URGENT DRUG RECALL

December 29, 2022

HEPARIN SODIUM
2,000 USP Units per 1,000 mL
(2 USP Units/mL)
In 0.9% Sodium Chloride Injection
SINGLE DOSE CONTAINER

Case NDC	Unit NDC	Lot Number	Expiration Date	Configuration/Count
0409-7620-59	0409-7620-49	5935283	1 Dec 2023	12 units per case

Dear Customer,

Hospira, Inc., a Pfizer company, is voluntarily recalling the above-referenced lot of **HEPARIN SODIUM**. Pfizer initiated this recall due to confirmed reports of leaking bags. Pfizer completed a Health Hazard Assessment which concluded that the use of the impacted product has a low probability of occurrence of moderate adverse events such as blood stream infections, wound infection, diarrhea, acute gastroenteritis, or abdominal pain. The potential risk to the patient arising from this issue is considered to be medium.

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

The recall of the above-referenced lot of **HEPARIN SODIUM** is being conducted to the **Hospital/Institution Level**.

Our records indicate that you may have received shipment of the affected lot which was distributed between **August 2022 through November 2022.** Please check your stock immediately to identify whether you have any intravenous (IV) bags from the recalled lot. If you have any of the affected product in your inventory, please stop distribution and use of the product immediately and promptly return it to Sedgwick Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8258 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 Inc. at 1-800-805-3093.

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 the accounts to immediately cease distribution and quarantine the affected product. Promptly contact Sedgwick at 800-805-3093 (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. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 1-844-646-4398 (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	800-438-1985, option 3 (8am to 7pm ET Monday through Friday) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Safety	800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events and product complaints

Sincerely,

Masum Hossain
US Commercial Lead, Hospital

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