



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

1133117

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-53442

November 19, 1999

Richard J. Denier, President
Universal Marketing Services, Inc.
5545 West Avenida de los Robles
Visalia, California 93291

WARNING LETTER

Dear Mr. Denier:

During an inspection of your firm, Universal Marketing Services, Inc., located at 5545 West Avenida de los Robles, Visalia, California 93291, conducted by Food and Drug Administration (FDA) Investigator Thomas W. Gordon on November 10, 1999, it was determined that this firm is distributing UDDERMINT and HoofTect.

The label for UDDERMINT contains the statements: "for Udder Health, "SOOTHES & CLEARS", "NATURAL PRODUCT", "NO ANTIBIOTICS", "NO DISCARDED MILK FROM HEALTHY UDDERS", and "...can also be used in conjunction with antibiotic treatment." The instructions for use are to massage approximately 10 ml into the quarter, apply 2-3 times per day after first milking/stripping out, and repeat for 2-4 days.

The promotional material for UDDERMINT states: "to maintain udder health by stimulating/activating the cow's own self defense mechanism and thereby helping to soothe and clear." "Dairy producers testify that Uddermint is effective in bringing down swelling and promotes softening while soothing infected udders." "Uddermint is not species specific and has been found effective for use with many species to aid in reducing inflammation."

The label for HoofTect contains the statements: "Provides lasting protection against damage and infection." "No withdrawal period for meat or milk."

The promotional material for HoofTect states: "HoofTect protects the hoof from primary damage, such as stone bruises, cracks, and abrasions by strengthening the hoof surface." "Primary damage can lead to more serious problems such as foot rot and abscesses by allowing the introduction of bacteria." "HoofTect is not a cure for hairy foot warts, but can be used in conjunction with other remedies to aid in the treatment." "When used on existing wounds, HoofTect acts as a liquid adhesive bandage..." "HoofTect is an excellent liquid adhesive bandage for cuts and abrasions on the animal's body." "Examples include skin wounds and dehorning." "HoofTect helps the healing process and minimizes excessive scabbing."

Additional promotional material for HoofTect states: "HoofTect aids in treating or preventing hoof rot, hairy foot warts, and abscesses." "Protects hooves against heel cracks and softening." "Seals in vital electrolyte fluids in dry conditions."

UDDERMINT and HoofTect are veterinary drugs. Under the Food, Drug, and Cosmetic Act (the Act), any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to effect the structure or function of man or other animals is defined as a "drug" under Section 201(g). Unless a drug is generally recognized as safe and effective for its labeled uses, it is a new animal drug under the law. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA).

UDDERMINT and HoofTect are "new animal drugs" within the meaning of Section 201(v) of the Act. We are unaware of any substantial scientific evidence which documents that these products are generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as being safe and effective for their labeled purposes. Since they are not the subject of approved NADA's, they are adulterated under Section 501(a)(5) of the Act. These products may not be marketed as presently labeled.

Furthermore, UDDERMINT and HoofTect are misbranded drugs under Section 502(f)(1) of the Act in that the products as labeled fail to bear adequate directions for use for the unsubstantiated drug claims in your promotional literature and on your web site.

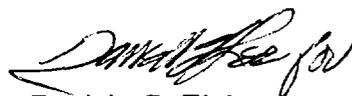
If you have not done so, you should register the manufacturer of these products and list these drugs with the FDA. For more information on registration and drug listing you may contact us.

The above is not intended to be an all-inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all veterinary drug products your firm manufactures, labels, and/or distributes are in compliance with all of the requirements of the Food, Drug, and Cosmetic Act.

You should take prompt action to correct the violations discussed in this letter. Failure to promptly correct these violations may result in regulatory action without further notice. Possible actions include a seizure and/or injunction.

We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to discontinue the marketing of these drugs or otherwise bring them into compliance. If corrective action cannot be completed within fifteen days, state the reason for the delay and the time within which the corrections will be made. Please direct your reply to Karen L. Robles, Investigator, United States Food and Drug Administration, 801 I Street Room 443, Sacramento, California, 95814

Sincerely yours,



Patricia C. Ziobro
Director
San Francisco District

Cc: Willard G. Clark, Vice President
15770 10th Avenue, Box 149
Hanford, California 93230

James L. Winter, General Manager/COO
6705 Winding Way
DeForest, Wisconsin 53532