

URGENT: VOLUNTARY DRUG RECALL

August 3, 2017
Event # 7354

| 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>Ibuprofen 400mg Tablets, USP</td> <td>0904-5853-60</td> <td>S-00148</td> <td>10-2019</td> <td>100 count bottles</td> </tr> </tbody> </table> <p style="margin: 0;">Distributed by: Major Pharmaceuticals Livonia, MI 48150</p> <p style="margin: 0; text-align: right;">Packaged by: A+ Secure Packaging 339 Mason Road LaVergne, TN 37086</p> | Product | NDC Number | Lot # | Expiry Date | Size | Ibuprofen 400mg Tablets, USP | 0904-5853-60 | S-00148 | 10-2019 | 100 count bottles |
|------------------------------|--|---------|-------------|-------------------|-------------|------|------------------------------|--------------|---------|---------|-------------------|
| Product | NDC Number | Lot # | Expiry Date | Size | | | | | | | |
| Ibuprofen 400mg Tablets, USP | 0904-5853-60 | S-00148 | 10-2019 | 100 count bottles | | | | | | | |
| REASON | <p>Major Pharmaceuticals is voluntarily recalling to the RETAIL LEVEL the product indicated in the table above. The recall was initiated “due to some 100 count bottles of Lot # S-00148 are incorrectly labeled as 500 count bottles”.</p> | | | | | | | | | | |
| ACTION | <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 1-866-792-5446 or e-mail: harvarddrug7354@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; margin-top: 10px;">Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 7354</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 | <ol style="list-style-type: none"> 1. This recall is being carried out to the RETAIL LEVEL and is only for the specific product / lots listed above. No other lots or packages are being recalled. 2. This product was shipped from our warehouse between 06-01-2017 and 07-26-2017. 3. For questions regarding returns, please contact Stericycle at 1-866-382-9260. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471. 4. To ensure proper credit, please return recalled merchandise before <u>November 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. 5. 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. | | | | | | | | | | |