DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Pkwy, HFS-607
College Park, Maryland 20740

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

FEB 25 2008

Morrell Neely
Herbal Hope, Inc.
311 N. Robertson Blvd.
Suite #684
Beverly Hills, CA 90211

Re: CFSAN-OC-08-04

Dear Mr. Neely:

The Food and Drug Administration (FDA) has reviewed your web site at the internet address http://www.herbalhope.net and has determined that the products Restoration, Real Relief, Invigorate, Breathless, and Immunity are promoted for conditions that cause the products to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your website 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 website include:

Restoration

- "A powerful diabetes drink, this herbal formula has been known to support the body (sic) ability to repair the pancreas..."

Real Relief

- "Arthritis drink...this formula has been known to repair the cartilage in the various joints throughout the body."

Invigorate

- "[T]his potent anti cancer drink..."

Breathless

- "This dietary supplement utilizes advanced herbal technology to produce an effective asthma drink."

Immunity

- "Created for HIV and AIDS patients, this drink has been known to raise the T-Cell count and reduce the Viral-Load in sufferers."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and, therefore, the products are new drugs under section 201(p) of the Act. New drugs may not be legally marketed in the United States 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.

In addition, your website provides a copy of a Certificate of FDA Registration. This Certificate is displayed along with your products in a manner that suggests that FDA has approved or otherwise sanctioned the marketing of your products and, implicitly, the representations you are making for it elsewhere on your web site. Your products are not approved by FDA, nor has FDA reviewed their formulations or the representations made for them. Therefore, the use of this information in the manner you display it in the promotion of your products is misleading, causing your products Restoration, Real Relief, Invigorate, Breathless, and Immunity to be misbranded within the meaning of section 502(a) of the Act, in that the labeling of these drugs suggest FDA approval [21 U.S.C. 352(a)]. Additionally, your dietary supplement products E^2, Weighin, Flush It, Sexual Energy Drink, and Wellness are misbranded within the meaning of 403(a)(1) of the Act, also by suggesting FDA approval [21 U.S.C. 343(a)(1)].

The violations described above are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

You should direct your reply to:

Quyen Tien
Compliance Officer
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway (HFS-608)
College Park, MD 20740

If you have any questions concerning this letter, please contact Compliance Officer Tien at 215-717-3705.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition