FRESENIUS KABI

URGENT DRUG RECALL

June 28, 2019

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial	**63323-117-61**	**101761**	**6120420**	**04-2020**	**12/07/2018**	**02/20/2019**
	63323-117-69	**NP101761**	**6120341**	**04-2020**	**12/06/2018**	**12/18/2018**

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 Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial.

This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to glass particulates found in 5 vials of the remaining inventory of batch 6120341 during an inspection for a quality investigation. Batch 6120420 is included in this recall as a precautionary measure because it was filled immediately post batch 6120341 as part of the same filling campaign.

The administration of glass particulate, if present in a parenteral drug, poses a moderate safety risk to patients. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur. No complaints related to glass particulate or adverse drug events have been received for either of these batches.

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 the batchese, 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 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
Sr. 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.com/us

FRESENIUS KABI

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL – Sterile Injectable

June 28, 2019 **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
Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial	**63323-117-61**	**101761**	**6120420**	**04-2020**	**12/07/2018**	**02/20/2019**
	63323-117-69	**NP101761**	**6120341**	**04-2020**	**12/06/2018**	**12/18/2018**

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 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 numbers 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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