DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
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November 6, 2007

CERTIFIED MAIL
RECEIPT REQUESTED

Rudy Mullis
The i-Group
P.O. Box 667
Siler City, North Carolina 27344

Dear Mr. Mullis:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.muscadinegrapeseeds.com and has determined that the product "North Carolina Muscadine Grape Seeds" is promoted for conditions that cause the product to be a drug 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 product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

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

North Carolina Muscadine Grape Seeds

- "Scientific research has shown that there are over 60 known diseases and conditions that are linked directly to these Free Radicals. Some of these diseases and conditions include: Allergies - Rheumatoid Arthritis - Cancer - Diabetes . . . Osteoporosis -Parkinson's Disease . . . Birth Defects - High Blood Pressure - Heart Disease - Schizophrenia - Hardening of the Arteries - Cardiovascular Disease . . . Crohn's Disease - Alzheimer's Disease . . . ."

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

- "*This product [MuscadineGrapeSeed] has lowered my Blood Pressure to the point that the Doctor has taken me off my Blood Pressure medications. . . . And my Cholesterol actually went down too!*" A.H. - North Carolina
- "*I have had arthritis most of my adult life. The MuscadineGrapeSeed product has really helped the inflammation that I suffer from every day.*" F.S. - South Carolina
- "*My whole family takes MuscadineGrapeSeeds, and the kids haven't had a cold . . . since we have been on it.*" M.P. - North Carolina

Furthermore, your product is not generally recognized as safe and effective for the above referenced uses and therefore, the product is a "new drug" 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 James MacLaughlin, Compliance Officer, at the address noted in the letterhead. If you have any questions concerning this letter, please contact James MacLaughlin at 404-253-1220.

Sincerely yours,

Mary H. Woleske
Director
Atlanta District