></tr></tbody></table>	Product	NDC Number	Lot Number	Expiry Date	Size	Rugby Diocto Liquid 50 mg/5 mL	0536-0590-85	20351701	03/2019	One Pint (473 mL)
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	Rugby Diocto Liquid 50 mg/5 mL	0536-0590-85	20351701	03/2019	One Pint (473 mL)						
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Rugby Diocto Syrup 60 mg/15 mL	0536-1001-85	22941701	03/2019	One Pint (473 mL)							
Distributed by: Rugby Laboratories Livonia, MI											
REASON	<p>We are voluntarily recalling to the RETAIL LEVEL the two products identified in the tables above which were manufactured by PharmaTech LLC. The recall was initiated due to adverse event reports received by the FDA which may indicate a risk of product contamination with <i>Burkholderia cepacia</i>. Use of docusate sodium solutions contaminated with <i>B. cepacia</i> may result in serious infections that could be life-threatening in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. Therefore, we are recalling all lots of the above identified products within expiry date.</p>										
ACTION	<ol style="list-style-type: none">1. Stop distributing and quarantine these affected lots.2. Please carry out a physical count and record this data on the Business Reply Form/Packing Slip which is included with this letter.3. Fax the Business Reply Form even if you do not have the recalled product to 1-888-667-1508 or e-mail: harvarddrug4974@stericycle.com4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 49745. If you have further distributed the product, please notify your Retail / Wholesale customers immediately and have them return the product back to you.										
OTHER INFORMATION	<ol style="list-style-type: none">1. This recall is being carried out to the RETAIL LEVEL and is only for the specific product / lots listed above. No other lots, packages, or formulations are being recalled.2. This product was first shipped from our warehouse on March 9, 2017.3. For questions regarding returns, please contact Stericycle at 1-888-641-9736. For all other questions, please contact Rugby Laboratories at 1-800-645-2158.4. To ensure proper credit, please return recalled merchandise before October 31, 2017. Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.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.										