URGENT: DRUG RECALL

November 30, 2021

5% Dextrose Injection, USP 50 mL

ADD-Vantage™ Unit

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-7100-68 (Unit of Use) 0409-7100-66 (Unit of Sale)	4923608	1MAY2022	50mg/mL, 50ml flex bag	5 bags to 1 container; 10 pouches/case

Dear Customer:

Hospira, Inc., a Pfizer company is voluntarily recalling the above lot of **5% Dextrose Injection, USP 50 mL** due to confirmed complaint trend for leaking primary containers on the vial port channel. Pfizer completed a Health Hazard Assessment, which concluded the use of the impacted product has an unlikely probability of being associated with adverse events of limited severity such as fever, malaise, chills, reduced efficacy, and severe adverse events such as sepsis or invasive systemic infections, especially in immunocompromised patients. There have been no reports of relevant adverse events associated with the lot number under investigation, and no relevant safety issues related to defective/leaking bags were identified as part of the post marketing safety database search.

The potential risk to the patient arising from this issue is considered to be low.

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…" HOSPIRA RECOMMENDS THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ATTACHED BUSINESS REPLY CARD (BRC) AND RETURN, 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 lots of **5% Dextrose Injection, USP 50 mL** is being conducted to the **Hospital/Institution Level**.

Our records indicate that you may have received shipment of the affected product between **June 2021** and **October 2021.** Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution and quarantine the product immediately. Promptly return it to Sedgwick 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 3886 using the label provided with this letter. **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 BRC, require additional shipping labels, or have questions regarding the return procedure

please contact Sedgwick at 1-800-805-3093. To ensure proper and timely credit, follow the instructions on the return label for returning the product.

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution and quarantine the affected product. Promptly contact Sedgwick at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET) to obtain a BRC to initiate the return process.

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 844-646-4398 (Mon.-Fri. 8 am-7 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 questions regarding this recall, please call the appropriate contact center below:

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (9am to 5pm ET Monday - Friday) www.pfizermedinfo.com	Medical inquiries
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

Sincerely,

Masum Hossain
Regional President
North America, Hospital Business Unit

Outer Wrap/5 Bags per Container

TO OPEN – PEEL AT NOTCH

Five/ADD-Vantage™ Units

For use only with ADD-Vantage™ system components.

The overwrap is a moisture barrier. Use units within 30 days of opening overwrap, as long as the use date does not exceed the printed expiration date. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard unit as sterility may be impaired. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]
Rx only

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Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

Hospira

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