



DEPARTMENT OF HEALTH AND HUMAN SERVICES

93973d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

April 25, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 19

Virginia Donohue
President

Tim Donohue
Executive Vice President

Bruce Livingood
Director

LifeLine Energetics, Inc.
2230 County Road H2
Moundsview, Minnesota 55112

Dear Ms. Donohue, Mr. Donohue, and Mr. Livingood:

On December 10, 11 and 16, 2002, we inspected your facility located at 2230 County Road H2, Moundsview, Minnesota. As a result of our investigation, we have determined that products manufactured or distributed by your firm fail to comply with the Federal Food, Drug, and Cosmetic Act (the Act).

Upon reviewing the promotional literature (e.g., "Directors Kit," newsletters) distributed by your firm, we have determined that many of your firm's products are promoted for conditions that cause these products to be drugs under Section 201(g)(1)(B) of the Act. The therapeutic claims in the promotional literature establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

In addition, because the products are not generally recognized as safe and effective for the conditions referenced in their labeling, they are also "new drugs" under Section 201(p) of the Act. New drugs may not be legally marketed in the United

Virginia Donohue, Tim Donohue, Bruce Livingood
April 25, 2003

States without prior approval from the Food and Drug Administration (FDA), as described in Section 505(a) of the Act.

Finally, the products identified below are also misbranded under Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use.

The following list identifies some of the products and their claims that fail to comply with the Act, as described above:

Baseline™ Essential Multi-Mineral Concentrate - Personal testimonials that this product cures, mitigates, treats, or prevents fibromyalgia (Mary S.); “episodes of fibrillation” (Anita); mononucleosis (Cate M.); and multiple sclerosis (Jo H.).

MagneCal™ Magnesium/Calcium Mineral Concentrate - “A lack of magnesium underlies our epidemic of heart disease, high blood pressure, diabetes and osteoporosis”; “Pain Relief...Migraines...preventing osteoporosis...Diabetes...Blood Pressure...Blocked Arteries...Heart Arrhythmias”; “...the ratio of magnesium to calcium in red blood cells may be a predictive value...to a number of age related degenerative diseases”; “creating an effective barrier to tooth decay”; personal testimonials that this product cures, mitigates, treats, or prevents fibromyalgia (Mary S.); “episodes of fibrillation” (Anita); mononucleosis (Cate M.); headaches (Virginia); and multiple sclerosis (Jo H.).

Immunitol™ Mineral Concentrate for a Healthy Immune System - “Silver is well known for its antimicrobial characteristics”; personal testimonials that this product cures, mitigates, treats, or prevents “a pre-cancerous spot” (Steve D.); and mononucleosis (Cate M.).

Performance +™ Ultimate Performance Enhancer Concentrate - Personal testimonials that this product cures, mitigates, treats, or prevents mononucleosis (Cate M.); and multiple sclerosis (Jo H.).

Germanium™ Mineral Ultra-Concentrate - Personal testimonial that this product cures, mitigates, treats, or prevents multiple sclerosis (Jo H.).

Chromium™ Mineral Ultra-Concentrate - Personal testimonial that this product cures, mitigates, treats, or prevents multiple sclerosis (Jo H.).

Vanadium™ Mineral Ultra-Concentrate - “assists in lowering elevated serum cholesterol and triglyceride levels.”

Silver™ Mineral Ultra-Concentrate - “The onset of a sore throat, athlete’s foot, topical infections or consuming “bad” food or water makes silver a valuable tool...”;

Virginia Donohue, Tim Donohue, Bruce Livingood
April 25, 2003

“...a powerful all-natural antiviral and antibacterial agent”; “...shown to be active against many strains of antibiotic-resistant microbes.”

Potassium™ Mineral Ultra-Concentrate - “endorses the use of ...potassium supplements just prior to bed time, as men are most prone to heart attacks during the night or early morning”; “A shortage of potassium can cause symptoms ranging from...irregular heart beats to...high blood pressure”; personal testimonial that this product cures, mitigates, treats, or prevents multiple sclerosis (Jo H.).

NutriZyme™ Essential Multi-Enzyme Blend - Personal testimonials that this product cures, mitigates, treats, or prevents diabetes (Ben H.); fibromyalgia (Mary S.); “episodes of fibrillation” (Anita); reaction to “wheat-containing products” (Maryann G.); and multiple sclerosis (Jo H.).

VitaCore™ Essential Vitamins and Antioxidants - “Curcumin Root Extract...anti-inflammatory. Anti-coagulant”; “**Green Tea leaf extract...Support for chemotherapy and radiation. May lower cholesterol”;** “**Grape Seed Extract...improves peripheral circulation, decreases platelet aggregation, capillary fragility”;** “**Garlic Bulb...May lower cholesterol...antibiotic effect”;** personal testimonials that this product cures, mitigates, treats, or prevents fibromyalgia (Mary S.); “episodes of fibrillation” (Anita); and multiple sclerosis (Jo H.).

SDG-35™ Concentrated Flax Lignans - “ongoing study of SDG’s impact on diabetes, lupus, multiple sclerosis, cancer and heart disease including high cholesterol, high blood pressure and atherosclerosis has produced very exciting results”; “Numerous studies have demonstrated flax lignan’s impact on diabetes, lupus, multiple sclerosis, cancer, heart disease...”; “Studies of SDG’s impact on diabetes, lupus, multiple sclerosis, cancer and heart disease including high cholesterol, high blood pressure and atherosclerosis are ongoing and have produced very positive results”; “**Histidine...helpful in the treatment of allergies, arthritis and anemia”;** “**Leucine... lowers elevated blood sugar levels”;** “**Methionine... aids in preventing buildup of fats in the liver and arteries which can obstruct blood flow to the brain, heart and kidneys...[and] helps prevent... osteoporosis”;** “**Phenylalanine...reduce[s] the pain associated with migraine headaches,...arthritis”;** “**Threonine...used to help prevent seizures”;** “The SDG compound has great potential for the prevention and treatment of both diabetes and hypercholesterolemic atherosclerosis...[and] has the ability to lower total cholesterol and to raise HDL-Cholesterol (good cholesterol) in the blood”; personal testimonials that this product cures, mitigates, treats, or prevents diabetes (Ben H.; Gloria E.); “heart palpitations...pain...due to fibrocystic disease” (Susan L.); “bad prostate” (Lee H.); “enlarged prostate and a heart that beats very irregularly” (Gloria E.’s husband); cancer (Lydia); and multiple sclerosis (Jo H.).

Page Four

Virginia Donohue, Tim Donohue, Bruce Livingood
April 25, 2003

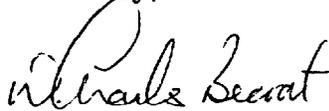
This letter is not intended to be an all-inclusive review of labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products, and/or an injunction against the manufacturer or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the letterhead.

Sincerely,


W. Charles Becoat
Director
Minneapolis District

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