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 Phenobarbital 15 mg Tablets, USP due to Labeling Error on Declared Strength

For Immediate Release

April 21, 2017

Contact

Consumers

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Announcement

Bellmawr, New Jersey, 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. C.O. Truxton, Inc. has not received any reports of adverse events related to this recall.

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.

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.

Adverse reactions or quality problems experienced with the use of this product 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.

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