URGENT: DRUG RECALL

August 24, 2022

PROPOFOL Injectable Emulsion, USP
(contains Benzyl Alcohol)

Tray NDC	Vial NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-4699-24	0409-4699-54	EA7470	01 JUN 2023	1 g/100 mL (10 mg/mL)	Tray of 10 x 100 mL Single Patient Use Fliptop Vials

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above referenced lot of **PROPOFOL Injectable Emulsion**. Pfizer initiated this recall due to a visible particulate observed in two vials during annual examination of retention samples. Pfizer completed a Health Hazard Assessment, which concluded that the use of the impacted product has a remote probability of being associated with potential adverse events, such as blockage of blood vessels, including decreased blood flow to the brain, heart attack, pulmonary embolus, and tissue necrosis. Hypersensitivity reactions and transmission of infectious disease can also occur. The overall potential risk to patients arising from this issue is considered to be medium.

To date, Pfizer 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 …" PFIZER 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 (BRF) AND RETURN IT, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Sedgwick at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lot of **PROPOFOL Injectable Emulsion** is being conducted to the **User level**.

Our records indicate that you received shipment of the affected product lot, which was distributed in **July 2020**. Please check your stock immediately against the table above. If you have any of the affected lot in your inventory, please discontinue use, stop distribution and quarantine the product immediately. Promptly return the product to Sedgwick; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 2801 using the enclosed pre-paid UPS label. **All returns are requested to be completed within six months of this notice date.** If you received this notification without the prepaid UPS label and BRF, require additional shipping labels, or have questions regarding the return procedure, please contact Sedgwick at 800-805-3093.

If you have further distributed the recalled product, please notify your accounts and/or additional locations which may have received the recalled product. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request the accounts to immediately cease distribution and

quarantine the affected product. Promptly contact Sedgwick at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET) to obtain pre-paid shipping labels to initiate the return process.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 844-646-4398 (Mon.-Fri. 8 am-7 pm ET).

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 call the appropriate contact center below.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 8 am-9 pm ET) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a week)	To report adverse events and product complaints

Sincerely,

Masum Hossain
Regional President
North America, Hospital Business Unit

PROPOFOL Injectable Emulsion (contains benzyl alcohol)

100 mL Single Patient Use Fliptop Vial