



HF1-35

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 206-486-8788
FAX: 206-483-4998

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Regulatory Letter: SEA 91-12

Larry B. Meier, Founder and CEO
Judy E. Meier, Co-Founder and Vice President
Anita K. Schneebele, Co-Founder and Vice President
Life Enthusiast Co-op
1336 South 336th Street
Federal Way, Washington 98003

REGULATORY LETTER

Dear Mr. and Mrs. Meier and Ms. Schneebele:

This letter is written in reference to the marketing of Excela, Trace Minerals, Andean Treasure, Cell Guard, Soyessence, Green Gold, and Sparkling Energy by your firm and by contract distributors in your multi-level marketing program.

We consider these products to be in serious violation of the food adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

SECTION

BRIEF DESCRIPTION

403(a)(1)

In that the labels and labeling falsely represent that these foods have nutritional properties when such properties are of no significant value or need in human nutrition, such as:

Excela: "High Energy Enzymatic Diet Enhancement," "A Superior Source of Balanced Amino Acids, Vitamins, Minerals, and Fiber" (label); "Every bottle of Excela provides *** dozens of vitamins, minerals, and trace elements including B-12, chromium, selenium, germanium--virtually all the known nutrients!" (Newsletter August 1989) (label); "Excela has an exponentially higher bioenergy level than any other food or supplement" (An Introduction to Life Enthusiast Co-op); "most potent and complete food concentrate system ever" (Newsletter June 1989); "an incomparably effective range of nutrients," "Dozens of vitamins, minerals and trace elements including *** germanium--virtually all the known nutrients!" (Newsletter August 1989); and "Excela is perfect meal replacer" (Newsletter December 1989/January 1990).

Sparkling Energy: "Food Concentrate Energy Enhancer *** This is an incredibly rich food."
(label)

Soyessence: "Significant representations of dozens of other minerals, including calcium, sulfur, iodine, natural beneficial fluorine, chloride, and silicon. Soyessence is 8.5% minerals by weight of which a very significant 1,230 mg is in the form of trace minerals."
(label)

403(a)(1),
201(n), &
21 CFR 101.9
(i)(1)

The following foods, Excela, Soyessence, Cell Guard, Green Gold, Sparkling Energy, and Andean Treasure are misbranded in that the label and/or labeling falsely represents, suggests, or implies that these foods are adequate or effective in the prevention, cure, or treatment of the labeled conditions, such as:

Excela/Sparkling Energy with Coenzyme Q10: Congestive heart failure, anti-aging, failing immune system, gum disease and tooth loss, failing eyesight, lethargy, loss of memory, preventing cardiac arrhythmias, lowering blood pressure, reducing ischemic or hypoxic injury, inhibiting lipid peroxidation in mitochondrial membranes, preventing toxicity from drugs. (An Introduction to Life Enthusiast Co-op and Newsletters)

Sparkling Energy: Increased sexual energy, improved mental energy, builds intrinsic muscle strength, control of wrinkling and age spots.
(label)

Green Gold/Excela/Soyessence/Sparkling Energy with Lecithin: Tendonitis, prevent accumulation of cholesterol or plaque formation in the arteries, enhanced creativity and IQ, replenish sexual reserves, aids in cleansing toxins and soreness out of muscles, lubricates joints, enhances hair growth, purifies the liver, dissolves calcified deposits from the joints and arteries, cell membrane defense against viruses, and enhances blood oxygen transfer. "When a man ejaculates, the fluid he loses is largely lecithin. This lost lecithin is not available to dissolve solidified cholesterol, and in my opinion accounts for most of the reason why heart disease hits men so much more than women." (An Introduction to Life Enthusiast Co-op and Newsletters)

Excelsa/Green Gold with Beta Carotene: Lowers risk of cancer, helps protect sun sensitive skin. (An Introduction to Life Enthusiast Co-op and Newsletters)

Excelsa/Green Gold with Barley and Wheat Grasses: Treatment of arthritis, asthma, diabetes, fatigue, gastrointestinal disorders, skin problems, heartburn, blood clots, migraine headaches, cancer, lymphoma, anti-aging, constipation, ulcers, and blood sugar problems. (An Introduction to Life Enthusiast Co-Op)

