

TAB

31



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUN 12 2007

JUN 21 10 12

Mr. Michael Matthews
Wellness International Network, Ltd.
5800 Democracy Drive
Plano, Texas 75024

Dear Mr. Matthews:

This is in response to your letter of May 10, 2007 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 notice states that Wellness International Network, Ltd. is making the claim "Support healthy levels of...cholesterol."

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. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is 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 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.

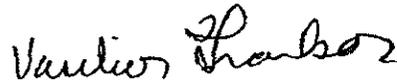
19975-0163

LET 945

Page 2 - Mr. Michael Matthews

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, 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, Dallas District Office, Office of Compliance, HFR-SW140



Wellness International Network, Ltd.

May 10, 2007

Office of Special Nutritional
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

MAY 30 2007

Re: Notification for Statements on Dietary Supplement Labeling

This notification is being filed on behalf of Wellness International Network, Ltd., a distributor of dietary supplement products (hereinafter "WIN"). Its business address is: 5800 Democracy Drive, Plano, TX 75024. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is Tranquility™.

A. The text of each structure-function statement for which notification is now being given is:

(Statement 1): Support healthy levels of triglycerides and cholesterol.

(Statement 2): Help manage stress and regulate the sleep cycle.

(Statement 3): Aid in relaxation.

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	myo-inositol
2.	valerian root
3.	inositol

1917

07-3789



Wellness International Network, Ltd.

I, Michael Matthews, am authorized to certify this Notification on behalf of WIN. I certify that the information presented and contained in this Notification is complete and accurate, and that WIN has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 5/10/07

By: 
Michael Matthews
Director of Regulatory Affairs



0509 6 JUN 22 P3:18

JUN - 5 2006

Ms. Stephanie Roach
QC Technician
New Chapter, Inc.
90 Technology Drive
PO Box 1947
Brattleboro, Vermont 05302

Dear Ms. Roach:

This is in response to your letter (undated) 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 statements will made for the product "CoffeeBerry:"

"[M]aintain healthy blood glucose levels"
"[M]aintain healthy cholesterol levels"
"[P]romote healthy blood pressure."

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 and blood pressure; that is, claims that do not establish that the claims are about blood glucose levels or blood pressure levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes) or blood pressure (hypertension), which are diseases. Therefore, because the claims you are making for this product represent that the product is intended to affect blood glucose, blood cholesterol, and blood pressure but do not also include a statement about it being intended to affect blood glucose, blood cholesterol, and blood pressure that are already in the normal ranges, they are implied disease claims.

Other claims, in the context that they are used, imply that other products for which you submitted notifications are intended to treat, prevent, or mitigate disease. The product "Peppermint Flavor Host Defense Throat Mist" is promoted to support immune function and host defense, and contains the statement "Traditionally used for fighting parasites."

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Page 2 - Ms. Stephanie Roach

The product "CoffeeBerry" uses the claim "Promotes normal fungal resistance." The product "Supercritical OreganoForce" uses a claim that it contains a "[S]pectrum 9380 synergistic antimicrobial oregano compounds."

The product "CoffeeBerry" also uses the claim "[M]ay assist in the maintenance of healthy glucose levels and protect against insulin resistance."

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, such as parasitic diseases, infectious diseases, and diabetes. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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,



Barbara O. Schneeman, Ph.D.
Director
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 England District Office, Office of Compliance, HFR-NE240

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

MAY - 3 2006

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

90 Technology Dr., PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is Supercritical Oreganoforce™.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Only Oreganoforce combines highly concentrated oregano oil plus a hydroethanolic water soluble oregano blend, yielding the widest spectrum (38) synergistic antimicrobial oregano compounds.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
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1.	Organic oregano leaf
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The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
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1.	Supercritical Oreganoforce™	Labeling
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I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] AC Technician [Title]

Date Signed: May 1, 2006

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06-4643 1

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

MAY - 3 2006

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is CoffeeBerry™.

The text of each structure-function statement for which notification is now being given is:

- (CoffeeBerry™) is abundant in polyphenols that:
- (Statement 1): help preserve natural antioxidants in the body
 - (Statement 2): protect cell membranes and human plasma against damaging oxidation
 - (Statement 3): neutralize toxic free radicals

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Label and labeling
2.	CoffeeBerry™	Label and labeling
3.	CoffeeBerry™	Label and labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

1
06-4643

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is CoffeeBerry™.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): ((CoffeeBerry™) is abundant in polyphenols that) help maintain healthy blood glucose levels.
- (Statement 2): Research indicates these glyconutrients are essential for the various complex biological systems to interact and function properly to prevent free-radical damage and to initiate cellular repair.
- (Statement 3): Foods with high ORAC values can absorb and neutralize those damaging free radicals and thus provide critical protection against that damage.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Label and labeling
2.	CoffeeBerry™	Label and labeling
3.	CoffeeBerry™	Label and labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is CoffeeBerry™.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Provides the extraordinary defense of more than 5 servings of antioxidant-rich fruits
- (Statement 2): These glyconutrients are essential for proper immune system function and support of cellular and connective tissue integrity
- (Statement 3): Shown in studies to help maintain healthy cholesterol levels

