ASD Healthcare
AmerisourceBergen

M-F 7:00AM to 6:00PM CST
asdhealthcare.com
800.746.6273
800.547.9413

September 9, 2019

Urgent: Hospira, Inc. Issues a Voluntary Recall for One Lot of Bacteriostatic Water for Injection USP

Dear ASD Healthcare Customer:

Hospira, Inc., a Pfizer Company, (Hospira) is initiating a voluntary recall of one lot of Bacteriostatic Water for Injection USP. The affected lot information is listed below.

This product is being voluntarily recalled due to a potential lack of sterility assurance. The use of the impacted product has a reasonable probability of being associated with limited adverse events such as fever, chills, malaise, and cutaneous abscess to severe adverse events such as invasive bacterial infections, septicemia, and bacterial meningitis. In addition, lack of sterility assurance has an unlikely probability of being associated with limited adverse events such as reduced therapeutic effect of the drug product that it is used to dilute or dissolve. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

Hospira provided the affected lot information below:

Product Description	NDC Number	Lot Number	Expiration Date
Bacteriostatic Water for Injection, USP, 25 x 30 mL	0409-3977-03	W20308	01 DEC 2019

To reduce any risk, we ask for your cooperation in taking the following action:

- Please examine your inventory immediately to determine if you have any impacted product in stock and quarantine the affected product.
- **If you have further distributed the recalled product, please immediately notify your individual locations or patients** with instructions to coordinate the return.
- **Contact Stericycle at 1-800-805-3093, Monday through Friday, 8a.m. - 5p.m. ET, for further direction on how to return the recalled product.**

For the full recall notice, please view the attached document on the following pages.

If you have any questions or concerns, please contact ASD Healthcare's customer service at **800.746.6273.**

URGENT DRUG RECALL

September 6th, 2019

BACTERIOSTATIC WATER for Injection, USP

FOR DRUG DILUENT USE ONLY

NDC	Lot Number	Expiration Date	Presentation	Configuration/ Count
Vial: 0409-3977-01 Carton: 0409-3977-03	W20308	01 DEC 2019	30 mL, Multiple dose	4 x 25 x 30mL vials

Dear Customer,

Hospira, Inc., a Pfizer company, ("Hospira"), is voluntarily recalling the above-referenced lot of **BACTERIOSTATIC WATER for Injection, USP** to the hospital/retail level, due to a potential lack of sterility assurance. The use of the impacted product has a reasonable probability of being associated with limited adverse events such as fever, chills, malaise, and cutaneous abscess to severe adverse events such as invasive bacterial infections, septicemia, and bacterial meningitis. In addition, lack of sterility assurance has an unlikely probability of being associated with limited adverse events such as reduced therapeutic effect of the drug product that it is used to dilute or dissolve. 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 ENCLOSED BUSINESS REPLY CARD 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 **BACTERIOSTATIC WATER for Injection, USP** is being conducted to the **hospital/retail Level**.

Our records indicate that you may have received shipment of the affected product between March 2018 and April 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 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.

The return label provided in this notification is for single use only, please DO NOT reproduce. If you have not received a return label or require additional assistance, please contact Stericycle 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they have redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital/retail Level. If additional copies of the letter and/or reply card are needed, please contact Stericycle at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

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