DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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October 25, 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Carol A. James
Inspired Living
P.O. Box 388
Dundee, Oregon 97115

Dear Ms. James:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.inspiredliving.com and has determined that the products "Etherium Gold," "Glucosamine Chondroitin MSM Complex," and "AllerFree" 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:

Etherium Gold (sold as capsules, oral spray, or powder)

"Great for ADD and ADHD"

"According to the Alphalearning Institute in Lugano, Switzerland, 'Our research also clearly shows that left-right brain imbalances are predominating in many mental … dysfunctions such as … attention deficit hyperactive disorders (ADHD). It is my professional opinion that Etherium Gold would be of tremendous benefit in any of these conditions and the most obvious answer as a healthy alternative to chemicals with harmful side effects.' "

"Etherium Gold is recommended for … anyone (children included) who may have … attention deficit disorder (ADD) and attention deficit hyperactive disorders (ADHD)."

Glucosamine Chondroitin MSM Complex

"Promotes … pain-free joints"

"Glucosamine and Chondroitin sulfates work synergistically to promote … pain-free joints."

"MSM has proven to be an effective pain reliever for osteoarthritis and other forms of inflammation. The herbal base of this formula, a rich source of organic minerals, is designed to assist with muscle and joint stiffness."

"Glucosamine and Chondroitin can be extremely effective in preventing osteoarthritis and can provide relief to existing conditions."

AllerFree

> "For the millions who suffer the effects of airborne allergens, AllerFree represents a safe, natural solution. Those who use it tell us they have never experienced such complete relief from a natural product."
>
> "Within about two weeks of use, AllerFree may substantially reduce the frequency and intensity with which the discomforts associated with allergic reactions occur. If the use of the enzymes is discontinued, however, such discomforts will recur."

In addition, the name of your product suggests that it is intended for use in the mitigation, treatment, or prevention of allergies, which are a disease as defined in 21 C.F.R. 101.93(g)(1).

Your web site also contains disease claims in the form of personal testimonials, including:

> "My son Brandon has severe Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, Mental Retardation, and Autism. We have used Etherium Gold on him and got some great results, his attention, hyperactivity, and verbalizing is a lot better."

Your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are "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 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 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 the FDA. You may respond in writing or by telephone to my attention at the Food and Drug Administration, 22201 23rd Drive Southeast, Bothell, Washington 98201-4421, 425-483-4940.

Sincerely,

/s/

Lisa M. Althar
Compliance Officer