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DEC 23 2005

Ms. Kristin Foster  
Quality Assurance Administrator  
New Chapter, Inc.  
22 High Street  
P.O. Box 1947  
Brattleboro, Vermont 05302

Dear Ms. Foster:

This is in response to your letter of December 12, 2005 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 claim "[R]educed fatigue associated with chemotherapy" for the product Zyflamend.

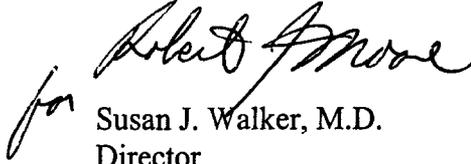
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product (i.e., that it will prevent a consequence of a disease therapy that is itself a disease within the meaning of 21 CFR 101.93(g)(1)) suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker". The signature is written in a cursive style and is positioned to the left of the typed name.

Susan J. Walker, M.D.

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**

DEC 19 2005

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 **Zyflamend®**

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

(Statement 1): In April 2003, research was presented on a comprehensive New Chapter® program, including Zyflamend, which significantly reduced fatigue associated with chemotherapy.

(Statement 2): I say this because modern science now recognizes that the health of major organ systems – immune, cardiovascular, metabolic, skeletal, the brain – is intimately connected to a healthy inflammation response, and Zyflamend represents the finest herbal approach to supporting a well-functioning inflammatory process.

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

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

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

<b><u>Statement Number</u></b>	<b><u>Brand Name</u></b>	<b><u>Label or Labeling?</u></b>
1.	Zyflamend®	Labeling
2.	Zyflamend®	Labeling

I, Kristin Foster 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 Dec 19, 2005 By: Kristin Foster, Quality Assurance Administrator  
[Name]  
[Title]

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