**U.S. Food and Drug Administration**
Protecting and Promoting *Your* Health

# Tri-Star Equine 10/29/14

**Department of Health and Human Services**

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751
Telephone: 407-475-4700
FAX: 407-475-4770

**VIA UPS NEXT DAY AIR**
**w/ DELIVERY CONFIRMATION**

**WARNING LETTER**
**FLA-15-05**
October 29, 2014

Mr. Jerry Glantz
Mr. Harry Glantz
Tri-Star Equine Marketing, LLC
16060 Loch Katrine Trail #7703
Delray Beach, FL 33446

Dear Mr. Jerry and Harry Glantz:

This letter concerns the marketing of the product Gastrotec by your firm, Tri-Star Equine Marketing, LLC. The U.S. Food and Drug Administration (FDA) reviewed your website at the internet address tristarequine.com and other websites where Gastrotec is promoted and sold including, but not limited to, ergogeniclabs.com and horseprerace.com.

We have determined that Gastrotec is intended for use in the mitigation, treatment, or prevention of disease in animals, which makes it a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 U.S.C. § 321(g)(1)(B)]. Under the FD&C Act, drugs intended for use in animals require an approved new animal drug application unless they are generally recognized as safe and effective. As discussed below, we have determined that your drug is not generally recognized as safe and effective, and is therefore unsafe under section 512(a)(1) of the FD&C Act [21 U.S.C. § 360b(a)], and adulterated under section 501(a)(5) of the FD&C Act [21 U.S.C. § 351(a)(5)], because you are marketing it without an approved new animal drug application.

Statements on your website and product labeling that show the product is intended for use in the mitigation, treatment or prevention of disease in animals include, but are not limited to, the following:

- “For the care of gastric and colonic ulcers in horses”
- “Gastrotec is the first product to conquer gastric ulcers in horses while also reaching the hind gut and treating the "colonic" ulcers ...”

Because Gastrotec is intended to mitigate, treat, or prevent disease in animals, it is a drug within the meaning of section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)]. Further, this product is a new animal drug, as defined by section 201(v) of the FD&C Act [21 U.S.C. § 321(v)], because it is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.

To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act [21 U.S.C. §§ 360b, 360ccc, and 360ccc-1]. Gastrotec is not approved or index listed by the FDA, and therefore the product is considered unsafe under section 512(a)(1) of the FD&C Act [21 U.S.C. § 360b(a)], and adulterated under section 501(a)(5) of the FD&C Act [21 U.S.C. § 351(a)(5)]. Introduction of an adulterated drug into interstate commerce is prohibited under section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

This letter is not intended to be an all-inclusive review of your products and their promotion. It is your responsibility to ensure that all of your products are in compliance with the Act and its implementing regulations. Failure to promptly correct the violations specified above may result in

enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include any documentation necessary to show that correction has been achieved. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please direct your response to the U.S. Food and Drug Administration, Salvatore N. Randazzo, Compliance Office, 555 Winderley Place, Suite 200, Maitland, FL 32751.

Sincerely,
/S/
Susan M. Turcovski
Director, Florida District

CC:
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Ergogenic Labs, LLC
11496 Pierson Rd, Unit C6
Wellington, FL 33414

Dr. Scott Mangini
5023 Vinings Circle
Wellington, FL 33414