# URGENT: DRUG RECALL

February 03, 2020

## Fentanyl Citrate Inj., USP - CII

| Vial NDC | Vial Lot Number | Tray NDC | Tray Lot Number | Expiration Date | Strength | Configuration/Count |
|---|---|---|---|---|---|---|
| 0409-9094-12 | 08-133-DK | 0409-9094-22 | 08133DK | 1FEB2021 | 50 mcg/mL | Tray containing 25 x 2 mL Single-dose Fliptop Vials |
| 0409-9094-12 | 08-134-DK | 0409-9094-22 | 08134DK | 1FEB2021 | 50 mcg/mL | Tray containing 25 x 2 mL Single-dose Fliptop Vials |

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above referenced lots of **Fentanyl Citrate Inj., USP**. Hospira initiated this recall due to confirmed customer reports for vials with the potential for loose metal overseal crimp defects. Pfizer completed a Health Hazard Assessment, which concluded that there is a reasonable possibility of moderate to severe adverse events such as lack of efficacy, sepsis/infections, CNS and respiratory depression due to unintentional opioid exposure. The potential risk to patients and Health Care Providers 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 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 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lots of **Fentanyl Citrate Inj., USP** is being conducted to the **Hospital/Institution level**.

Our records indicate that you may have received shipment of the affected lots, which were distributed from October 2019 to November 2019. 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 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 2713. **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 800-805-3093.

If you have further distributed any of these lots 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 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 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 800-438-1985 (Mon.-Fri. 9 am-5 pm ET).

Sincerely,

Navin Katyal
General Manager
Pfizer U.S. Hospital Business