Andean Treasure: Soothing and healing to skin. (Label and Newsletter - Special Edition, June 22, 1990)

Excelsa/Green Gold/Cell Guard with Antioxidant Enzymes: Detoxifies cells, multiple sclerosis, rheumatoid arthritis, post-flight fatigue, and increases energy levels. (An Introduction to Life Enthusiast Co-op and Newsletter)

21 CFR 101.9
(i)(3)

In that the labeling falsely represents that the lack of optimum nutritive quality of a food, by reason of the soil on which that food is grown, is or may be responsible for the inadequacy or deficiency in the quality of the daily diet, such as:

Excelsa: "Soil contains a limited supply of trace elements. Each crop removes some of these elements, so each successive crop contains smaller amounts." (An Introduction to Life Enthusiast Co-op)

"It would take literally hundreds and hundreds of pounds of that half-dead supermarket produce to equal the life energy concentrated into just one bottle of Excelsa." (Newsletter November 1989)

21 CFR 101.9
(i)(4)

In that the label and/or labeling falsely represents, suggests, or implies that the storage, transportation, processing, or cooking of food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet, such as:

Excelsa/Green Gold: "Many persons on typically processed (low enzyme) diets are making mostly withdrawals and very few deposits until their life-energy (health) is overdrawn. Excelsa

(Green Gold) is created to enhance the deposit ledger of your personal life-energy account." (label)

Soyessence: "Lecithin is removed from vegetable oil during the clarification process. Much is sold for industrial uses like lubrication of deep oil well drilling bits. Most of the remaining lecithin finds its way into processed foods like ice cream and margarine where its value is used up as an emulsifier. The high rancidifying oil content of these low grade lecithins raises the question of whether their consumption is of more or less value than none at all. These oils begin to turn rancid almost immediately, then average 18 months in transit and display before sale. 'Expiration' dates are 2 to 4 years later! SOYESSENCE is produced by a new high tech processing method that produces a far higher grade 5 to 25 times purer (less rancidifying) than other lecithins. LEC obtains fresh SOYESSENCE on a day to day basis to keep it moving directly from manufacturer to you within days of production." (label)

Excelsa/Green Gold/Cell Guard/Sparkling Energy: "Enzymes are the life electric nutrient form required by your cells in order to operate at optimum. Typical food processing destroys the life-active enzymes in raw food *** Our irrational supermarket diets - almost totally devoid of enzymes - and loaded with enzyme antagonists - aggravate the situation ever further *** It is this very uniqueness that separates LEC products from the 'dead' vitamins and minerals commonly produced and endorsed by degreed nutritionists and medical professionals." (An Introduction to Life Enthusiast Co-op)

Excelsa: "Foul your intricate cellular machinery with junk food and you start feeling poorly *** Where a human cell membrane will admit almost any junk food to clog itself or poison itself, your mitochondria are almost exclusively receptive to Q10 and ATP." (Newsletter 1989)

"Excelsa is only available directly from Life Enthusiast Co-op. This assures maximum enzyme activity 18 times fresher than possible through retail distribution." (Newsletter August 1989)

"Excelsa is a totally functional product. It contains no fillers. Every component has multiple purposes. It is the perfect high enzyme supplement to fill in where our dead supermarket diets leave off." (Newsletter February 1990)

21 CFR 101.9
(i)(5)

In that the label and labeling falsely represent, suggest, or imply that these foods have nutritional properties when such properties are of no significant value or need in human nutrition, such as:

Excelsa: "LIFE ENERGY *** High Energy Enzymatic Diet Enhancement *** 50mg Coenzyme Q10 *** 13,250mcg Chlorophyll *** 100mg RNA/DNA *** 75mg GLA *** 370mg Phosphatidylethanolamine *** 2 Million Units Antioxidant Enzymes *** Hundreds of other Enzymes *** 350mg Royal Jelly *** 93,000mcg Phycocyanine *** 435mg Phosphatidylcholine ***" (label)

