

URGENT DRUG RECALL

December 16, 2016

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Lot Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Midazolam Hydrochloride Injection, 5 mg / mL, 5 mL fill in a 5 mL amber vial	63323-412-05	410205	6007327	01-2017	03/12/2014	04/01/2016
			6007329	01-2017	12/05/2014	11/10/2015

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 lots of Midazolam Hydrochloride Injection, 5 mg / mL, 5 mL fill in a 5 mL amber vial. This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to out-of-specification (OOS) results for Largest Individual Unknown Impurity (LIUI) at the 33 month stability test station observed in 9 vials of lot 6007327 and 1 vial of lot 6007329. The investigation reveals that this issue is limited to the product lots indicated above.

Product samples yielding OOS results are currently undergoing analytical testing to identify the impurity. The associated health risk to patients is unknown at this time, and will be assessed once the impurity has been identified. No complaints or adverse event reports have been received for either lot number.

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

- Examine your stock **immediately** to determine if you have any product from the affected lots. 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 lots. Please have them 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>
- If you have the affected lots available, **immediately discontinue distributing or dispensing** the lots, 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
- PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL AT 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 Drug 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

URGENT PRODUCT RECALL RESPONSE FORM
URGENT: DRUG RECALL - Sterile Injectable
December 16, 2016
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>Lot Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
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			6007329	01-2017	12/05/2014	11/10/2015

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned lots.
2. If so, **immediately** discontinue distribution or dispensing of the affected lots 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 FAX IT BACK TO US IMMEDIATELY AT 1-708-649-8630.**
 - We currently do not have units of the lot 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 _____