



JUL 19 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeanine Bogashewicz
All Natural Health
3830 Sunrise Highway
Seaford, New York 11783

Ref. No. CL-05-HFS-810-185

Dear Ms. Bogashewicz:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.allnaturalusa.com> and has determined that the products "Kold Kare Cold & Flu Sinusitis" and "Cholestene" 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:

Kold Kare Cold & Flu Sinusitis

"Andrographis paniculata, the active ingredient in KARE-N-HERBS exclusive KOLD KARE, has proven to be an effective prophylactic against the common cold, flu and sinusitis. Double-blind clinical study has proven that recovery from fever and cold is faster with Andrographis paniculata. The active principle of Kold Kare tablets is bacteriostatic and virostatic, reducing tiredness by 30%, shivering by 50%, sore throat by 40%, muscular ache by 48%, and sinus pain and headache by 30% in comparison to control groups who took placebos. Kold Kare is a natural herbal dietary supplement that acts naturally against colds, flu, allergies and acute uncomplicated sinusitis. Formulated exclusively from the natural shrub Andrographis paniculata, used in China and India as a natural defense against respiratory diseases"

"At the first sign of a cold, take 4 tablets per day for 6 days. If you have a cold already, take 4 tablets a day for 10 days. To prevent cold, take 2 tablets twice daily. To help sinusitis problems, take 2 to 4 tablets every day."

In addition, the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of disease.

Cholestene

"Cholestene uses Red Yeast Rice that has been shown to help lower cholesterol levels."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" 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