DEPARTMENT OF HEALTH & HUMAN SERVICES

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

January 8, 2001

Ref. No. 01-HFD-310I-071

Ms. Marie Louise Tremblay
Synergy Systems
454 Las Gallinas Avenue, Suite 299
San Rafael, CA 94903

Dear Ms. Tremblay:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://SYNERGY-SYS.COM and has determined that the products, "Electrosonic Colloidal Silver", "Hawaiian Noni", and "Synergy Growth Factors", and other products being offered, are promoted for conditions that cause them to be drugs under section 201(g) of the Federal Food, Drug, 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 products and claims observed on your web site include, in part:

Electrosonic Colloidal Silver "Colloidal Silver is a powerful agent that has been shown to be effective in the treatment of a broad spectrum of infectious diseases. A proven and refined immune booster, it is also a potent antimicrobial and antifungal agent used for flu, ear infections, candida, athlete's foot, parasites, and diseases of the immune system."

Hawaiian Noni " Know Applications…. Depression and migraine headaches. Helps high blood pressure, arthritis, diabetes, allergies, and menstrual cramps. Has unique anti-pain effects. Has been shown effective for many types of bacteria including E. coli. Acts to enhance the immune system involving macrophages and/or lymphocytes. . . ." "…..Prozac-like …eases the joint pain…."

Synergy Growth Factors ". . . promotes anti-aging using IGF-1 Oinsulin Growth Factor), more potent than HGH (Human Growth Hormone)." "….Improves cell growth and regeneration…." "….alleviate tissue and joint pain, inflammation and injury."

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 "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 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.

Furthermore, your Internet site may be subject to statutes enforced by the Federal Trade Commission (FTC). Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. Sections 45 and 52. You are encouraged to consult the FTC Web site at http://www.ftc.gov/bcp/conline/pubs/dietsupp.htm for further information. The FTC Web site also provides copies of complaints and orders that have been filed by the FTC against companies making misleading or deceptive advertising claims on the Internet. Some of these complaints and orders can be found at http://www/ftc/gov/opa/2000/06/lanelabs.htm, http://www.ftc.gov/opa/2000/04/cure-all2.htm, and http://www.ftc.gov/opa/1999/9906/opcureall.htm. You may want to review your advertisement in light of these standards. Related questions should be directed to the FTC at (202) 326-3090.

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 statutes administered by both the FDA and FTC.

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 TARTM@CDER.FDA.GOV, or you may respond in writing to Ms. Margaret Tart, Food and Drug Administration, HFD-300, 7520 Standish Place, Rockville, Maryland 20855 or by telephone at (301) 594-0054.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration