

TAB

32



0506 6 JUN 22 P3:18

MAY 23 2006

Ms. Christine M. Humphrey, Esq.
C. Humphrey & Associates, P.A.
1001 Brickell Bay Drive
Suite 2002
Miami, Florida 33131

Dear Ms. Humphrey:

This is in response to your letter of April 20, 2006 to the Food and Drug Administration (FDA), on behalf of your client Healing Power, Inc.,¹ pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be made for the product DBCARE:

“Helps maintain normal blood sugar levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, claims that do not establish that the claims are about blood glucose levels that are already within normal limits imply that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose levels but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, it is an implied disease claim.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. 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

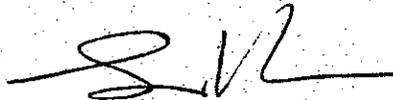
¹Healing Power, Inc., 30-21 43 Street, Suite #3, Astoria, New York 11103.

Page 2 - Ms. Christine M. Humphrey, Esq.

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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New York District Office, Office of Compliance, HFR-NE140
Healing Power, Inc., 30-21 43 St., Suite #3, Astoria, NY 11103



C. HUMPHREY & ASSOCIATES, P.A.

FOOD AND DRUG LAW
CUSTOMS AND INTERNATIONAL TRADE LAW
ADMINISTRATIVE LAW

April 20, 2006

1001 Brickell Bay Drive
Suite 2002
Miami, Florida 33131
Tel 786.245.0440
Fax 305.371.4120

APR 28 2006

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204

Re: Notice Pursuant to 21 USC § 343(r)(6) of Intent to Market Dietary Supplement with "Structure/Function" Statements

Dear Sir or Madam:

This notification is being filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 343(r)(6). The above is counsel for Healing Power, Inc., 30-21 43 Street, Suite #3, Astoria, NY 11103, which plans to market a dietary supplements bearing the following statements on the label and/or in the labeling:

Name of Supplements: DBCARE

Dietary ingredients: Karela extract
Amla extract
Jambubej extract (*eugenia jambolana*)
Mamejava extract (*enicostemma littorale*)
Kadiyatu extract
Methi extract
Galo extract (*Gulanshe Tino*)
Gudmaar extract (*gymnema sylvestre*)
Kadu extract (*Swertia chirayita*)
Neempan extract (*azadirachta indica*)
Halki extract

Structure/Function statements: "Carbohydrate metabolizer;" and
"Helps maintain normal blood sugar levels"

2006-4441

#1687

Office of Special Nutritionals

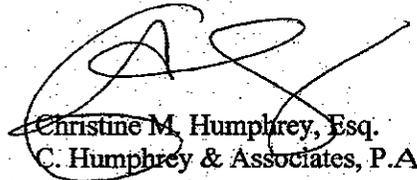
April 20, 2006

Page 2 of 2

The effect on the structure/function of the body arise from the proprietary blend of dietary ingredients present in DBCARE as listed on page 1 of this notice.

Should the FDA or the Office of Special Nutritionals have any questions, concerns, or comments regarding this 21 U.S.C. § 343(r)(6) notice, they may be directed to this office at the address, telephone, or fax number contained in this letter.

Very truly yours,



Christine M. Humphrey, Esq.
C. Humphrey & Associates, P.A.

C. HUMPHREY & ASSOCIATES, P.A.

1001 BRICKELL BAY DRIVE • SUITE 2002 • MIAMI, FLORIDA 33131
TELEPHONE: 786.245.0440 • FACSIMILE 305.371.4120



MAY -3 2006

Mr. Gilbert A. Fuller
Executive Vice President of Finance
& Chief Financial Officer
USANA Health Sciences, Inc.
3838 West Parkway Boulevard
Salt Lake City, Utah 84120-6336

Dear Mr. Fuller:

This is in response to your letter of April 7, 2006 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 letter states that the following statement will be made for the product Chelated Mineral:

