



MAY 22 2000

MAY 25 2001

Ms. Alison Sargent  
Graphics Coordinator  
New Chapter, Inc.  
22 High Street  
P.O. Box 1947  
Brattleboro, Vermont 05302

Dear Ms. Sargent:

This is in response to your letter of April 28, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that New Chapter, Inc. is making the following claims, among others, for the following products:

**Iron**

"Iron is especially useful...when there is blood loss from injury or surgery"

**Aloe Vera 200™**

"Promotes wound healing"  
"Reduces inflammation"

**Zingiforce™**

"...naturally reducing inflammation throughout the body"  
"Reduces inflammation"

**Supercritical DHA 100™**

"Reduces inflammation"  
"Counters a wide range of inflammatory compounds..."

**Zyflamend PM™**

"...reduces inflammation"  
"...a scientific breakthrough in herbal...inflammation reduction"

**Neurozyme™**

"Traditionally used to treat inflammation"  
"...reduce COX-2 initiated inflammation"  
"Counters a wide range of inflammatory compounds..."  
"...reduce inflammation"

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**Zyflamend™**

- "...reduces inflammation"
- "...a scientific breakthrough in herbal...inflammation reduction"
- "...naturally inhibits inflammatory COX-2"
- "...significantly multiplying anti-inflammatory effect..."
- "...inhibits both inflammatory COX and 5-LOX..."
- "...contains 51 anti-inflammatory phytonutrients"
- "...inhibits inflammatory COX-2"
- "...inhibit inflammatory COX-2"
- "Source of largest number of anti-inflammatory compounds..."

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, cure or mitigate diseases, such as inflammatory disorders, injuries, and consequences of surgery. 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, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also states that you are making claims for a product named **Tea Tree Plus™**. This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(I) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

**Tea Tree Plus™** is not a product "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(I) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(I) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product that appears to represent itself as an aromatherapy product and as a gargle is not subject to regulation as a dietary supplement because it is not "intended for ingestion."

Moreover, this product is represented to have "antimicrobial properties perfect for cold and flu season." As discussed above, 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 **Tea Tree Plus**™ suggest that it is intended to treat, prevent, cure or mitigate diseases, namely, infectious diseases and cold and influenza. 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 regulation under the drug provisions of the Act.

Please contact us if you require 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

Page 4 - Ms. Alison Sargent

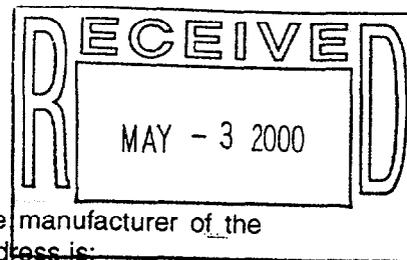
Copies:

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, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 Barnett, Dorsey, Nickerson)  
f/t:HFS-811:rjm:5/19/00:docname:70550.adv:disc47

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Zyflamend PM™.

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

- (Statement 1) : Inhibits the COX-2 enzyme and reduces inflammation
- (Statement 2) : Gently and safely promotes the experience of deep and satisfying sleep
- (Statement 3) : Promotes healthy joint function
- (Statement 4) : Promotes structural health and balances bone resorption
- (Statement 5) : Contains organic herbal anti-aging constituents that inactivate free radicals

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.                      | Hops, Chamomile, Feverfew, Holy Basil, Scutellaria, Ginger, Turmeric                         |
| 2.                      | Hops, Chamomile  |
| 3.                      | Hops, Holy Basil, Ginger, Turmeric   |
| 4.                      | Hops   |
| 5.                      | Ginger, Turmeric   |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zyflamend PM      | Label & Labeling          |
| 2.                      | Zyflamend PM      | Label & Labeling          |
| 3.                      | Zyflamend PM      | Label & Labeling          |
| 4.                      | Zyflamend PM      | Label & Labeling          |
| 5.                      | Zyflamend PM      | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: AC 2 SJA Graphics Coordinator  
(Name, Title)

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**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Zyflamend PM™.

