



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 26, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Cox Veterinary Laboratory, Inc. – RECALL [Animal Health]

AFFECTED PRODUCT: Gastroade Xtra

SUMMARY: Unclassified Recall; This recall has been initiated due to information from the FDA that Gastroade Xtra must have an approved new animal drug application to be legally marketed in the United States. Gastroade Xtra is not approved by the FDA. In addition, some lots may be sub-potent and pose a risk of continued ulceration.

Gastroade Xtra is labeled for the care of gastric ulcers in horses. Gastroade Xtra is a paste that is packaged in a 32 ml tube bearing the name Gastroade Xtra, Omeprazole 2.28g. Affected lots include Batch 0052 (UPC 091037382986) manufactured 5/29/2014.

This product was distributed nationwide.

SUGGESTED ACTION: For consumer inquiry only. Questions regarding this voluntary recall should be addressed to Jeanne Buffington by email at jeanne@coxvetlab.com from Monday to Friday, 10 am to 4pm, EST.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Cox Veterinary Laboratory, Inc. Issues Voluntary Recall of "Gastroade Xtra"

Contact:
Consumer:
Jeanne Buffington
jeanne@coxvetlab.com



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To promote and provide
essential public health services.

FOR IMMEDIATE RELEASE — January 23, 2015 — Chester, SC — Cox Veterinary Laboratory, Inc. is voluntarily recalling the lots of Gastroade Xtra identified below down to the consumer level distributed nationwide. Gastroade Xtra was previously marketed by Cox Veterinary Laboratory as an OTC drug for use in horses, and contains Omeprazole. This recall has been initiated due to information from the FDA that Gastroade Xtra must have an approved new animal drug application to be legally marketed in the United States. Gastroade Xtra is not approved by the FDA. In addition, some lots may be sub-potent and pose a risk of continued ulceration. As a consequence, Cox Veterinary Laboratory has ceased all production and sales of Gastroade Xtra and is recalling the product..

Because the FDA has not approved Gastroade Xtra, the safety and efficacy of the product has not yet been established. To date, however, there have been no reported adverse events associated with the use of Gastroade Xtra.

Gastroade Xtra is labeled for the care of gastric ulcers in horses. Gastroade Xtra is a paste that is packaged in a 32 ml tube bearing the name Gastroade Xtra, Omeprazole 2.28g.

Aided with the information provided by the FDA, Cox Veterinary Laboratory is notifying its distributors and customers by a letter sent certified mail directly and through this press release of this voluntary recall. Cox Veterinary Laboratory will arrange for a return of all recalled product. Consumers and distributors that have unused Gastroade Xtra should stop using this product immediately and contact Cox Veterinary Laboratory to arrange for the return of the product.

Horse owners, caretakers and veterinarians should report to the FDA any adverse events, including ineffectiveness, in horses that received unapproved omeprazole products. Information on reporting adverse events for approved or unapproved animal drugs can be found at: <http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm>. Complaints about approved and unapproved animal drug products can be reported by calling a [consumer complaint coordinator](#), within your FDA District Office or by filing a [Veterinary Adverse Drug Reaction](#) report.

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Questions regarding this voluntary recall should be addressed to Jeanne Buffington by email at jeanne@coxvetlab.com from Monday to Friday, 10 am to 4pm, EST.

Consumers should contact their veterinary healthcare provider if they have experienced any problems that may be related to the use of this drug product.

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

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*Cox Veterinary Laboratory, Inc. Issues
Voluntary Recall of “Gastroade
Xtra” Photo*

GASTROADE

(Omeprazole) *Xtra*

GASTROADE XTRA IS FOR THE PREVENTION OF STOMACH ULCERS IN HORSES.

GUARANTEED ANALYSIS: 2.28g Omeprazole per tube.

INGREDIENTS: Omeprazole, Calcium Carbonate, Bismuth Subsalicylate, Water, Xanthan Gum, Natural & Artificial Flavors.

INSTRUCTIONS: Use 8ml once daily. Each tube contains 4 doses.

CAUTION: STORE IN A COOL, DRY PLACE. KEEP OUT OF REACH OF CHILDREN.

NET CONTENTS: 32ml



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