URGENT: DRUG RECALL

March 19, 2019

8.4% Sodium Bicarbonate Injection, USP
50 mEq/50mL (1 mEq/mL)

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-6625-02	79-238-EV	1JUL2019	50 mEq/50 mL	Case Pack 4 x 25, 50mL
0409-6625-02	79-240-EV	1JUL2019	50 mEq/50 mL	Case Pack 4 x 25, 50mL
0409-6625-02	80-088-EV	1AUG2019	50 mEq/50 mL	Case Pack 4 x 25, 50mL

Dear Customer:

Hospira, Inc., a Pfizer company, ("Hospira") is voluntarily recalling the above referenced lots of 8.4% Sodium Bicarbonate Injection, USP due to the potential presence of particulate matter, confirmed as glass. The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected. To date, Hospira has not received reports of any adverse events associated with this issue for these lots. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

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 Stericycle Inc. at 1-800-805-3093 (Mon.-Fri. 8am-5pm ET).

The recall of the above-referenced lots are being conducted to the **Hospital/Institution level.**

Our records indicate you may have received shipment of the affected product between **August 2017 and September 2017.** Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution immediately and promptly return it to Stericycle using the

Hospira, Inc., a Pfizer company
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.pfizerinjectables.com

label provided with this letter. **All returns are requested to be completed within six months of this notice date.** 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 from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution of the affected product and promptly contact Stericycle at 1-800-805-3093 to obtain a BRC to initiate the return process.

Please contact Pfizer Customer Service at 1-844-646-4398 (Mon.-Fri. 8am-7pm ET) or your Pfizer representative regarding product availability and for questions regarding this market action.

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 you may contact Pfizer using the below information.

Contact	**Contact Information**	**Areas of Support**
Pfizer Medical Information	1-800-438-1985, option 3 (8am – 7pm ET Monday through Friday)	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,

Navin Katyal
General Manager, Pfizer Injectables
Pfizer Essential Health

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