DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dom Orlandi, President
Food Science Corporation
d/b/a DaVinci Laboratories of Vermont
20 New England Drive
Essex Junction, Vermont 05453

January 28, 2005

Ref. No. CL-04-HFS-810-111

Dear Mr. Orlandi:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.davincilabs.com and has determined that the products MSM, Methylsylfonylmethane 1000™, Octacosanol+™, TAP™ Garlic, Saw Palmetto, Cranberry, Echinacea, Rapid Balance-G.I.™, and Fibro-My-DMG™ 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:

MSM and Methylsylfonylmethane 1000™

- "[H]as been used as a nutritional support when allergies are present . . . because it coats the entire digestive tract, making it harder for most allergens to bind and cause damage.[H]elps to regulate pro-inflammatory enzymes to reduce pain and swelling associated with connective tissue dysfunctions."

Octacosanol+™

- "Octacosanol+™ contains the fall [sic] range of Poli cosanols that have been found beneficial in bringing Cholesterol into a more healthy normal range …."

TAP™ Garlic

- "Garlic has been found to be an effective yet gentle antimicrobial agent …."

Saw Palmetto

- "[C]ontains fatty acids believed to inhibit the conversion of testosterone thought to be responsible for prostate dysfunction."

Cranberry

- "The active ingredients in our Cranberry Extract--Cranberry, Malic Acid, Citric Acid, and Quinic Acid ... prevent microorganisms from adhering to the cells that line the bladder wall."

Echinacea

- "May help fight against cold and flu symptoms …. Echinacea angustifolia has been shown to exhibit antibiotic activity...."

Rapid Balance-G.I.™

- "[N]ormalizes the G.I. tract when there's digestive upset from tainted water, [or] the flu .... A dietary supplement containing MOS, Mannan oligosaccharides, which is a special type of polysaccharide that offers binding sites to sugar seeking pathogens, preventing them from binding to the gut wall."

Fibro-My-DMG™

- "A dietary supplement to support muscle and immune system functions, proper mood balance, and stress management. Fibro-My-DMG™ is an advanced nutritional supplement that combines N,N-Dimethylglycine (DMG), Malic Acid, GABA, NADH, and Magnesium Malate. These nutrients work synergistically to support proper mood balance, help cope with stress, reduce muscle aches and support immune system function. Fibro-My-DMG™ is designed for individuals experiencing constant muscle ache and stiffness, fatigue and sleeping problems."

In addition, the name "Fibro-My-DMG™" is an implied claim that the product is useful in treating fibromyalgia.

Furthermore, 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.

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