DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
7520 Standish Place, Room 254
Rockville, Maryland 20855

February 2, 2001

Ref. No. 01-HFD-310I-079

Ms. Linda Edwards
4716 Goshawk Dr.
Chesapeake, VA 23321
US

Dear Ms. Edwards:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://NATURESANSWERS.COM and has determined that the product "Masquelier's Pycnogenol" being offered, is promoted for conditions that cause the product to be a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)]. The product may be considered a drug because the therapeutic claims as shown on your web site establish its intended use as a drug.

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

Masquelier's Authentic FRENCH PYCNOGENOLS (also called OPCs) "…….is totally safe to use, 100% non-toxic and natural -- but powerfully effective …….Acts as a superior antioxidant, protecting cells in the body against destruction by free radicals. …Lowers LDL cholesterol levels, thus reducing the risk of cardiovascular disease…….. Reduces platelet aggregation, thus reducing the risk of atherosclerosis…….. Increases the strength and elasticity of blood vessels, protecting against rupture, leakage and degeneration." "Pycnogenol can help protect you from approximately eighty diseases, including... **Reduces risk of:** Heart Disease Cancer ….. **Strengthens blood vessels &** Maintains proper capillary permeability Reduces capillary fragility …….. Treats chronic venous insufficiency Reduces the risk of phlebitis ……**Diabetes** Reduces diabetic retinopathy…."

Furthermore, FDA has no information that your product is generally recognized as safe and effective for the above referenced conditions and therefore, it may also be a "new drug" under section 201(p) of the Act [21 USC 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 USC 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 or as cosmetics if certain therapeutic claims 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 (DSHEA), dietary supplements may be legally marketed with claims that they are intended to affect the structure or function of the body (structure/function claims) if certain conditions are met. Claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims) excepting health claims authorized for use by FDA, may not be made as they 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 statements allowed as structure/function claims and those that represent disease claims. This document is available on the Internet at http://vm.cfsan.fda.gov/~lrd/fr000106.html.

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter into the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, disease or structure/function claims may cause them to be new drugs.

Additional information is available in Title 21, Code of Federal Regulations, (21 CFR) Parts 310 and 330-358. These parts include the Final Rules for various OTC ingredients or products that may or may not be legally marketed without prior approval.

Furthermore, your Internet site may be subject to statutes enforced by the Federal Trade Commission (FTC). Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. Sections 45 and 52. You are encouraged to consult the FTC Web site at http://www.ftc.gov/bcp/conline/pubs/dietsupp.htm for further information. The FTC Web site also provides copies of complaints and orders that have been filed by the FTC against companies making misleading or deceptive advertising claims on the Internet. Some of these complaints and orders can be found at http://www/ftc/gov/opa/2000/06/lanelabs.htm, http://www.ftc.gov/opa/2000/04/cure-all2.htm, and http://www.ftc.gov/opa/1999/9906/opcureall.htm. You may want to review your advertisement in light of these standards. Related questions should be directed to the FTC at (202) 326-3090.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the statutes administered by both the FDA and FTC.

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 TARTM@CDER.FDA.GOV, or you may respond in writing to Ms. Margaret Tart, Compliance Officer, Food and Drug Administration, HFD-300, 7520 Standish Place, Rockville, Maryland 20855 or by telephone at (301) 594-0054.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration