Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, October 21, 2015 8:59 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Downing Labs, LLC Sterile Compounded Products: Recall - Lack of Sterility Assurance

AUDIENCE: Consumer, Pharmacy

ISSUE: Downing Labs, LLC is voluntarily recalling all lots of sterile products compounded and packaged by Downing Labs and that remain within expiry due to concerns over sterility assurance. The products were distributed nationwide and in the UK to patients and providers between April 20, 2015 and September 15, 2015. If there is a contamination in products intended to be sterile, patients are at risk of serious infections which may be life threatening.

BACKGROUND: The recall does not pertain to any non-sterile compounded medications prepared by Downing Labs.

RECOMMENDATION: Downing Labs is asking all patients and providers that received sterile compounded products from Downing Labs between April 20, 2015 and September 15, 2015 that remain within expiry to take the following actions:

- Discontinue use of the products;
- Set aside any unused product until further instructions are received on how to return the product; and
- Contact Downing Labs at 800-914-7435 from the hours of 8:30AM-5:00PM central time Monday-Friday, or e-mail at pharmacist@downinglabs.com to discuss the return of any unused sterile compounded products.

Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Providers who have dispensed any sterile product distributed by Downing Labs 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 firm's Press Release, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm468235.htm