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

Food and Drug Administration
7520 Standish Place - Room 254
Rockville, MD 20855

November 16, 2000

Ref. No. 01-HFD-310I-059

Ms. Lori Bass
Reach4Life Enterprises
7756 N. Polk
Fresno, CA 93722

Dear Ms. Bass:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.reach4life.com and has determined that products, including **Herba Green Tea Extract 100 mg.-2 oz. R4L Item #HBSHE008, Allergia-2 oz. R4L Item #HBSAL0005A, Cholestra-2 oz. R4L Item #HBSCH0017A, Headache-1 oz. R4L Item #HBSHE0021, Cold and Flu-30 Tablets R4L Item #ATK425118, 5-HTP 50 mg.-60 Capsules R4L Item #H0378126, MSM EYE DROPS-1 oz. R4L Item #TRMS218, Super Lysine Plus Cream, Super Lysine Plus-180 Tablets R4L Item Drug#QTSU2731118, 12-MGN-3 250 mg.-50 Capsules…R4L Item #12BF750** being offered are promoted for conditions that may cause them to be drugs under section 201(g) of the Federal Food,, and Cosmetic Act (the Act) [21 USC 321(g)]. The products may be considered drugs because the therapeutic claims as shown on your web site establish their intended use as drugs.

Examples of some of the products and claims observed on your web site include, in part:

"…**Herba Green Tea Extract**…HerbaSway's Green Tea extract is standardized with the active ingredient polyphenol, which is recognized as a potent cancer preventer. But more importantly, the fact the Green Tea is in pure liquid form, All of the cancer fighting polyphenol enters your body…"; "…**Allergia**…relieving the symptoms caused by asthma, hay fever and other inflammatory conditions…other respiratory symptoms…"; "…**Cholestra**…fighting aging-related ailments…controlling cholesterol…"; "…**Headacha**…heals your headache…ease your headaches including migraine headaches…protect the brain cells/nerves from damage due to poor circulation…"; "…**Cold and Flu**…ability to reduce the severity of colds and flu by enhancing the immune system…maintain a healthy immune system…"; "…**5-HTP**…overcome depression, obesity and insomnia…"; "…**MSM EYE DROPS**…MSM, or Methyl Sulfonyl Methane, is a rich source of sulfur…MSM Eye Drops are gentle, soothing…for tired or sore eyes caused by minor irritations… sulfur rich…Health & Personal Care-MSM Eye Drops…The Little-Known Mineral With Enormous Health Benefits…In therapeutic trials, MSM has been found to produce these significant benefits with no side effects:…ALLERGIES…anti-allergy medications were dramatically reduced with MSM…ARTHRITIS…relief from inflammation, swelling and stiffness…SPORTS PAIN…MIGRANES…CHRONIC CONSTIPATION…PARASITIC INFECTIONS…show MSM to be effective against a variety of parasitic, fungal and microbial problems of the intestines and urogenital tracts…"; "…**Super Lysine Plus Cream**…System Strengthener/Herpes Relief (For Sensitive Skin)…Dr. Griffith had demonstrated that lysine concentrations similar to those found in human blood could suppress herpes growth in lab cultures…Several clinical studies have supported the efficacy of lysine

supplementation for herpes therapy. In one survey, 88% of 1,543 herpes sufferers reported benefiting from lysine therapy…"; "…**Super Lysine PlusS-180 Tablets**…Combine taking the tablets with the use of our Super Lysine Plus+ cream for the most powerful effect. Users report that they take the tablets daily and increase dosage whenever symptoms are about to appear in order to prevent outbreaks…herpes, cold sore…"; "…**12-MGN-3**…MGN-3, the only natural immune complex proven to triple T-Cell, B-Cell, and NK (natural killer cell) protection…Studies…prove it can enhance specific aspects of immune activity…meant to arm the body's Natural Killer cells to seek and destroy dangerous invaders…".

Furthermore, FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, they may also be Anew drugs@ under section 201 (p) of the Act. 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 new drugs 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 or as cosmetics if certain therapeutic claims 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 (DSHEA), dietary supplements may be legally marketed with claims that they are intended to affect the structure or function of the body (structure/function claims) if certain conditions are met. Claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims) excepting health claims authorized for use by FDA, may not be made as they 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 statements allowed as structure/function claims and those that represent disease claims. This document is available on the Internet at http://vm.cfsan.fda.gov/~lrd/fr000106.html.

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, disease or structure/function claims may cause them to be new drugs.

Additional information is available in Title 21, Code of Federal Regulations, (21 CFR) Parts 310 and 330-358. These parts include the Final Rules for various OTC ingredients or products that may or may not be legally marketed without prior approval.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance 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 reach FDA electronically (e-mail) at Heller@CDER.FDA.GOV or you may respond in writing to Mr. Robert Heller, Compliance Officer, Food and Drug Administration, HFD-312, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-1065.

Sincerely yours,
/s/
David J. Horowitz, Esq.
Acting Director

Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration