



October 25, 1989

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S E
Bothell, WA 98021-4421
Telephone 206-486-8788

In reply refer to: Regulatory Letter SEA 90-1

Glenn M. Tanner, President
World Image Network, Inc.
317 Happy Day Blvd., Suite 140
Caldwell, Idaho 83606-1204

REGULATORY LETTER

Dear Mr. Tanner:

Investigations by the Food and Drug Administration reveal that you are distributing four foods (Green Essence, Green Essence Plus, Nutri Green, and Ultra Food Tabs) and two dietary supplements of vitamins and minerals (Ultra Trim and Energy Cycle) which are seriously adulterated and misbranded by their labels and labeling (pamphlet, "Discover the Difference"; booklet, "Ultra Slim System A Dynamic and New Natural Weight Loss System"; literature, "Proudly Presents the Winning Combination For Good Health"; magazine, "World Network News" June 1989; and news bulletin July 1989) under the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations (21 CFR) as follows:

<u>SECTION</u>	<u>BRIEF DESCRIPTION</u>
402(a)(2)(C)	<p>Green Essence Plus and Nutri Green are adulterated in that they contain chlorella, a food additive which is unsafe within the meaning of Section 409.</p> <p>Energy Cycle is adulterated in that it contains germanium sesquioxide, a food additive which is unsafe within the meaning of Section 409.</p>
403(a)(1)	<p>The four foods, which have no significant nutritional properties, are misbranded by the nutrition claims:</p> <p>Green Essence - nutritional health food (label), extremely rich in natural nutrients (literature);</p>

SECTION

BRIEF DESCRIPTION

403(a)(1)

Green Essence Plus - nutrient rich, valuable nutrients, richest source of xx vitamins, minerals, amino acids (label), a stronger nutrient profile (literature, magazine);

Nutri Green - nutrient rich, trace mineral rich (label), most nutritious, nutrient rich (magazine);

Ultra Food Tabs - low calorie, very low calorie, very low fat, energy producing, highly nutritious (label), low calorie, very low calorie, low fats, highly nutritious (booklet), very low calorie, low fats (literature).

21 CFR 101.9
(c)(7)(v)

The following three foods are misbranded in that no claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving and no claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving:

Green Essence Plus - No other food can supply the extraordinary balance of valuable nutrients, supplies the richest source of xx vitamins, minerals, trace minerals, amino acids, and nutrient rich natural substances ever available in a single food supplement (label); a super food with an extraordinary nutrient profile never before available in a single food supplement (literature).

SECTION

BRIEF DESCRIPTION

21 CFR 101.9
(c)(7)(v)

Nutri Green - superior nutrient profile, over 50% high quality protein, trace mineral rich algae containing about 65% protein (label, bulletin); the most nutritious greens formula (magazine); a real powerhouse of other nutrients such as vitamin B1, B2, B12, niacin, pantothenic acid, B6, folic acid, biotin xx vitamins A, C, E, xx minerals, xx calcium, magnesium, iron, iodine, and zinc (bulletin).

Ultra Food Tabs - high quality protein (label, booklet, literature), vitamin B complex member (label).

21 CFR 101.9(i)(1)

The following foods (Green Essence, Ultra Food Tabs) and dietary supplements of vitamins and minerals (Energy Cycle, Ultra Trim) are misbranded in that they are falsely represented as effective for the labeled conditions:

Green Essence - life-giving (label), cells can become strong and healthy (pamphlet);

Ultra Food Tabs - appetite control, satisfying hunger (label, booklet), blood sugar levels are kept in balance (booklet);

Energy Cycle - provides all of the energy producing nutrients in virtually calorie-free form, more energy, stress (booklet);

Ultra Trim - solves the problems of appetite out of control, treat obesity due to sluggish thyroid, control weight and metabolism, activate an underactive thyroid (booklet).

SECTION

BRIEF DESCRIPTION

21 CFR 101.9(i)(4)

Green Essence is misbranded in that the pamphlet falsely represents that - Today, many large food conglomerates mix chemical processing and food production, and it was not until we began to refine and process the nutrients out of our foods that poor health began to appear.

21 CFR 101.9(i)(5)

Green Essence (pamphlet), Green Essence Plus (label, literature), Nutri Green (label, magazine, bulletin) are misbranded in that they falsely represent nutritional benefit from chlorophyll for which no essential nutrient effect is known in humans.

403(a)(2) and
411(b)(2)(A) and (B)

Energy Cycle multiple vitamin mineral is misbranded in that bioflavonoid complex (citrus), rutin, inositol, PABA (para-aminobenzoic acid), bromelain, and papain which are not vitamins or minerals, may not be listed except as a part of a list of all the ingredients and may not be given prominence or emphasized.

403(i)(1)
21 CFR 101.3(b)(3)

Energy Cycle is misbranded in that the term "energy" is false and misleading since vitamins and minerals are not a significant source of calories.

Ultra Trim is misbranded in that the label fails to bear an appropriately descriptive name of the vitamin composition of this dietary supplement of Vitamins B6, C, and niacin.

403(i)(2)
21 CFR 101.4(b)(2)

Ultra Food Tabs is misbranded in that the ingredients tofu and yogurt which themselves contain two or more ingredients fail to be followed by a parenthetical listing on the label of all ingredients contained therein.

SECTION

BRIEF DESCRIPTION

403(j)
21 CFR 105.62,
105.66 and 105.69

The listed products are misbranded in that the labels fail to comply with the special dietary, hypoallergenic, caloric, and sodium labeling required by the following claims:

Green Essence Plus - free of added yeast
xx sweeteners, salt;

Nutri Green - contains no added starch,
sugar, etc.;

Ultra Food Tabs - free of added yeast,
salt, and very low calorie;

Energy Cycle - free of added yeast, dairy
products, sugar, salt;

Ultra Trim - free of added yeast, dairy
products, sugar, salt.

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. 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 U.S.C. 332 and 334).

In addition, we reviewed labels for "Green Essence," "Green Essence Plus," "Nutri Green," and "Ultra Food Tabs." The ingredient listing and name and address of the distributor should be on the same information panel without other intervening material in accordance with 21 CFR 101.2(e). We do not consider vitamin B₃ as an appropriate synonym for niacin on the "Ultra Trim" label.

Glenn M. Tanner, President
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You may address your response to Donald E. Peterson, Compliance
Officer, at this office.

Sincerely,

Roger L. Lowell
District Director

Enclosures:
FD&C Act
21 CFR Parts 101 and 105