"PREMIUM GOODS FOR LIFE-ENERGY *** A CREATIVE ADVANCE IN LIFE-ENERGY FOODS!" (Direct Order Form)

"Excelsa has an exponentially higher bioenergy level than any other food or supplement *** These enzymes have been the 'cherry on top' of my own nutritional program for 3 years now. During that time, I have taken anywhere from 3 million units to 30 million units per day." (20 Cell Guard and Excelsa) (Introduction to Life Enthusiast Co-op)

"EXCELA VALUE - A FOOD CONCENTRATE MIRACLE *** EVERY BOTTLE OF EXCELA PROVIDES *** Over 12 times the Chlorophyll of green barley juice powder by itself, a \$450 value! *** Over 10,000 mg of ROYAL JELLY with a retail value of \$22.00! *** The GLA Equivalent of 60 evening primrose caps, a \$15.00 value! *** The same antioxidant activity as 30,800 tablets of another SOD product with a retail price above \$4,700 (205 bottles). *** The Q10 equivalent of 2 tons of raw broccoli or 154 - 10 mg caps with a retail value of \$50.00. *** The soluble apple fiber of 30 medium apples that would cost about \$7.00. *** And much more, all in a special lecithin carrier for superb enzyme assimilation! *** BY FAR THE MOST POTENT AND COMPLETE FOOD CONCENTRATE SYSTEM EVER! SPARKLING WITH SUPER ABUNDANCE OF LIFE ACTIVATED ENZYMES!" (Newsletter June 1989)

"A comprehensive premium nutrition system
"EXCELA blends the highest possible enzyme potencies with our exclusive enzyme delivery formulation that unites enzymes with a special emulsifier to form liposome units with practically no surface tension.

"This facilitates the fastest possible enzyme absorption through membranes and into lymphatic receptors located in your mouth and digestive tract." (Newsletter August 1989)

"EXCELA was designed to be a powerful premium food concentrate with the potential to achieve the best results possible. EXCELA is powerful. It gets results. That is its purpose." (Newsletter November 1989)

"EXCELA, on the other hand, contains a superb complex of fatty acids, including the highly beneficial Omega 3 and GLA that are basic resources to your body's prostaglandin balance (cellular regulators). It also contains the essential linoleic, arachidonic and linolenic acids that are vital to the utilization of calcium and vitamins A, D, E and K.

"The essential fatty acids are the most concentrated source of chemical energy in your food.

"The lecithin in EXCELA functions as a 'greased funnel' that guides the huge enzyme molecules through the digestive tract membranes and into the lymphatic system where they can benefit your electric life energy level.

"Lecithin is a unique nutritional compound containing essential fatty acids, vitamins and minerals. Lecithin acts as an 'antifreeze' to keep cholesterol liquefied at body temperature so it can function in its essential roles in the blood cells, brain, digestive process, nervous system and sex hormones.

"The superb combination of EFAs (Essential Fatty Acids) in EXCELA work together synergistically to help balance your weight. First, they are exceptionally satisfying to your appetite. A glass of EXCELA can leave you feeling like you've had a meal, reducing your craving for expensive processed junk foods.

"Secondly, EXCELA's EFAs work together to mobilize unsightly stored fats into energy production.

"Yet, three teaspoonfuls of EXCELA contribute only 30 calories to your day's food intake, not bad, a meal's worth of protein and nutrients, yet only 30 calories." (Newsletter November 1989)

"EXCELA *** IT'S LIKE HAVING A NUTRITION EXPERT AT YOUR SIDE! *** EVERY DAY YOU GET... *** 2 Million Units Antioxidant Enzymes *** 350mg Coenzymes Q10 *** 12 Times The Chlorophyll of Barley Juice Alone *** ALL IN OUR POWERFUL ENZYME DELIVERY SYSTEM *** QUALITY *** Superb Grade Food Concentrates. *** 100% Genuinely Natural With All Cofactors Intact. *** CONVENIENCE *** Perfect Meal Replacer Enhances Your Fruit Juices With A Surprising Tropical Flavor--Hearty In Veggie Juices. *** Highly Satisfying! Ideal For Weight Management. Best Between Meals. *** Can't Be matched. You Could Spend Hundreds To Fill Your Cupboard With Isolated Nutritional Supplements And They Still Wouldn't Perform Like The Symphony Of Live Enzymes In EXCELA!" (Newsletter December 1989, January and February 1990)

