



JUL 30 1999

2780 '99 AUG -3 P3:27

Mr. Humberto Martin Del Campo  
President  
Terra Life Health Products Co., Inc.  
2527 Williams  
Brownsville, Texas 78520

Dear Mr. Martin Del Campo:

This is in response to your letter of July 01, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Terra Life Health Products Co., Inc. is making the following statements, among others, for specific ingredients in the product **"Terra Day Natural Herbal Energiser:"**

- Ma-Huang: "...relieve the immune system, respiratory complaints like bronchitis and asthma"
- Ginger: "...natural remedy for nausea, helps spasms [sic] and cramps, upset stomach, motion sickness. It helps expel gas...[m]ay also lower blood cholesterol levels and reduce inflammation"
- Ginko [sic] Biloba [sic]:
  - "...to treat asthma, allergies and coughs"
  - "...may help dizziness, stroke, depression"
- Bladderwrack: "normalize the thyroid gland aids in combating obesity"
- Fo-Ti: "...treat dizziness, infertility, anemia and constipation"
  - "...lowers blood cholesterol..."
  - "...prevent heart disease and cancer"
- Hawthorn Berries:
  - "...reduce blood pressure and prevent palpitations arhythmias [sic] and artherosclerosis [sic]
  - "Helps stabilize collagen [sic]. The protein normally found in joints that destroyed during inflammation [sic] and may be useful against arthritis"
- Saw Palmetto: "...treating enlargement of the prostate"
  - "...an expectorant used to treat respiratory complaints like colds, coughs..."
- Chromium proteinate & Picolinate:
  - "...lower elevated blood sugar, reduce cholesterol levels"
- Zinc: "...for proper wound healing"
- Boron Proteinate:
  - "...prevent bone loss and osteoporosis"
  - "...helps prevent arthritis"

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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Dallas District Office, Compliance Branch, HFR-SW140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (file, r/f)  
HFS-450 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
HFV-229 (Benz)  
GCF-1 (Barnett, Nickerson, Dorsey)  
f/t:rjm:HFS-456:7/30/99:66272.adv:disc39

TERRA LIFE HEALTH PRODUCTS CO INC.

66272

2527 Williams Brownsville Tex 78520 (956) 544 41 75



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Food and Drug Administration  
Office of special Nutritionals (HFS\_450)  
center for Food Safety and Applied Nutrition  
200C Street ,SW  
Washington ,DC 20204

NOTICE IS HEREBY GIVEN PURSUANT TO THE REQUIREMENTS OF SECTION 403(r)(6)(21U.S.C. 343(r)(6) OF THE FEDERAL FOOD AND DRUG AND COSMETIC ACT AND IN ACCORDANCE WITH THE REQUIREMENTS OF 21CFR 101.93 THAT YOUR FIRM NAME AND ADDRESS WITHIN THE PAST 30 DAYS COMMENCED MARKETING A DIETARY SUPPLEMENT BEARING THE FOLLOWING STATEMENTS ON THE LABEL AND/OR IN THE LABELING:

TEXT OF CLAIM

NAME OF INGREDIENT OR SUPPLEMENT THAT IS SUBJECT OF CLAIM

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)

THE UNDERSIGNED CERTIFIES THAT THE INFORMATION CONTAINED IN THIS NOTICED IS COMPLETE AND ACCURATE AND THAT MY FIRMS NAME HAS SUBSTANTATION THAT THE STATEMENT IS TRUTHFUL AND NOT MISLEADING.

Sincerely,

A handwritten signature in cursive script that reads "Humberto Martin Del Campo".

HUMBERTO MARTIN DEL CAMPO  
PRESIDENT.

NAME OF SUPPLEMENT TERRA DAY NATURAL HERBAL ENERGISER

SERVING SIZE 2 CAPLETS

CALCIUM	217 mg
Chromium	176 mcg
Kola nut extract	400 mg
Ephedra extract	290 mg
Propietary blend	48 mg
White willow bark, saw palmeto berries, beet root powder bladerwrack, foti , ginger,hawtorne berry powders.	

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Terra Nite RESTFUL HERBAL FORMULA WITH MELATONIN

SERVING SIZE 4CAPLETS

VITAMIN C	60mg
VITAMIN B6	6mcg
CALCIUM	295 mg
chromium picolinate	100mcg
POTASIUM	99 mg

PRPIETARY BLEND

VALERIAN ROOT, WILD LETUCE ,GINGER ROOT,  
L CARNITINE ASTRAGALUS, SCULLCAP,  
MELATONIN 1 mg.

