



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

4002 '03 JUN 24 A6:20

JUN 11 2003

Mr. Margaret E. Kilroy  
Quality Assurance Technician  
New Chapter, Inc.  
22 High Street  
P.O. Box 1947  
Brattleboro, Vermont 05302

Dear Ms. Kilroy:

This is in response to your letter of May 22, 2003 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 product **Supercritical Cold 'n Flu™** :

“...promote comfort during the cold and flu season.”

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 (including the product name “Supercritical Cold 'n Flu) suggests that it is intended to treat, prevent, or mitigate diseases, namely the common cold and influenza. 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.

975-0163

LET 705

**Page 2 - Ms. Margaret E. Kilroy**

**Please contact us if we may be of further assistance.**

**Sincerely yours,**

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal stroke extending to the right.

**Susan J. Walker, M.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-300**

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

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

RECEIVED  
MAY 30 2003  
BY: \_\_\_\_\_

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: 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 Supercritical Cold 'n Flu™.

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

(Statement 1): One of nature's most important immune defenders; containing, according to the USDA, at least 36 supportive constituents including the antioxidant compound carvacrol.

(Statement 2): Fresh supercritical extract delivers the broadest spectrum of nature's most effective immuno-supportive organosulphur molecules.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Oregano
2.	Garlic

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Supercritical Cold 'n Flu™	Label and Labeling
2.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret Kilroy Quality Assurance Technician  
[Name]  
[Title]

1 82569

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 3): Combination of Potency Assured™ angustifolia and purpurea extracts synergize to optimally modulate and enhance healthy immune response.

(Statement 4): Israeli research has demonstrated significant potential of this fruit extract's components to support healthy immune function.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
3.	Echinacea
4.	Elderberry

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
3.	Supercritical Cold 'n Flu™	Label and Labeling
4.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret E. Kilroy Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 5): Long history of use in traditional medicine for its treasured immune-supportive benefits.

(Statement 6): Traditionally combined with goldenseal and shown to possess novel immunoactive compounds.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
5.	Goldenseal
6.	Myrrh

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
5.	Supercritical Cold 'n Flu™	Label and Labeling
6.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret E. Kilroy Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 7): Asian herb extract prized for its ability to modulate immune function with its unique Potency Assured™ compounds called andrographolides.

(Statement 8): A rich source of safe and effective compounds, like polyphenols, valued for countering unfriendly flora and balancing the immune system.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
7.	Andrographis paniculata
8.	Green Tea

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
7.	Supercritical Cold 'n Flu™	Label and Labeling
8.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret Kilroy Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 9): Revered Chinese herb valued in traditional medicine for immune support and in modern research for enhancing natural killer cell activities.

(Statement 10): Natural sources of salicylic acid and other important phytochemicals to promote comfort during the cold and flu season.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
9.	Astragalus
10.	Wintergreen, Meadowsweet, Purple Willow

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
9.	Supercritical Cold 'n Flu™	Label and Labeling
10.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret E. Kilroy, Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 11): Rich in antioxidant flavonoid compounds to reduce damage caused by free radical stress.

(Statement 12): Long revered for its immune supportive effects to the chest and throat, recent British research shows at least 12 phytochemicals with immune-defensive benefits.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
11.	Melissa
12.	Ginger

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
11.	Supercritical Cold 'n Flu™	Label and Labeling
12.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret E. Kilroy, Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 11): Rich in antioxidant flavonoid compounds to reduce damage caused by free radical stress.

(Statement 12): Long revered for its immune supportive effects to the chest and throat, recent British research shows at least 12 phytochemicals with immune-defensive benefits.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
11.	Melissa
12.	Ginger

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
11.	Supercritical Cold 'n Flu™	Label and Labeling
12.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret Kilroy, Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 13): Time tested remedy for soothing the digestive system and countering unfriendly flora.

(Statement 14): From India and Ayurvedic medicine comes Andrographis paniculata, which we extract to provide Potency Assured™ levels of andrographolides to modulate immune functioning.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
13.	Peppermint
14.	Andrographis paniculata

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
13.	Supercritical Cold 'n Flu™	Label and Labeling
14.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret E. Kilroy, Quality Assurance Technician  
 [Name]  
 [Title]

**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:

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 Supercritical Cold 'n Flu™.

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

(Statement 15): From China, we benefit from astragalus, an adaptogen that promotes immune strength and enhances natural killer cell capabilities.

(Statement 16): From Europe and Western herbal traditions we find immune support from oregano, garlic, echinacea, goldenseal, and elderberry.

(Statement 17): From Japan we treasure the immune balancing power of green tea.

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

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
15.	Astragalus
16.	Oregano, Garlic, Echinacea, Goldenseal, Elderberry
17.	Green Tea

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

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
15.	Supercritical Cold 'n Flu™	Label and Labeling
16.	Supercritical Cold 'n Flu™	Label and Labeling
17.	Supercritical Cold 'n Flu™	Label and Labeling

I, Margaret Kilroy, 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: 5/22, 2003 By: Margaret Kilroy, Quality Assurance Technician  
 [Name]  
 [Title]