



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP - 1 1999

Rec'd 9/7/99

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 August 24, 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 statement, among others, for specific ingredients in the product "**Terra Day Natural Herbal Energizer:**"

Ginger: "...aids in combating obesity."

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 claim that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate a disease, namely, obesity. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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

975-0163

LET 297

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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-456:8/31/99:66951.adv:disc40

666957

TERRA LIFE HEALTH PRODUCTS

2527 Williams Ave.
Brownsville, Texas 78520
(956) 544-4175



August 24, 1999

Department of Health & Human Svcs.
Public Health Service
Food and Drug Admin.
200 C. Street SW HFS-456
Washington DC 20204

Dear Miss Lynn A. Larsen, Ph.D. Director:

This is in response to your letter of July 30, 1999.
Enclosed is the new information text of the product "Terra Day Herbal Energizer".

The new information was effective on August 6, 1999 to comply with The law (FDA) pursuant to 21U.S.C..343 ® (6) section 403®(6) of the Federal Food Drug and Cosmetic Act. The old information was destroyed.

If you have any questions or, should you need additional information I shall be glad to supply it.

Very truly yours,

A large, stylized handwritten signature in black ink, appearing to read "Humberto Martin del Campo".

Humberto Martin del Campo
Pres. Terra Life Prod. Co.



Terra Life
Health
Products, Co.

Terra Day

Herbal Energizer

Terra Day weight management is a carefully developed nutraceutical combination of thermogenic herbs, minerals and aminoacids to assist in achieving your weight management objective during walking hours.

Terra Day ingredients and the way they are thought to assist the body:

Ma Huang: an herb widely used to increase basal metabolic rate and burn calories.

White Willow: An herb aiding stomach, Kidneys, Bowels, Intestines.

Kola Nut: An herb to help improve energy and alertness.

Ginger: An herb that aids in combating obesity.

Ginko Biloba: An herb used to enhance the immune function.

Chromium Picolinate: An easily absorbed mineral shown to help reduce body fat and build lean body muscle.

Boron Proteinate: An easily absorbed form of mineral thought to help promote healthy bone structure.

Saw Palmeto: An herb that aids in building strenght and muscle tone.

Zinc: An easily absorbed form of mineral that assist the body in processing protein.

Terra Life
Health
Products Co.
2527
Williams Ave.
Brownsville,
Texas
78520

Para
Información
sobre
nuestros
suplementos
nutricionales
por favor
llame al
(956) 544-4175