From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Product Recall - PharMEDium Services, LLC
Date: Monday, January 04, 2016 9:53:24 AM

PharMEDium Services, LLC is voluntarily recalling 29 lots of 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 3 lots of 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag distributed to hospital customers. They have received complaints from hospitals for products that have been found to exhibit a slight discoloration in the admixture. The drug manufacturer's prescribing information advises not to use the product if it is discolored. For affected lots, see the firm press release.

Discoloration is indicative of degradation and could result in decreased potency due to oxidation of Norepinephrine Bitartrate. Decreased potency may result in a delayof achieving desired therapeutic effect. PharMEDium Services has not received any reports of adverse events to date related to this recall.

BACKGROUND: The product is used for blood pressure control in certain acute hypotensive states and is packaged in a 250 mL Viaflex Bag.

RECOMMENDATION: Hospital pharmacies that have the recalled 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag in stock should stop using and discard per the hospital destruction policy. Hospitals that may have shared these products with other hospitals should contact those hospitals that received the products.

Hospitals or other healthcare providers with questions regarding this recall can contact PharMEDium Services by calling 847-457-2244 or email at 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

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 SafetyInformation 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

[12/31/2015 - Firm Press Release - PharMEDium]

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