“Vanadium helps support healthy serum glucose levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, claims that do not establish that the claims are about blood glucose levels that are already within normal limits imply that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose levels but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, it is an implied disease claim.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. 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

97S 0163 LET 879

Page 2 - Mr. Gilbert A. Fuller

nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

AIMS:
2006-3658

April 7, 2006

APR 24 2006

Certified Mail Label No. 7005 0390 0005 7062 7274

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington, D.C. 20204

RE: *Notification of marketing a dietary supplement that bears on its label or its labeling a statement provided for in section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.*

Dear FDA Consumer Safety Officer:

USANA Health Sciences, Inc. submits this notification for its dietary supplement products that bear statements of nutritional support in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

Manufacturer of Dietary Supplement: USANA Health Sciences, Inc.
3838 West Parkway Blvd.
Salt Lake City, Utah 84120-6336

**Name of Dietary Supplements:
(including brand name)** "Essentials," "Mega Antioxidant," "Chelated Mineral," "Body Rox," "Usanimals," "HealthPak 100," "Optimizers," "Proflavanol & Provlavanol 90," "CoQuinone," "OptOmega," "BiOmega," "E-Prime," "Poly C," "Active Calcium," "Body Rox Calcium Chewable," "Procosa II," "Phytoestrin," "Palmetto Plus," "Visionex," "Ginkgo-PS."

Text of Statements Being Made for "Essentials™":

"They are designed to provide optimal nutritional support for every age group."

"MEGA ANTIOXIDANT™, a comprehensive formula of high-potency vitamins, antioxidants, and other important nutrients that every adult needs every day for efficient cellular metabolism and to counteract the damaging effects of free radicals."

1675

“Helps protect low-density lipoproteins (LDL) from oxidation and maintain immune function.”

“Vitamin E is one of the most important antioxidants in the human body because it helps to maintain strong cell membranes and helps protect LDL from oxidation.”

“USANA’s POLY C® is a complex of mineral ascorbates that helps to prolong vitamin C activity in the body.”

“Vitamin C is the master water-soluble antioxidant, offering health maintenance throughout the body.”

“Vitamin A promotes healthy skin and a strong immune system, and helps maintain good vision.”

“Lycopene, lutein, and zeaxanthin are carotenoid antioxidants involved in protecting against free-radical damage in the eyes and other organs.”

“USANA uses a mixture of carotenoids, providing a broad spectrum of antioxidant protection.”

“Coenzyme Q10 (CoQ10) is one of the most researched and well-accepted nutrients for cardiovascular health. A potent antioxidant, it is essential for energy production in our cells.”

“High levels of Coenzyme Q10 are especially important for a strong cardiovascular system.”

“The body’s ability to synthesize or absorb CoQ10 declines with age, but taking USANA’s MEGA ANIOXIDANT™ can help you maintain healthy levels of this important nutrient.”

“Alpha lipoic acid is a vitamin-like antioxidant that is both fat- and water-soluble. Easily absorbed through the gut and transported across cell membranes, it offers protection against free radicals, both inside and outside the cell.”

“MEGA ANTIOXIDANT™ contains carefully proportioned B-complex vitamins, which are fundamental to energy production, metabolism, and growth. They help retain normal homocysteine levels.”

Text of Statements Being Made for “Chelated Mineral”:

“Zinc is a component of hundreds of enzymes. It is associated with enzymes involved in carbohydrate, fat, and protein metabolism, as well as DNA and RNA replication.”

“Zinc functions as an antioxidant, aids in maintaining healthy bone structure development, maintains healthy immune functions, maintain healthy vision, and supports normal fetal growth.”

“Many studies have shown that selenium is important for maintaining prostate health.”

“Selenium has also been shown to help a healthy immune system.”

“Copper is essential for enzymes that help to synthesize collagen.”

“Also, copper is a critical component of the enzyme superoxide dismutase (SOD), and important antioxidant in cell cytoplasm, and acts as a catalyst in the formation of hemoglobin.”

“Manganese is an important co-factor in the production of glycosaminoglycans, compounds that make up connective tissues, bones, arteries, and other organs.”

