

Wright 10-30-89
HFI-35

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

October 26, 1989

Telephone 206-486-8788

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to: Regulatory Letter SEA 90-4

Lew A. Wheelwright, President, Co-owner
Kim L. Wheelwright, Vice President, Co-owner
Pro-Pac Labs
3911 S. Airport Road Bldg S-24
Ogden, Utah 84405

REGULATORY LETTER

Dear Mr. and Ms. Wheelwright:

Investigations by the Food and Drug Administration reveal that you manufacture and label "Green Essence Plus," "Nutri Green," "Ultra Food tablets," and "Energy Cycle tablets" for Glenn M. Tanner, President, World Image Network, Inc., Boise, Idaho. These products are seriously adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations (21 CFR) as follows:

SECTION

BRIEF DESCRIPTION

402(a)(2)(C)

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.

Energy Cycle is adulterated in that it contains germanium sesquioxide, a food additive which is unsafe within the meaning of Section 409.

403(a)(1)

The three foods, which have no significant nutritional properties, are misbranded by the nutrition claims:

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

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

SECTION

BRIEF DESCRIPTION

403(a)(1)

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

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).

Nutri Green - superior nutrient profile, over 50% high quality protein, trace mineral rich algae containing about 65% protein (label);

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

21 CFR 101.9(i)(1)

The foods, Green Essence and Ultra Food Tabs, are misbranded in that they are falsely represented as effective for the labeled conditions:

Green Essence - life-giving (label);

Ultra Food Tabs - appetite control, satisfying hunger (label);

<u>SECTION</u>	<u>BRIEF DESCRIPTION</u>
21 CFR 101.9(i)(5)	Green Essence Plus and Nutri Green 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.
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.
403(j) 21 CFR 105.62, 105.66 and 105.69	<p>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:</p> <p>Green Essence Plus - free of added yeast xx sweeteners, salt;</p> <p>Nutri Green - contains no added starch, sugar, etc.;</p> <p>Ultra Food Tabs - free of added yeast, salt, and very low calorie;</p>

Lew A. and Kim L. Wheelwright
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SECTION

BRIEF DESCRIPTION

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

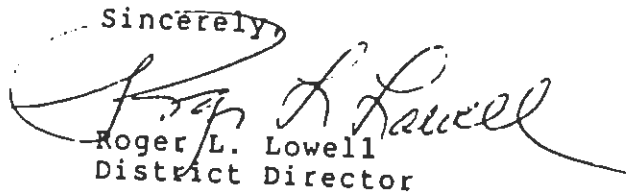
Ultra Trim - free of added yeast, dairy products, sugar, salt.

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).

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

