

URGENT: DRUG RECALL

January 19, 2018
Event # 6616

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 #'s</th> <th style="width: 20%;">Expiry Date</th> <th style="width: 10%;">Size</th> </tr> </thead> <tbody> <tr> <td rowspan="3" style="text-align: center;">Alprazolam 0.25mg Tablets C-IV</td> <td rowspan="3" style="text-align: center;">0904-5858-61</td> <td style="text-align: center;">1895E161A</td> <td style="text-align: center;">10-2018</td> <td rowspan="3" style="text-align: center;">10 x 10 Unit Dose</td> </tr> <tr> <td style="text-align: center;">2260F161A</td> <td style="text-align: center;">11-2018</td> </tr> <tr> <td style="text-align: center;">2888J161A</td> <td style="text-align: center;">04-2019</td> </tr> </tbody> </table> <p style="text-align: center;">Distributed by: Major Pharmaceuticals Livonia, MI 48152 USA</p>	Product	NDC Number	Lot #'s	Expiry Date	Size	Alprazolam 0.25mg Tablets C-IV	0904-5858-61	1895E161A	10-2018	10 x 10 Unit Dose	2260F161A	11-2018	2888J161A	04-2019
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REASON	<p>Major Pharmaceuticals is voluntary recalling to the RETAIL LEVEL, the product / lots indicated in the table above. This recall was initiated due to an out-of-specification result for an unknown impurity during a recent investigation. The impurity had an LC-Value of 0.3%, the stability protocol specification is NMT 0.2%.</p>														
ACTIONS TO BE TAKEN	<ol style="list-style-type: none"> 1. Stop distributing and quarantine the 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 1-855-205-2624 or email to harvarddrug6616@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 # 6616</p> </div> 5. If you have further distributed the product, please notify your Wholesale / Retail 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 / lots listed above. No other lots, packages, or formulations are being recalled.</p> <p>This product was shipped from our Indianapolis warehouse between 01/17/17 and 09/20/17.</p> <p>For questions regarding returns, please contact Stericycle at 1-866-490-8288. 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>May 20, 2018</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>														