“Manganese is an activator of numerous enzymes, and supplementation with manganese can enhance the SOD enzyme system to increase antioxidant activity.”

“Vanadium helps support healthy serum glucose levels.”

“It may also help maintain healthy thyroid function.”

Text of Statements Being Made for “Body Rox™”:

“Supplies a comprehensive and convenient formula of essential vitamins, minerals, and antioxidants for optimal health in the active teenage and young adult years.”

”BODY ROX™ provides a new, more potent combination of antioxidants that help young bodies maintain ideal health.”

“Vitamin A, converted from beta-carotene, is important for vision and health skin.”

“Adolescents need B vitamins in advanced amounts to meet the extra demands of growth, energy metabolism, and muscle tissue development.”

“Vitamin D is essential for uptake and utilization of calcium, and additional vitamin A and C are often necessary to compensate for erratic eating patterns.”

“Copper is important in maintaining a healthy immune system.”

Text of Statements Being Made for “Usanimals™”:

“USANIMALS™ contain a full array of antioxidants, vitamins, and minerals, in amounts designed especially for active, growing children, including advanced amounts of vitamins E and C, two of the most powerful antioxidants needed by the human body.”

"The comprehensive formulation of VISIONEX® is designed to support long-term eye health, especially when combined with preventive measures against exposure of the eyes to harmful environmental influences."

Text of Statements Being Made for "Ginkgo-PS™":

"Combines standardized, high-potency *Ginkgo biloba* extract, plus phosphatidylserine for healthy mental and cognitive function."

"Contains phosphatidylserine (PS), which is clinically proven to enhance memory."

"However, maintaining good nutrition, continuing physical and intellectual activity, and supplementing our diet with GINKGO-PS™ may extend mental acuity for years."

"Enhancing memory, attention span, and other neurological activity."

"More oxygen means more efficient use of other nutrients, which results in better mental performance, memory, and general cognitive function."

"PS is a component of all cell membranes and is essential to proper cell function."

"Measurable effects included enhanced memory, attention, and learning ability."

Gilbert A. Fuller declares:

1. That he is Executive Vice President of Finance and Chief Financial Officer of USANA Health Sciences, Inc. (hereinafter "Applicant") and is authorized to make this declaration;
2. That information contained in this statement is complete and accurate, and that USANA Health Sciences, Inc. has substantiation that the statement is truthful and not misleading.

DATED this 10th day of April 2006.

USANA Health Sciences, Inc.

By: 
Gilbert A. Fuller
Executive Vice President of Finance &
Chief Financial Officer



SEP 29 2004

Ms. Amy M. Abedi
Technical Nutrition Specialist
Anabolic Laboratories, Inc.
26021 Commercecentre Drive
Lake Forest, California 92630

Dear Ms. Abedi:

This is in response to your letter of June 30, 2004 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 letter states that the following statement will be made for the product **Alpha-Lipoic Acid 300 mg Capsules**:

“Supports healthy blood sugar.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, a claim that does not establish that the claim is about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, it is an implied disease claim.

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

978-0163

LET 782

Page 2 - Ms. Amy M. Abedi

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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



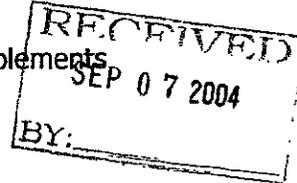
Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

June 30, 2004

Christine L. Taylor, Ph.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW
(HFS-450)
Washington, D.C. 20204



Dear Dr. Taylor:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Anabolic Laboratories, Inc. is offering for sale Alpha-Lipoic Acid 300 mg Capsules, as a dietary supplement. It contains the following structure/function statement: "Supports Healthy Blood Sugar." This will be sold as a private label product and the label contains the proper disclaimer as well.

Thank you,

A handwritten signature in black ink, appearing to read "Amy M. Abedi". The signature is stylized and overlaps the printed name below it.

Amy M. Abedi, R.D.
Technical Nutrition Specialist

8/24/88