



URGENT: PRODUCT RECALL

November 10, 2016

Our records indicate that your account has purchased, through Life-Assist, Inc. one or more of the following items being recalled by Hospira, Inc. Please check your inventory and remove **only the affected lots** from your shelves.

Complete this form (noting quantities to be returned) and fax to 1-800-222-1095.

Please be aware that Fentanyl Citrate is a Class II Narcotic and this recall will require Southern Anesthesia & Surgical to complete a DEA Form 222 to buy the product back from you. Upon receipt of your completed form, Southern Anesthesia & Surgical will issue you a buyback DEA Form 222 and mail it along with a FedEx return label to your facility.

All returns must be completed within 60 days of this notice date **(01/09/17)**.

If you do not possess any of the affected products, please disregard this notice. We apologize for any inconvenience this may cause and we appreciate your business.

PRODUCT: Fentanyl Citrate Injection, 0.05 mg/mL (50 mcg/mL) 2 mL Ampules, 10/Box, CII
Life-Assist Item #: SAS_DR9093-32
SAS Item #: 00409909332
NDC #: 0409-9093-32

Mfr Lot #	Expiration Date	Qty to Return (Unopened Boxes)	Qty to Return (Single Ampules)
59277EV*	1Nov2017		
60028EV*	1Dec2017		
60082EV*	1Dec2017		

**NOTE: The lot number indicated above may be followed by additional numbers from 01 to 99.*

Hospira, Inc. is voluntarily recalling these lots due to confirmed complaints of ampules with broken tips. Please see the attached manufacturer letter for further details.

SAS Account # 10397099 Account Name Life-Assist

Phone # () _____ Fax # () _____ Form completed by _____

Address return label should be sent to* _____

***Because this is a controlled substance, Fedex will only pick up the return from the address the product was originally shipped to (a current DEA certificate must be on file with Southern Anesthesia & Surgical, Inc.). Please ensure proper packaging of the returning product to prevent any damaged in transit. Southern Anesthesia & Surgical, Inc. will not issue credit for product received damaged due to insufficient packaging.*



URGENT: DRUG RECALL

November 1, 2016

FENTANYL CITRATE Injection, USP, 100 mcg Fentanyl/2mL CII

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-9093-32	59277EV	1Nov2017	50 mcg/mL	10 ampules per tray, 100 ampules per case.
0409-9093-32	60028EV	1Dec2017	50 mcg/mL	10 ampules per tray, 100 ampules per case.
0409-9093-32	60082EV	1Dec2017	50 mcg/mL	10 ampules per tray, 100 ampules per case.

*NOTE: The lot numbers may be followed by additional numbers from 01 to 99.

Dear Customer:

Hospira, Inc., a Pfizer company, ("Hospira"), is voluntarily recalling the above referenced lots of Fentanyl Citrate Injection, USP, 100 mcg Fentanyl/2mL due to confirmed complaints of ampules with broken tips. The potential risk of patient harm is considered low as the defective vials are readily identifiable.

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 FORM AND RETURN IT TO THE FAX NUMBER OR E-MAIL ADDRESS ON THE FORM, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS.~~ If you have any questions about responding to this letter, please contact Stericycle at 1-888-570-1678.

The recall of the above-referenced lots of Fentanyl Citrate Injection, USP is being conducted to the hospital/retail level.

Our records indicate you may have received shipment of the affected product between March 2016 and April 2016. Return affected product 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. To obtain a return kit, with a return label and 222 Form, please fill out and return the included business reply form. The return label provided in this notification is for single use only, please DO NOT reproduce. If you require additional assistance, contact Stericycle at 1-888-570-1678 (M-F, 8am to 5pm ET).~~

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

Page 1 of 2

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~~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 form are needed, please contact Stericycle at 1-888-570-1678.~~

Please contact Hospira Customer Care at 1-877-946-7747 (Mon-Fri, 8am to 5pm ET) or your Hospira 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, please contact Pfizer Medical Information at 1-800-615-0187.

Sincerely,

John Lane
General Manager U.S. Sterile Injectables