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JUN 12 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 letters dated June 5, 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)).

You state that you intend to make the claim "[P]romotes healthy levels of cholesterol" for the product Sea Buckthorn FSE.

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 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 ranges, it is an implied disease claim.

Your letters also state that New Chapter, Inc. is making the following statements for the following products:

Zyflamend, MWOI: Women's Synbiotic Nutrients, MWOI: Men's Synbiotic Nutrients, MWOI: Host Defense, NewMark's Fruits'n Greens, Gastro Complete, NewMark's Baikal Skullcap FSE, Blueberry Probiotic Complex

"[A]llergy support...nutritional support during cancer treatment"

Turmeric FSE, LifeShield, NewMark's Holy Basil FSE, MWOI: GWT 1000, NewMark's Ginger Tonic, MWOI: Daily Synbiotic Nutrients, MWOI: E&Selenium, Cruciferous Complex, NewMark's CoQ10+,

"[N]utritional support during cancer treatment"

Page 2 - Ms. Stephanie Roach

Other claims, in the context that they are used, imply that the product Pros-5LO is intended to treat, prevent, or mitigate a disease, namely benign prostate hypertrophy (BPH). It is represented using the claim "Supports healthy prostate function" as well as being represented to affect characteristic signs and symptoms of BPH (i.e., "[S]upport...normal urine flow, inflammation reduction...[M]odulating...inflammatory enzymes.")".

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. 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,



Robert J. Moore, Ph.D.
Team Leader, Compliance and Enforcement Team
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 England District Office, Office of Compliance, HFR-NE240

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

RECEIVED
JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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:
Sea Buckthorn FSE.

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

- (Statement 4): Sea buckthorn supports healthy digestive function, promotes normal vaginal tissue health, promotes normal respiratory function, and supports healthy bladder tissue.
- (Statement 5): All of these components positively influence cardiovascular health and support normal cellular growth.
- (Statement 6): Human clinical trials indicate that sea buckthorn blend promotes healthy levels of cholesterol and triglycerides and supports healthy platelet function.

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>
4.	Sea Buckthorn extract (<i>fruit and seed</i>), Rosemary (<i>leaf</i>), Calendula (<i>flower</i>)
5.	Sea Buckthorn extract (<i>fruit and seed</i>), Rosemary (<i>leaf</i>), Calendula (<i>flower</i>)
6.	Sea Buckthorn extract (<i>fruit and seed</i>), Rosemary (<i>leaf</i>), Calendula (<i>flower</i>)

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>
4.	Sea Buckthorn FSE	Labeling
5.	Sea Buckthorn FSE	Labeling
6.	Sea Buckthorn FSE	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

#1705

06 - 4949²

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc. which is the manufacturer of the product 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: Pros-5LO.

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

- (Statement 1): Supports healthy prostate function.
- (Statement 2): Pros-5LO provides comprehensive support for healthy prostate function, normal urine flow, inflammation reduction, and sexual health.
- (Statement 3): It contains supercritically extracted saw palmetto which concentrates the key lipophilic constituents responsible for modulating the 5-lipoxygenase (5LO) and cyclooxygenase inflammatory enzymes.

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

Statement **Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement**

1.

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

Statement **Brand Name** **Label or Labeling?**

1.

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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:
Baikal Skullcap FSE.

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

(Statement 7): Practitioner's Guide to using **NewMark™ 's Baikal Skullcap FSE** in Clinical Practice; allergy support, cardiovascular support, healthy inflammation response, immune support, joint/connective tissue, mood support, nutritional support during cancer treatment.

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>
7.	Baikal Skullcap (<i>root</i>)

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>
7.	Baikal Skullcap FSE	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc. which is the manufacturer of the product which bears the statement(s) 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: **Zyflamend®.**

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

- (Statement 13): Source of large number of antioxidant and inflammatory modulatory compounds (31) according to USDA database.
- (Statement 14): Unique baicalin phytonutrient complex, naturally promotes healthy inflammation response.
- (Statement 15): Practitioner's Guide to using **NewMark™ 's Zyflamend®** in Clinical Practice; allergy support, antioxidant, blood sugar support, bone support, cardiovascular support, cognitive support, detoxification support, gastrointestinal support, healthy inflammation support, immune support, joint/connective tissue, men's health, nutritional support during cancer treatment.

