From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, July 25, 2017 3:21 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Cantrell Drug Company Issues Voluntary Nationwide Recall of All Sterile Drug Products Due to Lack of Sterility Assurance

Cantrell Drug Company is voluntarily recalling all lots of unexpired sterile drug products to the hospital and user level due to lack of sterility assurance. The recalled products were distributed to health care facilities nationwide, except to the states of Connecticut, Hawaii, South Carolina and Vermont. To date, Cantrell has not received any reports of adverse events.

The affected products include all lots distributed February 16, 2017, to July 19, 2017, remaining within expiry, and they would be packaged in a syringe or IV bag. Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening.

"Cantrell has a longstanding commitment to quality and safety. We are voluntarily issuing a recall out of an abundance of caution after several issues were identified during a recent inspection of our facility," said Dell McCarley, Chairman and CEO of Cantrell Drug Company. "We regret any impact this recall has on our loyal customers and their patients."

Cantrell Drug Company 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 Cantrell Drug Company at 877-666-5222, Monday through Friday, between 9 a.m. and 5 p.m. CST.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.