Hospira Issues a Voluntary Nationwide Recall For One Lot Of 25% Dextrose Injection, USP (Infant) Due To The Presence of Particulate Matter

Consumers Contact: 1-888-345-4680
Media Contact: 610-329-1340

FOR IMMEDIATE RELEASE - April 21, 2017 **– LAKE FOREST, Ill.,** Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of 25% Dextrose Injection, USP, (Infant) pre-filled syringe to the hospital/user level due to the presence of particulate matter, identified as human hair, found within an internal sample syringe.

In the event that the particulate is administered to a patient, it could result in local swelling, irritation of blood vessels or tissue, blockage of blood vessels and/or systemic allergic response to the particulate. Administration of the particulate could also result in localized phlebitis, pulmonary emboli, pulmonary granulomas, immune system dysfunction, pulmonary dysfunction, and pulmonary infarction. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the physician to visually inspect the product for particulate matter and discoloration prior to administration. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

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25% Dextrose Injection, USP,(Infant) is indicated for use via slow IV injection to treat symptomatic episodes of hypoglycemia (fasting blood glucose < 40 mg/100 ml) in neonates or older infants to restore depressed blood glucose values and control symptoms.

25% Dextrose Injection, USP,(Infant) 2.5 grams (250 mg/mL), 10 mL Single-dose prefilled syringe, NDC:0409-1775-10, Lot 58382EV, Expiry Date 1OCT 2017 is packaged in a carton containing 1 pre-filled syringe per carton, 5 x 10 syringes per case. The lot was distributed from February 2016 through October 2016 nationwide in the United States and Puerto Rico. Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform health care professionals in your organization of this recall. 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 redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital/user level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States.

For additional assistance, call Stericycle at 1-888-570-1678 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Complaint Management	1-800-438-1985 (24 hours a day, 7 days per week)	To report adverse events or product complaints
Pfizer Medical Information	1-800-615-0187 (8am-7pm ET, M-F)	Medical inquiries

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax:** Download form **www.fda.gov/MedWatch/getforms.htm** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.

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