



0814 6 SEP 25 P2:43

SEP 18 2006

Ms. Ashley Chapin
Regulatory Compliance Administrator
New Chapter, Inc.
90 Technology Drive
P.O. Box 1947
Brattleboro, Vermont 05302

Dear Ms. Chapin:

This is in response to your letter of August 25, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that New Chapter, Inc. is making the following claims for the product **Headache Relief**:

“Headache Relief.”

“Used historically to approach many different kinds of pain...fevers...best-studied relief for headache discomfort by the London Migraine Clinic.”

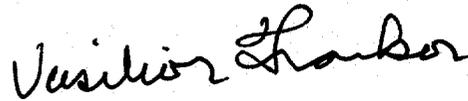
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent,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

97S 0163 LET 901

Page 2 - Ms. Ashley Chapin

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.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-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**

SEP - 8 2006

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

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

- (Statement 1): Headache Relief
- (Statement 2): Supporting normal cerebrovascular blood flow.
- (Statement 3): Effective Herbal Relief

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.	Feverfew, Green Tea, Wintergreen, Ginger, Meadowsweet, Purple Willow, California Poppy, Rosemary, Lavender, Hops, Valerian
2.	Feverfew, Green Tea, Wintergreen, Ginger, Meadowsweet, Purple Willow, California Poppy, Rosemary, Lavender, Hops, Valerian
3.	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</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Headache Relief™ *	Label
2.	Headache Relief™ *	Label
3.	Headache Relief™ *	Label

I, Ashley Chapin, 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.

Signed By: Ashley Chapin
Ashley Chapin
Regulatory Compliance Administrator

Date: Sept. 1, 2000e

#1773

06-7042

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

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

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

(Statement 4): Used historically to approach many different kinds of pain including cramps and fevers, feverfew has also been declared the best-studied relief for headache discomfort by the London Migraine Clinic.

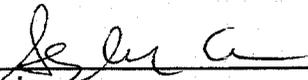
The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
4.	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</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
4.	Headache Relief™ *	Label

I, Ashley Chapin, 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.

Signed By: 
Ashley Chapin
Regulatory Compliance Administrator

Date: Sept. 1, 20006