URGENT: DRUG RECALL

February 07, 2018

Hydromorphone Hydrochloride Injection, USP - CII
High Potency Formulation

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-2634-01	71330DD	1NOV2018	10 mg/mL	Carton of 10 x 1 mL Single-dose Vials

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above referenced lot of **Hydromorphone Hydrochloride Injection, USP**. Hospira initiated this recall due to confirmed customer reports for the presence of empty or cracked vials. Pfizer completed a Health Hazard Assessment, which concluded that although there have been no reports of relevant adverse events, the use of or exposure to the impacted product may be associated with adverse events such as sharps injury in healthcare professionals, localized vein inflammation, end-organ granuloma, local tissue granulomas, and soft-tissue or systemic infections. The potential risk to a patient or healthcare professional arising from this issue 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 **Hydromorphone Hydrochloride Injection, USP** is being conducted to the **Hospital/Institution level**.

Our records indicate that you may have received shipment of the affected lot, which was distributed from March 2017 to July 2017. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution and quarantine it immediately. Complete a physical count of your affected inventory and record this data on the BRC that is included with this letter. Return the postage paid BRC to Stericycle Inc. even if you do not have the affected product lots.

Upon receipt of your completed BRC by Stericycle Inc., a Product Return Package, including a DEA Form 222, Packing Slip and pre-paid UPS Return Service shipping label, will be forwarded to you by Stericycle Inc. on behalf

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

of Pfizer Inc. A completed DEA Form 222 is required to process your return. Once you receive the Product Return Package, complete the Packing Slip and enclose the completed Packing Slip and DEA Form 222, along with the product returns, in a return carton. Please attach the pre-paid UPS Return Service shipping label to the outside of the carton and return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 5128. **All returns are requested to be completed within six months of this notice date.** If you received this notification without the BRC or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

If you have further distributed any of this lot to other wholesale or hospital/institution level accounts, please forward a copy of this letter along with your sub-recall customer notifications to those accounts immediately. Please request that 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.

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 Medical Information at 1-800-615-0187 (Mon.-Fri. 8 am-7 pm ET).

Sincerely,

Navin Katyal
General Manager, Pfizer Injectables
Pfizer Essential Health

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