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

- (Statement 6) : New Chapter's patent-pending Zyflamend PM™ formulation represents a scientific breakthrough in herbal COX-2 inhibition and inflammation reduction
- (Statement 7) : In addition, recent scientific studies also suggest that COX-2 inhibition may serve an important function in promoting normal cell growth in the colon, pancreas, breast tissue, and other organ systems
- (Statement 8) : This nighttime formulation is also designed to naturally promote deeply restful and satisfying sleep
- (Statement 9) : New Chapter has extensively researched the herbal pharmacopoeia and international medical databases and discovered that the following time-tested herbs, properly extracted and blended in the correct proportions, contain at least 8 phytonutrients that may safely and significantly inhibit COX-2 and gently and safely promote the experience of deep and satisfying sleep

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> |
|-------------------------|--|
| 6.                      | Hops, Chamomile, Feverfew, Holy Basil, Scutellaria, Ginger, Turmeric                         |
| 7.                      | Hops, Chamomile, Feverfew, Holy Basil, Scutellaria, Ginger                                   |
| 8.                      | Hops, Chamomile  |
| 9.                      | Hops, Chamomile, Feverfew, Holy Basil, Scutellaria, Ginger, Turmeric                         |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 6.                      | Zyflamend PM      | Label & Labeling          |
| 7.                      | Zyflamend PM      | Label & Labeling          |
| 8.                      | Zyflamend PM      | Label & Labeling          |
| 9.                      | Zyflamend PM      | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent, Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Zyflamend PM™.

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

- (Statement 10): Supercritical extract marked for humulone, a potent COX-2 inhibitor that also significantly promotes structural health and balances bone resorption.
- (Statement 11): Dual extracts Potency Assured™ to include COX-2 inhibitor apigenin. Traditionally used to support a natural state of deep restfulness.
- (Statement 12): Supercritical extract marked for parthenolide, a proven COX-2 inhibitor, promoting normal cerebral vascular activity and body temperature.
- (Statement 13): Contains the powerful COX-2 inhibitor ursolic acid, which significantly enhances detoxification and reduces inflammation

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> |
|-------------------------|--|
| 10.                     | Hops   |
| 11.                     | Chamomile  |
| 12.                     | Feverfew   |
| 13.                     | Holy Basil (Ocimum Sanctum)  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 10.                     | Zyflamend PM      | Label & Labeling          |
| 11.                     | Zyflamend PM      | Label & Labeling          |
| 12.                     | Zyflamend PM      | Label & Labeling          |
| 13.                     | Zyflamend PM      | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Aliz Srgt Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend PM™**.

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

(Statement 14): Contains COX-2 inhibitor baicalein, traditionally recognized for its calming influence.

(Statement 15): Supercritical extract inhibits both inflammatory COX-2 and 5-LO and offers numerous anti-aging constituents.

(Statement 16): Delivers curcumin and other essential anti-aging phytonutrients that inactivate free radicals and reduce inflammation.

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> |
|-------------------------|--|
| 14.                     | Scutellaria  |
| 15.                     | Ginger   |
| 16.                     | Turmeric   |

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

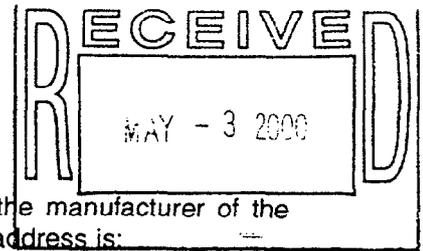
| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 14.                     | Zyflamend PM      | Label & Labeling          |
| 15.                     | Zyflamend PM      | Label & Labeling          |
| 16.                     | Zyflamend PM      | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Iron

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

(Statement 1) : Iron is especially useful during pregnancy, menstruation and when there is blood loss from injury or surgery.

(Statement 2) : Eleuthero/Lemon Balm herbal extract complex supports digestion and adaptation to stress

(Statement 3) :

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.                      | Iron Wholefood Complex   |
| 2.                      | Eleuthero/Lemon Balm herbal extract complex  |
| 3.                      |  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Iron              | Labeling                  |
| 2.                      | Iron              | Labeling                  |
| 3.                      |                   |                           |

I, Alison Sargent, 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 is truthful and not misleading

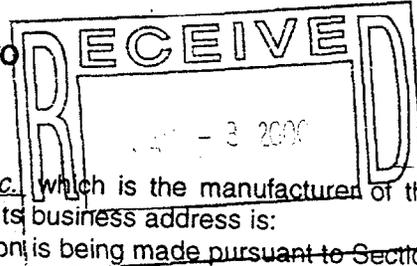
Date Signed: April 28, 2000

By: Alison Sargent, Graphics Coordinator  
(Name, Title)

(Revised 4/00)

705

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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Aloe Vera 200™.

