DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph Mercola
Optimal Wellness Center
1443 West Schaumburg, Suite 250
Schaumburg, IL 60194

February 16, 2005

Ref. No. CL-04-HFS-810-134

Dear Dr. Mercola:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.mercola.com and has determined that the products Living Fuel Rx™, Tropical Traditions Virgin Coconut Oil, and Chlorella are promoted for conditions that cause these products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of diseases. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Living Fuel Rx™

"In today's society people are simply not meeting their nutritional needs. We see evidence of this with the rampant illnesses including cancer, cardiovascular disease, diabetes, autoimmune diseases, etc. Living Fuel Rx is an exceptional countermeasure to this lifestyle, meeting all of your nutritional needs."

Tropical Traditions Virgin Coconut Oil

"Reduce the risk of heart disease"
"Lower your cholesterol"
"Improve conditions in those with diabetes and chronic fatigue"
"Improve Crohn's, IBS [Irritable Bowel Syndrome], and other digestive disorders"
"Prevent other disease and routine illness with its powerful antibacterial, antiviral and antifungal agents"
"A Delicious Way to Prevent Disease …"
"[V]irgin coconut oil is rich in lauric acid, a proven antiviral, antibacterial and antifungal agent that is very beneficial in attacking viruses, bacteria, and other pathogens …."
"Coconut oil also raises metabolic rate …. A faster metabolic rate stimulates increased production of needed insulin and increases absorption of glucose into cells, thus helping both Type I and Type II diabetics."

"For those with Crohn's and IBS, the anti-inflammatory and healing effects of coconut oil have been shown to play a role in soothing inflammation and healing injury in the digestive tract."
"The fatty acids in coconut oil can kill herpes and Epstein Barr viruses …. They kill Candida and giardia. They kill a variety of other infectious organisms, any of which could cause chronic fatigue."

Chlorella

"Normalize your blood sugar and blood pressure"
"Fight cancer"
"One of the ways to fight cancer is the use of agents to stimulate macrophage production and activity. Interferon is a natural secretion of the body that is thought to be a stimulator of macrophages and tumor necrosis factor (TNF). Chlorella stimulates the activity of T-cells and macrophages by increasing interferon levels thus enhancing the immune system's ability to combat foreign invaders whether they are bacteria, viruses, chemicals, or foreign proteins."

Your products are not generally recognized as safe and effective for the above referenced conditions and therefore, these 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 new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are 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 if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations. With regard to your Living Fuel Rx™ product, which your website describes as an "optimized superfood meal replacement," please note that products represented for use as a meal replacement do not meet the definition of a dietary supplement in section 201(ff) of the Act [21 U.S.C. § 321(ff)] and may not be marketed as such.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, 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 structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply 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 Kenneth.Taylor@CFSAN.FDA.GOV, or you may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Dr. Taylor at (301) 436-1439.

Sincerely,

/s/

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition