DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

MAY 24, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Urban Nutrition
P.O. Box 1258
New York, NY 10018

Ref. No. CL-05-HFS-810-144

To Whom It May Concern:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.urban-nutrition.com, http://www.urbannutritioninc.com, http://www.findlongevitynow.com, http://www.findserenitynow.com, and http://www.mydailydose.com and has determined that the products Longevity™, Serenity™, and MyDailyDose 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 sites establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the products with these claims violates the Act.

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

Longevity™

"[P]rotecting the cells of your entire body from toxins and disease."
"Longevity delivers 2-AEP directly to the outer cell walls to strengthen, seal, and protect your cells from toxins and diseases entering and infecting your healthy cells."
"2-AEP has been approved by the German Health Authority (FDA equivalent) as an **official treatment for Multiple Sclerosis [MS].** In fact, 2-AEP is the *only* natural Official MS treatment reimbursed by the equivalent of the German Social Security System." (emphasis in original)
"[T]he essential minerals in Longevity™ strengthen the cell wall by sealing the pores. This sealing effect protects our healthy cells from penetrations of toxins, bacteria and viruses. The 2-AEP in Longevity is the ultimate defense against…degenerative disease…100% Money Back Guaranteed."
"Human Growth Hormone (HGH) [an ingredient in the product] is an endocrine hormone…. HGH affects almost every cell in the body…. Osteoporosis can be prevented, and heart attack and stroke risk factors are diminished. HGH can also benefit emphysema patients by improving their oxygen uptake."
"In 1968, the German Health Authority (called Bundesgesundheitampt, which is the equivalent to the American National Institute of Health, the parent of the U.S. FDA, or the Australian Ministry of Health, the parent of the TGA) declared Longevity™ an official medication in the treatment of Multiple Sclerosis."
"Along with the disorder of the gas metabolism in Asthma and Degenerative Lung Disease, there is also often an undesirable mobilization of Calcium from the bones, which is due to excess carbon dioxide in the blood. This 'is likewise prevented by additional Longevity™.'"

Under heading "General Treatment Protocols":

"Degenerative Disease Prevention or Reoccurrence: 3 - 500mg Capsules per day."

"Multiple Sclerosis Prevention (MS): 4 - 500 mg Capsules every day …."

"Asthma: 3 – 500 mg Capsules 3 times per day (9 total/day)."

"Degenerative Disease Patients: 3 - 5, 500 mg Capsules per day to help stop the disease from spreading by entering the healthy cells."

Serenity™

"Serenity is the first effective, safe & natural anti depressant and Mood Stabilizer for depression…."

MyDailyDose

"Dr. Nieper's E-Complete [a component of the product] will…clear blockage in arteries, lower cholesterol levels, …."
"Dr. Nieper's Mineral Membrane Complex [a component of the product] is a combination of Calcium, Magnesium and Potassium combined with his patented substance: 2-AEP. … [which] delivers the minerals it is combined with to your outer cell walls to strengthen, seal, and protect your cells from toxins and diseases entering and infecting your healthy cells."

Your web sites also contain disease claims in the form of personal testimonials, including:

"My doctor told me that if I was not going to completely change my lifestyle and start eating a sensible diet and do some exercise every day, I was going have a heart attack by the time I was 50. Since I hate vegetables and exercise, I starting [sic] taking My Daily dose because I have three friends that take it religiously. Four months later, doc said my cholesterol was down to healthy levels…."

"I have been taking Dr. Nieper's Serenity for over 1 year now. It replaced my Prozac prescription and my depression is a thing of the past."

Furthermore, 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 sites 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 sites, 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