DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stephen Levine, Ph.D.
Allergy Research Group®
30806 Santana Street
Hayward, CA 94544

November 24, 2004

Ref. No. CL-04-HFS-810-105

Dear Dr. Levine:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://allergyresearchgroup.com and has determined that the products AllerAid Herbal, Fibrenase III –Lumbrokinase, Palmetto Complex II with Lycopene, TMG (Trimethylglycine), XCraving®, Brainstorm®, and 200 Mg of Zen are promoted for conditions that cause these 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 these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of diseases. The marketing of these products with these claims violates the Act.

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

AllerAid Herbal

- "It is designed to support the body in balancing and correcting the underlying dysfunctions that contribute to the symptoms of allergy."

Fibrenase III –Lumbrokinase

- "Research has shown lumbrokinase to support the body in breaking up and dissolving the unhealthy coagulation of blood…."

Palmetto Complex II with Lycopene

- "The studies revealed low levels of lycopene in abnormal prostate tissue."

TMG (Trimethylglycine)

- "Studies have shown cerebrospinal fluid levels of S-adenosylmethionine (SAMe) to be low in patients…resulting in demyelination in the brain and degeneration of the spinal cord. TMG has been shown to restore levels of SAMe in the cerebrospinal fluid."

XCraving®

- "[C]ontains nutrients that support insulin regulation, blood sugar normalization …."

Brainstorm®

- "L-glutamine [an ingredient in the product] is a precursor of GABA, an antidepressant neurotransmitter."

200 Mg of Zen

- "The anxiolytic, muscle relaxant, and sedative effects of the benzodiazepines, e.g. Librium and Valium, rely upon the facilitation of…GABA [an ingredient in the product]. There is evidence that anxiety and panic disorders are associated with…a decrease in GABA's function as an inhibitory mediator."

Your products are not generally recognized as safe and effective for the above referenced conditions and therefore, these 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 new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are 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 reach FDA electronically (e-mail) at Kenneth.Taylor@CFSAN.FDA.GOV, or you may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, 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 Dr. Taylor at (301) 436-1439.

Sincerely,

/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