URGENT: DRUG RECALL

June 29, 2018

Daptomycin For Injection, 500mg per Vial

NDC Number	Lot Numbers	Expiration Date	Strength	Configuration/Count
0409-0106-01	712453A	1-Nov-18	500 mg per Vial	1 vial/Carton 10 Cartons/bundle 10 bundles/shipper
	771803A	1-May-19		
	792103A	1-Jul-19		
	800903A	1-Aug-19		
	810853A	1-Sep-19		
	841703A	1-Dec-19		
	841753A	1-Dec-19		
	850553A	1-Jan-20		

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above listed lots of Hospira's **Daptomycin for Injection** 500 mg, Lyophilized Powder For Solution, Single Dose Vial to the **Hospital/Retail level.**

Hospira's decision is based on a review of safety information regarding reported infusion reactions associated with Hospira's Daptomycin for Injection, observed in the above listed lots. The most common infusion reaction adverse events reported were chills, tremor, pyrexia and dyspnea. Other infusion reaction adverse events reported included events such as tachycardia and blood pressure changes.

This recall decision is made out of an abundance of caution for patients while Hospira continues its investigation into the reported infusion reactions.

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 TO US, 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).

Our records indicate that you may have received shipment of one or more of the affected lots between January 2017 through June 2018. 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 3073 using the enclosed pre-paid UPS label. 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.

If you have further distributed any of these lots to other Wholesale or Hospital/Retail 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 lots and promptly return the product directly to the above Stericycle, Inc. address.

Wholesalers/distributors/hospitals/retailers/physicians and healthcare providers with an existing inventory of the lots which are being recalled, should stop use and distribution and quarantine immediately as well as inform all other Healthcare Professionals in their organization as appropriate. Hospitals or retailers that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. Please contact Stericycle at 1-800-805-3093 for return instructions.

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 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. Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (8am to 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