DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Food Safety and
Applied Nutrition, HFS-607
5100 Paint Branch Parkway
College Park, MD 20740

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 9, 2005

The Way Up
946 Avenida Palos Verdes
Palm Springs, CA 92262

Dear Sir/Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.thewayup.com and has determined that the products Remifemin™ and Prolongevity Mega Soy Extract 135mg are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. 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:

- Remifemin product: "[I]t may provide benefit for … uterine fibroids & fibrocystic breast disease."

- Prolongevity Mega Soy Extract: "Mega Soy supplies the dose of isoflavones found to help: Prevent osteoporosis…. Prevent certain cancers. Prevent cholesterol gallstones. Improve impaired kidney functioning…. Protect against prostate cancer…. Modulate the effects of estrogen & testosterone in a favorable way, thus reducing their risk of inducing cancer."

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. Your Remifemin™ and Prolongevity Mega Soy Extract products are also misbranded within the meaning of section 502(f)(1) of the Act,

in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

This letter is not an all-inclusive review of your website and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products [21 U.S .C. §§ 332 and 334]. You should take prompt action to correct the violations identified in this letter and any other violations of the Act. Failure to do so may result in enforcement action without further notice.

Furthermore, you should be aware that laws enforced by the Federal Trade Commission (FTC) govern claims made in advertising, including print, broadcast, websites, and other electronic media. The FTC Act, 15 U.S.C. § 41 et seq., prohibits unfair or deceptive acts and practices, including false and unsubstantiated advertising claims. It is against the law to make health claims without substantiation or to overstate the health benefits of the products you promote. Be aware that product claims can be communicated to consumers in a variety of ways, including product name, website name, product testimonials, endorsements, or use of metatags.

Please advise this office, in writing, 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.

Your reply should be addressed to Quyen Tien, Compliance Officer, at the above letterhead address.

Sincerely,

/s/

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