Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, January 28, 2016 2:25 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: SPOTCHEM II Test Strips by Arkray: Class I Recall - Inaccurate Blood Sugar Readings

ISSUE: Arkray is recalling the SPOTCHEM II Basic PANEL-1 Reagent Test Strip and SPOTCHEM II Glucose Reagent Test Strip because they may report falsely low blood glucose levels. Because the test strips are reporting falsely low blood glucose when the true levels are above 265 mg/dL, there is a risk that the health care provider would not diagnose hyperglycemia (high blood sugar) including Diabetic Ketoacidosis and Hyperosmolar Hyperglycemic Syndrome in a timely manner and fail to treat elevated blood glucose levels.

There have been no reports of illness or injury from the use of the SPOTCHEM II Test Strips, but this issue may cause serious injury or death. Affected products include:

- **Lot Numbers**: PN5C26 and EA4M78
- **Manufacturing Dates**: November 2014 to September 2015
- **Distribution Dates**: February 18, 2015 to October 13, 2015
- **Devices Recalled in the U.S.**: 99 boxes (25 foiled packaged test strips per box) in Florida, Illinois, Kentucky, Michigan, North Carolina, New York, Ohio and Tennessee

BACKGROUND: The Arkray Factory Inc. SPOTCHEM II Basic PANEL-1 Reagent Test Strip and SPOTCHEM II Glucose Reagent Test Strip are used to test blood sugar (glucose) levels in blood samples. This product is intended for use with the SPOTCHEM EZ analyzer.

RECOMMENDATION: The firm sent an Urgent Medical Device Recall letter to customers beginning on December 18, 2015. The letter identified affected product, stated the reason for recall and provided instructions for returning unused product to the firm. The letter stated that replacement product will be shipped accordingly and provided free of charge.

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

[01/28/2016 - Recall Notice - FDA]