From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, June 22, 2017 1:45 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Potassium Phosphate and Succinylcholine by Advanced Pharma: Recall - Potential Lack of Sterility Assurance

ISSUE: Advanced Pharma, Inc. d/b/a Avella of Houston is conducting a limited, voluntary recall due to Hospira Inc.'s June 15, 2017 recall announcement that microbial growth was detected during a routine simulation of the manufacturing process and therefore there was a lack of sterility assurance. The products being recalled by Advanced Pharma were repackaged and/or compounded at its Houston, Texas facility using certain Hospira products. The recalled products are specific lots of Potassium Phosphate and Succinylcholine Chloride. This is a secondary recall based on a Hospira's recent recall.

Per Hospira, in the event that impacted product is administered to a patient, there is a reasonable probability that the patient may experience adverse events ranging from fever, chills and malaise, to severe adverse events including systemic invasive mycoses or systemic bacterial sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated.

BACKGROUND: These products were not distributed directly to patients or consumers, but rather to healthcare facilities (e.g. hospitals).

RECOMMENDATION: Avella and Advanced Pharma are notifying customers of the voluntary recall by phone, email and overnight mail. Customers in Arizona, California, Colorado, Delaware, Georgia, Louisiana, Nebraska, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah and Washington that have any of the affected medications that are being recalled should immediately discontinue use and return the unused portion to Avella Specialty Pharmacy. Customers with any of the affected medications can also reference Advanced Pharma's website for more information on the specific lot numbers affected, product images, forms and contact information: www.avella.com/AP-Hospira-recall. For a full list of Advanced Pharma products, please visit www.avella.com/sourceb-products.

Patients and healthcare providers with questions regarding this recall can contact Avella Specialty Pharmacy recall line at (877) 292-4323, Monday through Friday, between 6am and 6pm Pacific Standard Time or via e-mail at ProductRecall@avella.com. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

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 company press release, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm564303.htm