



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

079 7 10-1 110
JAN - 3 2007

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 letters of December 13, 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 claim, among others, for the products **Rhodiolaforce 100™** and **Rhodiolaforce 300™** :

“Rhodiola also protects the heart...preventing the kind of damage that can lead to heart attacks or heart failure.”

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 these products suggest that they are intended to treat, prevent, or mitigate disease, namely heart disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 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.

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

97S 0163 LET 920

Page 2 - Ms. Ashley Chapin

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-NE140

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

DEC 21 2016

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 **Rhodiolaforce 100™**.

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

(Statement 1): Thriving in high altitudes and in nature's most challenging climates, this most resilient herbal is intensively studied for calming stress, increasing energy, metabolism of fat, enhancing memory, and boosting the body's immune defenses.

(Statement 2): Rhodiola also protects the heart in several ways, including boosting the energy available to heart muscles, thereby preventing the kind of damage that can lead to heart attacks or heart failure.

(Statement 3): And its unique group of antioxidant compounds also helps protect cells and DNA from being damaged by unstable oxygen compounds.

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. | Rhodiola (<i>Rhodiola rosea</i>) |
| 2. | Rhodiola (<i>Rhodiola rosea</i>) |
| 3. | Rhodiola (<i>Rhodiola rosea</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.	Rhodiolaforce 100™	Labeling
2.	Rhodiolaforce 100™	Labeling
3.	Rhodiolaforce 100™	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: Dec. 13, 20016

06-9316

1830

**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 **Rhodiolaforce 300™**.

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

(Statement 1): Thriving in high altitudes and in nature's most challenging climates, this most resilient herbal is intensively studied for calming stress, increasing energy, metabolism of fat, enhancing memory, and boosting the body's immune defenses.

(Statement 2): Rhodiola also protects the heart in several ways, including boosting the energy available to heart muscles, thereby preventing the kind of damage that can lead to heart attacks or heart failure.

(Statement 3): And its unique group of antioxidant compounds also helps protect cells and DNA from being damaged by unstable oxygen compounds.

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.	Rhodiola (<i>Rhodiola rosea</i>)
2.	Rhodiola (<i>Rhodiola rosea</i>)
3.	Rhodiola (<i>Rhodiola rosea</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.	Rhodiolaforce 300™	Labeling
2.	Rhodiolaforce 300™	Labeling
3.	Rhodiolaforce 300™	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: Dec. 13, 20006

06-9316