



DEPARTMENT OF HEALTH & HUMAN SERVICES

Wag 5-23-89
Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

REGULATORY LETTER

Los Angeles District
1821 West Pico Boulevard
Los Angeles, California 90015-2486
Telephone (213) 252-7583

May 17, 1989

Yoshihide Hagiwara, M.D., President
and Kunio Suzuki, General Manager
Green Foods Corporation
Victoria Business Park
129 E. Savarona Way
Carson, CA 90746

LA 28-9

Dear Dr. Hagiwara:

This letter is written in reference to the marketing of Green Magma and Sodex by your firm. We consider these products to be in serious violation of the food misbranding provisions of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION

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

BRIEF DESCRIPTION

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:

Green Magma -

"necessary to activate immune system cells" (leaflet GFC7)
"energizes" (pamphlet Drink Your Salad) "eliminating body diseases, increasing energy, reducing age";
"eliminated constipation, acne, pancreatitis, high blood pressure, diabetes, gastritis, liver disorders, asthma, menstrual cramps, hemorrhoids"; "prevented carcinogenic substances" (reprint Whole Life Times) "detoxify cellular tissue and slow down cellular oxidation (aging)"; "used as a medicine for reducing overweight conditions or for dissolving intestinal or liver hardenings";
"for reversing the development of tumors and other swellings";

"reduced appetite"; "less fatigue"; "less need for sleep" (Reprint East West Journal).

Sodex -

"to act as a deterrent to DNA damage, radiation, poisoning and the aging process" (reprint Whole Life Times) "incredible healing effect"; "anti-aging agent"; "a cell protector and may slow down the aging process"; "lessens the effects of radiation"; "acts as an anti-inflammatory compound"; "may prevent the irreversibility of cell damage following a heart attack" (reprint East West Journal)

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:

Green Magma -

"health food" (label and package) "maximize potency"; "more complete food"; "40-60% light weight protein"; "highest potassium of most vegetables"; "highest chlorophyll of grasses"; "high in carotene" (leaflet GPC 7) "balanced vegetable nutrition"; "energizes"; "nutritional food"; "the highest quality naturally potent and balanced green food available to human kind today"; maximum amount of nutritional essence"; "protects the enzymes, proteins, vitamins and other active nutrients"; "high content of chlorophyll"; "Vitamins: 25 different natural vitamins, including beta carotene (A), B complex family, C, and many others. Minerals: Potassium, calcium, phosphorus, iron, magnesium, manganese, zinc, copper and many

trace elements. Amino Acids: 19 different amino acids including all 8 essential amino acids." (pamphlet Drink Your Salad!)

"highly balanced in protein, mineral, vitamin xx content"; "three times more vitamin C than oranges, ten times more calcium than cow's milk, five times more iron than spinach, two times the amount of copper, selenium and manganese than nutritional yeast" (reprint Whole Life Times).

"most balanced concentration of vitamins, minerals, proteins"; "best source of these nutrients"; "high concentrations of magnesium and iron"; "four times the vitamin B1 in whole wheat flour" (East West Journal).

Sodex -

"2000 units per 4 tablets"; each tablet contains Superoxide Dismutase 500 units Catalase 125 units' (label and pkg.); "help in digesting and absorbing other nutrients" (East West Journal).

We also consider Sodex to be adulterated and in serious violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION

402(A) (2) (C)

BRIEF DESCRIPTION

The product, Sodex, containing Superoxide Dismutase, is adulterated within the meaning of section 402(a) (2) (C) in that it is a food additive which is unsafe within the meaning of section 409(a), since its use and intended use is not in conformity with a regulation or exemption in effect pursuant to section 409.


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.

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 products and use of the misbranding labeling. 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 and/or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

Your response should be directed to:

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
1521 West Pico Boulevard
Los Angeles, CA 90015

Sincerely,


George J. Gerstenberg
District Director
Los Angeles District Office



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