



JUL 21 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 letters of June 20 and 24, 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 submissions state that New Chapter, Inc. is making the following claims, among others, for the following products:

Cold and Flu™

“Enhances immune resistance during cold and flu season;”

Aloe Vera 200™

Promotes wound healing;”

Green & White Tea

“...Lu Yu explained that tea cured....pains, and depression;”

Immortal Mushrooms™

“...support individuals undergoing radiation treatments;”

“Ideal for nutritional support during chemotherapy and radiation.”

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 these products (including the product name “Cold and Flu”) suggest that they are intended to treat, prevent, or mitigate diseases, namely the common cold and influenza, injuries, pain and depression. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

975-0163

LET 709

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 be '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

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

RECEIVED
JUL 10 2003
BY: _____

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 Immortal Mushrooms™.

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

(Statement 1): For profoundly enhanced immune functioning, for vigor and physical stamina, for lung health and athletic performance

(Statement 2): Considered the ultimate longevity tonic, supports cardiovascular, liver and nervous system 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>
1.	Vitamin C, Ginger, Reishi Mycelia, Shiitake Mycelia, Reishi Extract, Maitake Extract, Shiitake Extract, Cordyceps (<i>dong-chong-zia-cao</i>) Extract, Coriolus Extract
2.	Reishi

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.	Immortal Mushrooms™	Label
2.	Immortal Mushrooms™	Label

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: June 24, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
[Name]
[Title]

85036
1

**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 Immortal Mushrooms™.

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

(Statement 3): Recent Japanese research demonstrates that this mushroom uplifts multiple parameters of immune function including T cells and natural killer cells, and also assists normal blood sugar metabolism.

(Statement 4): Recognized as synergistic with Reishi and Cordyceps, the freeze dried proprietary LEM extract is potency assured for immunobalancing orally active polysaccharides.

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.	Maitake
4.	Shiitake

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.	Immortal Mushrooms™	Label
4.	Immortal Mushrooms™	Label

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: June 24, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
 [Name]
 [Title]

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

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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 Immortal Mushrooms™.

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

(Statement 5): Believed responsible for added endurance and vigor of gold medal winning Chinese Olympic team.

(Statement 6): Ideal to nutritionally support individuals undergoing radiation treatments.

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.	Cordyceps
6.	Coriolus

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.	Immortal Mushrooms™	Label
6.	Immortal Mushrooms™	Label

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: June 24, 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 Immortal Mushrooms™.

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

(Statement 7): Supports immune function and noted by Dr. Morishige MD, PhD, to maximize tonic mushroom efficacy.

(Statement 8): Powerful and multifaceted immune system enhancement.

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.	Vitamin C
8.	Vitamin C, Ginger, Reishi Mycelia, Shiitake Mycelia, Reishi Extract, Maitake Extract, Shiitake Extract, Cordyceps (<i>dong-chong-zia-cao</i>) Extract, Coriolus Extract

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.	Immortal Mushrooms™	Label
8.	Immortal Mushrooms™	Label and Labeling
9.		

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: June 24, 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 Immortal Mushrooms™.

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

(Statement 9): Ideal for nutritional support during chemotherapy and radiation treatments.

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.	Vitamin C, Ginger, Reishi Mycelia, Shiitake Mycelia, Reishi Extract, Maitake Extract, Shiitake Extract, Cordyceps (<i>dong-chong-zia-cao</i>) Extract, Coriolus Extract

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>
10.	Immortal Mushrooms™	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: June 24, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
[Name]
[Title]

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

JUL 14 2003

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 Green & White Tea.

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

(Statement 1): Delivers unique, synergistic white tea antioxidant polyphenols

(Statement 2): Profound cardiovascular and cellular protection

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.	White Peony Tea
2.	White Peony and Green Sencha 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>
1.	Green & White Tea	Label and Labeling
2.	Green & White Tea	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: June 20, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
[Name] [Title]

85023 1

**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 Green & White Tea.

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

(Statement 3): In 2737 B.C., a Chinese medical text exalted tea as a health tonic, and in 780 A.D. the Chinese tea master Lu Yu explained that tea cured aches, pains, and depression.

(Statement 4): In 1211, Eisai Myo-an, the founder of Zen Buddhism, praised tea as an elixir to promote good health and long life.

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.	White Peony and Green Sencha Tea
4.	White Peony and Green Sencha 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>
3.	Green & White Tea	Label and Labeling
4.	Green & White Tea	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: June 20, 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 Green & White Tea.

