

URGENT: OTC DRUG RECALL

September 18, 2017
Event # 4116

PRODUCT	<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr style="background-color: #f2f2f2;"> <th style="text-align: center;">Product</th> <th style="text-align: center;">NDC Number</th> <th style="text-align: center;">Lot #</th> <th style="text-align: center;">Expiry Date</th> <th style="text-align: center;">Size</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Magnesium Citrate Oral Solution Lemon flavored</td> <td style="text-align: center;">0904-6304-77</td> <td style="text-align: center;">0326736</td> <td style="text-align: center;">08-2018</td> <td style="text-align: center;">10 oz. (296 mL)</td> </tr> </tbody> </table> <p style="margin: 0;">Distributed by: Major Pharmaceuticals Livonia, MI 48152 USA</p> <p style="margin: 0; text-align: right;">Recalled by: Vi-Jon, Inc.</p>	Product	NDC Number	Lot #	Expiry Date	Size	Magnesium Citrate Oral Solution Lemon flavored	0904-6304-77	0326736	08-2018	10 oz. (296 mL)
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Magnesium Citrate Oral Solution Lemon flavored	0904-6304-77	0326736	08-2018	10 oz. (296 mL)							
REASON	<p>We have been informed by Vi-Jon, Inc., that they are recalling to the <u>RETAIL LEVEL</u>, the product indicated in the table above. The recall was initiated due to “out-of-specification results for magnesium oxide concentration, where the investigation did not conclusively invalidate the original results, potentially leading to inconsistencies in blend uniformity”.</p>										
ACTIONS TO BE TAKEN	<ol style="list-style-type: none"> 1. Stop distributing and quarantine the affected lot. 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 1-888-480-2856 or email to harvarddrug4116@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;"> <p>Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 4116</p> </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	<p>This recall is being carried out to the <u>RETAIL LEVEL</u> and is only for the specific product / lot listed above. No other lots, packages, or formulations are being recalled.</p> <p>This product was shipped from our Indianapolis warehouse between 08/29/16 and 11/30/16.</p> <p>For questions regarding returns, please contact Stericycle at 1-888-708-5723. For medical-related questions, please contact your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.</p> <p>To ensure proper credit, please return recalled merchandise before <u>December 20, 2017</u>. Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.</p> <p>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.</p>										