

# URGENT: DRUG RECALL

April 24, 2019

<b>PRODUCT</b>	<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="text-align: center;">Product</th> <th style="text-align: center;">NDC Number</th> <th style="text-align: center;">Size</th> <th style="text-align: center;">Lot Number</th> <th style="text-align: center;">Expiry Date</th> </tr> </thead> <tbody> <tr> <td>Divalproex Sodium ER 250mg Tablets, USP</td> <td style="text-align: center;">0904-6363-61</td> <td style="text-align: center;">10 x 10 Unit Dose</td> <td style="text-align: center;">M02250</td> <td style="text-align: center;">10-2020</td> </tr> </tbody> </table> <p style="margin: 0;">Distributed by: Major Pharmaceuticals 17177 N. Laurel Park Dr., Suite 233 Livonia, MI 48152</p> <p style="margin: 0; text-align: right;">Recall Issued by: Dr. Reddy's Laboratories Inc. 107 College Road East Princeton, NJ 08540</p>	Product	NDC Number	Size	Lot Number	Expiry Date	Divalproex Sodium ER 250mg Tablets, USP	0904-6363-61	10 x 10 Unit Dose	M02250	10-2020
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<b>REASON</b>	<p>We have been informed by Dr. Reddy's Laboratories Inc., that they are voluntarily recalling the product indicated in the above table. This recall was initiated due to "exposure of the product to above 50% relative humidity levels during packaging operations".</p>										
<b>ACTIONS TO BE TAKEN</b>	<ol style="list-style-type: none"> <li>1. Stop distributing and quarantine the affected lot.</li> <li>2. Please carry out a physical count and record this data on the Business Reply Form / Packing Slip which is included with this letter.</li> <li>3. Fax the Business Reply Form <b>even if you do not have the recalled product to 1-877-410-5552 or email to <a href="mailto:HarvardDrug10089@stericycle.com">HarvardDrug10089@stericycle.com</a>.</b></li> <li>4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to:           <div style="margin-left: 40px;">             Stericycle, Inc.              2670 Executive Dr., Suite A              Indianapolis, IN 46241              Attn: Event # 10089           </div> </li> <li>5. If you have further distributed the product, please notify your <b>Wholesale / Retail</b> customers immediately and have them return the product back to you.</li> </ol>										
<b>OTHER INFORMATION</b>	<p>This recall is being carried out to the <b>RETAIL LEVEL</b> and is only for the specific product / lot listed above. No other lots, packages, or formulations are being recalled.</p> <p><b>This product was shipped from our Indianapolis warehouse between 03/14/2019 and 04/18/2019.</b></p> <p>For questions regarding returns, please contact Stericycle at 1-888-345-5359. For medical-related questions, please contact Dr. Reddy's Laboratories / DLSS at 1-888-375-3784 or your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.</p> <p><b>To ensure proper credit, please return recalled merchandise before <u>July 30, 2019</u>.</b> 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>										



**BUSINESS REPLY FORM / PACKING SLIP**

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

Major Pharmaceuticals  
Livonia, MI 48152

**April 24, 2019**

**Product:** Divalproex Sodium Extended-Release 250mg Tablets, USP  
**Affected NDC Number:** 0904-6363-61  
**Affected Lot Number** M02250  
**Exp. Date:** 10-2020  
**Package Size:** Unit Dose Cartons of 100 Tablets

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 or email to Stericycle at: **Fax: 1-877-410-5552**  
**Email: [HarvardDrug10089@stericycle.com](mailto:HarvardDrug10089@stericycle.com)**

Wholesaler Name: \_\_\_\_\_ Wholesaler Acct #: \_\_\_\_\_

Debit Memo Number: \_\_\_\_\_

Signature: \_\_\_\_\_ Title: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

**Please check one:**

- We do not have any of the recalled products on hand.**
- We have quarantined the following recalled product(s) and will return them as requested:**

**Affected Lot Number: Divalproex Sodium Extended-Release 250mg Tablets, USP**

NDC / UPC Number	Lot Number	Expiration Date	Whole Units on Hand	Partial Units on Hand
0904-6363-61 3 09046 36361 3	M02250	10-2020		