



MAY 17 2007

2007 5 7 10:23 AM

Ms. Ashley Chapin
New Chapter, Inc.
90 Technology Drive
PO Box 1947
Brattleboro, Vermont 05302

Dear Ms. Chapin:

This is in response to your letters of May 8, 2007 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 products:

Prostate 5LX

“Recent scientific research...suggests that New Chapter’s supercritically extracted Saw Palmetto has been used successfully for the treatment of benign [prostatic] hyperplasia and prostatitis.”

Zyflamend

“[U]sed to dispel heat or fever...”

“[N]ormalize temperature.”

“[H]ealthy inflammation response is key to prmoting [sic] healthy joint function...”

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 (for example, benign prostatic hypertrophy and prostatitis, arthritis, fevers). 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 your client intends to make claims of this nature, they 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.

1997S-0163

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Page 2 - Ms. Ashley Chapin

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios H. Frankos". The signature is fluid and cursive, with the first name "Vasilios" being more prominent and the last name "Frankos" written in a more compact, connected style.

Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

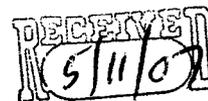
Copies:

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



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 **Prostate 5LX®.**

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

(Statement 1): Modulates 5-lipoxygenase and promotes normal prostate cell growth.

(Statement 2): New Chapter's Prostate 5LX formulation contains supercritical extracts of Ginger, which as reflected in the USDA and major university phytochemical databases, is nature's richest herbal source of 5-LX (5-lipoxygenase enzymes) modulates (24 phyto-nutrient modulators).

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.	Saw Palmetto, Green Tea, Urtica, Ginger, Selenium, Rosemary
2.	Saw Palmetto, Green Tea, Urtica, Ginger, Selenium, Rosemary

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.	Prostate 5LX	Label and Labeling
2.	Prostate 5LX	Label and Labeling

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: May 8, 2007

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07-3371

**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 **Prostate 5LX®**.

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

(Statement 6): Recent scientific research at the Institut fur Pharmazeutische Biologie, Munich, Germany suggests that New Chapter's supercritically extracted Saw Palmetto has been used successfully for the treatment of benign hyperplasia and prostatitis.

(Statement 7): In this in vitro study, New Chapter's supercritical Saw Palmetto was found to modulate COX-2 and 5-LX, while fractioned Saw Palmetto showed no modulation of 5-LX.

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>
6.	Saw Palmetto
7.	Saw Palmetto

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>
6.	Prostate 5LX	Label and Labeling
7.	Prostate 5LX	Label and Labeling

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 C
Ashley Chapin

May 8, 2007

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 Zyflamend®.

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

(Statement 1): Researchers at major U.S. universities have subjected the culinary herb to the rigors of modern science and discovered it possesses some of the most effective free-radical scavenging or anti-aging constituents known in nature.

(Statement 2): In traditional healing systems, Hu zhang was used to treat a wide range of imbalances, including those challenging the skin, immune, and cardiovascular systems.

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.	Rosemary (<i>leaf</i>)
2.	Hu Zhang (<i>root and 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.	Zyflamend®	Label and Labeling
2.	Zyflamend®	Label and Labeling

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: May 8, 2007

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

(Statement 3): It is the same molecule that is believed to be responsible for the beneficial cardiovascular and positive inflammation-modulating effects of red wine.

(Statement 4): Chinese goldenthread has been used in Chinese herbal medicine for thousands of years to "dispel heat" and support digestive and immune functions.

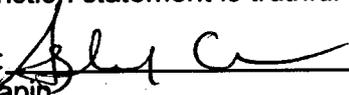
The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
3.	Hu Zhang (<i>root and rhizome</i>)
4.	Chinese Goldthread (<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>
3.	Zyflamend®	Label and Labeling
4.	Zyflamend®	Label and Labeling

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

(Statement 5): Native Americans also used it to dispel heat or fever and heal digestive imbalances.

(Statement 6): Famous healers and scholars from ancient Greece and Rome such as Hippocrates and Pliny regarded oregano as a valuable healing plant for digestive and respiratory imbalances.

(Statement 7): In traditional Chinese medicine, baikal skullcap was used to counter toxicity and to normalize temperature

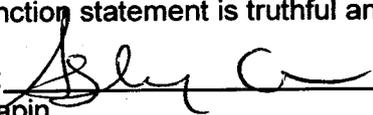
The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
5.	Chinese Goldthread (<i>root</i>)
6.	Oregano(<i>leaf</i>)
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>
5.	Zyflamend®	Label and Labeling
6.	Zyflamend®	Label and Labeling
7.	Zyflamend®	Label and Labeling

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

(Statement 8): While a certain amount of Omega 6 fats are required for health, an imbalance of Omega 6 fats relative to Omega 3 fats (obtained from high quality nuts, seeds, and fish oil) has been shown to promote inflammation.

(Statement 9): Dual-extracts (both supercritical and hydroethanolic extracts) of Zyflamend's herbs provide the broadest spectrum of both fat and water soluble herbal constituents, maximizing synergies and therapeutic effect.

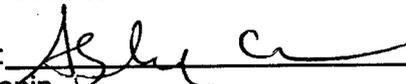
The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
8.	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>) and Baikal Skullcap(<i>root</i>).
9.	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>) and 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>
8.	Zyflamend®	Label and Labeling
9.	Zyflamend®	Label and Labeling

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

(Statement 10): According to recent market research data, Zyflamend is now America's #1 selling herbal response for inflammation in the natural products industry.

(Statement 11): Researchers from numerous prestigious medical research universities all seem to agree that a healthy inflammation response is key to promoting healthy joint function, normal cell growth, and cardiovascular health.

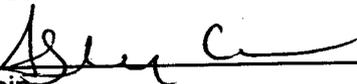
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<u>Statement</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
10.	Rosemary (leaf), Turmeric(rhizome), Ginger(rhizome), Holy Basil(leaf), Green Tea(leaf), Hu Zhang(root and rhizome)), Chinese Goldthread(root), Barberry(root), Oregano(leaf) and Baikal Skullcap(root).
11.	Rosemary (leaf), Turmeric(rhizome), Ginger(rhizome), Holy Basil(leaf), Green Tea(leaf), Hu Zhang(root and rhizome)), Chinese Goldthread(root), Barberry(root), Oregano(leaf) and Baikal Skullcap(root).

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>
10.	Zyflamend®	Label and Labeling
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