Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, October 05, 2016 1:24 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: I.V. Flush Syringes by Nurse Assist: Recall - Potential Link to Burkholderia Cepacia Bloodstream Infections

ISSUE: Nurse Assist announced voluntary recall of all unexpired lots of I.V. Flush Syringes due to a potential link to Burkholderia cepacia bloodstream infections with the product. According to the U.S. Centers for Disease Control and Prevention (CDC), the effects of Burkholderia cepacia on people "vary widely, ranging from no symptoms at all to serious respiratory infections, especially in patients with cystic fibrosis." Nurse Assist voluntarily recalled its I.V. Flush Syringes after becoming aware of patients that developed Burkholderia cepacia bloodstream infections while receiving intravenous care using prepackaged saline flushes from Nurse Assist.

BACKGROUND: The lots being recalled were distributed to customers and distributors between 02/16/16 and 09/30/16. Product can be identified by the labeling on the packaging and device. To see a list of affected Product Codes and lot numbers, see the Firm Press Release.

RECOMMENDATION: Nurse Assist urges all healthcare facilities with affected product to discontinue use and return the product to the supplier. Recalled product should be returned for credit by contacting Nurse Assist Customer Service at 1-800-649-6800 ext. 10, Monday through Friday, between the hours of 8am and 5pm, Central Time.

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:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm524085.htm