

URGENT DRUG RECALL

March 16, 2017

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
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 **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>.
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

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

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

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
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			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 **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.
3. 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 _____