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>
13.	Oregano (<i>leaf</i>)
14.	Baikal Skullcap (<i>root</i>)
15.	Rosemary (<i>leaf</i>), Turmeric (<i>rhizome</i>), Ginger (<i>rhizome</i>), Holy Basil (<i>leaf</i>), Green Tea (<i>leaf</i>), Hu Zhang (<i>root and rhizome</i>), Chinese Goldthread (<i>root</i>), Barberry (<i>root</i>), Oregano (<i>leaf</i>), Baikal Skullcap (<i>root</i>)

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>
13.	Zyflamend®	Labeling
14.	Zyflamend®	Labeling
15.	Zyflamend®	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

**NOTIFICATION PURSUANT TO
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AND 21 CFR §101.93**

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **MWOI: Women's Synbiotic Nutrients.**

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

- (Statement 4): **Optimal Stress Response** – The soothing benefits of chamomile and lavender are combined and enhanced with the adaptogenic effects of eleuthero and American ginseng.
 (Statement 5): **Proprietary Blend of Superfoods and Spices** – Features what is considered by many to be the world's most important functional foods and herbs for health and longevity: organic spinach, organic blueberry, turmeric, and ginger.
 (Statement 6): Practitioner's Guide to using **NewMark™'s Women's Synbiotic Nutrients** in Clinical Practice; allergy support, antioxidant, bone support, daily nutritional support, hormone balance, immune support, nutritional support during cancer treatment, skin health, women's 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>
4.	Chamomile (<i>flower</i>), Lavender (<i>flower</i>), Eleuthero (<i>root</i>), and American Ginseng (<i>root</i>)
5.	Organic Spinach (<i>leaf</i>), Organic Blueberry (<i>fruit</i>), Turmeric (<i>rhizome</i>), and Ginger (<i>rhizome</i>).

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>
4.	MWOI: Women's Synbiotic Nutrients	Labeling
5.	MWOI: Women's Synbiotic Nutrients	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
 Stephanie Roach
 Quality Control Technician
 Date: June 5, 2006

JUN - 8 2006

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

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **Turmeric FSE.**

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

- (Statement 1): Powerful antioxidant, detoxification support, and promotes a healthy inflammation response.
- (Statement 2): Turmeric is a traditional Indian spice and medicine that has been researched for its ability to promote a healthy inflammation response, support cardiovascular health, and support normal cell growth.
- (Statement 3): Practitioner's Guide to using **NewMark™ 's Turmeric FSE** in Clinical Practice; antioxidant, cardiovascular support, cholesterol support, cognitive support, detoxification support, gastrointestinal support, healthy inflammation response, immune support, joint/connective tissue support, nutritional support during cancer treatment, skin 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.	Turmeric (<i>rhizome</i>)
2.	Turmeric (<i>rhizome</i>)
3.	Turmeric (<i>rhizome</i>)

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.	Turmeric FSE	Labeling
2.	Turmeric FSE	Labeling
3.	Turmeric FSE	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949
1

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc. which is the manufacturer of the product which bears the statement(s) 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: **MWOI: Men's Synbiotic Nutrients.**

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

- (Statement 3): Proprietary Blend of Superfoods and Spices – Features what is considered by many to be the world's most important functional foods and herbs for health and longevity: organic spinach, organic blueberry, turmeric, and ginger.
 (Statement 4): Practitioner's Guide to using **NewMark™'s Men's Synbiotic Nutrients** in Clinical Practice; allergy support, antioxidant, bone support, daily nutritional support, hormone balance, immune support, men's health, nutritional support during cancer treatment, skin 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>
3.	Organic spinach (<i>leaf</i>), organic blueberry (<i>fruit</i>), Turmeric (<i>rhizome</i>), and Ginger (<i>rhizome</i>).
4.	Vitamin C, Vitamin D, Vitamin E, Vitamin K, Vitamin B1, Vitamin B2, Niacin, Vitamin B6, Folate, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Mixed Carotenoids, Schizandra (<i>berry</i>), Maca (<i>root</i>), Artichoke (<i>leaf</i>), Fenugreek (<i>seed</i>), Cinnamon (<i>bark</i>), Oregano (<i>leaf</i>), Cumin (<i>seed</i>), Coriander (<i>seed</i>), Rosemary (<i>leaf</i>), Clove (<i>bud</i>), Allspice (<i>berry</i>), Peppermint (<i>leaf</i>), organic Spinach (<i>leaf</i>), Soy Lecithin, organic Blueberry (<i>fruit</i>), Turmeric (<i>rhizome</i>), Ginger (<i>rhizome</i>)

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>
3.	MWOI: Men's Synbiotic Nutrients	Labeling
4.	MWOI: Men's Synbiotic Nutrients	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
 Stephanie Roach
 Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **LifeShield®**.

