From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, January 02, 2018 1:05 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Compounded Sterile Products by PharMEDium Services: Recall - Lack of Sterility Assurance

Compounded Sterile Products by PharMEDium Services: Recall - Lack of Sterility Assurance

AUDIENCE: Pharmacy

ISSUE: PharMEDium Services is voluntarily recalling certain lots of drug products to the hospital/user level due to a lack of assurance of sterility. Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening.

See the press release for a listing of affected products.

BACKGROUND: PharMEDium conducted a retrospective review of all commercially distributed product lots compounded in the Memphis location currently within their labeled expiration date in response to an FDA request regarding microbial control program during recent inspection to provide verification of acceptable microbiological testing results of the ISO5 environment, personnel glove sampling results, media fill results, sterility testing results, and endotoxin results. The review indicated that a total of 55 lots of different products impacting 25,327 units had two unsuccessful media fills. The remaining lots were associated with environmental monitoring or personnel monitoring excursions in the ISO 5 space on hood/surface and glove tip. Finished product release testing for both sterility and endotoxin were acceptable. Although there were no defects identified in these products, as a conservative measure, a recall is being initiated.

The recalled products were distributed nationwide in the USA to hospitals/clinics.

RECOMMENDATION: PharMEDium Services is notifying customers of the voluntary recall by phone. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website for more information on the specific lot numbers affected and contact information: www.pharmedium.com.

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at (847) 457-2220, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at dantonio@pharmedium.com.

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/ucm591048.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.