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Labeling
2.	CoffeeBerry™	Labeling
3.	CoffeeBerry™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is CoffeeBerry™.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Shown in studies to promote healthy blood sugar levels
- (Statement 2): Shown in studies to greatly reduce free-radical damage
- (Statement 3): Shown in studies to be as effective as estrogen in promoting bone health

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Labeling
2.	CoffeeBerry™	Labeling
3.	CoffeeBerry™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is CoffeeBerry™.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Derivatives identified in coffee are substantially more potent than Vitamin C
 (Statement 2): Research indicates helps promote healthy blood sugar levels
 (Statement 3): Shown in studies to slow the oxidation of LDLs thus promoting cardiovascular health.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Labeling
2.	CoffeeBerry™	Labeling
3.	CoffeeBerry™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **CoffeeBerry™**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Research shows it can be a preventative against the damages of oxidative stress

(Statement 2): Shown in studies to be cell-protective, immuno-modulatory, and to promote a healthy inflammation response

(Statement 3): Shown to promote healthy blood pressure

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Labeling
2.	CoffeeBerry™	Labeling
3.	CoffeeBerry™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach QC Technician
[Name] [Title]

Date Signed: April 26, 2006

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is CoffeeBerry™.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Research indicates it could have potential to combat the negative effects of stress
- (Statement 2): Promotes normal fungal resistance and is an effective means of detoxification
- (Statement 3): Protects cells against oxidative stress

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Labeling
2.	CoffeeBerry™	Labeling
3.	CoffeeBerry™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach QC Technician
[Name] [Title]

Date Signed: April 26, 2006

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **CoffeeBerry™**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Research indicates that nutrients present in whole coffee fruit may assist in the maintenance of healthy glucose levels and protect against insulin resistance and other age-related conditions

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Coffeeberry
2.	Coffeeberry
3.	Coffeeberry

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	CoffeeBerry™	Labeling
2.	CoffeeBerry™	Labeling
3.	CoffeeBerry™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

MAY - 3 2006

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Peppermint Flavor Host Defense® Throat Mist™.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Used by Europeans for more than 2,000 years, from the time of Discorides and before, and independently revered by the Haida First Peoples of British Columbia, recent studies have found this mushroom to have powerful immunoactive effects against airborne elements.

(Statement 2): Traditionally used for fighting parasites, this mushroom has yielded several natural protective compounds, including betulinic acids and other constituents unified to form an immunoactive matrix of nutrients.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Agarikon
2.	Birch Polypore

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Peppermint Host Defense® Throat Mist™	Labeling
2.	Peppermint Host Defense® Throat Mist™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] QC Technician [Title]

Date Signed: April 26, 2006

06-4643 1

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 90 Technology Drive, PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is Peppermint Flavor Host Defense® Throat Mist™.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Borne from the Chinese Acacia tree, this mushroom, an elegant display of grace and beauty, has long been admired and heralded by Asians for thousands of years as *The Mushroom of Immortality.*

(Statement 2): The way of life is synergism of allies: In this vein, we combine the most potent of mushrooms to help support immune function and *host defense.*

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Red Reishi
2.	Red Reishi

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Peppermint Host Defense® Throat Mist™	Labeling
2.	Peppermint Host Defense® Throat Mist™	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

By: Stephanie Roach [Name] DC Technician [Title]

Date Signed: April 26, 2006



MAY - 3 2006

Mr. James Komorowski
Vice President, Technical Services
& Scientific Affairs
Nutrition 21, Inc.
4 Manhattanville Road
Suite 202
Purchase, New York 10577-2197

Dear Mr. Komorowski:

This is in response to your letter of April 14, 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 statements will be made for the product Chromax chromium picolinate:

“Promote healthy cholesterol”
“[S]upports healthy cholesterol...”

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. Therefore, because the claims you are making for this product represent that the product is intended to affect blood cholesterol levels but do not also include a statement about it being intended to affect blood cholesterol levels that are already in the normal range, they are implied disease claims.

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 statements that you are making for this product suggest that it is intended to treat, prevent, 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

975 0163 LET 882

Page 2 - Mr. James Komorowski

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



AIMS:
2006-3656

James R. Komorowski, MS
VP, Technical Services & Scientific Affairs
Direct- 914-701-4519
Fax -914-696-0860
Email: Jkomorowski@nutrition21.com

April 14, 2006

APR 24 2006

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Re: Chromax® Chromium Picolinate

Dear Sir or Madam:

Pursuant to Section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act) and to Food and Drug Administration regulation 21 CFR § 101.93, Nutrition 21, Inc. is providing marketing notification of the following product and labeling claims.

