



FEB 23 2005

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Frederick Leto  
GMS Corporation  
6278 North Federal Highway #240  
Fort Lauderdale, Florida 33308

Ref. No. CL-04-HFS-810-130

Dear Mr. Leto:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.molocure.com> and has determined that the product "A.M.P. Molo-Cure®" is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

**A.M.P. Molo-Cure®**

"Multitudes are testifying to full recoveries from "incurable" auto-immune and digestive diseases with A.M.P. Molo-Cure® without drugs or side effects."

"This natural solution is crucial [sic] for sufferers of all auto-immune disorders, IBD, Ulcerative Colitis (UC), Crohn's Disease, Irritable Bowel Syndrome (IBS), Diverticulitis, Diverticulosis, Chronic Fatigue Syndrome, Ulcers, Acid Reflux Disease, (GERD), Allergies ..."

"The AMP molecule: Helps stop the bleeding, damage and leakage of the intestine wall... [a]cts as a potent anti-inflammatory agent to reduce inflammation ... [p]romotes and accelerates the tissue healing process... [h]as direct anti-bacterial, anti-viral, anti-fungal, anti-yeast and anti-parasitic effects."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 USC § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 USC 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention of disease are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 CFR) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Linda J. Webb, Compliance Officer, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition