From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, July 31, 2017 2:02 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: 0.9% Sodium Chloride Injection by ICU Medical: Recall - Presence of Particulate Matter

ISSUE: ICU Medical, Inc. is voluntarily recalling one lot of 0.9% Sodium Chloride Injection, USP 1000 mL to the hospital/user level due to a confirmed customer complaint of particulate matter identified as stainless steel within a single flexible container.
Injection of particulate matter could potentially lead to limited adverse events such as allergic reactions, local irritation and inflammation in organs or tissues, or other serious adverse health consequences.

BACKGROUND: 0.9% Sodium Chloride Injection, USP 1000 mL is an intravenous solution indicated for parenteral replenishment of fluid. The affected product lot was manufactured in the U.S. by Hospira, a Pfizer company, on February 1, 2016 and was distributed nationwide to Hospira customers between April 14, 2016 and February 2, 2017. The affected lot is: NDC 0409-7983-09, Lot # 61-841-FW Expires January 01, 2018 - 1000mL Single Dose Flexible Container.

RECOMMENDATION: Prior to administration, healthcare professionals, as instructed in the product labeling, should visually examine the product for particulate matter and discoloration and should discard if a defect is identified.

ICU Medical is notifying its distributors and customers of this recall by letter and is arranging for the return of all recalled products. Hospitals/distributors that have product that is being recalled should stop use/further distribution and return to place of purchase. Customers with questions regarding this recall can call ICU Medical at 1-800-441-4100 Monday through Friday between the hours of 8 a.m. and 5 p.m. Central time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

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/ucm569225.htm