

URGENT: DRUG RECALL

August 28, 2017

PRODUCT	<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 30%;">Product</th> <th style="width: 20%;">NDC Number</th> <th style="width: 20%;">Lot #</th> <th style="width: 20%;">Expiry Date</th> <th style="width: 10%;">Size</th> </tr> </thead> <tbody> <tr> <td>Enalapril Maleate Tablets, USP 2.5 mg</td> <td>0904-5609-61</td> <td>DR10821A</td> <td>02-2019</td> <td>10 x 10 Unit Dose</td> </tr> </tbody> </table> <p style="text-align: center;">Distributed by: Major Pharmaceuticals 17177 N. Laurel Park Dr., Suite 233 Livonia, MI 48152</p> <p style="text-align: right;">Recall Issued by: Wockhardt Limited</p>	Product	NDC Number	Lot #	Expiry Date	Size	Enalapril Maleate Tablets, USP 2.5 mg	0904-5609-61	DR10821A	02-2019	10 x 10 Unit Dose
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Enalapril Maleate Tablets, USP 2.5 mg	0904-5609-61	DR10821A	02-2019	10 x 10 Unit Dose							
REASON	<p>We have been informed by Wockhardt that they are voluntarily recalling to the Retail Level the product indicated in the above table. This recall was initiated because “at 3 Month Accelerated Stability Testing (40°C / 75% RH), an Out of Specification was reported for related compound test for the Lot No. DR10635 on November 16, 2016. During further OOS investigation and impact analysis at Wockhardt India, Lot No. DR10636 & DR10821 were discovered with increased impurity levels as compared to typical long-term stability results. Hence the firm has decided to recall all the three (3) lots of this product.” Subsequently Major Pharmaceuticals is Recall the above repackaged product lot.</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 1-734-743-7181 or email to dmcpherson@thdg.com 4. Contact Major Customer service at (800) 616-2471, ext. 6491 to obtain a return authorization for your recalled product. Please have your account, invoice, and item numbers available when you call. 5. Return the affected recalled product to: <div style="margin-left: 20px;"> Major Pharmaceuticals Attn: Recalled Product 8401 Bearing Drive, Suite 100 Indianapolis, IN 46268 </div> 6. 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 RETAIL LEVEL 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 07/31/17 and 08/17/17.</p> <p>For questions regarding returns, please contact Major Pharmaceuticals at 1-800-616-2471 ext. 6491. For medical-related questions, please contact Wockhardt Limited customer care at 1-800-445-4290. 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>November 28, 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>										