



## **Get 100 Percent – Your Horse’s Health Depends on It**

As a horse owner, you want the best health care possible for your horse – and in turn, you want your horse to give 100 percent effort. But are the products you are giving your horse 100 percent of what they claim to be?

Recently, horse owners using some alleged equine ulcer prevention or treatment products have been unpleasantly surprised to learn the ingredients in some products just didn’t add up to their label claims. This information came to light when the U.S. Food and Drug Administration (FDA) tested them. In fact, one of the products, Gastroade Xtra, only contained 36.3 percent of the label claim.<sup>1</sup> Another, Omeprazole Oral Paste, was tested and found to be sub-potent at just 68.1 percent of the label claim.<sup>2</sup>

Because the companies were mispromoting their products as being “for use in the mitigation, treatment or prevention of disease in animals,”<sup>1-8</sup> they received warning letters. The companies and products include:

- Horse Gold, Inc. – GastroMax3
- HorsePreRace – Omeprazole Oral Paste, Omeprazole/Rantidine Oral Paste
- Tri-Star Equine – Gastrotec
- Douglas J. Gordon, Teton Equine – UlcerCure OTC
- Cox Veterinary Laboratory, Inc. – Gastroade Xtra
- Ceva Animal Health Pty Ltd. – Omoguard Paste
- Abler, Inc. – AbGard, Abprazole, Abprazole Plus, Abler Omeprazole
- Multivet USA, Inc. – Gastro37 OTC

The FDA admonished these companies for promoting their products “for use in the mitigation, treatment or prevention of disease in animals.”<sup>1-8</sup> When companies market their products for such use, they fall under the Federal Food, Drug and Cosmetic Act (FD&C Act) and therefore are considered drugs. None of these

companies had obtained FDA approval of their products, meaning the products have not been evaluated for safety, effectiveness or quality.<sup>9</sup>

So how can horse owners avoid getting less than 100 percent in the future? The first step is to work with a veterinarian.

“It is critically important for owners and trainers to consult with their veterinarians before giving medications or supplements to their horses. With so many non-FDA approved products on the market today, communication with your veterinarian is prudent to help ensure safe and effective therapeutic treatment of the equine patient,” says Jeff Blea, DVM, former president of the American Association of Equine Practitioners and partner in vonBluecher, Blea, Hunkin Equine Medicine and Surgery in Sierra Madre, Calif.

Besides working with their veterinarians, horse owners can educate themselves about the types of products available and what FDA drug approval means to the health and well-being of their horses. The FDA approval process includes rigorous safety and efficacy testing before the drug is approved. In addition, once approval is granted, the FDA continually monitors the manufacturing process to ensure quality and consistency from batch to batch, reviews the label to verify truthfulness and investigates reports of adverse events.<sup>9</sup>

Consumers can determine if a product has received FDA approval by looking on the package for a six-digit New Animal Drug Application (NADA) number and the statement “Approved by the FDA.” In the case of generic drugs, look for the Abbreviated New Animal Drug Application (ANADA) number.

Another option is to go to [AnimalDrugs@FDA](mailto:AnimalDrugs@FDA), <http://www.accessdata.fda.gov/scripts/animaldrugsatfda/> and search the database.

The only product that has been proven and is FDA-approved for the prevention of equine stomach ulcers is ULCERGARD® (omeprazole). The only product proven and FDA-approved for the treatment of equine stomach ulcers is GASTROGARD® (omeprazole).<sup>10,11</sup>

To learn more about the types of products available, the FDA approval process and identifying FDA-approved drugs, visit the website [www.equinedrugfacts.com](http://www.equinedrugfacts.com).

## **About Merial**

Merial is a world-leading, innovation-driven animal health company, providing a comprehensive range of products to enhance the health, well-being and performance of a wide range of animals. Merial employs approximately 6,200 people and operates in more than 150 countries worldwide with close to \$2 billion of sales in 2013.

Merial is a Sanofi company.

For more information, please see [www.merial.com](http://www.merial.com).

## **IMPORTANT SAFETY INFORMATION**

ULCERGARD can be used in horses that weigh at least 600 pounds. Safety in pregnant mares has not been determined.

Caution: Safety of GASTROGARD in pregnant or lactating mares has not been determined.

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<sup>1</sup>FDA correspondence to Cox Veterinary Laboratory, Inc. Available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm422544.htm>. Accessed November 12, 2014.

<sup>2</sup>FDA correspondence to Horse PreRace. 10/29/2014. Available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm421133.htm>. Accessed November 6, 2014.

<sup>3</sup>FDA correspondence to Tri-Star Equine 10/29/2014. Available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm421167.htm>. Accessed November 6, 2014.

<sup>4</sup>FDA correspondence to Douglas J. Gordon 10/29/2014. Available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm421214.htm>. Accessed November 12, 2014.

<sup>5</sup>FDA correspondence to Horse Gold, Inc. 10/29/2014. Available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm421146.htm>. Accessed November 6, 2014.

<sup>6</sup>FDA correspondence to Ceva Animal Health Pty Ltd 10/29/2014. Available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm422549.htm>. Accessed November 12, 2014.

<sup>7</sup>FDA correspondence to Abler Inc 10/29/2014. Available at:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm422545.htm>. Accessed November 12, 2014.

<sup>8</sup>FDA Correspondence to Multivet USA, Inc. Available at:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm421707.htm>. Accessed November 12, 2014.

<sup>9</sup>U.S. Food & Drug Administration. Unapproved Animal Drugs. Available at:

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UnapprovedAnimalDrugs/default.htm>. Accessed January 23, 2015.

<sup>10</sup>ULCERGARD product label.

<sup>11</sup>GASTROGARD product label.