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

(Statement 1) : Promotes wound healing

(Statement 2) : Reduces inflammation

(Statement 3) : Supports immune function

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.                      | Freeze-dried Aloe Vera juice concentrate   |
| 2.                      | Freeze-dried Aloe Vera juice concentrate   |
| 3.                      | Freeze-dried Aloe Vera juice concentrate   |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Aloe Vera 200     | Labeling                  |
| 2.                      | Aloe Vera 200     | Labeling                  |
| 3.                      | Aloe Vera 200     | Labeling                  |

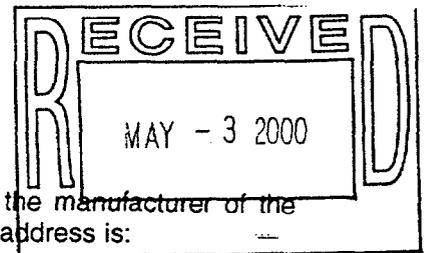
I, Alison Sargent, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function is truthful and not misleading

Date Signed: April 26, 2000

By: Dir Int Graphics Center  
(Name, Title)

70550

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zingiforce™**.

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

(Statement 1) : Recent scientific studies, including one published in the *Proceedings of the National Academy of Sciences*, suggests that 5-lipoxygenase inhibition may serve an important role in supporting normal cell growth and activity in a number of the body's organ systems.

(Statement 2) : Scientific research further supports Zingiforce as an effective prostaglandin modulator, naturally reducing inflammation throughout the body.

(Statement 3) : Zingiforce promotes fat-digesting bile and starch-digesting saliva.

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.                      | Ginger/Rosemary  |
| 2.                      | Ginger/Rosemary  |
| 3.                      | Ginger/Rosemary  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zingiforce        | Label & Labeling          |
| 2.                      | Zingiforce        | Label & Labeling          |
| 3.                      | Zingiforce        | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

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705-50

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Zingiforce™.

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

(Statement 4) : The active ingredients of Zingiforce promote the growth of beneficial intestinal microorganisms, which are vital for intestinal health.

(Statement 5) : Zingiforce contains at least 12 anti-aging and cardiotoxic constituents that inactivate oxygen free-radicals, some of these constituents being up to 40 times more effective than Vitamin E.

(Statement 6) : Supports stomach, liver and intestinal health

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> |
|-------------------------|--|
| 4.                      | Ginger/Rosemary  |
| 5.                      | Ginger/Rosemary  |
| 6.                      | Ginger/Rosemary  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 4.                      | Zingiforce        | Label & Labeling          |
| 5.                      | Zingiforce        | Label & Labeling          |
| 6.                      | Zingiforce        | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 20, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zingiforce™**.

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

(Statement 7) : Reduces inflammation

(Statement 8) : Contains certified organic herbal anti-aging constituents that inactivate free-radicals

(Statement 9) : Supports blood platelet health and cardiovascular function

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> |
|-------------------------|--|
| 7.                      | Ginger/Rosemary  |
| 8.                      | Ginger/Rosemary  |
| 9.                      | Ginger/Rosemary  |

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

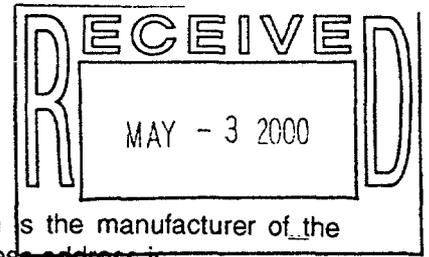
| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 7.                      | Zingiforce        | Label & Labeling          |
| 8.                      | Zingiforce        | Label & Labeling          |
| 9.                      | Zingiforce        | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent, Director  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical DHA 100™**.

