From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, June 19, 2017 1:25 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Clindamycin Injection ADD-Vantage Vials by Alvogen: Recall - Lack of Sterility Assurance

ISSUE: Alvogen is voluntarily recalling seven lots of Clindamycin Injection USP ADD-Vantage Vials to the hospital/retail level due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the product. Clindamycin Injection is manufactured for Alvogen by Hospira Inc., a Pfizer Company.

In the event that impacted product is administered, there is a reasonable probability that the patient may experience adverse events, ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. To date, Alvogen has not received any reports of adverse events associated with use of the product.

BACKGROUND: Clindamycin Injection, USP is indicated in the treatment of serious infections caused by susceptible bacteria. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. See the MedWatch Safety alert which includes a link to the Company Announcement for list of product lot numbers affected which were distributed nationwide in the USA to wholesalers and hospitals between May 2016 and June 2017.

RECOMMENDATION: Alvogen is notifying its distributors and customers via an Urgent Drug Recall Notice and is arranging for return of all recalled products. Anyone with existing inventory is requested to stop use and further distribution of the impacted lots, and quarantine the product immediately.

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.

Link to MedWatch Safety Alert:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563546.htm