
From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, August 18, 2017 4:58 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Sterile Drug Products by Bella Pharmaceuticals: Recall - Lack of Sterility Assurance

ISSUE: Bella Pharmaceuticals is voluntarily recalling all lots of unexpired sterile drug products due to lack of sterility assurance. The recalled products were distributed to health care facilities nationwide. This company is not licensed to ship into California.

Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, Bella Pharmaceuticals has not received any reports of adverse events.

BACKGROUND: The affected products include all lots distributed April 17, 2017, to August 10, 2017, remaining within expiry, and they would be packaged in a syringe, vial or eye dropper. For a list of products affected by this recall see the [Firm Press Release](#).

RECOMMENDATION: Bella Pharmaceuticals is notifying its customers by email and phone, and is arranging for the return of all recalled products. Anyone with product subject to the recall should stop using it and contact the company. To return medication or request assistance related to this recall, contact Bella Pharmaceuticals at 877-235-5279, Monday through Friday, between 9 a.m. and 5 p.m. CST.

Health care professionals are encouraged to report any adverse events to FDA's MedWatch 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.