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

- (Statement 1) : Supports brain health and neuronal membrane integrity
- (Statement 2) : Reduces inflammation
- (Statement 3) : DHA is a fundamental building block of cellular membranes, most notably neuronal membranes in the brain
- (Statement 4) : According to USDA, nature's richest known source of the phytonutrient called eugenol, which enhances the metabolism of DHA, inactivates free radicals and promotes nerve cell health

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.                      | DHA  |
| 2.                      | Ginger   |
| 3.                      | DHA  |
| 4.                      | Clove  |

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

| <u>Statement Number</u> | <u>Brand Name</u>     | <u>Label or Labeling?</u> |
|-------------------------|-----------------------|---------------------------|
| 1.                      | Supercritical DHA 100 | Label & Labeling          |
| 2.                      | Supercritical DHA 100 | Label & Labeling          |
| 3.                      | Supercritical DHA 100 | Label & Labeling          |
| 4.                      | Supercritical DHA 100 | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title) 170551

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

This notification is being filled 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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Supercritical DHA 100™.

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

- (Statement 5) : Counters a wide range of inflammatory compounds, offers many anti-aging constituents that inactivate disruptive free radicals.
- (Statement 6) : Nature's rich source of anti-aging constituents, including phytonutrients that optimize memory.
- (Statement 7) : Recognized in Traditional Chinese and Indian Ayurvedic traditions to promote calmness and mental clarity
- (Statement 8) : Delivers curcumin and other essential anti-aging phytonutrients that inactivate free radicals

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> |
|-------------------------|--|
| 5.                      | Ginger   |
| 6.                      | Rosemary   |
| 7.                      | Sage   |
| 8.                      | Turmeric   |

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

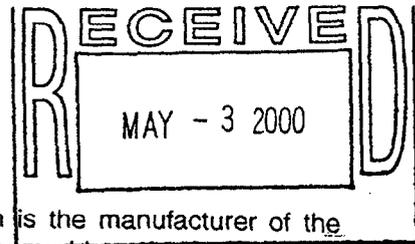
| <u>Statement Number</u> | <u>Brand Name</u>     | <u>Label or Labeling?</u> |
|-------------------------|-----------------------|---------------------------|
| 5.                      | Supercritical DHA 100 | Label & Labeling          |
| 6.                      | Supercritical DHA 100 | Label & Labeling          |
| 7.                      | Supercritical DHA 100 | Label & Labeling          |
| 8.                      | Supercritical DHA 100 | Label & Labeling          |

I, Alien Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alien Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Neurozyme™**.

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

- (Statement 1) : Promotes mental clarity
- (Statement 2) : Inhibits acetylcholinesterase, supports neurotransmission
- (Statement 3) : Modulates beta amyloid oxidation, supports normal cerebrovascular health
- (Statement 4) : Reduces cortisol
- (Statement 5) : Neurozyme™ brings together a multifaceted and patent-pending formulation of these scientifically and traditionally confirmed herbal supports, which provide a safe and easy method to promote the long-term clarity of our mental functioning

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.                      | Ginkgo, Bacopa, Red Wine, Melissa, Sage   |
| 2.                      | Ashwaganda, Chinese Club Moss, DHA, Rosemary, Paeonia   |
| 3.                      | Cat's Claw, DHA, Clove  |
| 4.                      | Chamomile, Holy Basil   |
| 5.                      | Ginkgo, Cat's Claw, Gotu Kola, Ashwaganda, Chinese Club Moss, Bacopa, DHA, Clove, Rosemary, Chamomile, Holy Basil, Red Wine, Melissa, Ginger, Sage, Turmeric, Paeonia |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Neurozyme         | Label & Labeling          |
| 2.                      | Neurozyme         | Label & Labeling          |
| 3.                      | Neurozyme         | Label & Labeling          |
| 4.                      | Neurozyme         | Label & Labeling          |
| 5.                      | Neurozyme         | Label & Labeling          |

I, Allison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Allison Sargent Graphics Coordinator  
(Name, Title)

170550

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Neurozyme™.

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

- (Statement 6) : Used by millions and confirmed in scientific research to promote neuro transmissions and enhance cognitive function
- (Statement 7) : Recent research at the Federation of Societies for Experimental Biology showed a modulating effect on beta amyloid oxidation and a significant synergy with ginkgo
- (Statement 8) : Traditionally revered in India for memory enhancement and shown in scientific research to counter beta amyloid oxidation
- (Statement 9) : Traditionally regarded in India to support mental clarity, shown in recent research to increase stress tolerance and counter acetylcholinesterase

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> |
|-------------------------|--|
| 6.                      | Ginkgo   |
| 7.                      | Cat's Claw   |
| 8.                      | Gotu Kola  |
| 9.                      | Ashwaganda   |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 6.                      | Neurozyme         | Label & Labeling          |
| 7.                      | Neurozyme         | Label & Labeling          |
| 8.                      | Neurozyme         | Label & Labeling          |
| 9.                      | Neurozyme         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 23, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Neurozyme™**.

