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

Food and Drug Administration
College Park, Maryland 20740

FEB 1 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David Friedlander
Vitamin Power, Inc.
39 St. Mary's Place
Freeport, New York 11520

Ref. No. CL-04-HFS-810-109

Dear Mr. Friedlander:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.vitaminpower.com and has determined that the products "Vitamin E & Selenium Antioxidant Complex," and "Green Tea Extract Capsules" 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 USC § 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:

Vitamin E & Selenium Antioxidant Complex
"[M]ay counteract the inflammation and deficient respiration associated with asthma.""[Selenium is] recognized to be effective in colon and rectal cancers. Vitamin E is known to be useful in helping reduce the risk of lung and breast cancer."
"Vitamin E and Selenium are also reported to be … beneficial to people with liver disorders."

Green Tea Extract Capsules
"Green Tea … contains natural antioxidant compounds known as polyphenols useful in fighting tumors and also helping prevent and treat rheumatoid arthritis."

Your Vitamin E & Selenium Antioxidant Complex and Green Tea Extract Capsules are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, Vitamin E & Selenium Antioxidant Complex and Green Tea Extract Capsules are misbranded under section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. 352(f)(1)].

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 of disease 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 regulated as drugs.

Certain over-the-counter drugs may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 CFR) 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 Linda J. Webb, Compliance Officer, 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 Ms. Webb at (301) 436-2375.

Sincerely yours,

/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