Hospira
A Pfizer Company

URGENT: DRUG RECALL

September 20, 2018

Meropenem For Injection, USP (I.V.)

Carton NDC	Vial NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-3506-01	0409-3506-11	609G047	10 2018	1 gram/vial	Carton containing 25 vials

Dear Customer:

Hospira, Inc. (Hospira), a Pfizer company, is voluntarily recalling the above referenced lot of **Meropenem For Injection, USP (I.V.)**. Hospira initiated this recall following a customer report for yellow discoloration of vial contents after reconstitution. Further investigation confirmed this discoloration may have been caused by a loss of container integrity. Pfizer completed a Health Hazard Assessment, which concluded that exposure to the impacted product has an unlikely probability of being associated with adverse effects such as reduced treatment efficacy and severe adverse events such as sepsis or invasive systemic infections. There have been no reports of relevant adverse events associated with this lot. The likelihood that healthcare professionals would fail to detect the product discoloration and administer the impacted product to a patient is regarded as low. The overall potential risk to a patient arising from the administration of non-sterile Meropenem due to a container closure integrity failure 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 ..." 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 ENCLOSED POSTAGE-PAID BUSINESS REPLY CARD (BRC) AND RETURN IT, 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 lot of **Meropenem For Injection, USP (I.V.)** is being conducted to the **Hospital/Institution level.**

Our records indicate that you received shipment of the affected lot, which was distributed from September 2017 to December 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 Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 6599 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 BRC, require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

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

If you have further distributed any of this lot to other wholesale or hospital/institution level accounts, please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request that they immediately cease distribution of the affected lot and promptly return the product directly to the above Stericycle Inc. address. Your accounts do not need to fill out a BRC; however, if they have inventory of the affected product, they can contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product returns. Further authorization is not required for product returns.

Reimbursement for the returned product will be made by credit memorandum. Please contact Pfizer Customer Service at 1-844-646-4398 (Mon.-Fri. 8 am-7 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 contact Pfizer Medical Information at 1-800-438-1985 (Mon.-Fri. 8 am-7 pm ET).

Sincerely,

Navin Katyal
General Manager, Pfizer Injectables
Pfizer Essential Health

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