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

(Statement 10): Traditionally used to treat inflammation, shown in modern research to counter acetylcholinesterase

(Statement 11): Traditionally regarded for anti-anxiety and anti-fatigue effects, recent research shows "bacosides" support mental clarity and learning

(Statement 12): Supports brain health and neuronal membrane integrity

(Statement 13): According to USDA, nature's richest known source of the phytonutrient called eugenol which accentuates DHA Omega 3 and is shown to inactivate free radicals like superoxide and promote nerve cell health

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> |
|-------------------------|--|
| 10.                     | Chinese Club Moss  |
| 11.                     | Bacopa   |
| 12.                     | DHA  |
| 13.                     | Clove  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 10.                     | Neurozyme         | Label & Labeling          |
| 11.                     | Neurozyme         | Label & Labeling          |
| 12.                     | Neurozyme         | Label & Labeling          |
| 13.                     | Neurozyme         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Neurozyme™.

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

- (Statement 14): The traditionally revered "memory herb" which USDA database confirms contains at least 8 phytonutrients to inhibit the neurotransmission "challenger" acetylcholinesterase
- (Statement 15): Dual extracts offer stress cortisol reduction and phytonutrients apigenin and ursolic acid to reduce COX-2 initiated inflammation
- (Statement 16): A rich source of phytonutrients including specific flavonoids that are shown in epidemiological research to be associated with mental clarity and healthy mental functioning
- (Statement 17): Reported historically to "renew youth" and "strengthen the brain," recent research shows it contains multiple phytonutrients that concentrate in the hippocampus "learning center"

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> |
|-------------------------|--|
| 14.                     | Rosemary   |
| 15.                     | Chamomile, Holy Basil  |
| 16.                     | Red Wine   |
| 17.                     | Melissa  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 14.                     | Neurozyme         | Label & Labeling          |
| 15.                     | Neurozyme         | Label & Labeling          |
| 16.                     | Neurozyme         | Label & Labeling          |
| 17.                     | Neurozyme         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Neurozyme™.

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

- (Statement 18): Counters a wide range of inflammatory compounds, offers many anti-aging constituents that inactivate disruptive free radicals
- (Statement 19): Recognized in Traditional Chinese and Indian Ayurvedic traditions to promote calmness and mental clarity
- (Statement 20): Delivers curcumin and other essential anti-aging phytonutrients that inactivate free radicals and reduce inflammation
- (Statement 21): Revered in Traditional Chinese Medicine as a systemic tonic, contains phytonutrients that support healthy neurotransmission

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> |
|-------------------------|--|
| 18.                     | Ginger   |
| 19.                     | Sage   |
| 20.                     | Turmeric   |
| 21.                     | Paeonia  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 18.                     | Neurozyme         | Label & Labeling          |
| 19.                     | Neurozyme         | Label & Labeling          |
| 20.                     | Neurozyme         | Label & Labeling          |
| 21.                     | Neurozyme         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the 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 1) : New Chapter's patent pending Zyflamend™ formulation represents a scientific breakthrough in herbal COX-2 inhibition and inflammation reduction.

(Statement 2) : In addition, recent scientific studies also suggest that COX-2 inhibition may serve an important function in promoting normal cell growth in the colon, pancreas, breast tissue and other organ systems.

(Statement 3) : Contains the powerful COX-2 inhibitor ursolic acid, which significantly enhances detoxification and reduces inflammation.

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.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |
| 2.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |
| 3.                      | Holy Basil  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zyflamend         | Label & Labeling          |
| 2.                      | Zyflamend         | Label & Labeling          |
| 3.                      | Zyflamend         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

70550

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the 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 1) : Unique curcumin phytonutrient complex, naturally inhibits inflammatory COX-2; synergistic with green tea, significantly multiplying anti-inflammatory effect of green tea polyphenols.

(Statement 2) : Supercritical extract inhibits both inflammatory COX and 5-LOX and offers numerous anti-aging constituents.

