



4000 '03 JUN 24 A6:20

JUN -9 2003

Ms. Margaret E. Kilroy  
Quality Assurance Technician  
New Chapter, Inc.  
22 High Street  
PO Box 1947  
Brattleboro, Vermont 05302

Dear Ms. Kilroy:

This is in response to your letter of May 13, 2003 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 claim, among others, for the product **Headache Relief**:

“Blocks the formation of inflammatory prostaglandins.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, in conjunction with the name of the product (i.e., Headache Relief), suggests that it is intended to prevent disease (i.e., headaches). 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. 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 20852.

975-0163

LET 703

Page 2 - Ms. Margaret E. Kilroy

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

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

**Copies:**

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

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

RECEIVED  
MAY 21 2003  
BY

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 St. 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 Headache Relief.

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

(Statement 1): Full spectrum parthenolides from supercritically extracted feverfew, supporting normal cerebral vascular blood flow.

(Statement 2): Blocks the formation of inflammatory prostaglandins.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Feverfew
2.	Feverfew, Green Tea, Wintergreen, Ginger, Meadowsweet, Purple Willow, California Poppy, Rosemary, Lavender, Hops, Valerian

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.	Headache Relief	Label and Labeling
2.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 20003 By: Margaret E. Kilroy, Quality Assurance Technician  
[Name]  
[Title]

84482  
1

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

This notification is being filed on behalf of New Chapter, Inc., which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. 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 Headache Relief.

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

(Statement 3): Used historically to approach many different kinds of pain including cramping and fevers, the London Migraine Clinic declares that feverfew offers the best studied relief for headache discomfort.

(Statement 4): Used in Europe since ancient times to counter headaches, rosemary is one of nature's best researched herbs for relief from oxidative stress, a condition that can lead to the common headache.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
3.	Feverfew
4.	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>
3.	Headache Relief	Label and Labeling
4.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 2003 By: Margaret E. Kilroy, QA Technician  
[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 St. 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 Headache Relief.

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

(Statement 5): An herb that has been known for centuries as a response to occasional stress, lavender helps promote a calm and peaceful mind.

(Statement 6): Used for thousands of years for relief from headaches and other painful conditions, recent research shows that ginger possesses numerous constituents that can inhibit that formation of inflammatory prostaglandins.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
5.	Lavender
6.	Ginger

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.	Headache Relief	Label and Labeling
6.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 2003 By: Margaret E. Kilroy, QA Technician  
[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 St. 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 Headache Relief.

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

(Statement 7): Humankind's most popular and healthful herbal beverage, research at prestigious medical universities shows green tea and its naturally occurring caffeine content can help counter headache discomfort.

(Statement 8): One of the most sacred therapeutic herbs in Celtic tradition and recommended in ancient Ayurvedic medicine for pain and stomach complaints, meadowsweet is now recognized as a rich source of anti-inflammatory salicylic acid.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statements</u>
7.	Green Tea
8.	Meadowsweet

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.	Headache Relief	Label and Labeling
8.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 2003 By: Margaret E. Kilroy, QA Technician  
 [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 St. 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 Headache Relief.

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

(Statement 9: Native Americans crushed the leaves to relieve strained muscles and inflammations, the herb is today recognized as one of nature's richest sources of anti-inflammatory salicylic acid.

(Statement 10): Noted by the Greek physician Hippocrates as a valuable herb for pain relief, the herb is now recommended in European pharmacopoeias for its gentle anti-inflammatory benefits.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statements</u>
9.	Wintergreen
10.	Purple Willow

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>
9.	Headache Relief	Label and Labeling
10.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 2003 By: Margaret E. Kilroy, QA Technician  
[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 St. 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 Headache Relief.

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

(Statement 11): Used traditionally by Native Americans for its sedative properties, recent French research confirms the poppy's anti-stress effects and ability to significantly improve sleep.

(Statement 12): Scientific research has clearly identified that the parthenolides within the feverfew flower have singular value in providing headache relief.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statements</u>
11.	California Poppy
12.	Feverfew

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>
11.	Headache Relief	Label and Labeling
12.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 2003 By: Margaret Eckelroy, QA Technician  
[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 St. 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 Headache Relief.

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

(Statement 13): *New Chapter's* exclusive supercritical CO2 extraction creates a uniquely high potency and stable parthenolide content enhanced with an array of nature's best recognized and synergistic herbs to promote comfort and release from the common headache.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statements</u>
13.	Feverfew, Green Tea, Wintergreen, Ginger, Meadowsweet, Purple Willow, California Poppy, Rosemary, Lavender, Hops, Valerian

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>
13.	Headache Relief	Label and Labeling

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

Date Signed: May 13, 2003 By: Margaret E. Kilroy, QA Technician  
[Name]  
[Title]