FRESENIUS KABI

URGENT DRUG RECALL

December 16, 2016

Product Name/Product size	NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
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 **DESTROY** all product from the above-mentioned lots 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 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 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 lots available, **immediately** discontinue distributing or dispensing the lots, 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 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

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 Events (ADEs) 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,

12/16/16

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

December 16, 2016 **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	Lot Number	Expiration Date	First Ship Date	Last Ship Date
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**

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 **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 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 **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** _____

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