From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, December 05, 2017 4:47 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Pharmacist Choice Alcohol Prep Pads by Simple Diagnostics: Recall - Lack of Sterility Assurance and Other Quality Issues

ISSUE: Simple Diagnostics is voluntarily recalling three lots of Pharmacist Choice Alcohol Prep Pads (UPC # 898302001050, NDC # 98302-0001-05), which were manufactured by Foshan Flying Medical Products Co. Ltd., located in China, due to the lack of sterility assurance and other quality issues. The affected lots are:

SD2070421201 (Exp. 12/2019)
SD2070420925 (Exp. 09/2019)
SD2070420601 (Exp. 12/2019)

The affected lots were distributed between 10/18/2016 and 07/19/2017.

The use of impacted Alcohol Prep Pads could result in adverse events such as infections.

BACKGROUND: Pharmacist Choice Alcohol Preps are supplied to distributors and pharmacies. Pharmacist Choice Alcohol Preps are used by health care professionals and patients for preparation of the skin prior to injection, as well as in first aid to decrease germs in minor cuts, scrapes and burns.

RECOMMENDATION: Simple Diagnostics is notifying its distributors and customers by issuing a “Dear Customer” letter and arranging for the return of all recalled products. Healthcare providers that have affected lots of Pharmacist Choice Alcohol Prep Pads that have been recalled should stop using the product and should return them to Simple Diagnostics.

Health professionals and consumers with questions regarding this recall can contact Simple Diagnostics at 1-877-342-2385.

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/ucm587711.htm