From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, April 21, 2017 4:54 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Phenobarbital 15 mg Tablets, USP by C.O. Truxton: Recall - Labeling Error on Declared Strength

AUDIENCE: Pharmacy, Patient

ISSUE: C.O. Truxton, Inc. is voluntarily recalling lot 70952A of Phenobarbital Tablets, USP, 15 mg, to the consumer/user level. The manufacturer received a confirmed customer complaint that a bottle labeled as phenobarbital 15 mg was found to contain phenobarbital 30 mg tablets.

This mislabeled product could expose the consumer or their pet(s) to potential overdosing that can cause severe intoxication which may lead to cardiogenic shock, renal failure, coma or death.

BACKGROUND: The product is indicated for use as a sedative or anticonvulsant and is packaged in 1000 count bottles, NDC 0463-6160-10, UPC 7 0463616010 6, lot number 70952A, expiration date 11/17. The 15 mg Tablet is debossed with “West-ward 445” on one side and blank on the reverse side; the 30 mg Tablet is debossed with “West-ward 450” on one side and scored on the reverse side. The product was distributed Nationwide in the USA to Physician & Veterinarian Treatment Centers.

RECOMMENDATION: C.O. Truxton, Inc. is notifying all customers on record who purchased the affected product via US Mail which includes a recall letter, recall response form and is arranging for full credit returns, replacements, etc. of all recalled product. Consumers/distributors/retailers that have recalled product should stop using the product and return their product to their place of purchase.

Consumers with questions regarding this recall can contact C.O Truxton, Inc. by phone at (856) 933-2333, Monday to Friday between the hours of 9am and 5pm (EST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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/ucm554358.htm