From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, August 31, 2017 11:00 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Vancomycin Hydrochloride for Injection, USP, 750 mg/vial by Hospira: Recall - Presence of Particulate Matter

ISSUE: Hospira is voluntarily recalling one lot of Vancomycin Hydrochloride for Injection, USP, 750 mg/vial (NDC 0409-6531-02) lot 632153A, to the hospital/retailer level. The recall was due to a confirmed customer report for the presence of particulate matter, confirmed as glass, within a single vial. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

In the event the particulate is administered to a patient, it may result in phlebitis, end-organ granuloma or micro-embolic effects, or gastrointestinal trauma. The risk is reduced by the possibility of detection. The label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

BACKGROUND: Vancomycin Hydrochloride is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant staphylococci. Vancomycin Hydrochloride USP, 750 mg/vial NDC: 0409-6531-02, Lot 632153A, Expiry Date 01 MAR 2018, is packaged in a carton containing 10 units. The lot was distributed from August 2016 through January 2017 nationwide in the United States and Puerto Rico.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine 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 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 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

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/ucm574261.htm