



FAX COVER

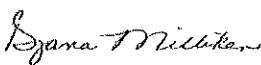
From: National Distribution & Contracting, Inc.
 Djana Milliken – Compliance
 URGENT
 This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.

To: Purchasing or Regulations
 Department

Date: 9/12/2016

Pages: 3 (Including cover page)

Regarding:
 Major Pharmaceuticals
 Urgent: Drug /Product Recall

Comments:
 Dear Distributor,
 Attached is a letter we received from Major Pharmaceuticals regarding the recall on eye wash. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices. Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.
 Thanks,

 Djana Milliken

URGENT: DRUG / PRODUCT RECALL

September 8, 2016
Event # 5046

PRODUCT	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)
			G15906	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	
	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	
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. 						



9/12/2016

Major Pharmaceuticals - Eye Wash # 700194

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 Or email to: Compliance@ndc-inc.com

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return
700194			

- I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.
- We have inspected our inventory and have no product related to this recall

Completed by: (Print Name /Signature/Date) _____

Returned Completed form to:

Fax #:

Email:

Djana Milliken

615.229-6801

compliance@ndc-inc.com

Delivering Efficiency to Healthcare®

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