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

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

March 9, 2001

Mitchell R. Fiedler
Healing Edge Sciences
7451 Warner Ave. Suite E169
Huntington Beach, CA 92647 US

Ref. No. 01-HFD-310-093

Dear Mr Fiedler:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.healingedge.net and has determined that a number of products being offered on this site are promoted for conditions that may 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 of the products and claims observed on your web site include, in part:

MGN-3
"Cancer," "triples the number and excites the activity of the natural killer cells…These killer cells become fully activated…The cells patrol the blood and lymph systems, attacking foreign and cancerous cells," "breast, cervical, prostate [cancers], leukemia and multiple myeloma," "curative effect on many viral and bacterial problems."

Crangel
"cystitis and urinary tract infections…acidifies the urine, lowering the pH and creating a less favorable environment for bacteria. It appears to prevent bacteria from attaching to the lining of the bladder and urethra and exerts bacteriostatic activity in the urine."

Ag-Cidal
"broad spectrum antimicrobial"

Prozaplex
"rapidly replacing drug antidepressants…the majority of depression patients are on hypericum and no longer on antidepressants drugs…anxiety, insomnia, chronic viral lymphadenitis associated with depression and instability, and panic disorders."

Pancreas Tonic
"REVERSES diabetes"

Adrenal Cortex Extract (Sublingual Liquid)

“Sublingual absorption is 3 to 10 times greater than oral administration...” “Addison’s disease....hypoglycemia, inflammation, drug and alcohol withdrawal...trauma, allergies...resistance to infection..”

Spes(Cancer & Immune Disorders)
“...reduction of cancer pain...proven anti-cancer properties...comparable to morphine...inhibits cancer cell gene...suppresses cancer cell growth...Improves RBC, hemoglobin, platelet and white blood cell numbers. Acts synergistically with chemotherapy or radiation to reduce their adverse effects. Improves GI function, appetite, night sleep and quality of life of terminally-ill patients.”

Progest Cream
Reference to progesterone in product labeling and claims that the ingredient delivery is “transdermal”, “cancer,” ”provides a convenient means of supplementing progesterone... supports progesterone deficiencies seen in menopausal and perimenopausal women...premenstrual syndrome...”

Also, your homeopathic product, Dioxyclor DC34 is offered for uses that causes it to be a prescription drug. Homeopathic products are not exempt from prescription drug regulations; therefore, such products must be dispensed by prescription. In addition, the product label must bear the statement "Rx only." Selling these products without a prescription will render them misbranded under section 503(b)(1) [21 USC 353(b)(1)] of the Act.

Prescription use claims for Dioxychlor DC3 include: “natural antibiotic…anaerobes…effective antiviral, antibacterial, antifungal…effectiveness against chronic viral syndromes (HIV, EBV, and CFS), candida albicans, environmental illness… Food poisoning/Amoebic dysentery… bacterial contamination on food (vegetables, seafood, poultry, pork…”

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 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 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 DAVISJ@CDER.FDA.GOV, or you may respond in writing to Jan Davis, Compliance Officer, Food and Drug Administration, HFD-314, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-0070.

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