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

(Statement 4): **LifeShield** is the ultimate herbal antioxidant formula for support of normal cell growth.

(Statement 5): Practitioner's Guide to using **NewMark™ 's LifeShield** in Clinical Practice; antioxidant, cardiovascular support, detoxification support, healthy inflammation response, nutritional support during cancer treatment.

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>
4.	Turmeric (<i>rhizome</i>), Green Tea (<i>leaf</i>), Clove (<i>bud</i>), Ginger (<i>rhizome</i>), Parsley (<i>seed</i>), Peppermint (<i>leaf</i>), Rosemary (<i>leaf</i>)
5.	Turmeric (<i>rhizome</i>), Green Tea (<i>leaf</i>), Clove (<i>bud</i>), Ginger (<i>rhizome</i>), Parsley (<i>seed</i>), Peppermint (<i>leaf</i>), Rosemary (<i>leaf</i>)

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>
4.	LifeShield®	Labeling
5.	LifeShield®	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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:
MWOI: Host Defense®.

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

(Statement 3): Practitioner's Guide to using **NewMark™ 's Host Defense** in Clinical Practice; allergy support, cardiovascular support, cholesterol support, healthy inflammation response, immune support, joint/connective tissue support, nutritional support during cancer treatment.

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>
3.	Organic Maitake (<i>mycelium</i>), organic The Brazilian Blazei (<i>mycelium</i>), organic Shaga (<i>mycelium</i>), organic Reishi (<i>mycelium</i>), organic Cordyceps (<i>mycelium</i>), organic Mesima (<i>mycelium</i>), organic Yun Zhi (<i>mycelium</i>), organic Lion's Mane (<i>mycelium</i>), organic Maitake (<i>fruitbodies</i>), organic Artist's Cronk (<i>mycelium</i>), organic Oregon Polypore (<i>mycelium</i>), organic Agarikon (<i>mycelium</i>), organic Ice Man Fungus (<i>mycelium</i>), organic Shiitake (<i>mycelium</i>), Organic Birch Polypore (<i>mycelium</i>), organic Suehirotake (<i>mycelium</i>)

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>
3.	MWOI: Host Defense®	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949₃

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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:
Holy Basil FSE.

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

(Statement 4): Practitioner's Guide to using **NewMark™ 's Holy Basil FSE** in Clinical Practice; adrenal/stress support, blood sugar support, detoxification support, energy support/stamina, healthy inflammation response, mood support, nutritional support during cancer treatment.

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>
4.	Holy Basil (<i>leaf</i>)

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>
4.	Holy Basil FSE	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

**NOTIFICATION PURSUANT TO
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AND 21 CFR §101.93**

JUN - 8, 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **MWOI: GWT 1000.**

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

- (Statement 1): Antioxidant, detoxification support, promotes a healthy inflammation response.
(Statement 2): According to major university data bases, green tea contains at least 51 phytonutrients shown to promote a healthy inflammation response, confer profound cardiovascular and cellular protection, support detoxification, and support a healthy metabolism.
(Statement 3): Practitioner's Guide to using **NewMark™ 's GWT 1000** in Clinical Practice; antioxidant, blood sugar support, cardiovascular support, cholesterol support, detoxification support, energy support/stamina, healthy inflammation response, immune support, nutritional support during cancer treatment, weight management.

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.	Organic extracts of White Peony and Green Sencha Teas (<i>leaf</i>)
2.	Organic extracts of White Peony and Green Sencha Teas (<i>leaf</i>)
3.	Organic extracts of White Peony and Green Sencha Teas (<i>leaf</i>)

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.	MWOI: GWT 1000	Labeling
2.	MWOI: GWT 1000	Labeling
3.	MWOI: GWT 1000	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

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

JUL 1 3 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: Gastro Complete.

