



MAR 14 2005

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

Judy Gaines  
Gaines Nutrition  
2840 Fletcher Parkway  
Suite 421  
El Cajon, California 92020

Ref. No. CL-04-HFS-810-141

Dear Ms. Gaines:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.gaines.com> and has determined that the products "CLA," "Cayenne/Goldenseal," "AC-Q," and "Asthmol" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

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

**CLA (Designs for Health)**

"It is a naturally-occurring fatty acid that supports areas of cancer prevention, keeping arteries clear and aids in helping fight colds and flus [sic]."

**Cayenne/Goldenseal (Nature's Way)**

"[E]qualize high ... blood pressure.... [R]educes serum cholesterol and cholesterol plaquing."

**AC-Q (Health Concerns)**

"Treats joint and muscle pain .... Treats degenerative diseases ... including arthritis. Used for traumatic and sports injuries: the formula works well for acute lower body injuries .... Also used for fibromyalgia."

**Asthmol (Hamida Pharma)**

"Asthmol is designed to enhance the breathing of people affected by asthma, bronchitis ...."

In addition, under the "Products by Category" section of your web site, you offer several products for diseases, which causes the products to be drugs under section 201(g)(1) of the Act. Examples of some of the disease categories listed on your web site for which you offer products include: "Allergy," "Anti-Viral," "Arthritis," "Asthma," "Cold & Flu," and "Osteoporosis."

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 U.S.C. § 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 U.S.C. § 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 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 C.F.R.) 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