



September 25, 2007

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

James Riley  
MDR Fitness Corporation  
14101 Northwest Fourth Street  
Sunrise, Florida 33325

Ref. No. CFSAN-OC-UL07-08

Dear Mr. Riley:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://mdri.com> and has determined that the products MDR Longevit-E, MDR CardioTone, MDR Fibromy Support, and MDR Estro-Support<sup>TM</sup> 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:

**MDR Longevit-E**

- “Advanced blend of Tocotrienols, Alpha Lipoic Acid, and Phosphatidyl Choline for: ... Blood Sugar Control.”
- “Studies suggest palm Tocotrienols may help:
  - Reduce cholesterol levels.
  - Reverse blockage of the carotid arteries
  - Reduce risk of platelet aggregation ....” [footnotes omitted]
- “MDR Longevit-E contains ascorbyl palmitate, a special fat-soluble form of Vitamin C, which extends Vitamin E’s antioxidant activity. And because it is fat soluble, the outside fatty layers of cell membranes (where free radicals do most of their damage) are better protected, such as LDL or “bad” cholesterol, which converts into artery-clogging plaque when damaged.” [footnote omitted]
- “Another exciting ... ingredient in MDR Longevit-E is Phosphatidyl Choline. Naturally found in eggs, choline may help control cholesterol levels ....”

## **MDR CardioTone**

- “Do you suffer from heart disease, cardiovascular disease, high cholesterol levels, diabetes, hypertension or high triglyceride levels? ... MDR's new CardioTone is full of beneficial antioxidants, vitamins, and minerals that have been shown in clinical studies to help those suffering from heart disease, hypertension, diabetes, and high cholesterol levels.”
- “This exciting new formula contains Vitamin A and the natural carotenoids: Beta Carotene, Alpha Carotene, Lutein, Lycopene and Zeaxanthin .... [R]esearchers report that they may help protect against certain types of cancers and vision loss.”
- “Doctors now look very closely at homocysteine levels in their patients because high levels are directly related to an increased risk of cardiovascular disease, particularly arteriosclerosis (hardening of the arteries) and heart attacks. But there is good news. Increasing your intake of Vitamins B6, B12, and Folate can reduce Homocysteine blood levels thereby decreasing your risk of heart problems .... That’s why the doctors at MDR made sure that CardioTone contains these important B vitamins. Vitamin B6 can also be beneficial for those suffering from hypertension. A recent study done on twenty patients revealed that after four weeks of Vitamin B6 supplementation, their blood pressure was significantly reduced.” [reference numbers omitted]
- “Thiamine (Vitamin B1) [an ingredient in CardioTone]: ... Doctors gave Vitamin B1 to patients taking Furosemide with congestive heart failure. Their condition significantly improved. A substantial number of people with congestive heart failure may be deficient in Thiamine.” [reference numbers omitted]
- “L-Carnitine [an ingredient in CardioTone]: ... A study of over 100 patients with suspected heart attacks evaluated the benefit of L-Carnitine supplementation over a period of 28 days. At the end of the study the Carnitine group had better blood lab values, less pain in the heart and fewer irregular heart beats. Scientists found that taking certain heart medications for irregular heart beats with L-Carnitine makes them work better than taking the heart medications alone.” [reference numbers omitted]
- “Co-Q10 [an ingredient in CardioTone]: A natural enzyme and antioxidant, Co-Q10 has been used to treat congestive heart failure with great success. It can thin the blood of patients with ischemic heart disease and increase resistance to free radical damage caused by LDL. ... Scientists compared cardiac patients treated with traditional methods versus those treated with Co-Q10. After three years, only 24% of patients treated with regular methods were alive while 75% of the Co-Q10 patients were still ticking. Co-Q10 can also help normalize blood pressure. When medical researchers gave Co-Q10 to 109 hypertension patients, 51% of them were able to discontinue medications within five months. Co-Q10 can benefit diabetics as well. Diabetics, as compared to non-diabetics, have lower levels of Co-Q10 dependent enzymes in their pancreas. 36% of a group of diabetics receiving Co-Q10 therapy showed reduced levels of blood Glucose and over half experienced improved ketone levels.” [reference numbers omitted]

### **MDR Fibromy Support**

- “What Causes Fibromyalgia? One theory is that the immune systems of FMS sufferers’ [sic] may not be functioning properly. In this case, patients are prescribed drugs to help strengthen their immune system. That’s why it also [sic] important to increase your intake of certain nutrients such as those contained in Fibromy Support.”
- “Amino Acids [an ingredient in Fibromy Support]: Help build up serotonin levels. A deficiency may cause depression in fibromyalgia sufferers.”
- “Vitamin B1 [an ingredient in Fibromy Support]: ... Some symptoms of a deficiency may include depression ... [and] attention deficit.”
- “Green Tea Leaf Extract [an ingredient in Fibromy Support]: One of the causes of joint pain is the breakdown of cartilage. The pain comes from the resulting inflammation. Scientists recently discovered that the antioxidants found in Green Tea may reduce inflammation by inhibiting production of an enzyme responsible for breaking down cartilage.” [footnote omitted]
- “Grape Seed Extract [an ingredient in Fibromy Support]: Antioxidant compounds found in Grape Seeds have been shown to inhibit inflammatory agents in the body.” [footnote omitted]

### **MDR Estro-Support™**

- “MDR MDR Estro-Support™ provides ... traditionally used phytoestrogenic plant extracts for superior results. ... These ingredients include: Soy Isoflavones[.] ... Soy has also been shown to reduce cholesterol in hypercholesterolemic men, increase HDL, and protect LDL from oxidation.” [footnote omitted]
- “A recent study of breast cancer survivors treated with Black Cohosh [an ingredient in MDR Estro-Support™] reported improvements in symptoms such as: ... Heart Palpitations ... Depression ...” [footnote omitted]
- “Animal studies revealed that Grape Seed Extract [an ingredient in MDR Estro-Support™] may also reduce hypertension in postmenopausal women.” [footnote omitted]

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 Lynn Szybist, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway (HFS-608), College Park, Maryland, 20740. If you have any questions concerning this letter, please contact Ms. Szybist at 301-436-2040.

Sincerely,

Jennifer Thomas  
Director  
Division of Enforcement  
Center for Food Safety  
and Applied Nutrition