

URGENT: MARKET WITHDRAWAL

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: 15%;">Lot Number</th> <th style="width: 15%;">Expiry Date</th> <th style="width: 15%;">Lot Number</th> <th style="width: 15%;">Expiry Date</th> </tr> </thead> <tbody> <tr> <td rowspan="6" style="text-align: center; vertical-align: middle;">NDC 0904-5858-61 Alprazolam 0.25mg Tablets C-IV 10 x 10 Unit Dose</td> <td>4698L151A</td> <td>01-2018</td> <td>0786B161A</td> <td>06-2018</td> </tr> <tr> <td>4699L151A</td> <td>01-2018</td> <td>0786B161B</td> <td>06-2018</td> </tr> <tr> <td>4699L151B</td> <td>02-2018</td> <td>1389D161A</td> <td>07-2018</td> </tr> <tr> <td>4699L151C</td> <td>02-2018</td> <td>1389D161B</td> <td>07-2018</td> </tr> <tr> <td>0508B161A</td> <td>02-2018</td> <td>2886J161A</td> <td>02-2019</td> </tr> <tr> <td>0508B161B</td> <td>03-2018</td> <td>2886J161B</td> <td>02-2019</td> </tr> </tbody> </table> <p style="text-align: center;">Distributed by: Major Pharmaceuticals Livonia, MI 48152 USA</p> | Product | Lot Number | Expiry Date | Lot Number | Expiry Date | NDC 0904-5858-61 Alprazolam 0.25mg Tablets C-IV 10 x 10 Unit Dose | 4698L151A | 01-2018 | 0786B161A | 06-2018 | 4699L151A | 01-2018 | 0786B161B | 06-2018 | 4699L151B | 02-2018 | 1389D161A | 07-2018 | 4699L151C | 02-2018 | 1389D161B | 07-2018 | 0508B161A | 02-2018 | 2886J161A | 02-2019 | 0508B161B | 03-2018 | 2886J161B | 02-2019 |
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| Product | Lot Number | Expiry Date | Lot Number | Expiry Date | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| | 4699L151B | 02-2018 | 1389D161A | 07-2018 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 4699L151C | 02-2018 | 1389D161B | 07-2018 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| | 0508B161B | 03-2018 | 2886J161B | 02-2019 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| REASON | <p>Major Pharmaceuticals is voluntarily withdrawing from the market to the RETAIL LEVEL, the product / lots indicated in the table above. This market withdrawal has been initiated due to a recent investigation where test results on 3 other lots resulted in an out-of-specification result for an unknown impurity. Therefore, as a precautionary measure we are withdrawing these lots from the market.</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 of the affected product to 1-855-205-2624 or email to harvarddrug6616@stericycle.com. 4. Return the affected product and the Packing Slip using the prepaid UPS Return Service shipping label to: <ul style="list-style-type: none"> Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 6616 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 market withdrawal is being carried out to the RETAIL LEVEL and is only for the specific product / lots listed above.</p> <p>This product was shipped from our Indianapolis warehouse between 02/19/16 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 market withdraw 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> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |