Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, May 06, 2016 1:40 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - PharMEDium Services, LLC

PharMEDium Services, LLC is voluntarily recalling the codes/lots of sterile preparations compounded with a single recalled lot of Fresenius Kabi Sensorcaine-MPF (bupivacaine HCl) to the hospital level. Fresenius Kabi recalled the specific lot at issue due to identification of particulate matter characterized as glass during reserve sample inspection. The list of affected codes/lots can be found on PharMEDium's website at www.PharMEDium.com.

Fresenius Kabi indicated in its recall notice that the presence of glass particulate matter in solution, if undetected and administered via the epidural route, could block drug administration, delaying therapy. If the particulate is able to pass through the catheter and enter the body, this could result in local inflammation, mechanical disruption of tissue or cause an immune response to the particulate. PharMEDium Services has not received any reports of adverse events to date related to the Fresenius Kabi recall.

The drug products affected by this recall are indicated for the production of local or regional anesthesia or analgesia for surgery procedures, diagnostic and therapeutic procedures and for obstetrical procedures. The affected codes are contained in the attached list including lot number and expiration dates. The product was distributed to hospital customers and acute surgery centers in the United States.

PharMEDium Services has contracted with Inmar Pharmaceutical Services to coordinate this recall. Inmar will send notification via electronic mail to all affected customers, request an accounting of remaining units, quarantine the affected products and ensure the destruction of products.

Hospital pharmacies or acute surgery centers that have one or more of the products referenced in this notice should immediately remove from all points of use and quarantine in accordance with applicable hospital policy. Hospital pharmacies or acute surgery centers that may have shared these products with other hospitals should contact those hospitals that received the products.

Hospital or health care providers with questions regarding this recall can contact PharMEDium Services by calling 847-457-2244 or quality1@pharmedium.com Monday through Friday, 8:00 AM to 5:00 PM, Central Standard Time. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.