DEPARTMENT OF HEALTH & HUMAN SERVICES **Food and Drug Administration**

200 Chestnut Street
US Customs House, Room 900
Philadelphia, Pennsylvania 19106

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 14, 2005

John Luby
Viable Herbal Solutions
190 Fletcher Drive
Morrisville, Pennsylvania 19067

Ref. No. CL-05-HFS-810-197

Dear Mr. Luby:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.herbal-solutions.com and has determined that the products "*B.A.V.* Botanical Anti-Viral Immune System Support," and "Arctic Root" 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:

***B.A.V.* Botanical Anti-Viral Immune System Support**
"Botanical Anti-Viral Immune System Support … provides herbal ingredients that have historically been shown to have anti-viral and anti-bacterial activity." [emphasis in original]
"This immunity support formulation kills germs that cause fevers and infections."
"Fevers of all kinds, including the rare typhoid, malaria, and meningitis, have been successfully treated and/or prevented by these herbal ingredients."
"PURPOSE OF FORMULATION: Herbal support to help alleviate fevers and general ailments due to common colds and influenza; fight infection …."
"OTHER APPLICATIONS: Botanical support for the following: Amoebic infections …. To support conditions such as … obesity, gout … venereal disease …."

Your website also makes disease treatment and prevention claims for several ingredients of *B.A.V.* Botanical Anti-Viral Immune System Support, including the following:

ECHINACEA
"Echinacea has been widely used by Native Americans … for hundreds of years as an antiseptic, an analgesic …."
"Echinacea is also used extensively by herbalists and alternative health care providers to … reduce inflammations, treat colds and flu, and fight infections."
"Scientists have found that Echinacea helps to activate macrophages, key immune system elements that are directly involved in the destruction of bacteria, viruses, other infectious agents and cancer cells."
"A report in the December 1984 issue of Infection and Immunity demonstrated that a polysaccharide fraction derived from Echinacea purpurea significantly increased the killing effect of macrophages on tumor cells."

GOLDENSEAL
"Goldenseal's benefits can be attributed to its alkaloids, especially hydrastine and berberine. … Hydrastine has also been reported to lower blood pressure …. Berberine and its sulfate, berberine sulfate, have been demonstrated to have anti-cancer activity in vitro, and also have been shown to have anti-bacterial[] [and] anti-fungal … activity, as well."

LICORICE ROOT
"[A]n excellent anti-inflammatory which has been used successfully … to reduce the symptoms of stiff, inflamed and sore muscles & joints."

CAT'S CLAW
"[H]elps … people experiencing different stomach & bowel disorders, including colitis, Crohn's disease, irritable bowel syndrome, and leaky bowel syndrome."
"In addition, the presence of glycosides, proanthocyanidins and beta sitosterol help provide anti-viral, anti-tumor and anti-inflammatory support for the body."

PAU D'ARCO
PAU D'ARCO is an antibacterial agent … and also exhibits numerous anti-viral properties."
"Derived from the inner bark of a native South American tree, this herb has strong anti-yeast and anti-fungal properties. … This herb has also been used historically for a variety of conditions, including candidiasis, … all types of infection, diabetes, ulcers, rheumatism, allergies, and liver disease."

CAYENNE
"[L]ower[s] overall blood pressure."
"Cayenne also helps regulate cholesterol and lipid levels."

In addition, the use of the term "anti-viral" in the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of diseases caused by a virus.

Arctic Root
"Arctic Root is native to Siberia and Europe, and has been used there for the treatment of … anemia, depression, … impotence, and infections."
"In Central Asia, Arctic Root was prescribed for tuberculosis, cancer, and influenza."
"In Germany, Arctic Root has been used for pain, headache … and as an anti-inflammatory."
"Arctic Root has also been ... used to treat … erectile dysfunction."
"Arctic Root is now being studied for its positive attributes in fighting depression, Parkinson's, ADD, and fibromyalgia."

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 to Richard C. Cherry, Compliance Officer at the address noted on the letterhead. If you have any questions concerning this letter, please contact Mr. Cherry at (215) 717-3075.

Sincerely yours,

/s/

Steven L. Carter
Director, Compliance Branch
Philadelphia District