From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	5 Percent Dextrose Injection USP in PAB Container by B. Braun Medical: Recall - Leakage and/or Particulate Matter
Date:	Wednesday, March 30, 2016 8:10:20 AM

AUDIENCE: Pharmacy, Nursing

ISSUE: B. Braun Medical Inc. is recalling one lot of 5% Dextrose Injection USP 100/150mL container (Lot #J5J706, catalog #S5104-5264, NDC 0264-1510-32) to the consumer level. B. Braun recently identified an adverse quality trend in customer complaints reporting that some containers in lot J5J706 exhibited leakage and, in a few instances, visible particulate matter identified to be microbial growth.

A compromise of container integrity has the potential for leakage of the solution, usually identified prior to the use of the product. Leaking containers allow contamination of the solution, which can and has led to microbial contamination. Intravenous administration of a non-sterile product can result in serious infections that may be life-threatening.

BACKGROUND: This product is intended for intravenous administration and may be used as a diluent and delivery system for intermittent administration of compatible drug additives. The product is packaged in B. Braun's PAB (Partial Additive Bag) container with 64 units per case. The affected lot J5J706, which expires 10/31/2016, was distributed nationwide to licensed distributors, hospitals, and pharmacies.

RECOMMENDATION: B. Braun is notifying its distributors and customers by certified mail and is arranging for the return of all recalled product. Distributors and customers that have inventory of lot J5J706, 5% Dextrose Injection USP 100/150mL container, should discontinue use immediately and contact B. Braun Medical Inc.'s Customer Support Department at 1-800-227-2862 Monday through Friday, 8 a.m. to 6 p.m. (EST) for instructions for returning the affected product and to arrange for replacement product.

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

[03/29/2016 - Press Release - B. Braun Medical]

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