URGENT: DRUG RECALL

December 3, 2018

Vancomycin Hydrochloride for Injection, USP 750 mg
Vancomycin Hydrochloride for Injection, USP 1 g

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-6531-02	840053A	1DEC2019	750 mg	CASE PACK 10 x 10- 750 MG
0409-6533-01	840103A	1DEC2019	1 g	CASE PACK 10 x 10- 1 GM
0409-6533-01	842313A	1DEC2019	1 g	CASE PACK 10 x 10- 1 GM

Dear Customer:

Hospira, Inc., a Pfizer company, ("Hospira") is voluntarily recalling the above referenced lots of Vancomycin Hydrochloride for Injection, USP due to the potential for these lots to contain vials with high or low fill weights for the lyophilized product.

Pfizer completed a Health Hazard Assessment which concluded that the use of the impacted product has a reasonable probability of being administered to the patient at a sub-therapeutic or more potent dosage that may result in lack of efficacy, antibiotic resistance or severe adverse events such as ototoxicity and nephrotoxicity. The overall potential risk for patients arising from this quality issue is considered to be high.

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 are being conducted to **the Hospital/Institution level.**

Our records indicate you may have received shipment of the affected product between **April 2018 and August 2018.** Please check your stock immediately against the table above. If you have any of the affected product in

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

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 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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