



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7114
FAX: (612) 334-4142

January 18, 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Steve Merrill
Sheepish
326 Main Street
Racine, Wisconsin 53403

Ref. No. CL-07-HFS-810-240

Dear Mr. Merrill:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <http://store.sheepish.us> and <http://www.bodyofknowledge.net> and has determined that the products "Gan Mao Ling," "Pau d'Arco," and "Kyolic Aged Garlic Extract Lecithin Cholesterol Formula 104" 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 sites 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 sites include:

[from your web site at the Internet address <http://store.sheepish.us>]

Gan Mao Ling

"This formula is very effective for treating colds and flu."

Pau d'Arco

"[T]he inner bark of the Purple Lapacho tree yields naphthoquinones, anthraquinones and other phytopharmaceuticals Scientific research has shown these substances to be: anti-inflammatory ... anti-fungal, anti-parasiticial [sic], anti-viral, anti-bacterial, and anti-yeast."

[from your web site at the Internet address <http://www.bodyofknowledge.net>]

Kyolic Aged Garlic Extract Lecithin Cholesterol Formula 104

"Lecithin ... has been shown to decrease cholesterol in studies. Choline has been shown to lower blood pressure slightly."

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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

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writing to Tyra S. Wisecup at the address on the letterhead. If you have any questions concerning this letter, please contact Ms. Wisecup at (612) 758-7114.

Sincerely,

A handwritten signature in cursive script that reads "W. Charles Becoat".

W. Charles Becoat
Director
Minneapolis District

HTW/ccl