URGENT: DRUG RECALL

October 3, 2019

10% LMD in 5% Dextrose Injection

(Dextran 40 in Dextrose Injection, USP)

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-7418-13 (Unit of Use) 0409-7418-03 (Unit of Sale)	87-095-JT	1MAR2020	10 g /100 mL	500 mL single-dose flexible containers; 12 overwrapped individual containers per case

Dear Customer:

Hospira, Inc., a Pfizer company, ("Hospira") is voluntarily recalling the above lot of **10% LMD in 5% Dextrose Injection** (Low Molecular Weight Dextran for Intravenous Administration **[Dextran 40 in Dextrose Injection, USP]**), to the hospital level, due to a manufacturing molding process defect resulting in variations on the additive port surface, which may lead to potential product leakage.

Pfizer completed a Health Hazard Assessment, which concluded a remote probability of product being administered to patients and associated with adverse events as the leak in the bag would likely be detected by Healthcare Practitioners. The potential risk to patients arising from this issue is considered medium. In the unlikely event the impacted product is administered, adverse events may include fever, chills, and sepsis, or invasive systemic infections due to microbial contamination. It can also be associated with reduced efficacy due to loss of product or drug instability. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

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. 8 am-5 pm ET).

The recall of the above-referenced lots of **10% LMD in 5% Dextrose Injection** is being conducted to the **Hospital level**.

Our records indicate that you may have received shipment of the affected product between **September 2018** and **July 2019**. 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 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. 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 (Mon.-Fri. 8 am-5 pm ET) 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 medical questions regarding the product you may contact Pfizer using the below information.

Contact	**Contact Information**	**Areas of Support**
Pfizer Medical Information	1-800-438-1985, option 3 (9am to 5pm 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, U.S. Hospital Business Unit
Pfizer Biopharmaceuticals Group