

URGENT: DRUG / PRODUCT RECALL

September 8, 2016
Event # 5046

PRODUCT	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Product</th> <th style="width: 15%;">NDC Number</th> <th style="width: 10%;">Lot #'s</th> <th style="width: 10%;">Expiry Date</th> <th style="width: 10%;">Lot #'s</th> <th style="width: 10%;">Expiry Date</th> <th style="width: 10%;">Size</th> </tr> </thead> <tbody> <tr> <td rowspan="7">Major Label Eye Wash</td> <td rowspan="7">0904-6491-20</td> <td>G15905</td> <td>10/2018</td> <td>G16902</td> <td>01/2019</td> <td rowspan="7">4 oz. (118 mL)</td> </tr> <tr> <td>G15908</td> <td>10/2018</td> <td>G16903</td> <td>01/2019</td> </tr> <tr> <td>G15907</td> <td>10/2018</td> <td>G16905</td> <td>02/2019</td> </tr> <tr> <td>G15910</td> <td>11/2018</td> <td>G16906</td> <td>02/2019</td> </tr> <tr> <td>G15911</td> <td>11/2018</td> <td>G16907</td> <td>02/2019</td> </tr> <tr> <td>G15912</td> <td>11/2018</td> <td>G16910</td> <td>03/2019</td> </tr> <tr> <td>G16901</td> <td>01/2019</td> <td>G16911</td> <td>03/2019</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Product</th> <th style="width: 15%;">NDC Number</th> <th style="width: 10%;">Lot #'s</th> <th style="width: 10%;">Expiry Date</th> <th style="width: 10%;">Lot #'s</th> <th style="width: 10%;">Expiry Date</th> <th style="width: 10%;">Size</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Rugby Label Eye Irrigating Solution</td> <td rowspan="3">0536-1083-97</td> <td>G15908</td> <td>10/2018</td> <td>G16908</td> <td>02/2019</td> <td rowspan="3">4 oz. (118 mL)</td> </tr> <tr> <td>G15909</td> <td>11/2018</td> <td>G16912</td> <td>03/2019</td> </tr> <tr> <td>G16904</td> <td>01/2019</td> <td>G16913</td> <td>03/2019</td> </tr> </tbody> </table>	Product	NDC Number	Lot #'s	Expiry Date	Lot #'s	Expiry Date	Size	Major Label Eye Wash	0904-6491-20	G15905	10/2018	G16902	01/2019	4 oz. (118 mL)	G15908	10/2018	G16903	01/2019	G15907	10/2018	G16905	02/2019	G15910	11/2018	G16906	02/2019	G15911	11/2018	G16907	02/2019	G15912	11/2018	G16910	03/2019	G16901	01/2019	G16911	03/2019	Product	NDC Number	Lot #'s	Expiry Date	Lot #'s	Expiry Date	Size	Rugby Label Eye Irrigating Solution	0536-1083-97	G15908	10/2018	G16908	02/2019	4 oz. (118 mL)	G15909	11/2018	G16912	03/2019	G16904	01/2019	G16913	03/2019
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REASON	<p>We have been informed by United Exchange Corp. that they are voluntarily recalling to the RETAIL LEVEL the two products indicated in the tables above. The recall was initiated "due to complaints received which raised concerns that product sterility was potentially impacted. Use of a contaminated product could be calamitous for any population since there is a reasonable probability of a potentially sight threatening eye infection. Therefore, we are recalling all lots of the above identified product 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 1-800-651-8198 or e-mail: harvarddrug5046@stericycle.com. 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <div style="text-align: center; margin: 10px 0;"> Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 5046 </div> 5. 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 December 14, 2015. 3. For questions regarding returns, please contact Stericycle at 1-800-651-9279. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471 or Rugby Laboratories at 1-800-645-2158. 4. To ensure proper credit, please return recalled merchandise before <u>December 30, 2016</u>. 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. 																																																												

BUSINESS REPLY FORM / PACKING SLIP

Please make a copy of this form to include with your product return shipment.

Major Pharmaceuticals / Rugby Laboratories

September 8, 2016

Event # 5046

Products: Major Label Eye Wash / Rugby Label Eye Irrigating Solution

Affected NDC Numbers: 0904-6491-20 / 0536-1083-97

Package Size: 4 oz. (118 mL)

Your timely response to the recall notification is requested. Please fill out and fax this reply form within five (5) days, even if you do not have the recalled product. Thank you.

Please complete and fax to: **Stericycle at: Fax: 1-800-651-8198 or e-mail: harvarddrug5046@stericycle.com**

Customer Name: _____ Customer Acct #: _____

Street Address: _____

City: _____ State: _____ Zip Code: _____

Debit Memo Number: _____

Signature: _____ Date: _____

Title: _____

Affected Lot Numbers:

Product	NDC #	Lot #	Expiration Date	Bottles on Hand
Major Label Eye Wash 4 oz. (118 mL)	0904-6491-20	G15905	10/2018	
		G15906	10/2018	
		G15907	10/2018	
		G15910	11/2018	
		G15911	11/2018	
		G15912	11/2018	
		G16901	01/2019	
		G16902	01/2019	
		G16903	01/2019	
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