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# TERRA LIFE HEALTH PRODUCTS, CO.

## An Ancient Formula, with XXI Century Ingredients.

For your information . . .

### TERRA DAY

**Terra Day** is a Weight Program to loss weight. Exclusive developed for Terra Life Products. Our nutrient product Terra Day is a combination of thermogenic herbs and minerals, to assist in achieving your weight management objective, to losse weight in a safe way with objective during waking hours. Termogenesis is the process of raising the basal metabolic rate, which increase energy for work and play. With the increased energy, more fat is burned.

The ingredients are:

**Ma-Huang:** This herb is been used in China for thousands of years. Aids the metabolism of fat. A natural stimulant that increase the metabolism rate and caloric burn. Helps the termogenesis with others herbs. In China has been used to relieve the immune system, respiratory complaints like bronchitis and asthma.

**Kola Nut:** Builds stamina is a natural, energy booster, natural appetite suppressant. Kola nut will not burn vital muscle tissue, but will cause your body to burn stored fat.

**Ginger:** It has been used since ancient times by Greeks, Chinese and others as a medicine and for flavoring. Ginger is taken today for its calming effects on the dygestive system and is the premier natural remedy for nausea, helps spasms and cramps, upset stomach and motion sickness. It helps expel gas, helps intestinal circulation. Ginger may also lower blood cholesterol levels and reduce inflammation, it is a popular spice and flavoring giner cookies.

**White Willow:** Helps to burn fat, natural aspirin reduce pain, fever, reumatic and muscle pain discomfort.

**Ginko Bilova:** One of the world's most ancient tree species. It has been used by Chinese to treat asthma, allergies and coughs. Currently is gaining popularity for its ability to improve brain functions and boost memory and alertness. Researchers say that stimulates circulation in the brain, may help dizziness, stroke, depression. Ginko acts as an antioxidant. Helps to glucose.

**Bladderwrack:** Helps normalize the thyroid gland and aids in combating obesity.

**Fo-Ti:** It is a China herb. Famous as a rejuvenating and longevity herb. In China where is taken to prevent premature aging, increase fertility and maintain youthful strenght and vigor. Also helps and used to treat dizziness, infertility, anemia and costipation. There is evidence that it lowers blood cholesterol and it is currently being studies Fo-Ti for its ability to prevent heart disease and cancer.

**Hawthorn Berries:** A native herb from Europe. It enjoys a long history of use as heart tonic and studies have confirmed that the

plant is a rich source of bioflavonoids and other compounds that help heart functions. Howthorn Berries is an effective antioxidant. It can reduce blood pressure and prevent palpitations arhythmias and artherosclerosis. Helps stabilize collagen. The protein normally found in joints that destroyed during inflammation and may be useful against arthritis.

**Saw Palmetto:** Is derived the dark berries of small palm tree, traditionally been used as an aphrodisiac and to tonify the male reproductive system. Studies confirm an effect on male sex hormones and exhibited positive clinical results in treating enlargement of the prostate. It is also an expectorant used to treat respiratory complaints like colds, coughs, polysaccharides with potential immune boosting effects.

**Beet-Powder:** Enriches the blood.

**Chromium Proteinat & Picolinate:** It is an essential nutrient absolutely required for good healt. Nine of Ten Americans do not get an adecuate amount of chromium in their diet because chromium is lost durinf food procesing and they don't eat food containing chromium. Chromium can help reduce body fat, retain build lean muscle, lower elevated blood sugar, reduce cholesterol levels. Chromium deficiencies can cause difficulties in regulating blood sugar.

**Zinc:** Is a trace mineral essential for proper wound healing, male sexual potency, immunity, liver detoxification and numerous other bodily functions.

**Boron Proteinat:** Is a mineral that may be necessary to help prevent bone loss and osteoporosis. There's also evidence that helps prevent arthritis.

This ingredients help not only with thermogenesis but also you will obtain increase mental clarity, memory, reduced appetite, balance blood sugar, build muscle tissue and a better health.

Suggested use: take 1 tablet 4 times daily, one before breakfast or 2 after breakfast, 2 more before you take lunch. Don not take after 3:00 p.m., some people need more, some less, you need to adjust supplement to your personal needs for best results. Do not take over 4 caplets per day.

Caution: Not for pregnant or nursing women, or if you have high blood pressure.