



APR - 9 2007

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

Dear Ms. Chapin:

This is in response to your letter of March 14, 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 claim “[T]o keep blood pressure where it belongs. In the normal range” and “[F]or optimal blood pressure-balancing effects.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claims you are making for this product, including the name of the product, represent that the product is intended to affect blood pressure but do not also include a statement about them being intended to affect blood pressure that is already in the normal range, they are implied disease claims.

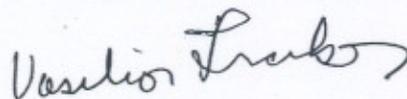
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases. 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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Page 2 - Ms. Ashley Chapin

Please contact us if you require further assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Vasilios Frankos". The signature is written in a cursive style with a long, sweeping tail on the final letter.

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 Compliance, HFR-NE240

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

RECEIVED
3/20/07

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 **Blood Pressure Take Care™.**

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

(Statement 1): A unique, patented, full spectrum extract of grape seed, discovered by scientists at the University of California, has been shown to keep blood pressure where it belongs. In the normal range.

(Statement 2): New Chapter's Blood Pressure Take Care™ delivers a safe, effective, and clinically studied all-natural extract and combines it with additional natural cardiosupportives for optimal blood pressure-balancing effects.

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.	FutureNatant, Grapeseed extract, Hawthorn, Motherwort, Grape Juice
2.	FutureNatant, Grapeseed extract, Hawthorn, Motherwort, Grape Juice

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.	Blood Pressure Take Care	Label and Labeling
2.	Blood Pressure Take Care	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: March 14, 2007

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