October 7, 2016

URGENT: Actavis issues voluntary recall of 1 lot of NIFEdipine 10 mg Capsules, USP

Dear ASD Healthcare Customer:

Actavis is issuing a voluntary recall of 1 lot of NIFEdipine 10 mg Capsules, USP. This recall is being initiated due to a complaint from a pharmacist reporting that 1 foreign capsule, orange colored and imprinted “PROCARDIA Pfizer 260,” was found in a sealed 100 count bottle of Actavis’ NIFEdipine 10 mg Capsules, USP. No other lots of Actavis’ NIFEdipine 10 mg Capsules, USP have been found with this alleged product mix problem.

Procardia® is the brand version of NIFEdipine and both are indicated for the management of angina (chest pain). These drugs are considered bioequivalent enough that they can be substituted with each other. The use of or exposure to the product may cause a temporary or medically reversible adverse event, and the probability of serious adverse health consequences is likely remote.

Actavis provided the following affected lot information:

<table>
<thead>
<tr>
<th>Manufacturer NDC</th>
<th>Lot Number</th>
<th>Package Size</th>
<th>Expiry Dates</th>
<th>Distribution Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>0228-2497-10</td>
<td>0598B151</td>
<td>100 Count Bottles</td>
<td>03/2018</td>
<td>11/13/15 to 7/25/16</td>
</tr>
</tbody>
</table>

Please check your inventory for the specific product lot mentioned above. Place any recalled product on hold, and contact GENCO for information on disposal of affected product at 866.303.6043.

For the full recall notice please view the attached documents in the following pages.
Dear Valued Customer:

This is to advise you of a voluntary recall of 1-lot of NIFEdipine 10 mg Capsules, USP. Specific product information are given in the sections that follow, which details (1) recalled product information, (2) reason for recall, (3) depth of recall, (4) health hazard, and (5) instructions for returning the recalled lot.

This recall is being made with the knowledge of the Food and Drug Administration.

### RECALLED PRODUCT INFORMATION

<table>
<thead>
<tr>
<th>Recalled Lot</th>
<th>NDC</th>
<th>Size</th>
<th>Dates Distributed (From - To)</th>
<th>Exp. Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0598B151</td>
<td>0228-2497-10</td>
<td>100 Count Bottles</td>
<td>11/13/2015 - 7/25/2016</td>
<td>03/2018</td>
<td>Yellow soft gel capsule imprinted with 497</td>
</tr>
</tbody>
</table>

### RECALL INFORMATION

**Level:** RETAIL

**Reason:** Actavis received a complaint from a pharmacist reporting that one (1) foreign capsule, orange colored and imprinted “PROCARDIA Pfizer 260”, in a sealed 100 count bottle of Actavis’ NIFEdipine 10 mg Capsules, USP. No other lots of Actavis’ NIFEdipine 10 mg Capsules, USP have been found with this alleged product mix problem.

**Health Hazard Evaluation:** Procardia® is the brand version of NIFEdipine and both are indicated for the management of angina (chest pain). These drugs are considered bioequivalent enough that they can be substituted with each other. The alleged foreign Procardia capsule was identified as the same strength as the Actavis NIFEdipine product. However, since the alleged foreign capsule is not the Actavis product, NIFEdipine lot 0598B151 is being recalled. The use of or exposure to the product may cause temporary or medically reversible adverse event, and the probability of serious adverse health consequences is likely remote.

### ACTIONS REQUIRED

Upon receipt of this letter, please take the following actions:

1. Stop distribution and quarantine lot 0598B151.
2. **If you have further distributed this product lot, please notify your customers of this recall to the RETAIL level and follow the instructions given here for responding and for returning the recalled product.**
3. Carry out a physical count of the recalled lot number 0598B151 that is in your possession and record the amount(s) on the enclosed postage paid Business Reply Card (BRC) and Packing slip.
4. **Even if you do not have the recalled product lot in your inventory, please mail the postage paid Business Reply Card within five (5) business days. To assure that we can account for all customers it is imperative that you return the Business Reply Card even if you do not have product in stock.**
5. Attach the prepaid FedEx Authorized Return shipping label to the outside of the return carton. Return the recalled product and completed Packing Slip to Actavis’ recall processor:
   
   **GENCO Pharmaceutical Services, 6101 North 64th Street, Milwaukee, WI 53218**
   
   Please contact GENCO Pharmaceutical Services if these recall actions are unclear.

### CONTACT INFORMATION AND CREDIT

<table>
<thead>
<tr>
<th>Product Returns</th>
<th>Medical Inquiries/ Adverse Events/Product Complaints</th>
<th>Reimbursements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact GENCO at:</td>
<td>Contact Actavis at:</td>
<td>Contact Actavis at:</td>
</tr>
<tr>
<td>866-303-6043</td>
<td>800-432-8534</td>
<td>973-265-3533</td>
</tr>
<tr>
<td>7 am - 5 pm CST</td>
<td>8am - 5pm EST</td>
<td>9am - 5pm EST</td>
</tr>
</tbody>
</table>

FDA contact information for reporting adverse events/quality complaints:

Online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or call FDA at 1-800-FDA-1088

Credit will be issued only for the recalled product lot 0598B151 that you return. All product received in response to this recall, which is not associated with this recall, will be destroyed and credit will not be issued.

We appreciate your cooperation in this product recall, and regret any inconvenience that this may have caused. Thank you for your assistance in this matter.

Sincerely yours,

Actavis Pharma Inc.