FRESENIUS KABI

URGENT DRUG RECALL

March 04, 2022

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Sodium Acetate Injection, USP, 400 mEq / 100 mL (4 mEq / mL), 100 mL fill in a 100 mL vial	63323-032-00	322100	6124193	05/2022	09/08/2020	12/22/2020
			6124196	05/2022	11/16/2020	01/27/2021
			6124226	05/2022	12/22/2020	03/22/2021
			6124532	06/2022	01/27/2021	04/13/2021
			6125333	12/2022	04/06/2021	06/01/2021
			6125678	01/2023	06/23/2021	09/27/2021
			6126846	08/2023	10/07/2021	11/17/2021

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned batches of Sodium Acetate Injection, USP, 400 mEq / 100 mL (4 mEq / mL), 100 mL fill in a 100 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to particulate matter found in retention and/or stability samples of seven batches distributed in the US. The investigation revealed that this issue is limited to the product batches indicated above.

Administration of products containing particulate matter could result in venous and arterial emboli, abscesses, granulomas in visceral organs, phlebitis, inflammatory reactions, infections at the injection site. No adverse event reports have been received for the batch numbers.

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 vials from the affected batches. Quarantine any affected stock. 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 quarantine and 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 https://www.fresenius-kabi.com/us/pharmaceutical-product-updates.

2. If you have the affected batches available, **immediately** quarantine and discontinue distributing, dispensing, or using any vials from the affected batches, and **DESTROY** all vials 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

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 Drug Events (ADE) reporting

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

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

Sincerely,

Melanie Power-Burns
Senior Vice President Quality Assurance

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Main: 847-550-2300
Toll Free: 888-391-6300
www.fresenius-kabi.com/us

FRESENIUS KABI

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL – Sterile Injectable

March 04, 2022 **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
Sodium Acetate Injection, USP, 400 mEq / 100 mL (4 mEq / mL), 100 mL fill in a 100 mL vial	63323-032-00	322100	6124193	05/2022	09/08/2020	12/22/2020
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			6125678	01/2023	06/23/2021	09/27/2021
			6126846	08/2023	10/07/2021	11/17/2021

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.

3. PLEASE COMPLETE THE INFORMATION BELOW AND SEND BACK TO US IMMEDIATELY VIA EMAIL AT FK-NARECALLS@FRESENIUS-KABI.COM OR FAX TO 1-708-649-8630.

☐ We currently **do not** have units of the above-mentioned batch numbers on hand.

☐ We are **DESTROYING**: _____ vials **OR** _____ trays/cartons

From: Hospital (other):_____

Street Address:_____

City, State, Zip code: _____

Contact Name (Please Print)_____ Telephone#_____

Contact Email_____ Fax#_____

Signature:_____ Date_____

☐ I have identified and contacted direct account customers that have been shipped or may have been shipped this product.

From:
Facility:
Street Address:
City, State, Zip Code:

Signature:_____ Date_____

Fresenius Kabi USA, LLC
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Lake Zurich, IL 60047

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