From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, April 24, 2017 8:49 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: 25% Dextrose Injection, USP (Infant) by Hospira: Recall - Particulate Matter

AUDIENCE: Pharmacy

ISSUE: Hospira 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. The affected lot is NDC: 0409-1775-10, Lot 58382EV, Expiry Date 1OCT 2017

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.

BACKGROUND: 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.

RECOMMENDATION: 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. 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

Read the MedWatch safety alert, including a link to the press release, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm554544.htm