(Statement 3) : *Proceedings of the National Academy of Sciences* report green tea polyphenols markedly reduce COX-2. Major university database notes green tea contains 51 anti-inflammatory phytonutrients.

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.                      | Turmeric   |
| 2.                      | Ginger   |
| 3.                      | Green Tea  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zyflamend         | Label & Labeling          |
| 2.                      | Zyflamend         | Label & Labeling          |
| 3.                      | Zyflamend         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the 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 1) : Dual extracts offer highly concentrated, full spectrum, COX-2 inhibition and support detoxification.

(Statement 2) : Richest known resveratrol source, shown scientifically to inhibit inflammatory COX-2.

(Statement 3) : Unique berberine phytonutrient complex, naturally inhibits inflammatory COX-2.

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.                      | Rosemary   |
| 2.                      | Huzhang  |
| 3.                      | Chinese Goldthread & Barberry  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zyflamend         | Label & Labeling          |
| 2.                      | Zyflamend         | Label & Labeling          |
| 3.                      | Zyflamend         | Label & Labeling          |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 23, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the 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 1) : Source of largest number of anti-inflammatory compounds (31) according to *USDA database*.
- (Statement 2) : Unique baicalin phytonutrient complex, naturally inhibits inflammatory COX-2.
- (Statement 3) : New Chapter has extensively researched the herbal pharmacopoeia and international medical databases and discovered that the following time-tested herbs, properly extracted and blended in the correct proportions, contain at least 8 phytonutrients that may safely and significantly inhibit COX-2.
- (Statement 4) : Reduces inflammation

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.                      | Oregano   |
| 2.                      | Scutellaria   |
| 3.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |
| 4.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zyflamend         | Label & Labeling          |
| 2.                      | Zyflamend         | Label & Labeling          |
| 3.                      | Zyflamend         | Label & Labeling          |
| 4.                      | Zyflamend         | Label                     |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Alison Sargent Graphics Coordinator  
(Name, Title)

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the 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 1) : Promotes healthy joint function.
- (Statement 2) : Inhibits cyclooxygenase-2 (COX-2) and promotes normal cell growth
- (Statement 3) : Contains organic herbal anti-aging constituents that inactivate free-radicals
- (Statement 4) : Inhibits the COX-2 enzyme and reduces inflammation

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.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |
| 2.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |
| 3.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |
| 4.                      | Holy Basil, Turmeric, Ginger, Green Tea, Rosemary, Huzhang, Chinese Goldthread, Barberry, Oregano & Scutellaria |

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

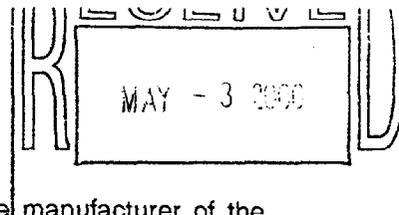
| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Zyflamend         | Label & Labeling          |
| 2.                      | Zyflamend         | Label                     |
| 3.                      | Zyflamend         | Label & Labeling          |
| 4.                      | Zyflamend         | Labeling                  |

I, Alison Sargent, 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 is truthful and not misleading

Date Signed: April 29, 2000

By: Miz S. A. Graphics Coordinator

**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: 22 High Street, P.O. Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of the DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Tea Tree Plus™

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

(Statement 1) : Aromatherapy essential oils with profound uplifting, tension-relieving and antimicrobial properties perfect for cold and flu season

(Statement 2) : The ultimate gargle to support immune system health

(Statement 3) : Excellent blended with olive oil to relieve muscle tension

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.                      | Oils of Peppermint, Eucalyptus & Tea Tree  |
| 2.                      | Oils of Peppermint, Eucalyptus & Tea Tree  |
| 3.                      | Oils of Peppermint, Eucalyptus & Tea Tree  |

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

| <u>Statement Number</u> | <u>Brand Name</u> | <u>Label or Labeling?</u> |
|-------------------------|-------------------|---------------------------|
| 1.                      | Tea Tree Plus     | Labeling                  |
| 2.                      | Tea Tree Plus     | Labeling                  |
| 3.                      | Tea Tree Plus     | Labeling                  |

I, Alison Scragg, 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 is truthful and not misleading

Date Signed: April 28, 2000

By: Aiz J. J. Graphics Coordinator  
(Name, Title)

70530