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

Food and Drug Administration
College Park, Maryland 20740

AUG 21 2006
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Patrick S. Galvin
Herbal Groups, Inc.
21822 Lassen Street, Suite A
Chatsworth, California 91311

Ref. No. CL-06-HFS-810-237

Dear Mr. Galvin:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.longlifesolutions.net and http://www.herbalgroups.com and has determined that the product "Prostalex Plus" 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 sites 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 sites include:

Prostalex Plus
"**Prostalex Plus** is designed to … reduce the need to urinate during sleep and multiple times throughout the day. This one-of-a-kind daily supplement [is] for men who want to live a long, full life without the fear of prostate problems."
"Relieve Yourself of Frustrating Urination Problems!

- Do You Get Up Multiple Times During the Night to Urinate?
- Do You Have Trouble Starting Your Stream?
- Do You Constantly Feel Like You Have to Go to the Bathroom?
- Pain during bowel movements?

… If left unattended, the prostate gland can interfere with your normal, healthy flow of urine. Now, there's a product that has been shown to reduce the size of an enlarged prostate naturally."
"The makers of *Longlife Solutions* have created a unique product that contains 11 hand-selected, high-quality ingredients that work together to shrink the size of a man's prostate and restore proper prostate function and health."
"Longlife Solutions - the makers of Prostalex Plus - is so committed to creating a quality product that really works, that we put Prostalex Plus through a series of clinical studies. The findings were nothing less than spectacular! Every single man in the study group - that's 100% of the participants - showed tremendous signs of a reduced prostate gland within several weeks! With a reduced prostate, the men also showed decreased signs of abnormal urinations. In short, they got up much less at night to urinate than before; they had less trouble starting their stream; and they reduced the frustrating urge to always have to go to the bathroom *right now*."

"These fine ingredients have long been researched to reduce an enlarged prostate and restore better prostate health. According to the *University of Maryland Medical Center*, studies suggest that stinging nettle in combination with other herbs, especially saw palmetto, may be an effective treatment for benign prostatic hyperplasia (BPH), relieving urinary symptoms such as reduced urinary flow, incomplete emptying of the bladder, post urination dripping, and the constant urge to urinate."
"We added additional important ingredients such as pygeum bark, beta sitosterol and pumpkin seeds which have all been recommended in preventing or treating prostate-related issues like BPH."

- "Stop getting up in the middle of the night to urinate!
- Stop rushing out of movies to get to the bathroom!
- Stop straining to start your urination flow!
- And stop worrying about prostate cancer and associated problems!

If there was a chance of preventing one of man's most painful and deadly diseases, wouldn't you take that supplement?"

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also 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 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/

Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
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and Dietary Supplements
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