From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	Sodium Bicarbonate Injection, USP by Hospira: Recall - Particulate Matter
Date:	Tuesday, March 22, 2016 3:23:12 PM

AUDIENCE: Pharmacy, Nursing

ISSUE: Hospira, Inc. is recalling one lot of 8.4% Sodium Bicarbonate Injection, USP (NDC: 0409-6625-02, Lot 56-148-EV, Expiry 1AUG2017) at the hospital/retail level due to the presence of a particulate within a single–dose glass fliptop vial. The issue was identified through a confirmed complaint.

The product is packaged 50 mEq (1mEq/mL), 4.2 grams (84 mg/mL), 50mL, Single-dose, packaged 4 boxes of 25 vials per case. The lot was distributed nationwide in the U.S. to wholesalers and hospitals in December 2015.

If the particulate is not observed prior to IV administration and breaks off into smaller particulates, passing through the catheter, it may result in localized inflammation, allergic reaction, including anaphylaxis, granuloma formation or microembolic effects (IV only). Larger particulates may block the infusion of solution, potentially resulting in a delay in therapy.

BACKGROUND: Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis; in the treatment of certain drug intoxications, in poisoning by salicylates or methyl alcohol and in certain hemolytic reactions. Sodium bicarbonate also is indicated in severe diarrhea, which is often accompanied by significant loss of bicarbonate.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform Healthcare 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/retail 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 1-888-965-6077 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 in the press release.

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

[03/18/2016 - Press Release - Hospira]

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