From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Sterile Products by Wells Pharmacy Network: Recall - Concern for Lack of Sterility Assurance
Date: Friday, September 23, 2016 10:00:59 AM

Sterile Products by Wells Pharmacy Network: Recall - Concern for Lack of Sterility Assurance

AUDIENCE: Pharmacy, Patient

ISSUE: Wells Pharmacy Network is voluntarily recalling all sterile human and veterinary products prepared between February 22, 2016 and September 14, 2016, and that remain within expiry due to FDA concern over a lack of sterility assurance. See the press release for a listing of affected prodcuts and lot numbers.

Administration of a drug product intended to be sterile that has microbial contamination may result in infections that may be serious and life-threatening.

BACKGROUND: The recalled products were used for a variety of indications. No vial or portion of any lot of these medications has been found to be non sterile. All recalled products have a label that includes the name Wells Pharmacy Network, logo, drug name, and expiration date. If unsure, customers can call the pharmacy to determine if their product is on the list. To date, no adverse events have been reported.

RECOMMENDATION: All patients and providers that received any sterile compounded products prepared between February 22, 2016 and September 14, 2016, and that remain within expiry, should take the following actions:

- Discontinue use of the products;
- Quarantine any unused product until further instructions are received on how to return the product; and
- Contact WPN at the Quality hotline at (800) 794-2360 Monday through Friday, between 9:00 am and 6:00 pm EST or email at WPNQuality@wellsrx.com to discuss the return of any unused sterile product.

Providers who have dispensed any sterile products prepared between February 22, 2016 and September 14, 2016 to a patient(s) for use outside of the provider's office should contact the patient(s) to whom product was dispensed and advise the patient(s) of this recall.
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:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm522103.htm

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