From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	0.9 Percent Sodium Chloride Solution for Irrigation by Baxter: Recall - Presence of Particulate Matter
Date:	Thursday, February 18, 2016 4:36:07 PM

AUDIENCE: Pharmacy

ISSUE: Baxter International is voluntarily recalling one lot of 0.9% Sodium Chloride Irrigation, USP, 500 mL Plastic Pour Bottle solution - Lot G120162, expiration 11/30/2018 - to the hospital/user level. This product is being recalled due to a customer complaint prior to use for the presence of particulate matter, identified as an insect.

Sodium Chloride Irrigation solution with foreign material contamination potentially could result in a series of complications dependent in which anatomic location the irrigation is used, which could include inflammatory reaction, foreign body reaction, and infection which could be life-threatening.

BACKGROUND: 0.9% Sodium Chloride for Irrigation USP – 500 mL is an isotonic solution intended for irrigation. This solution can be used to rinse debris and residue from wounds and as a single use for rinsing/irrigation during surgical procedures. It may also be used to flush or rinse medical equipment such as catheters.

The lot being recalled was distributed to customers and distributors in the United States between November 12, 2015 and January 11, 2016.

RECOMMENDATION: Baxter is notifying its distributors and customers by letter that they should not use product from the recalled lot. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.

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

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