



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 2049 N  
Public Health Service  
Food and Drug Administration

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

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

**WARNING LETTER**

July 23, 1998

WL-39-8

Joseph A. Deihl, President  
Mayor Pharmaceutical Laboratories, Inc.  
2401 South 24th Street  
Phoenix, AZ 85034

Dear Mr. Deihl:

This letter is in reference to "VitaMinophen DIETARY SUPPLEMENT SPRAY", and other products which are manufactured or marketed by your firm under the "VITAMIST" trade name.

**"VitaMinophen DIETARY SUPPLEMENT SPRAY"**

This product is labeled to contain Vitamin B1, Vitamin B6, and acetaminophen 4.0 mg per dose, and is labeled "For the temporary relief of minor aches and pains."

**"VITAMIST ORGANIC NUTRIMENT SPRAY SMOKE-LESS"**

This product contains numerous ingredients including valerian root, blue cohosh, and echinacea root, and is labeled "to quit smoking."

**"Melatonin DIETARY SUPPLEMENT SPRAY"**

This product contains 1 mg Melatonin per dose, and is labeled "to create healthy patterns of sleep."

**"VITAMIST CardioCare DIETARY SUPPLEMENT SPRAY"**

This product contains numerous ingredients including valerian root, garlic extract, and is labeled "to help those at risk detect and prevent heart failure . . . This heart tonic is an arsenal of natural herbs that fuel the fight to combat heart failure."

This products listed above, and the other "Dietary Supplement Sprays" marketed by your firm are to be sprayed into the mouth, and are intended to be absorbed through the oral mucosa directly into the bloodstream. The labeling for these products states that they are different from conventional tablets, pills, or capsules which must dissolve and travel through the digestive tract before they can be absorbed into the bloodstream.

The Dietary Supplement Health and Education Act (DSHEA) became law on October 25, 1994, and amended the Federal Food, Drug, and Cosmetic Act (Act). Section 201(ff)(2)(A)(I) of the Act defines the term "dietary supplement" to be a product that "is intended for ingestion in a form described in section 411(c)(1)(B)(I)." This section defines "form" to mean "tablet, capsule, powder,

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softgel, gelcap, or liquid form." Consequently, your products, which are not intended for ingestion, do not meet the definition of "dietary supplement" as defined in section 201 (ff)(2)(A)(i) of the Act.

Because they are not ingested, and their labeling claims that they are intended to treat, prevent, cure, or mitigate disease; or are intended to affect the structure or any function of the body of man, these products are drugs, as defined in section 201(g) of the Act, and new drugs (section 201 (p) of the Act). They may not be legally marketed in the United States since they are not approved (section 505). They are also misbranded (section 502(f)(1) of the Act) because the labeling fails to bear adequate directions for use.

The above list of violation is not intended to be an all-inclusive of those that exist at your firm. It is your responsibility to ensure that the drug products you market meet all requirements of the Act and its implementing regulations. Federal Agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to collect these violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific actions you will take to correct the violations. Your response should include an explanation of each step being taken to prevent 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.

Your written reply should be addressed to:

Mary M. LoVetere  
Compliance Officer  
U.S. Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, CA 92612-2445

Sincerely,

  
Elaine C. Messa  
District Director