



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

October 26, 1989

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Telephone 206-486-8788

In reply refer to: Regulatory Letter SEA 90-2

Lee Dryer  
Nutrition Research, Inc.  
4276 Jackson Creek  
Bozeman, Montana 59715

REGULATORY LETTER

Dear Mr. Dryer:

Investigations by the Food and Drug Administration reveal that Mr. Glenn Tanner, President of World Image Network, Inc., Boise, Idaho, has contacted you for formulation and labeling of the firm's Ultra Slim System products in addition to your manufacture of Green Essence for Mr. Tanner. These products are seriously misbranded by labels and labeling entitled "Ultra Slim System A Dynamic and New Natural Weight Loss System" under the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations (21 CFR) as follows:

SECTION

BRIEF DESCRIPTION

403(a)(1)

Green Essence and Ultra Food Tabs, which have no significant nutritional properties, are misbranded by the nutrition claims:

Green Essence - nutritional health food (label), extremely rich in natural nutrients (literature);

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).

SECTION

BRIEF DESCRIPTION

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

Ultra Food Tabs is 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. The label, booklet, and literature describe Ultra Food Tabs as being high quality protein and the label states it contains Vitamin B complex members.

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);

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).

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

| <u>SECTION</u>                        | <u>BRIEF DESCRIPTION</u>  |
|---------------------------------------|---|
| 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 is misbranded in that the pamphlet falsely represents nutritional benefit from chlorophyll for which no essential nutrient effect is known in humans.   |
| 403(a)(2) and<br>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)<br>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)<br>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.  |

Lee Dryer  
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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:

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," "Ultra Trim," 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 B<sub>3</sub> as an appropriate synonym for niacin on the "Ultra Trim" label.

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