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

(Statement 5): By the end of the 20th century, scientists identified hundreds of beneficial phytonutrients within the tea leaf that were shown to dramatically enhance immune and cardiovascular functioning and prolong healthy life.

(Statement 6): In 2003, New Chapter[®] takes the world's finest certified organic white and green teas, extracts them at the perfect temperature, and delivers in concentrated form their full range of unique polyphenols for all to enjoy.

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.	White Peony and Green Sencha Tea
6.	White Peony and Green Sencha 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>
5.	Green & White Tea	Label and Labeling
6.	Green & White Tea	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: June 20, 2003 By: Margaret E. Kelly, Quality Assurance
 [Name] Technician
 [Title]

**NOTIFICATION PURSUANT TO
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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 Green & White Tea.

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

(Statement 7): Scientists have long associated this longevity with, in part, the Japanese people's regular consumption (often over 10 cups a day) of tea.

(Statement 8): Researchers at the Saitama Cancer Center Research Institute reported in 2000 that people who drank more than ten cups a day of tea experienced significantly better heart and immune system health than those who drank under three cups a day.

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.	White Peony and Green Sencha Tea
8.	White Peony and Green Sencha 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.	Green & White Tea	Label and Labeling
8.	Green & White Tea	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: June 20, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
 [Name]
 [Title]

**NOTIFICATION PURSUANT TO
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AND 21 CFR §101.93**

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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 Green & White Tea.

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

(Statement 9): Green and white teas are known to contain the highest concentration of health-promoting antioxidants.

(Statement 10): Increases thermogenesis, energy, and fat metabolism

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.	White Peony and Green Sencha Tea
10.	White Peony and Green Sencha 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>
9.	Green & White Tea	Label and Labeling
10.	Green & White Tea	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: June 20, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
 [Name]
 [Title]

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

JUL 14 2003

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 Cold and Flu™.

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

(Statement 1): Enhances immune resistance during cold and flu season

(Statement 2): 10 beneficial probiotics cultured in immune-boosting organic fruits, vegetables, and herbs

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.	American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria (<i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i>)
2.	American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria (<i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i>)

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.	Cold and Flu™	Label and Labeling
2.	Cold and 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: June 20, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
 [Name]
 [Title]

185023

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

JUL 14 2003

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 Aloe Vera 200™.

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

- (Statement 1): Induces glutathione detoxification enzymes
- (Statement 2): Delivers soothing polysaccharides to support healthy GI functioning
- (Statement 3): Our exclusive 200:1 concentrate of Aloe Vera is: Freeze-dried and certified organic

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.	Freeze dried Aloe Vera juice concentrate
2.	Freeze dried Aloe Vera juice concentrate
3.	Freeze dried Aloe Vera juice concentrate

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.	Aloe Vera 200™	Label
2.	Aloe Vera 200™	Label
3.	Aloe Vera 200™	Label

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: June 20, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
 [Name]
 [Title]

185023

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

JUL 14 2003

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 Aloe Vera 200™.

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

(Statement 4): Our exclusive 200:1 concentrate of Aloe Vera is: Equivalent (1 tablet) to two ounces of fresh juice.

(Statement 5): Our exclusive 200:1 concentrate of Aloe Vera is: A whole leaf extract, not simply the inner gel.

(Statement 6): Our exclusive 200:1 concentrate of Aloe Vera is: Extremely potent, containing 95% of the total naturally occurring polysaccharides.

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 Statemet</u>
4.	Freeze dried Aloe Vera juice concentrate
5.	Freeze dried Aloe Vera juice concentrate
6.	Freeze dried Aloe Vera juice concentrate

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>
4.	Aloe Vera 200™	Label
5.	Aloe Vera 200™	Label
6.	Aloe Vera 200™	Label

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: June 20, 2003 By: Margaret E. Keirny, 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 Aloe Vera 200™.

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

(Statement 7): Promotes wound healing

(Statement 8): Reduces inflammation

(Statement 9): Supports 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>
7.	Freeze dried Aloe Vera juice concentrate
8.	Freeze dried Aloe Vera juice concentrate
9.	Freeze dried Aloe Vera juice concentrate

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.	Aloe Vera 200™	Labeling
8.	Aloe Vera 200™	Labeling
9.	Aloe Vera 200™	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: June 20, 2003 By: Margaret E. Kilroy, Quality Assurance Technician
 [Name]
 [Title]