



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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>
1.	Organic oregano leaf

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.	Supercritical Oreganoforce™	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: May 1, 2006

06-4643 1

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**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

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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

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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.

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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]

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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]

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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 [Name] QC Technician [Title]

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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

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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

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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>
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- | | | |
|----|---------------------------------------|----------|
| 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

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

(Statement 1): Borne from the Chinese Acacia tress, 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] AC Technician [Title]

Date Signed: April 26, 2006