



JUN 14 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Brant Shapiro
Smartbomb, Inc.
aka: SBDC
66 Morris Street
Morristown, NJ 07960

Ref. No. CL-05-HFS-810-161

Dear Mr. Shapiro:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.smartbomb.com> and has determined that the products "Fruits of Life," "ARIZONA NATURAL CHAPARRAL," and "RM-10," as well as other products, are promoted for conditions that cause the 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 the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

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

Fruits of Life

Claims for ingredients in the product:

"Blueberry: Recent studies have shown that blueberries ...may ... play a significant role in preventing cancer."

"Strawberry: [C]ontains anthocyanin, a plant chemical that helps protect against heart disease."

"Raisin: Raisins (dried grapes), contain more ... resveratrol, a phytonutrient shown to have cancer-prevention effects. Raisins are a rich source of polyphenols and proanthocyanidins, which are recommended in prevention and treatment protocols for cardiovascular disease, cancer, inflammatory conditions, asthma, diabetes, liver disease, cataracts, and macular degeneration."

"Flavanoids: Flavonoids contain antibacterial and antiviral properties... The flavonoids present in Fruits of Life contain properties which ... repair ... cardiac irregularities arising from a decrease in blood flow and arterial blockage."

"Ellagic Acid: Strawberries, blackberries, raspberries, and blueberries contain the anticancer compound ellagic acid.... According to Dr. Gary D. Stoner, a pathologist at the Medical College of Ohio, ellagic acid is an antioxidant that helps detoxify cancer-causing agents in several different ways. Ellagic acid helps inhibit four different types of cancer causing agents, including aflatoxin and nitrosamines. Medical findings in Europe further show that ellagic acid reduces the incidence of birth defects, promotes wound healing, reduces and reverses chemically induced liver fibrosis, and is helpful in the fight against heart disease.'

ARIZONA NATURAL CHAPARRAL

"The most famous chaparral account surrounds an 87-year old man who had had three operations for melanoma (on his face) before deciding to try another approach to his situation. He was completely cured by use of chaparral in a tea form."

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“This is an antioxidant that ... seems to have other benefits, including protecting tissue from damage when exposed to carcinogens.”

“Chaparral may also be useful in combatting certain bacteria and viruses and has shown much promise with herpes.”

“Native American medicine men and women as well as Hispanic curanderos have been using chaparral for centuries, this for a wide range of conditions from asthma to cancer, especially melanomas and leukemia, but I have seen it very successfully used for breast and ovarian cancer as well.”

RM-10

“For much of the last hundred years science has been searching for a cure for cancer, arthritis, and even the common cold.”

Claims for ingredients in the product:

“Ganoderma lucidum (Reishi):... Reishi appears to ... have a strong effect against tumors and cancer. A potential treatment for arthritis, ... and has been found to prevent and treat hardening of the arteries, angina, and shortness of breath associated with coronary heart disease.”

“Cordyceps sinensis: ... Cordyceps sinensis ... strengthens the body's resistance to bacteria and viruses. It has further been used in China ... to relieve excessive fatigue, anemia, and depression.”

“Coriolus versicolor: It is considered to be a very powerful anti-bacterial, ... anti-tumor agent ... Coriolus versicolor has been helpful in treating and decreasing the recurrence of gastric cancer and significantly inhibits the growth of leukemia cells.”

“Lentinula edodes (Shiitake): Extracts from this mushroom have been shown to be effective against Type 1 Herpes Simplex virus as well as depressed immune system function, cancer, AIDS, environmental allergies, candida infections, and frequent colds and flu. Shiitake has been used in the Orient for prevention of high blood pressure, controlling cholesterol levels ...”

“Agaricus blazei: Has ... anti-tumor, anti-viral, and blood sugar lowering properties.”

“Grifola frondosa (Maitake): ... [T]he Maitake mushroom ... has anti-tumor effects.”

“Hericium erinaceus: Commonly prescribed ... for prevention of GI tract cancer.”

“Poria cocos: ... [I]s ... used to ... lower blood sugar levels.”

“Tremella fuciformis: ... [I]s recommended in China to assist in ... gastritis, and reduce fever.”

“Polyporus umbellatus: In a Chinese clinical study of 146 patients, Polyporus umbellatus was used to reduce the recurrence of bladder cancer by nearly 50%. It has been very useful in the treatment of urinary tract infections and may limit leukemia cell proliferation. It is also a potent anti-bacterial ...”

“Aloe Vera: ... Aloe helps to reduce inflammation ... as well as regulate blood sugar levels. It ... contains anti-bacterial, anti-viral nutrients ...”

“Uncaria tomentosa: Herbal practitioners around the world have used Uncaria tomentosa to treat a variety of conditions including arthritis, AIDS, allergies, ... ulcers, colitis, irritable bowel syndrome, Crohn's disease, and conditions involving chronic inflammation. It further helps lower blood pressure, reduces inflammation, and prevents the spread of tumors and viral infection.”

In addition, we note that your website identifies diseases under the webpage “CONDITIONS,” including “BLOOD SUGAR CONTROL,” “CANDIDA,” and “FIBROMYALGIA.” Products listed on pages under these diseases include “Jarrow Glucose Optimizer,” “Candex,” and “Fibro-Response.”. Such product categories cause the products listed under them to be drugs under section 201(g)(1) of the Act.

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and, therefore, the 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 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 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 respond in writing to Linda J. Webb, Compliance Officer, 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 Ms. Webb at (301) 436-2375.

Sincerely yours,

/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