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

Food and Drug Administration
College Park, Maryland 20740

APR 24 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Xuelin Li, Ph.D.
ActiveHerb Technology, Inc.
10855 Sorrento Valley Road, Suite 204
San Diego, California 92121

Ref. No. CL-07-HFS-810-252

Dear Dr. Li:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.activeherb.com and has determined that the products "Shan Zha Jiang Zhi Wan," "Yu Quan Wan" and "Saw Palmetto" 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:

Shan Zha Jiang Zhi Wan
"[P]revents arteriosclerosis†. The herbal formula is used for high cholesterol, coronary heart disease, angina pectoris and hypertension†."
In addition, the product is listed as a remedy for arteriosclerosis, cholesterol control, coronary heart disease, angina, and hypertension via the list of links on the home page and the page entitled "Herbal Remedies for your concerns." A list of recommended remedies sold on the site appears when the user clicks on the link for a disease or condition in one of these lists.

Yu Quan Wan
"[U]sed for excessive thirst and asthenia due to diabetes."
"Great for use with diabetic patients. Chronic kidney disease and cough. Tuberculosis patients also benefit. High blood pressure, use of this herb will help eliminate side effects from steroids."
In addition, the product appears on a list of recommended remedies for diabetes that consumers can view by clicking the "Diabetes" link on the home page or the page entitled "Herbal Remedies for your concerns."

Saw Palmetto
"May be as effective as [P]roscar for BPH.†"
"Research has shown that standardized Saw Palmetto extract helps reduce symptoms related to prostate enlargement (benign prostatic hyperplasia, or BPH) such as the frequency and urgency of urination.† It may be as effective as [P]roscar yet has fewer side effects."
"**Saw Palmetto Health Benefits**
Saw palmetto counts for 90% of prescriptions for BPH in Germany. Many clinical trials have been conducted by researchers in USA and Europe to evaluate the use of Saw Palmetto in the treatment of prostate enlargement. In a meta analysis of Saw Palmetto clinical trials conducted in Europe, indeed saw palmetto is found to effectively relieve the symptoms of BPH …."
"Both trials found that patients who took Saw Palmetto showed more improvement in the prostate symptoms than the patients who took placebo."

"Saw palmetto was also compared side by side with Proscar for BPH treatment. Proscar is a prescription drug for the first line BPH treatment. Basically the trials concluded that saw palmetto is as effective as [P]roscar in relieving BPH symptoms but saw palmetto has less side effects than [P]roscar" (footnotes omitted).
"**Saw Palmetto Science**
How might Saw Palmetto relieve the symptoms of BPH? BPH is caused by the cell overgrowth in the prostate gland due to the male sex hormone DHT. Saw Palmetto seems to regulate DHT."
"**Saw Palmetto Side Effects**
Side effects are few in the Saw Palmetto clinical trials and less common than the BPH drugs such as Proscar."
"Another advantage of Saw Palmetto over [P]roscar is that Saw Palmetto does not interfere [with] the PSA test for prostate cancer."

Under "**Saw Palmetto for benign prostatic hyperplasia (BPH) or lower urinary tract symptoms (LUTS) … USA trials**":
"[T]he authors found that patients receiving both saw palmetto and placebo showed some improvement of BPH symptoms. Saw palmetto gave a bigger improvement than placebo …."
"At the trial end, patients receiving saw palmetto had their I-PSS [International Prostate Symptom Score] score improved 4.4 points from 16.7 to 12.3 (the smaller the better)[.]"
"The USA trial results are … in line with the much larger trials in Europe that support the positive effect of saw palmetto in relieving BPH or LUTS symptoms …."

Under "Saw Palmetto Frequently Asked Questions":
"Can I use saw palmetto for prostatitis?
Some people use saw palmetto for prostatitis."
"Does Saw Palmetto help prostate problems? …
Saw palmetto helps prostate enlargement problem[s] without altering PSA and you can check it in detail[] here."

Your web site also contains disease claims in the form of personal testimonials under the heading "My Saw Palmetto Stories," including:
"**Saw Palmetto has a mild [V]iagra effect"**
"**Saw Palmetto improved my BPH …**"
"[I] read a report comparing saw palmetto to [F]inisteride [sic] … it stated saw palmetto was just as effective as [P]ropecia [at] reducing the symptoms of BPH ... so [I] tried it and within a month [I] was noticing … reduced frequency of trips to the bathroom, saw palemetto [sic] is definitely worth trying out …."

In addition, your Saw Palmetto product appears on lists of recommended remedies for prostate enlargement and prostatitis that consumers can view by clicking the appropriate link on the home page or the page entitled "Herbal Remedies for your concerns."

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 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.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition