

Food and Drug Administration College Park, Maryland 20740

September 10, 2007

<u>CERTIFIED MAIL</u> RECEIPT REQUESTED

Martin Nutraceuticals, Inc. 10580 North McCarron Boulevard Suite 115 -160 Reno, Nevada 89503

Ref. No. CFSAN-OC-UL07-06

To Whom It May Concern:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.martinnutra.com and has determined that the products "Arthrizyme" and "Maximum Slim" 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:

Arthrizyme

- "Arthrizyme is a systemic oral enzyme designed to revolutionize the way arthritis is naturally treated."
- "Arthrizyme is a unique blend of systemic enzymes designed to provide superior antiinflammatory benefits. Unlike any other natural joint health product, Arthrizyme not
 only significantly reduces inflammation; it assists the body's healing process.
 Arthrizyme's ability to reduce both inflammation and speed up the healing process
 makes it the only ideal supplement for arthritis and injuries of any kind."
- "Systemic oral enzymes (Arthrizyme) will revolutionize the way we treat diseases. . . . Studies to date have shown that systemic oral enzymes (Arthrizyme) benefits rheumatoid arthritis, renal fibrosis, sports trauma, acute and chronic bronchitis, sinusitis, prostatitis, urinary tract infections, pelvic inflammatory disease, herpes simplex, pancreatitis, systemic lupus erythematosus ... and burns. Ongoing studies include the effect enzyme therapy has on breast cancer, Alzheimer's, Multiple Sclerosis, Tinnitus...."

In addition, the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of disease, as do the other references to arthritis and joint and muscle pain on your web site.

Maximum Slim

• "A frightening 30% of the population are clinically obese. The short term and long term devastation that obesity bring to society is staggering. Obesity is a major contributor to heart disease[,] diabetes[,] and certain cancers. * * * Finally there is a safe all natural supplement that really works in helping people to combat this menace to our society."

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 Kristen Moe,

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Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, HFS-608, 5100 Paint Branch Parkway, College Park, Maryland 20740. If you have any questions concerning this letter, please contact Kristen Moe at 301-436-2064.

Sincerely,

/s/

Jennifer A. Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition