URGENT DRUG RECALL

November 06, 2025

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial	**63323-739-11**	**63323-739-12**	**730912**	**6133156**	**08/2026**	**01/02/2025**	**02/11/2025**
				6133194	**08/2026**	**02/04/2025**	**04/11/2025**
				6133388	**10/2026**	**04/15/2025**	**05/23/2025**

Dear Customer/Healthcare Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned batches of Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to out-of-specification (OOS) endotoxin results of certain reserve samples for batch 6133194 that were tested as part of an investigation for non-serious adverse event reports. Based upon current investigation, batches 6133156 and 6133388 are also included in this recall as a precautionary measure. Please refer to Attachment A for label examples.

The Health Hazard Evaluation concluded moderate risk to patients. Non-serious adverse event reports potentially associated with the OOS have been received for batch 6133194. No adverse event reports have been received for batches 6133156 and 6133388 to date. Elevated endotoxin levels can precipitate severe systemic reactions such as sepsis and septic shock. Severe responses may include inflammatory and life-threatening immune responses and death.

You are required to return all product from the above-mentioned batch numbers 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. 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 return the product to Fresenius Kabi (see enclosed information). 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, or dispensing any vials from the batches, and return all vials to Fresenius Kabi, USA, LLC located at 11900 122nd Street, Pleasant Prairie, WI 53158, 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.

3. **PLEASE COMPLETE THE ENCLOSED "URGENT DRUG 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	DepartmentInformation 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 United States Food and Drug Administration (FDA).

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

Sincerely,

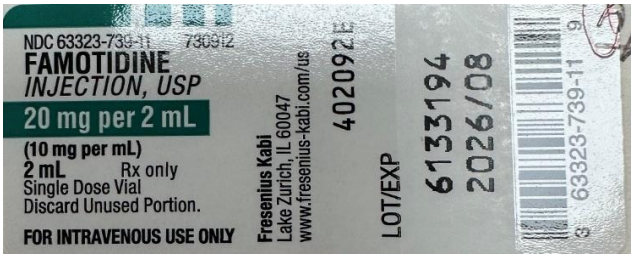
Anthony Giessert, Ph.D.
Senior Vice President, Quality Assurance
Fresenius Kabi USA, LLC

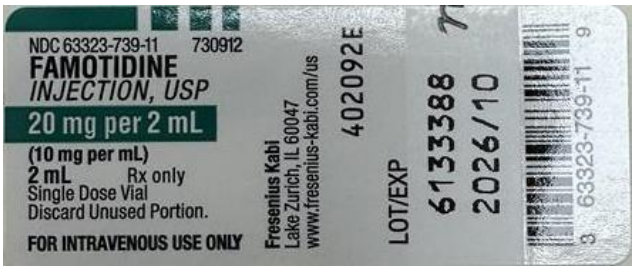
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

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

URGENT DRUG RECALL

Attachment A
Labeling Examples





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FRESENIUS KABI

URGENT: DRUG RECALL – Sterile Injectable

URGENT DRUG RECALL RESPONSE FORM

November 06, 2025 **Please complete and fax to: 1-708-649-8630**

To: Fresenius Kabi USA, LLC **Attn:** Quality Assurance Department

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial	**63323-739-11**	**63323-739-12**	**730912**	**6133156**	**08/2026**	**01/02/2025**	**02/11/2025**
				6133194	**08/2026**	**02/04/2025**	**04/11/2025**
				6133388	**10/2026**	**04/15/2025**	**05/23/2025**

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 11900 122nd Street, Pleasant Prairie, WI 53158 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 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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FRESENIUS KABI

ATTN: URGENT DRUG RECALL

PACKING SLIP FOR VOLUNTARY RECALL

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
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				6133194	08/2026	02/04/2025	04/11/2025
				6133388	10/2026	04/15/2025	05/23/2025

Vials (1 each) OR

Trays/Cartons Returning (Circle One)

Hospital (other) _____

Street Address _____

City, State, Zip code _____

Signature _____

PLEASE ENCLOSE THIS FORM WITH YOUR RETURN

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Lake Zurich, IL 60047

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