"SPARKLING ENERGY *** HIGH ENZYME FOOD CONCENTRATE ENERGY ENHANCER *** 75 MG COENZYME Q10 150 mg Royal Jelly 180 mg Lecithin *** This is an incredibly rich food." (label)

"75 mg Q10 & 150 Royal Jelly/Serving" (Direct Order Form)

"SOYESSENCE *** 98% Phosphatides *** 3,525 mg Phosphatidyl Choline *** 540 mg Choline *** 3,000 mg Phosphatidyl ethanolamine *** 4,425 mg Linolenic Acid *** 525 mg Linoleic Acid *** Significant representations of dozens of other minerals including Calcium, *** sulphur, Iodine, Natural Beneficial Fluorine, Chloride and Silicon. SOYESSENCE is 8.5% minerals by weight of which a very significant 1,230 mg is in the form of trace minerals." (label)

21 CFR 101.9
(1)(6)

The Excela and Green Gold are misbranded in that the label and labeling falsely represent, suggest, or imply that a natural vitamin in a food is superior to an added or synthetic vitamin, or to differentiate in any way between vitamins naturally present from those added:

"SYNTHETIC VITAMINS VERSUS FOOD CONCENTRATES
EXAMPLE: CAROTENE." (An Introduction to Life Enthusiast Coop)

"Natural versus 'Natural.'" (Newsletter October 1989)

"Scientific Proof Natural Is Definitely Better" (Newsletter December 1989)

constipation, weight loss, ulcers, and blood sugar problems. (An Introduction to Life Enthusiast Co-Op)

Andean Treasure: Soothing and healing to skin, sunburns, and aching feet. (label and Newsletter - Special Edition, June 22, 1990)

Excelsa/Green Gold/Cell Guard with Antioxidant Enzymes: Detoxifies cells, multiple sclerosis, rheumatoid arthritis, post flight fatigue, and increases energy levels. (An Introduction to Life Enthusiast Co-op and Newsletter)

Because such labeling includes statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Further, we are unaware of any substantial scientific evidence which documents that these drugs are generally recognized as safe and effective for the above-referenced disease conditions or any other disease conditions. Accordingly, marketing of these drugs is a violation of the Act as follows:

SECTION

BRIEF DESCRIPTION

502(a) The articles of drug are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the use in the prevention or treatment of the above-listed conditions.

502(f)(1) The articles of drug are misbranded in that their labeling fails to bear adequate directions for use in the prevention or treatment of the above-listed disease conditions for which the articles are represented or suggested, and are not exempt from this requirement under Code of Federal Regulations, Title 21, Section 201.115 (21 CFR 201.115) since the articles are new drugs within the meaning of Section 201(p) and no approval of any application filed pursuant to Section 505(b) are effective for these drugs.

The articles of drug are further misbranded in that their labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which they are offered are not amenable to self-

diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for the purposes for which they are intended.

505(a) The articles may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approval of any applications filed pursuant to Section 505(b) are effective for such drugs.

The above enumeration of deficiencies should not be construed as an all inclusive list of violations which may be in existence with your products. It is your responsibility to ensure that all requirements of the Act and the regulations promulgated thereunder are being met.

Mr. Meier, this is not the first Regulatory Letter you have received concerning the distribution of products in a false and fraudulent manner in violation of the Federal Food, Drug, and Cosmetic Act. We have also received documentation that a couple of your major distributors, Art and Verna Meakin, Art Meakin and Associates, Austin, Texas, are misbranding your products with similar claims in their newsletters and audiocassette tapes.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of these violative products. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 U.S.C 332 and 334). You may direct your response to L. Jean Rauch, Acting Compliance Officer, at this office.

Sincerely yours,

ROGER L. LOWELL
District Director

Enclosures:
FDC Act
21 CFR 101