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

- (Statement 1): Support for intestinal health.
- (Statement 2): Gastro Complete is designed to soothe the gastrointestinal tract, promote healthy immune function, reduce the formation of toxins in the bowel, support healthy microflora balance, and support normal bowel function.
- (Statement 3): Practitioner's Guide to using **NewMark™'s Gastro Complete** in Clinical Practice; allergy support, detoxification support, gastrointestinal support, healthy inflammation response, immune support, nutritional support during cancer treatment.

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.	Okra (<i>fruit</i>), organic Spinach (<i>leaf</i>), organic Blueberry (<i>fruit</i>), organic Cumin (<i>seed</i>), organic Ginger (<i>rhizome</i>), Chlorella Regularis, Nutritional yeast, organic Soy
2.	Okra (<i>fruit</i>), organic Spinach (<i>leaf</i>), organic Blueberry (<i>fruit</i>), organic Cumin (<i>seed</i>), organic Ginger (<i>rhizome</i>), Chlorella Regularis, Nutritional yeast, organic Soy
3.	Okra (<i>fruit</i>), organic Spinach (<i>leaf</i>), organic Blueberry (<i>fruit</i>), organic Cumin (<i>seed</i>), organic Ginger (<i>rhizome</i>), Chlorella Regularis, Nutritional yeast, organic Soy

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.	Gastro Complete	Labeling
2.	Gastro Complete	Labeling
3.	Gastro Complete	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: Ginger Tonic.

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

- (Statement 1): Enhances digestion and relieves nausea.
(Statement 2): Ginger supports healthy digestion, promotes a healthy inflammation response, promotes platelet health and cardiovascular function, and increases the absorption and utilization of other herbs and nutrients by as much as 2-2.5 times.
(Statement 3): Practitioner's Guide to using **NewMark™'s Ginger Tonic** in Clinical Practice; gastrointestinal support, healthy inflammation response, nutritional support during cancer treatment.

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.	Organic Honey, Ginger Juice (<i>rhizome</i>), organic Ginger extract (<i>rhizome</i>)
2.	Organic Honey, Ginger Juice (<i>rhizome</i>), organic Ginger extract (<i>rhizome</i>)
3.	Organic Honey, Ginger Juice (<i>rhizome</i>), organic Ginger extract (<i>rhizome</i>)

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.	Ginger Tonic	Labeling
2.	Ginger Tonic	Labeling
3.	Ginger Tonic	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **Organic Fruits 'n Greens.**

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

(Statement 1): Practitioner's Guide to using **NewMark™ 's Fruits 'n Greens** in Clinical Practice; allergy support, antioxidant, blood sugar support, bone support, cardiovascular support, daily nutritional support, detoxification support, gastrointestinal support, hormone balance, healthy inflammation response, immune support, nutritional support during cancer treatment, weight management.

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>
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- | | |
|----|--|
| 1. | Organic Spinach, organic Blueberry, organic Kale, organic Parsley, organic Cranberry, organic Red Cabbage, organic Green Cabbage, organic Broccoli, organic Brussels Spouts, organic Okra, organic Papaya, organic Rose Hips, organic Pomegranate, organic Concord organic Grapes, organic Oats, organic Brown Rice, organic Turmeric, organic Ginger, organic Cinnamon, organic Chicory |
|----|--|

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. | Organic Fruits 'n Greens | Labeling |
|----|--------------------------|----------|

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **MWOI: E & Selenium.**

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

- (Statement 1): Gamma tocopherol, the predominant form of vitamin E found in food, has been found to be more effective than alpha-tocopherol, the primary supplemented form of vitamin E, at modulating lipid peroxidation and promoting a healthy inflammation response.
 (Statement 2): It is also essential for normal thyroid function and is a co-factor for glutathione peroxidase, an important defense against oxidative damage.
 (Statement 3): Practitioner's Guide to using **NewMark™'s E & Selenium** in Clinical Practice; antioxidant, cardiovascular support, daily nutritional support, detoxification support, nutritional support during cancer treatment, thyroid support.

