FRESENIUS KABI

URGENT DRUG RECALL

March 16, 2017

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

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 return 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 return the product to Fresenius Kabi (see enclosed information). Your customers may retrieve the recall letter and response form at http://www.fresenius-kabi.us/products/pharmaceutical-products/product-updates.html
2. If you have the affected batches available, **immediately** discontinue distributing or dispensing any units from the batches, and return all units to Fresenius Kabi, USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106, via FedEx Ground, using the enclosed return goods label and packing slip. A FedEx Ground label can be obtained by checking the box and noting your mailing address on the enclosed Urgent Product Recall Response Form. It will be mailed to you upon receiving your request. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.
3. **PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK 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

Number	Department	Reason to Call
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Event (ADE) reporting

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

Fresenius Kabi USA, LLC
2045 N. Cornell
Melrose Park, IL 60160

Main: 708-343-6100
Toll Free: 888-391-6300
www.fresenius-kabi.us

FRESENIUS KABI

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

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

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 return all units to Fresenius Kabi USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106 via FedEx Ground using the enclosed return goods label and packing slip. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.
3. **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 returning _____ vials **OR** _____ trays/cartons

# of Labels needed _____

☐ I have identified contacted direct account customers that have been shipped or may have been shipped this product. Please send FedEx Ground Shipping Labels to the address below.

FROM: Hospital (other):_____

Street Address:_____

City, State, Zip code: _____

Signature:_____

From:

FACILITY:
ADDRESS:
CITY, STATE, ZIP:

Signature _____ **Date** _____

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