C.O. Truxton – Recall of phenobarbital and amitriptyline

- On May 8, 2017, the FDA announced that C.O. Truxton is expanding a voluntary consumer/user level recall to include additional lots of phenobarbital and amitriptyline tablets due to a label-mix up error.
    - The initial recall notice was due to a customer complaint that a bottle labeled as phenobarbital 15 mg was found to contain phenobarbital 30 mg tablets.
- Out of an abundance of caution, C.O. Truxton is recalling all products that were repackaged into a Truxton Incorporated label.
- Per C.O Truxton, the recalled phenobarbital and amitriptyline tablets are labeled for human use, but used primarily for veterinary care. These tablets were distributed nationwide directly to veterinarians and healthcare providers.

Product Description	NDC #	Lot # (Expiration date)	Tablet appearance side one	Tablet appearance side two
Phenobarbital 15 mg tablets, 1000 count bottle	0463-6160-10	70952A (11/2017), 70915A (8/2017), H15A55 (11/2017), 71162A (10/2018)	West-ward 445, white	blank, white
Phenobarbital 30 mg tablets, 1000 count bottle	0463-6145-10	70926A (11/2017), 70981A (1/2018), H15A59 (8/2018)	West-ward 450, white	score line, white
Phenobarbital 60 mg tablets, 1000 count bottle	0463-6151-10	70881A (7/2017), H15A68 (1/2018), 70980A (2/2018), 71416A (5/2020)	WW 455, white	blank, white
Phenobarbital 100 mg tablets, 100 count bottle	0463-6152-01	70989A (2/2018), 70973A (1/2018)	WW 458, white	score line, white
Phenobarbital 100 mg tablets, 1000 count bottle	0163-6152-10	70973A (1/2018), H15A76 (2/2018), 71346A (12/2019)	WW 458, white	score line, white
Phenobarbital 100 mg tablets, 1000 count bottle	0463-6152-01	70989A (2/2018)	WW 458, white	score line, white
Amitriptyline 50 mg tablets, 100 count bottle	0463-6352-10	C0260416A (3/2018)	2103, beige	V, beige

- Phenobarbital is indicated for use as a sedative or anticonvulsant.
- Amitriptyline is indicated for the relief of symptoms of depression.

Continued . . .

- If mislabeled, inadvertent exposure to, or overdose of phenobarbital could cause severe intoxication which may lead to cardiogenic shock, renal failure, coma, or death in humans and animals.

- If mislabeled, inadvertent exposure to, or overdose of amitriptyline could cause uneven heartbeats, extreme drowsiness, confusion, agitation, vomiting, hallucinations, hot or cold sensations, muscle stiffness, seizures, or fainting in humans and animals.

- To date, C.O. Truxton has not received any reports of adverse events related to this recall.

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

- For any questions regarding this recall, contact C.O. Truxton at **1-800-257-7704**.

- Consumers should contact their healthcare provider or veterinarian if they have experienced any problems that might be related to taking the recalled phenobarbital and/or amitriptyline tablets.