Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

C.O. Truxton, Inc. Issues Voluntary Nationwide Recall of Amitriptyline HCL Tablets, USP 50mg and Phenobarbital Tablets, USP 15mg, 30mg, 60mg, 100mg Due to Potential Label Mix-Up

For Immediate Release

May 8, 2017

Contact

Consumers

Paul F. Devine
(800) 257-7704

Announcement

Bellmawr, New Jersey, C.O. Truxton, Inc. is expanding their - 04/21/2017 voluntary recall, as a precaution to include the following C.O. Truxton, Inc. products, registered NDC numbers and corresponding lot numbers, to the consumer/user level. C.O. Truxton has not received any complaints for the products listed below - however, due to the initial recall resulting from a label mix-up error, out of an abundance of caution, we are recalling all products that were repackaged into a Truxton Incorporated label.

Product Name	NDC Code	Lot Number	Expiration
Phenobarbital Tablets, USP 15mg (1000)	0463-6160-10	70915A	August 2017
		H15A55	November 2017

Product Name	NDC Code	Lot Number	Expiration
		70952A	November 2017
		71162A	October 2018
Phenobarbital Tablets, USP 30mg (1000)	0463-6145-10	70926A	November 2017
		70981A	January 2018
		H15A59	August 2018
Phenobarbital Tablets, USP 60mg (1000)	0463-6151-10	70881A	July 2017
		H15A68	January 2018
		70980A	February 2018
		71416A	May 2020
Phenobarbital Tablets, USP 100mg (100)	0463-6152-01	70989A	February 2018
		70973A	January 2018
Phenobarbital Tablets, USP 100mg (1000)	0163-6152-10	70973A	January 2018
		H15A76	February 2018
		71346A	December 2019
Phenobarbital Tablets, USP 100mg (1000)	0463-6152-01	70989A	February 2018
Amitriptyline Tablets, USP 50mg (100)	0463-6352-10	C0260416A	March 2018

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 causeuneven heartbeats, extreme drowsiness, confusion, agitation, vomiting, hallucinations, hot or cold sensations, muscle stiffness, seizures (convulsions), or fainting in humans and animals. C.O. Truxton, Inc. has not received any reports of adverse events related to this recall.

Phenobarbital is indicated for use as a sedative or anticonvulsant and is packaged in the following configurations:

NDC	Package Size	Strength (mg)	Tablet Appearance Side One	Tablet Appearance Side Two
0463-6160-10	1000	15	West-ward 445, white	Blank, white
0463-6145-10	1000	30	West-ward 450, white	Score line, white
0463-6151-10	1000	60	WW 455, white	Blank, white
0463-6152-01	100	100	WW 458, white	Score line, white

NDC	Package Size	Strength (mg)	Tablet Appearance Side One	Tablet Appearance Side Two
0463-6152-10	1000	100	WW 458, white	Score line, white

Amitriptyline is indicated for use as a tricyclic antidepressant and is packaged in the following configuration:

NDC	Package Size	Strength (mg)	Tablet Appearance Side One	Tablet Appearance Side Two
0463-6352-10	100	50	2103, beige	V, beige

The product was distributed nationwide in the U.S.A. to physician & veterinarian treatment centers.

C.O. Truxton, Inc. is notifying all customers on record who purchased the above listed products under Truxton Incorporated label/NDC via US Mail with a recall letter and recall response form. C.O. Truxton, Inc. 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 immediately and return their product to the place of purchase.

Consumers with questions regarding this recall can contact C.O Truxton, Inc. by phone at (800) 257-7704, Monday to Friday between the hours of 9am and 5pm (EST). Consumers should contact their physician, healthcare provider, or veterinarian if they have experienced any problems that may be related to taking or administering these drug products.

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

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://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 a fax to 1-800-FDA-0178
- For reporting animal adverse drug events and product defects, please follow the link to the directions and the FORM FDA 1932a found at: **http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm (http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm)**

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

Link to original PR (/Safety/Recalls/ucm554329.htm)

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