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

Food and Drug Administration
College Park, Maryland 20740

AUG 21 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Deepali Khanna
HerbalSalon, LLC
6625 Green Valley Circle, Suite 302
Culver City, California 90230

Ref. No. CL-06-HFS-810-228

Dear Mr. Khanna:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.herbalsalon.com and has determined that the products "Himalaya Shuddha Guggulu," "Himalaya ProstaCare," and "Himalaya Gymnema" 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:

Himalaya Shuddha Guggulu
"[H]elps in removing excess cholesterol from the body."
"[A] very effective herbal medicine for controlling cholesterol …."
"[K]nown to be effective against the common cold …."

Himalaya ProstaCare
"This revolutionary blend helps:
Promotes free and normal urinary flow
…
Helps against benign prostatic enlargement (BPH)
Prostatitis
Dysuria
BPH with high PSA"

Himalaya Gymnema
"Gymnema for Diabetes"
"Its principle [sic] constituent is gymnemic acid which has anti-diabetic properties."
"[B]elieved to neutralize excessive sugar present in the body in diabetes mellitus. The leaf extracts contain gymnemic acid which is said to inhibit hyperglycemia. It has also been shown to have a regenerative effect on pancreatic beta cells and is insulinotropic."
"The leaf extract … is useful in glycosuria ….
"The extract in vitro was effective against diabetes and insulinotropic action was observed in rabbits. The plant is … diuretic."

"**Action**: A [sic] herb which … is beneficial in diabetes mellitus. It diminishes excessive blood sugar."
"**Indication**: It is used in Diabetes Mellitus."

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

cc:

Joseph M. Chimbel
Himalaya USA
10440 Westoffice Drive
Houston, Texas 77042