66 Hudson Boulevard East
New York, NY 10001-2192

URGENT: DRUG RECALL

August 04, 2025

ABBOJECT® Syringe
Epinephrine Injection, USP

Case NDC	Vial NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-4933-10	0409-4933-05	LY3681	2026-FEB	1 mg/10 mL (0.1mg/mL)	Bundle of 10 cartons / One 10 mL vial and injector per carton. Five bundles per case
0409-4933-10	0409-4933-05	LY4360	2026-FEB	1 mg/10 mL (0.1mg/mL)	Bundle of 10 cartons / One 10 mL vial and injector per carton. Five bundles per case
0409-4933-10	0409-4933-05	LY4416	2026-FEB	1 mg/10 mL (0.1mg/mL)	Bundle of 10 cartons / One 10 mL vial and injector per carton. Five bundles per case

ABBOJECT® Syringe
8.4% Sodium Bicarbonate Injection, USP

Case NDC	Vial NDC	Lot Number	Expiration Date	Strength	Configuration/ Count
0409-6637-14	0409-6637-24	LH2671	2026-NOV	50 mEq/50 mL (1 mEq/mL)	Bundle of 10 cartons / One 50 mL vial and injector per carton. Five bundles per case

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above referenced lots of **Epinephrine Injection, USP and 8.4% Sodium Bicarbonate Injection, USP** due to a potential lack of sterility assurance. Pfizer has completed a Health Hazard Assessment which concluded that the use of these impacted products has a low probability of being associated with adverse events in patients including death, cardiopulmonary arrest, septic shock, organ injury, and bacteremia ranging from limited to serious severity. Immunocompromised patients and patients with pre-existing conditions or patients undergoing invasive procedures are at potentially greater risk. The overall potential risk to the patient arising from this issue is considered to be high.

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

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DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Sedgwick at 1-877-650-0365 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lots of **Epinephrine Injection and 8.4% Sodium Bicarbonate Injection** is being conducted to the **Hospital/Institution** level.

Our records indicate that you received shipment of the affected product lots which were distributed from **March 13, 2025 through May 14, 2025.** Please check your stock immediately against the table above. If you have any of the affected lots in your inventory, please discontinue use, stop distribution and quarantine the product immediately. Promptly return the product to Sedgwick; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 4468 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 877-650-0365.

If you have further distributed the recalled product, please notify your accounts and/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 877-650-0365 (Mon.-Fri. 8 am-5 pm ET) to obtain pre-paid shipping labels to initiate the return process.

Reimbursement for the returned product will be made by credit memorandum. Please contact Pfizer Customer Service at 844-646-4398 (Mon.-Fri. 8 am-6 pm ET) or your Pfizer representative regarding product availability and 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 medical questions regarding the product, please call the appropriate contact center below.

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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax**: Download form at **www.fda.gov/MedWatch/getforms.htm** or call 1-800-332-1088 to request a reporting form. Then complete the form and return it to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Sincerely,

Najah Sampson

Najah Sampson
Commercial Lead, U.S. Hospital
Pfizer

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ABBOJECT® Syringe
Epinephrine Injection, USP Product Photo

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8.4% Sodium Bicarbonate Injection, USP Product Photo