

July 12, 1988

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTEDFood and Drug Administration
Seattle Field Office
5009 Federal Office Building
909 First Avenue
Seattle WA 98174

Telephone: 206-442-5300

- In reply refer to: Regulatory Letter SEA-88-13

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REGULATORY LETTER

Dear Mr. Tanner:

This letter is written in reference to the marketing of Barley Green, Sodex (SOD), Yucca Fiber, High Desert Propolis, Superzymes, and Dr. Willard's Catalyst Altered Water Concentrate 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 misbranding provisions of the Federal Food, Drug, and Cosmetic Act as follows:

403(a)(1) and 201(n)
21 CFR 101.9(i)(1)

In that the labeling falsely represents, suggests or implies that these foods are adequate or effective in the prevention, cure, mitigation or treatment of the labeled conditions such as:

Barley Green - necessary to trigger bodily functions; body builder; helpful in dissolving protein and fat deposits

in the body; for stamina; energy and strength; improvement of mild depression; more rapid healing of injuries, operations and some infections; increased tolerance to alcohol; minimal or no hang-over; helps to lower blood pressure; calming effect on hyperactive children. Cancer, weight loss, stomach problems, sodium deposits in crotch area, swollen ankles, and arthritis. (Questions and Answers on Barley Green by Herbert Nam, M.D.). (Barley Green "You'll feel the difference", Barley Green at a Glance, Product Fact Sheet). (Videotape American Image Revised) (Cassette Tape - Dottie LeFore Let's Get Started) (AIM February, May, August 1987).

Sodex - preventing what otherwise might be irreparable cell damage; prevent the destruction of our body cells; probably helps retard aging and theoretically might retard the development of cancerous changes in the cells. (Product Fact Sheet SODEX Superoxide Dismutase). (Video Tape American Image Revised)

Yucca Fiber - anti-stress agents and restoring the pH balance; allows the intestines to absorb water and nutrient much more efficiently. (Yucca Fiber label and Product Fact Sheet and New Product).

High Desert Propolis - an effective stimulant for the body's immune system; most strengthening. (High Desert Propolis label).

Superzymes - healthy mental attitude; cell exercise; cell protection. (Superzymes label).

Dr. Willard's Catalyst Altered Water Concentrate - increase in the rate of

nutrient dissolution and assimilation; helps the immune system by carrying away the cell wastes through the lymphatic system; penetrates the cell wall and carries with it nutrients to the living organism more efficiently. (The Original Doctor Willard's Catalyst Altered Water instruction sheet).

21 CFR 101.9(i)(4)

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

Barley Green - dyes, bleaches, preservatives, thickeners, sweeteners, etc. that drastically effect the quality of food we consume each day; any food you've cooked over 120 degrees has had most of the vitamins and enzymes destroyed; America has made a tragic mistake by shifting to and relying upon processed foods. (Barley Green "You'll feel the difference"). (Video Tape American Image Revised) Cassette Tape Barley Green Meeting Siloam Springs, Arkansas, January 6, 1986, Dr. Tom Morter.

Sodex - due to improper eating habits, processed foods and chemical additives, our bodies are constantly producing damaging free radicals. (Sodex Superoxide Dismulataase sheet).

21 CFR 101.9(i)(5)

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

Barley Green - highest quality, naturally potent and balanced; more energy; supercharged with nutrition and energy;

superior food, exceptionally high in calcium, magnesium, phosphorus and potassium; unknown nutrients yet to be discovered; there are trace amounts of 14 other minerals plus vitamins B12, B15, K, P, and F; rich in vitamins, minerals, live enzymes, chlorophyll and protein; most prolific, balanced supply of nutrients that exist on earth in a single source. (Barley Green "You'll feel the difference"). (Video Tape American Image Revised)

Sodex - 2000 units per 4 tablets. (product label).

Yucca Fiber - 1300 mg.; active ingredients. (Yucca Fiber label).

High Desert Propolis - rich in biologically active vitamins, especially B-complex, C, E, and A, amino acids and trace minerals such as copper, iron, manganese, zinc, and an abundance of bioflavonoids commonly known as vitamin P. (High Desert Propolis sheet).

Superzymes - work nutritionally; 36 gm.; trace elements. (Product label).

Dr. Willard's Catalyst Altered Water Concentrate - will increase the potency of your vitamins.

403(i)(2)
21 CFR 101.4

Dr. Willard's Catalyst Altered Water Concentrate label fails to bear a designation of ingredients. (Product label).

403(a)(1) and 301(n)

The label declaration "Numerous Laboratories including FDA have tested Dr. Willard's Catalyst Altered Water and found it to contain Non-Toxic ingredients" is misleading in that it suggests that the product has been approved by the FDA, which is contrary to fact.

Furthermore, promotional material (labeling) distributed by your firm for Barley Green and Sodex states or suggests among other examples, the following:

Barley Green is reported to increase energy and reduce the abnormalities in Dixie's legs and ankles in the booklet, AIMing for Health N Wealth. In the May 1987 issue of AIM, Harry Schneider, Ph.D., writes that he and his wife are working with a woman diagnosed as having a terminal illness. "She has started taking Barley Green and her progress has been very encouraging." On Page 3, February 1987 issue of AIM, Olga Obarrio reports about a person that has been bedridden that is now stronger, does housework, and drives her car after taking Barley Green. In the August 1987 issue of AIM, Helen L. Shaw reports spontaneous remission for cancer due to taking Barley Green. The Fact Sheet for Sodex states the value of SOD lies in the ability to dismutate (deactivate) free radicals. This alteration of the free radical prevents what might otherwise be irreparable cell damage.

Because such labeling includes statements which represent and suggest that the articles Barley Green and Sodex 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 Federal Food, Drug, and Cosmetic 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 disease 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 Regulation 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 Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder are being met.

For your information, investigations at several of your contract A.I.M., Inc., distributors reveal that the distributors have prepared their own labeling, including printed brochures, audio cassette tapes, video tapes, booklets and pamphlets that represent and suggest that:

Glen M. Tanner
Page 7

Barley Green has been shown to be safe and effective in promoting, curing or treating AIDS's, Alzheimers, mentally disturbed patients, cancer, arthritis, chest pains, tonsillitis, multiple sclerosis, diabetes, inactive thyroid, ulcers, blood clots, poliomyelitis, sinus problems, lupus, colitis, asthma, emphysema, allergies, warts, and skin sores.

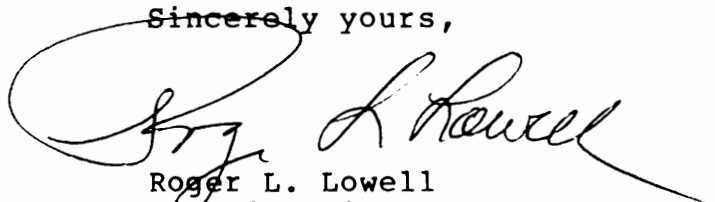
Sodex and Superzymes have shown a marked improvement in patients with Alzheimers and mental disturbances. Superzymes are a concentrated form of live enzymes that neutralize toxins in the body and help the body recover from injuries and degenerative diseases.

High Desert Propolis provides cell protection and is a natural antibiotic to fight viruses present for the flu and colds.

In this regard, we are enclosing copies of Regulatory Letters we have recently issued to some of your distributors. We are advising you of these actions so that you can take appropriate corrective measures to prevent further violative activities at all of your distributors.

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 drug 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 Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334). You may direct your response to Donald E. Peterson, Compliance Officer at this office.

Sincerely yours,



Roger L. Lowell
District Director

Enclosures:
FDC Act
21 CFR Part 101