Name of dietary supplement: Chromax® chromium picolinate

Distributor: Nutrition 21, Inc.
4 Manhattanville Road
Purchase, NY 10577

Dietary ingredients: Chromium picolinate

Statements of nutritional support:

1. Chromium is an essential trace mineral for a healthy metabolism
2. Optimize your insulin function
3. Optimize your metabolic health
4. Control carbohydrate cravings
5. Fight weight gain
6. Maintain heart health
7. Promote healthy cholesterol
8. Helps maintain healthy blood sugar metabolism
9. Chromium is also a vital part of your natural mechanism for regulating blood sugar and activating various enzymes for energy production.
10. It also supports healthy cholesterol and heart health
11. Promotes healthy blood sugar
12. Supports overall cardiovascular health
13. Helps increase energy

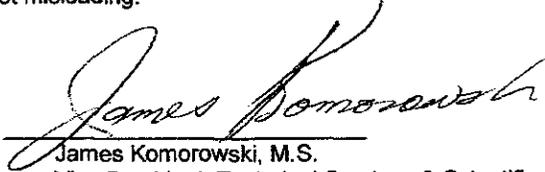
Nutrition 21, Inc.

4 Manhattanville Road, Suite 202 • Purchase, NY 10577-2197 • Phone 914 701-4500 • Fax 914 696-0860 • www.nutrition21.com

#1676

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

By



James Komorowski, M.S.

Vice President, Technical Services & Scientific Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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JUN 21 2002

Mr. Ira L. Goldberg
President
Source Naturals, Inc.
23 Janis Way
Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letters of February 2, 2002 and May 13, 2002 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)).

The product **Policosanol Cholesterol Complex** uses the claim "...help maintain cholesterol levels within the normal range." 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 claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

The product **Gluco-Science™** uses the claim "Products that support healthy 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 your claim about control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar level that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

975-0163

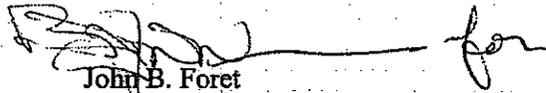
LET 619

Page 2 - Mr. Ira L. Goldberg

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 a disease. 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,



John B. Foret

Director

Division of Compliance and Enforcement

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-300

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

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

Source Naturals, Inc.
Scotts Valley, CA 95066

February 02, 2002

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

RECEIVED
JUN 14 2002
BY:

RE: Notification of Nutritional Support Statements

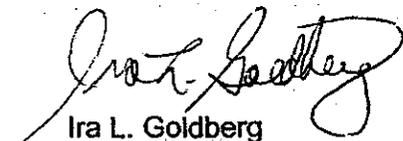
Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Gluco-Science™ a dietary supplement. Source Naturals® is the manufacturer of Gluco-Science™.

Statements being made in the labeling of Gluco-Science™:

- (1) Products that support healthy blood sugar levels are projected to be among the industry's top five growth areas.
- (2) This Bio-Aligned Formula™ supports multiple body systems: Glucose/carbohydrate metabolism, insulin/pancreatic activity, heart and circulatory system, nervous system, and vision.

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.



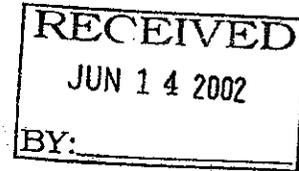
Ira L. Goldberg
President, Source Naturals, Inc.

80857

Source Naturals®
23 Janis Way
Scotts Valley, CA 95066

May 13, 2002

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



RE: Notification of Nutritional Support Statements

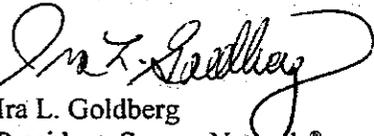
Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of, Policosanol Cholesterol Complex a dietary supplement. Source Naturals® is the manufacturer of Policosanol Cholesterol Complex.

Statements being made in the labeling of Policosanol Cholesterol Complex:

- (1) Bio-Aligned Formula supports multiple body systems: heart, blood vessels, nervous system, thyroid, liver and gastrointestinal tract.
- (2) Provides 500 mg of curcumin, the amount shown in research to reduce serum lipid peroxides and help maintain cholesterol levels within the normal range.
- (3) The antioxidant green tea inhibits LDL oxidation and promotes healthy blood vessels, according to animal and *in vitro* studies.
- (4) Myricetin, a powerful antioxidant, inhibits LDL oxidation, according to *in vitro* research.

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.


Ira L. Goldberg
President, Source Naturals®

80857