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.	Vitamin E
2.	Selenium
3.	Vitamin E, Selenium, Cinnamon (<i>bark</i>), Fenugreek (<i>seed</i>), Oregano (<i>leaf</i>), Cumin (<i>seed</i>), Coriander (<i>seed</i>), Rosemary (<i>leaf</i>), Clove (<i>bud</i>), Allspice (<i>berry</i>), Peppermint (<i>leaf</i>), organic Spinach (<i>leaf</i>), organic Blueberry (<i>fruit</i>), Turmeric (<i>rhizome</i>), Ginger (<i>rhizome</i>)

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.	MWOI: E & Selenium	Labeling
2.	MWOI: E & Selenium	Labeling
3.	MWOI: E & Selenium	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
 Stephanie Roach
 Quality Control Technician

Date: June 5, 2006

06-4949
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JUN - 8 2006

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

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **MWOI: Daily Synbiotic Nutrients.**

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

(Statement 1): Practitioner's guide to using **NewMark™ 's Daily Synbiotic Nutrients** in Clinical Practice; antioxidant, bone support, daily nutritional support, immune support, nutritional support during cancer treatment, skin 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.	Vitamin C, Vitamin D, Vitamin E, Vitamin K, Vitamin B1, Vitamin B2, Niacin, Vitamin B6, Folate, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Iron, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, GTF Chromium, Molybdenum, Potassium, Mixed Carotenoids, and Soy Lecithin.

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.	MWOI: Daily Synbiotic Nutrients	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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:
Cruciferous Complex.

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

(Statement 4): Furthermore, cruciferous compounds have been shown to alleviate the negative effects of estrogen by promoting a healthy ratio of 2-OH/16-OH-estrogen
(Statement 5): Practitioner's Guide to using **NewMark™'s Cruciferous Complex** in Clinical Practice; cardiovascular support, detoxification support, hormone balance, nutritional support during cancer treatment, skin health, women's 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>
4.	Organic Broccoli (<i>sprouted seed</i>), organic Cauliflower (<i>sprouted seeds</i>), organic Daikon Radish (<i>sprouted seeds</i>), organic Cabbage (<i>sprouted seeds</i>), organic mustard (<i>sprouted seeds</i>), organic Kale (<i>sprouted seeds</i>)
5.	Organic Broccoli (<i>sprouted seed</i>), organic Cauliflower (<i>sprouted seeds</i>), organic Daikon Radish (<i>sprouted seeds</i>), organic Cabbage (<i>sprouted seeds</i>), organic mustard (<i>sprouted seeds</i>), organic Kale (<i>sprouted seeds</i>)

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>
4.	Cruciferous Complex	Labeling
5.	Cruciferous Complex	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **A New Paradigm in Efficacy: CoQ10+.**

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

(Statement 4): Practitioner's Guide to using **NewMark™'s CoQ10+** in Clinical Practice; antioxidant, blood sugar support, cardiovascular support, cognitive support, energy support/stamina, immune support, nutritional support during cancer treatment.

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>
4.	CoQ10

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>
4.	A New Paradigm in Efficacy: CoQ10+	Labeling

I, Stephanie Roach am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

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

JUN - 8 2006

This notification is being filed on behalf of NewMark: A Division of New Chapter, Inc., which is the manufacturer of the product which bears the statement(s) 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: **Blueberry Probiotic Complex.**

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

(Statement 7): Practitioner's Guide to using **NewMark™ 's Blueberry Probiotic Complex** in Clinical Practice; allergy support, antioxidant, blood sugar support, cardiovascular support, cognitive support, detoxification support, gastrointestinal support, healthy inflammation response, immune support, nutritional support during cancer treatment.

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>
7.	Organic Blueberry (<i>fruit</i>), organic Lemon (<i>peel</i>), organic Green Tea (<i>leaf</i>), organic Parsley (<i>leaf</i>), organic Cumin (<i>seed</i>), organic Ginger (<i>rhizome</i>), organic Soy, organic Blackstrap molasses

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>
7.	Blueberry Probiotic Complex	Labeling

I, Stephanie Roach, am authorized to certify this Notification on behalf of NewMark: A Division 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.

Signed By: Stephanie Roach
Stephanie Roach
Quality Control Technician

Date: June 5, 2006

06-4949