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

Food and Drug Administration
College Park, Maryland 20740

DEC 15 2004
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lynn Schulz
JSA Enterprises
dba JAS Management, Inc.
425 4th Avenue SE
Cairo, Georgia 39828

Ref. No. CL-04-HFS-810-110

Dear Lynn Schulz:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.plantationherbals.com and http://www.theundrugs.com and has determined that the products "KL Capsules," "HBC Capsules," "AS Capsules," "Salus SR Stroke Capsules," "Tangcotrol D Capsules," and "Gourdin" 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 sites 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 sites include:

KL Capsules, HBC Capsules, and AS Capsules
From www.theundrugs.com:
"They will … help reduce the risk of contracting SARS and other infectious diseases."

HBC Capsules
From www.theundrugs.com:
"Lowers High Cholesterol, Treats Heart Disease … (neuropathy)"
"Release you from the … pain in the chest resulting from Coronary Heart Disease."
"Effectively treat Angina Pectoris, Myocardial Infarction, Arrhythmia, Myocardial Anemia, Atherosclerosis."
"Reduce the bad Cholesterol in your Blood."
"Lower your Blood Pressure."
"Cancer inhibiting functions. Anti Tumor effect."

Salus SR Stroke Capsules
From www.theundrugs.com:
"In most cases these capsules will help you recover if you have suffered a stroke and have any of the following symptoms:… hemiplegia (paralysis of one side of the body) … dysphasia (impairment of speech and verbal comprehension)."

Tangcotrol D Capsules
From www.theundrugs.com:
“Lower blood sugar… Treat Retinopathy.”

Gourdin
From www.theundrugs.com:
"Gourdin fights the root cause of Diabetes…"

From www.plantationherbals.com:
“In clinical test, when administered to the patients suffering from both Type I and II diabetes, Gourdin helped to improve blood sugar readings.”
“Reduces Cholestrol (sic) …”
“Diabetic Neuropathy…Gourdin regulates the complex metabolism associated with high blood sugar allowing your blood sugar to return to a normal range. With a return to normal blood sugars … the symptoms of diabetic Neuropathy improve. The same can be said for Diabetic Retinopathy which affects the eyes. Pain and inflammation in Joints may also improve."
“[B]ladder infections …”

Furthermore, FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, the products may also be “new drugs” 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 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 conditions 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 into 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 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