URGENT: DRUG RECALL

December 27, 2023

Bleomycin for Injection, USP

15 Units Single Dose ONCO-TAIN™ Glass Fliptop Vial

For Intravenous, Intramuscular, Subcutaneous and Intrapleural use

NDC	Lot Number	Expiration Date	Concentration	Configuration/Count
61703-332-18	BL12206A	30JUN2024	15 units per vial lyophilized	1 vial per carton, 112 vials per case

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling to the user level the above referenced lot of **Bleomycin for Injection, USP**, due to a confirmed customer report for the presence of glass particulate within a single vial. Pfizer completed a Health Hazard Assessment, which concluded the use of impacted product has an unlikely probability of occurrence of adverse events such as injection site reaction, localized vein inflammation or phlebitis, thrombus, embolus and/or end-organ granuloma or life-threatening blood clot events.

To date, Pfizer has not received reports of any adverse events associated with this issue.

FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM …" PFIZER RECOMMENDS THAT YOU RESPOND TO THIS RECALL EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED BUSINESS REPLY FORM (BRF) AND RETURN IT, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Sedgwick at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lot of **Bleomycin for Injection, USP** is being conducted to the **User level**.

Our records indicate you received shipment of the affected product lot, which was distributed from **January 11, 2023 through May 11, 2023**. Please check your stock immediately against the product table above. If you have any of the affected lot in your inventory, please stop distribution, discontinue use, and quarantine the product immediately. Promptly return the product to Sedgwick; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8891 using the enclosed pre-paid UPS label. **All returns are requested to be completed within six months of this notice date.** If you received this notification without the prepaid UPS label and BRF, require additional shipping labels, or have questions regarding the return procedure, please contact Sedgwick at 800-805-3093.

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Please conduct a sub-recall to those accounts, communicate this

recall information immediately, request they immediately cease distribution and quarantine the affected product. Further, please instruct entities which may have received the recalled product from you if they have redistributed the product, they should notify their accounts, locations or facilities of the recall. If additional copies of the letter and/or response form are needed, please contact Sedgwick at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 1-844-646-4398 (Mon.-Fri. 8 am-6 pm ET).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you.

If you have any medical questions regarding the product, please call the appropriate contact center below.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	1-800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day; 7 days a week)	To report adverse events and product complaints

Sincerely,

Masum Hossain
U.S. Hospital Lead

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