From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Product Recall - FDA Medwatch - Bayer
Date: Thursday, January 12, 2017 9:16:05 AM

Medrad Intego PET Infusion System Source Administration Sets by Bayer: Recall - Particulates Generated in Vial

AUDIENCE: Risk Manager, Nuclear Medicine, Pharmacy

ISSUE: Bayer has determined all Source Administration Sets used with the Medrad Intego PET Infusion System may produce a particulate matter in the medicine vials. The particulates may be created when the tip of the needle pushes through the rubber top of the vial. If this occurs, the particulate matter could enter into the patient and cause serious adverse health consequences including infection, damage of tissue, and death.

BACKGROUND: The Medrad Intego PET Infusion System controls and delivers medications from a chamber to a patient through a needle inserted into a vein during nuclear medicine procedures. Nuclear medicine procedures are used to diagnose and treat diseases such as cancer, thyroid disease, and heart disease. The product was distributed between October 9, 2008 to October 11, 2016 and the recall was initiated November 7, 2016, see the recall notice for the full list of batch numbers affected.

RECOMMENDATION: Immediately discontinue the use and quarantine any unused affected product and do one of the following:

- Retain the quarantined Source Administration Sets to be used when the new qualified in-line filter is received. OR
- Quarantine Source Administration Sets stock and contact Bayer Customer Care at 1-800-633-7231 opt. 2 to receive a Returned Goods Authorization number and return the product to Bayer accordingly.

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 recall notice, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm536705.htm