



9/18/56d

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

October 15, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ray Winn
President
Winn, Inc.
600 South 400 West
Smithfield, Utah 84335

Ref. #: DEN-02-02

Dear Mr. Winn:

On July 25, 2001, the U.S. Food and Drug Administration (FDA) made an inspection of your medicated feed manufacturing facility. The inspection found that you are manufacturing a free choice feed containing the Type A Medicated Article, Lasalocid/Bovatec 68, for use in cattle and sheep.

In accordance with Title 21 Code of Federal Regulations, Part 558.311 (21 CFR 558.311), you must use a FDA approved formula and have a valid FDA Medicated Feed Mill License to manufacture a free choice feed for cattle or sheep containing Lasalocid/Bovatec 68. Failure to have an approved formula is a violation of Section 512(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (the Act). Failure to have a valid FDA Medicated Feed Mill License is a violation of Section 512(a)(2)(B) of the Act. These violations cause your product to be deemed unsafe for the purposes of Section 501(a)(6) and 402(a)(2)(C)(ii) of the Act and are therefore adulterated.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to make immediate and lasting corrections may result in regulatory action without further notice such as seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law.

Your firm's product labels for **20% Nutra*Beef – Medicated**, **30% Nutra*Beef – Medicated**, and **30% Cattleman's Nutra*Beef – Medicated** should be revised as follows:

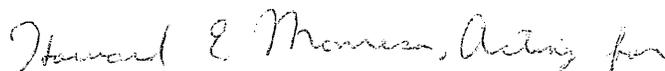
- The indication for these products is defined in 21 CFR 558.311(e)(1), subparts (vi) and (vii). The regulation defines the use as continuous at levels that range from 10 to 30 grams per ton of complete feed. Animals should receive between 100 and 360 mg lasalocid per day. The level of 600 g/ton is clearly excessive and violates the regulation. The feeding instructions do not make it clear that this product has to be fed continuously in a complete feed. Considering how high levels of crude protein are in these products, it is obvious that they are not intended as a complete feed.
- The statement “For ruminants only” is inappropriate and misleading. This product is approved for some ruminants, not all of them.
- In the ingredient section, the correct spelling is “proteinate” not “protenate”. The common or usual name for the ingredient “live yeast culture” is yeast culture”.
- The current CFR and FR should be consulted to verify the appropriate warning and caution statements.

Labels for **Nutra*Beef – All Natural Protein, Key*Lix Sheep, Key*Lix 20%, All Natural Protein, Winn 2 lb and 4 lb Dairy Supplement, 6-12 and 12-12 Livestock Mineral, Key*Lix 20%, 30% and 30% Cattleman’s Key*Lix, Hi-Mag Livestock Mineral, Key*Lix Dry Cow and Key*Lix Close-Up Dry Cow, Key*Lix Equine and Key*Lix Equine Plus, Nutra-Phos 10, and Nutra Production Plus**, also require corrections.

It is your responsibility to assure that the products you market are in compliance with the law. You may want to hire an independent consultant knowledgeable in the legal marketing of these products for guidance.

Your response should be sent to Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,



Thomas A. Allison
District Director