DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
College Park, Maryland 20740

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marc Wilcox
N101, Inc.
6252 Romaine Street
Los Angeles, California 90038

Ref. No. CL-07-HFS-810-258

Dear Mr. Wilcox:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.n101.com and has determined that the products "Yucca," "GlucoActive," "Garlic (Odor Controlled)," and "Sinus and Respiratory" 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:

Yucca
"Beneficial in the Treatment of Arthritis, Osteoporosis, and Inflammatory Disorders"

GlucoActive
"Scientific studies have shown that Cinnulin PF® … may reduce the risk factors for diabetes."
"Clinical studies have shown Cinnamon may assist with glucose control and decreases fasting glucose levels when taken consistently."
"GlucoActive provides a proprietary glucose support compound that further helps improve glucose management safely and naturally."
"ActiVin® Grape Seed extract … contains natural flavonoids called procyanidins that improve glucose levels."

Garlic (Odor Controlled)
"Supports healthy cholesterol levels by reducing serum cholesterol."
"Also used to … protect against infection …."
"Also used to lower blood pressure …."

Sinus and Respiratory
"[C]old and flu…."

In addition, we note that your web site identifies several products under the categories "Arthritis Relief," "Blood Sugar Regulation," "Cholesterol Control," and "Cold & Flu Remedies" including "Inflama-Rest," "Oregulin," "Best Red Yeast Rice," "Flu Guard," and "Cold Care P.M." products, for example. Such product headings and categories cause the products listed under them to be drugs under section 201(g)(1) of the Act because they imply that the products are useful in the cure, mitigation, treatment or prevention of these diseases.

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 Kristen L. Moe, 5100 Paint Branch Parkway (HFS-608), College Park, MD., 20740. If you have any questions concerning this letter, please contact Kristen L. Moe at 301-436-2064.

Sincerely,

/s/

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