



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 10, 2003
Ettore Alosio
President
Micelle Laboratories LLC
20481 Crescent Bay Drive
Lake Forest, CA 92630

W/L 25-03

Dear Mr. Alosio,

During an inspection of your manufacturing facility located in Lake Forest, California, conducted between September 4 and 9, 2002, and on November 11, 2002, our investigator documented that you are manufacturing animal products including Arthramine Advanced, Arthramine Plus, Anti-Gas, Champ Chewable Nutritional Pebbles, Calmative, Dermaplex, and Dermasol spray/gel. These products are unapproved new animal drugs. Because these products are not approved under a New Animal Drug Application, they are unsafe under Section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) and adulterated under Section 501(a)(5) of the Act.

Under Section 201(g) of 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 affect the structure or any function of the body of man or other animals" is regarded as a "drug." The following statements are examples of the drug claims that appear on the labeling and/or promotional materials (including your web site) for these products:

Arthramine Advanced: "aids in the relief of joint stiffness, osteoarthritis, pain and inflammation"; "dissolves and eliminates cellular debris that causes pain and swelling"; "helps reduce pain, stiffness and swelling due to inflammation"; "aids in reduction of symptoms of arthritis."

Arthramine Plus: "reverses damaging effects of stress and age to joints"; "helps to reduce inflammation and joint pain"; "dissolves and eliminates cellular debris that causes pain and swelling"; "blocks initial stages of inflammation"; "more effective than aspirin at relieving pain"; "natural pain relief."

Anti-Gas: "helps reduce...bowel discomfort."

Champ Chewable Nutritional Pebbles: "builds and repairs tissues"; "helps reduce pain, stiffness, and swelling."

Calmative: "reduces stress"; "calms 'high energy' pets"; "reduces nervousness"; "helps lower stress...and separation anxiety."

Dermaplex: "eliminates . . . irritated skin."

Dermasol spray/gel: "aids in the elimination of hot spots (moist eczema) and inflamed skin caused by chronic licking, scratching, and chewing, flea and insect bites."

Because the labeling and promotional materials for these products include statements which represent and suggest that the products are intended to be used in the cure, mitigation, treatment or prevention of disease, or are intended to affect the structure or function of animals, these products are drugs within the meaning of Section 201(g) of the Act.

Unless a drug is generally recognized by qualified experts as safe and effective for its intended uses, it is a "new animal drug" under Section 201(v) of the Act. We have no evidence that these products are generally recognized as safe and effective; therefore, they are new animal drugs. A new animal drug may not be legally marketed unless it is the subject of an Approved New Animal Drug Application (NADA). NADAs may be approved on the basis of adequate scientific data which the applicant submits as evidence of the safety and effectiveness of the product.

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These products are unsafe under Section 512(a)(1) of the Act because they are new animal drugs for which your firm does not have an approved application. Because they are unsafe under Section 512 of the Act, they are also adulterated under Section 501(a)(5) of the Act.

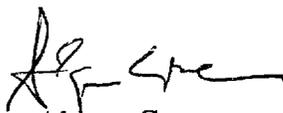
The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operations and the products you manufacture and distribute are in compliance with the law. You should take prompt action to correct these violations 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 fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made. If you have any questions or need clarification regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 798-7739.

Your reply should be directed to:

MaryLynn Datoc
Acting Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,



Alonza Cruse
District Director