



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

June 19, 1998

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

d1673b

Re: 98-DAL-WL-39

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Joe Edge, Co-Owner  
Aubrey/Pilot Point Professional Products  
821 East Production Drive  
Pilot Point, Texas 76258

Dear Mr. Edge:

Investigation of your veterinary products sales facility located at 821 East Production Drive, Pilot Point, Texas, by the Food and Drug Administration (FDA) on January 15, 1998, February 18, 1998, and February 23, 1998, revealed the sale and promotion of veterinary drugs, "Beef PRO-RESPONSE Show Formula"; "Lamb-Sheep/Goat PRO-RESPONSE Show Formula"; "Swine PRO-RESPONSE Show Formula"; and "Equine PRO-RESPONSE Weanling/Yearling Formula, 2 Yr Old & Older Halter Horse Show Formula, and Performance Horse & Competition-Plus Formulas", which are adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). The products are also misbranded within the meaning of Section 502(f)(1) of the Act.

Our investigation determined that you provide labeling in the form of product information sheets which include, but are not limited to, the following claims:

"Stimulates Endocrine System"

"Increases Appetite"

"Improves Hair Coat"

"Promotes Growth/Weight"

For Equine PRO-RESPONSE Formulas, you provide product labeling and product information sheets bearing the following claims:

2 Yr. Old & Older Halter Horse

- \*\*\* Quick Recovery From Strenuous Exercise/Stress"
- \*\*\* Replacement of Electrolytes Lost Through Sweating/Exertion/Exercise"
- \*\*\* Prevention of Muscle Cramps"
- \*\*\* Improved Oxygen Efficiency of Muscle"

Performance Horse Formula

- \*\*\* Provide Elements Essential For Articular Cartilage And Connective Tissues"
- \*\*\* Aid Bonding of Collagen Fibers And Retention of Lubricating Moisture"
- \*\*\* Speed Healing of Damaged Tendons and Ligaments"
- \*\*\* Help Reduce Pain and Inflammation"
- \*\*\* Give Greater Strength to Healed Tissues"
- \*\*\* Help with Healing Bone Fractures, Torn Ligaments, Arthritis, Joint Disease and Increase Mobility"

Under Section 201(g)(1) of the Act, a "drug" is defined, in part, as any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal, or intended to affect the structure or function of man or other animal. Because of the claims promoted on the labeling and the product's intended use, your various PRO-RESPONSE products meet this definition.

The drugs are adulterated under Section 501(a)(5) in that they are new animal drugs, as defined in Section 201(v) of the Act, which are unsafe within the meaning of Section 512. Section 201(v) defines a new animal drug as one, the composition of which is such that the drug is not generally recognized among qualified experts as safe and effective for use, under the conditions prescribed, recommended or suggested in the product's labeling. Section 512, in part, deems a new animal drug unsafe unless it is the subject of an approved New Drug Application (NADA). NADA's may be approved on the basis of adequate scientific data which the applicant submits as evidence of the safety and effectiveness of the product.

The drugs are also misbranded under Section 502(f)(1) of the Act. A drug is misbranded unless its labeling bears adequate directions for its intended use. You are using promotional materials and information sheets which also bear unsubstantiated drug claims. Product labels with adequate directions for use cannot be written for products with unsubstantiated therapeutic claims.

Page 3 - Mr. Joe Edge, Co-Owner  
June 19, 1998

If the "drug" claims are removed from all product labels, labeling, and promotional material, the above-mentioned products would be regulated as foods. Sarsaparilla is not listed in Title 21, Code of Federal Regulations, as a food substance that is generally recognized as safe (GRAS), and may require an approved food additive petition to be included in the PRO-RESPONSE products. Before marketing these products, please submit revised product labeling, promotional material, and information on the safety of sarsaparilla used, to the Center for Veterinary Medicine, Division of Compliance (HFV-232), 7500 Standish Place, Rockville, Maryland 20855, for review.

The above is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that your overall operation and the products you label, promote, and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Also include any available documentation demonstrating that corrections have been made.

Your response should be directed to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

  
Joseph R. Baca  
District Director