From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, July 31, 2017 2:10 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Cyclobenzaprine HCl and Amantadine HCl by Apace Packaging: Recall - Potential Mislabeling

ISSUE: Apace Packaging LLC is voluntarily recalling one lot of Cyclobenzaprine HCl Tablet, USP 5 mg 50ct Unit Dose, NDC# 50268-190-15, Lot Number 16710 and one lot of Amantadine HCl Capsule, USP 100 mg 50ct Unit Dose NDC# 50268-069-15, Lot Number 16710 to the Retail level. These products have been recalled due to a potential mislabeling. A small number of cartons containing Cyclobenzaprine HCl Tablets 5 mg UD Blister Cards may potentially be mislabeled as Amantadine HCl Capsules, USP 100 mg. The unit dose blisters inside the carton are correctly labeled as Cyclobenzaprine HCl Tablet, USP 5 mg.

Unintentional dosing with Cyclobenzaprine HCl may potentially lead to the development of life-threatening serotonin syndrome, which has been reported with Cyclobenzaprine HCI when used in combination with other drugs, such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), tramadol, bupropion, meperidine, verapamil, or MAO inhibitors. The effects of alcohol, barbiturates, and other CNS depressants may be enhanced, and may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle. Amantadine has a precaution in its prescribing indication about the abrupt discontinuation of the medicine. Missed doses of Amantadine in a few patients with Parkinson's disease have experienced a parkinsonian crisis, i.e., a sudden marked clinical deterioration, when this medication was suddenly stopped.

BACKGROUND: Cyclobenzaprine HCl 5mg 50ct Unit Dose (NDC# 50268-190-15) is used for the relief of muscle spasms and Amantadine HCl 100mg 50ct Unit Dose (NDC# 50268-069-15) is used for the treatment of Parkinson's and drug-induced extrapyramidal reactions and the treatment of various viral-based conditions. Both products are packaged in 50-count hospital unit dose cartons (10 unit doses per card, 5 cards per carton). The affected lot of Cyclobenzaprine and Amantadine is Lot 16710 with an expiration date of 07/2018. The subject products were fully distributed to R&S Northeast, and then further distributed nationwide.

RECOMMENDATION: Apace Packaging LLC has notified its distributors and customers by email and is arranging for return of all recalled product. Distributors that have any of the subject product which is being recalled should contact Customer Service at AvKARE, Inc. at 931-292-6222 to arrange for the return of the product.

Consumers with questions regarding this recall can contact Apace Packaging by 270-434-2722 Monday-Friday (8am – 4pm CST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug 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 press release, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm569056.htm