March 16, 2017

**URGENT DRUG RECALL**

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC (“Fresenius Kabi”), formerly APP Pharmaceuticals, LLC, is voluntarily recalling the above-mentioned batches of Fluphenazine Decanoate Injection, USP 25 mg / mL, 5 mL fill in a 5 mL vial.

This recall is being performed to the user level. Fresenius Kabi is taking this action due to out-of-specification (OOS) results for Assay at the 13 month stability test station for batch 6112346. Analysis suggests the potential for batches 6111141, 6111222, and 6112725 to also be OOS prior to expiry due to the common use of a supplier lot of API. Therefore, as a precautionary measure, these 3 additional batches (6111141, 6111222, and 6112725) are included in this recall. The investigation reveals this issue is limited to the four product batches indicated above.

The Health Hazard Evaluation concluded that the OOS assay value observed is unlikely to be clinically significant. No adverse events have been reported for any of these batches of Fluphenazine Decanoate Injection, USP 25 mg / mL, 5 mL fill in a 5 mL vial.

You are required to **DESTROY** all product from the above-mentioned batches that you have in your possession. To implement this recall, please do the following:

1. Examine your stock immediately to determine if you have any product from the affected batches. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product of this recall and direct them to discontinue distributing or dispensing the affected batches. Please have them prepare to **DESTROY** the product. Your customers may retrieve the recall letter and response form at [http://www.fresenius-kabi.us/products/pharmaceutical-products/product-updates.html](http://www.fresenius-kabi.us/products/pharmaceutical-products/product-updates.html).

2. If you have the affected batches available, immediately discontinue distributing, dispensing, or using the batches, and **DESTROY** all units using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will NOT be issued covering the quantity until a letter of destruction is received from you.

3. **PLEASE COMPLETE THE ENCLOSED “URGENT PRODUCT RECALL RESPONSE FORM” AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL TO FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

**CONTACT NUMBERS:** Use the following contact phone numbers. Hours of operation: Monday through Friday 8:00 am to 5:00 pm CST

<table>
<thead>
<tr>
<th>Number</th>
<th>Department</th>
<th>Reason to Call</th>
</tr>
</thead>
<tbody>
<tr>
<td>(866) 716-2459</td>
<td>Quality Assurance Department</td>
<td>Information on how to return product</td>
</tr>
<tr>
<td>(800) 551-7176</td>
<td>Vigilance or Medical Affairs</td>
<td>For clinical/technical information/Adverse Events (ADE) reporting</td>
</tr>
</tbody>
</table>

This recall is being made with the knowledge of the US Food and Drug Administration (FDA).

We apologize for any inconvenience this voluntary recall may cause you.

Sincerely,

Melanie Power-Burns  
Vice President Quality Assurance
URGENT PRODUCT RECALL RESPONSE FORM

**URGENT: DRUG RECALL** – Sterile Injectable

March 16, 2017  Please complete and fax to: 1-708-649-8630

| To: Fresenius Kabi USA, LLC |
| Attn: Quality Assurance Department |

<table>
<thead>
<tr>
<th>Product Name/Product size</th>
<th>NDC Number</th>
<th>Product Code</th>
<th>Batch Number</th>
<th>Expiration Date</th>
<th>First Ship Date</th>
<th>Last Ship Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluphenazine Decanoate Injection, USP 25 mg / mL, 5 mL fill in a 5 mL vial</td>
<td>63323-272-05</td>
<td>27205</td>
<td>6111141</td>
<td>07/17</td>
<td>09/01/2015</td>
<td>12/10/2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6111222</td>
<td>08/17</td>
<td>12/10/2015</td>
<td>03/19/2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6112346</td>
<td>01/18</td>
<td>02/29/2016</td>
<td>04/26/2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6112725</td>
<td>03/18</td>
<td>08/16/2016</td>
<td>01/16/2017</td>
</tr>
</tbody>
</table>

1. Examine your inventory immediately to determine if you have any product from the above-mentioned batches.

2. If so, immediately discontinue distribution or dispensing of the affected batches and DESTROY all units using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will NOT be issued covering the quantity until a letter of destruction is received from you.

Please complete this form and send it back to us immediately via email at FK-NARECALLS@FRESENIUS-KABI.COM or fax at 1-708-649-8630.

☐ We currently do not have units of the batch number(s) on hand.

☐ We are DESTROYING ________ vials OR ________ trays/cartons

☐ I have identified and contacted direct account customers indicated below that have been shipped or may have been shipped this product. They have prepared to DESTROY the product.

FROM: Hospital (other): ____________________________
Street Address: ____________________________
City, State, Zip code: ____________________________
Signature: ____________________________

From: FACILITY:
ADDRESS: ____________________________
CITY, STATE, ZIP: ____________________________
Signature: ____________________________ Date: ____________________________