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

# HorsePreRace 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-15-04**
October 29, 2014

Mr. Simon Jones
Horse PreRace
635 N Orange Ave
Orlando, FL, 32801
info@horseprerace.com

Dear Mr. Jones:

This letter concerns your marketing of several products including, but not limited to, Omeprazole Oral Paste, Omeprazole/Ranitidine Oral Paste, Gastrotec, Gastromax3, Flunixin, Synedem, Toltrazuril Paste, and Super Tie Up on your website at the internet

address horseprerace.com. The U.S. Food and Drug Administration (FDA) reviewed your website, where you promote and sell these products, and obtained and tested samples of your Omeprazole Oral Paste product.

We have determined that the above referenced products are intended for use in the mitigation, treatment, or prevention of disease in animals, which makes them drugs 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 these drugs are not generally recognized as safe and effective, and are 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 them without approved new animal drug applications. In addition, the drug Omeprazole Oral Paste is adulterated under section 501(c) of the FD&C Act [21 U.S.C. § 351(c)], as testing of the drug revealed that its strength differs from the strength stated on the label.

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

**Omeprazole Oral Paste**
- "INDICATIONS- Ulcers, poor condition, dull coat, loss of appetite"
- "CATEGORY- Stomach care, equine ulcers, EGUS"

**Omeprazole/Ranitidine Oral Paste**
- "INDICATIONS- Ulcers, poor condition, dull coat, loss of appetite"
- "CATEGORY- Stomach care, equine ulcers, EGUS"

**Gastrotec**
- "The newest innovation in the battle against equine ulcers."

**Gastromax3**
- " ... formulated for one of the most prevalent problems in the equine industry. For those who don't know, the prevalence of gastric ulceration in Thoroughbreds and Standardbreds in racing varies from 70 to 94 percent."

**Flunixin**
- "... recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse, dogs and camels."

• "Recommended for the alleviation of visceral pain associated with colic in the horse."

**Synedem**

• "Indications: In all species: Pulmonary edema, pulmonary congestion, ascites, renal edema, pregnancy edema, cardiac edema, hepatic edema."

**Toltrazuril Paste**

• "... represents a new standard in coccidiosis control in Race Horses, Camels, Pigeons, Greyhounds & Alpacas."

**Super Tie Up**

• "INDICATIONS- Vasodilator to improve blood flow and minimize tying-up, fatigue and muscle damage."

• "Horses : Rhabdom yo lysis, azoturia, tying up, exertional myopathy syndrome ... "

The above referenced products are only a sampling of the violative products you are currently marketing. Similarly, the above referenced claims are only a sampling of statements that demonstrate the intended uses of your products.

Because the above referenced products are intended to mitigate, treat, or prevent disease in animals, they are drugs within the meaning of section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)]. Further, these products are new animal drugs, as defined by section 201(v) of the FD&C Act [21 U.S.C. § 321(v)], because they are 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]. The above referenced products are not approved or index listed by the FDA, and therefore the products are 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)].

In addition, testing by FDA of samples of the drug Omeprazole Oral Paste revealed that the amount of active ingredient (omeprazole) in the drug did not correspond with the amount represented on the labeling. Specifically, the drug was found to be sub-potent at 68.1% of the label claim for potency. The product is therefore adulterated under section 501(c) of the FD&C Act [21 U.S.C. § 351(c)], in that its strength differs

from that which it purports or is represented to possess.

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 ofthe 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:
Mr. Simon Jones
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