



FEB 20 2007

151 7 10 10 2 05

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

Dear Ms. Chapin:

This is in response to your letter of February 2, 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)) on behalf of Sarah's Tea, Inc. Your submission stated that New Chapter, Inc. is making the following claims, among others, for the product **Cinnamonforce**:

“[H]as the ability to lower cholesterol and potentially reverse the course of obesity.”

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 diseases (i.e., hypercholesterolemia and obesity). 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.

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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 "Vasilios Frankos". The signature is written in a cursive style with a long, sweeping tail on the final letter.

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

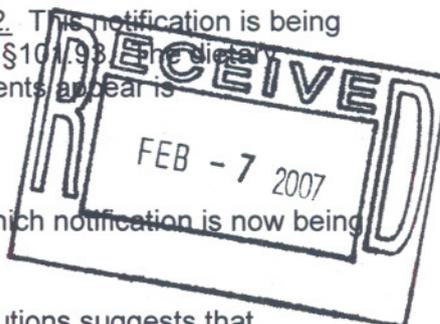
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

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

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

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 **Cinnamonforce™**.



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

(Statement 1): Research from numerous prestigious institutions suggests that cinnamon, an ancient spice, possesses a unique power - it assists the body's conversion of sugar into energy and has the ability to lower cholesterol and potentially reverse the course of obesity.

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>
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1.	Cinnamon
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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.	Cinnamonforce	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: Feb. 2, 2007

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