

URGENT: DRUG RECALL

December 27, 2016
Event # 2780

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: 15%;">Lot #</th> <th style="width: 15%;">Expiry Date</th> <th style="width: 20%;">Size</th> </tr> </thead> <tbody> <tr> <td>Aripiprazole 2mg Tablets</td> <td>0904-6509-04</td> <td>T-00601</td> <td>04-2017</td> <td>3 x 10 Unit Dose</td> </tr> </tbody> </table> <p style="margin-left: 40px;">Distributed by: Major Pharmaceuticals 31778 Enterprise Drive Livonia, MI 48150 USA</p> <p style="margin-left: 400px;">Recalled by: Apotex Corp.</p>	Product	NDC Number	Lot #	Expiry Date	Size	Aripiprazole 2mg Tablets	0904-6509-04	T-00601	04-2017	3 x 10 Unit Dose
Product	NDC Number	Lot #	Expiry Date	Size							
Aripiprazole 2mg Tablets	0904-6509-04	T-00601	04-2017	3 x 10 Unit Dose							
REASON	We have been informed by Apotex Corp., that they are recalling to the RETAIL LEVEL , the product indicated in the table above. The recall was initiated due to “the lot may not meet specification limit for assay test throughout the shelf life of the product”.										
HEALTH ASSESSMENT	Based on the profound overdose data and the established wider therapeutic index of Aripiprazole, it is concluded that there is minimal risk to the patients who may get exposed to the impacted tablets from this lot.										
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 1-877-275-2731 or email to harvarddrug2780@stericycle.com. 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <p style="margin-left: 40px; text-align: center;">Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 2780</p> 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 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 09/17/15 and 06/17/16.</p> <p>For questions regarding returns, please contact Stericycle at 1-877-271-1472. 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>March 15, 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>										