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APR - 3 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. *SP - must say "maintain"*

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.

975 0163 LET 935

Page 2 - Ms. Ashley Chapin

Please contact us if you require further assistance.

Sincerely yours,



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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07-1910



2431 6 APR 10 P1:59

MAR 29 2006

Mr. David Hsu  
New Century Company  
3392 Falcon Ridge Road  
Diamond Bar, California 91765

Dear Mr. Hsu:

This is in response to your letter of March 15, 2006 to the Food and Drug Administration (FDA), on behalf of your client Natural Health Care, Inc.<sup>1</sup>, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be made for the product Blood Pressure Formula:

“Helps to maintain healthy blood pressure.”

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, claims that do not establish that the claims are about blood pressure that is already within normal limits imply that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

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 suggests that it is intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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

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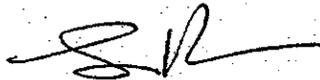
<sup>1</sup>Natural Health Care, Inc., 618 Reyes Dr., Walnut, CA 91789.

Page 2 - Mr. David Hsu

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 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.

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, Los Angeles District Office, Office of Compliance, HFR-PA240

**NEW CENTURY COMPANY**

3392 Falcon Ridge Rd., Diamond Bar, CA 91765 U.S.A.

Tel: (909) 861-7575 Fax: (909) 396-8706

Office of Nutritional Products,  
Labeling, and Dietary Supplement (HFS-810)  
CFSAN  
Food and Drug Administration  
5100 Paint Brush Parkway  
College Park, MD 20740

2006-2304

RECEIVED  
MAR 22 2006  
BY: HFS 810

March 15, 2006

**R. E. POST MARKET NOTIFICATION**

To whom it may concern,

As the authorized consultant, agent and official correspondent for the following importer, I am sending you their 4 product labels as enclosed for the post market notification.

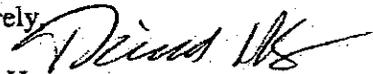
Importer / distributor:

Natural Health Care Inc.  
618 Reyes Dr.  
Walnut, CA 91789

Tel: (626) 617-7770, Fax: (909) 385-0344

Please let me know how it be accepted by FDA. If you need any other information, please feel free to call me or send letter to me.

Sincerely,



David Hsu

# 1637

**BLOOD PRESSURE FORMULA  
DIETARY SUPPLEMENT**

**Helps to maintain healthy blood pressure**

**Net weight: 2 oz. (60 grams), total 100 capsules**

**Product of China**

<b>Supplement Facts</b>	
<b>Serving size: 2 capsules</b>	
<b>Serving per container: 50</b>	
<b>Amount per serving</b>	<b>% Daily value</b>
Proprietary blend 1200 mg	*
Chinese skullcap ( <i>Scutellaria baicalensis</i> ) root 390 mg	*
Xia Ku Cao (Heal-all) ( <i>Prunella vulgaris</i> ) 320 mg	*
Jiu Hua ( <i>Chrysanthemum morifolium</i> ) flower 260 mg	*
Japanese sophora ( <i>Sophora Japonica</i> ) flower 230 mg	*
<b>*Daily value not established</b>	

**Inactive ingredient:** Gelatin

**Distributor:** Natural Health Care Inc.  
Walnut, CA 91789

This statement has not been evaluated by FDA, this product is not intended to diagnose, treat, cure, and prevent any disease.

**Directions:** Take 2 capsules each time, three times a day. Take with warm water.

**Storage:** Store at a dry and cool place.

**Warning:** Do not use if the bottle seal is broken or missing. Keep out of reach of children.



FEB - 4 2005

Mr. Dongning Wen  
President  
KNature Corporation  
2489 173<sup>rd</sup> Place NE  
Redmond, Washington 98052

Dear Mr. Wen:

This is in response to your letters of January 12, 2005 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 letters state that the following statement, among others, will be made for the product Evening Primrose Oil: "[M]aintain blood pressure."

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 a claim about the control of blood pressure: that is, a claim that does not establish that the claim is 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 claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

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 suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 20855.

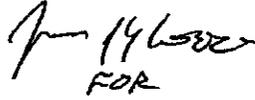
978-0163

LET 807

Page 2 - Mr. Dongning Wen

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker" with "FOR" written below it.

Susan J. Walker, M.D.

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, Seattle District Office, Office of Compliance, HFR-PA340

**KNATURE CORPORATION**

2489 173rd Pl. NE  
Redmond, WA 98052

Tel: (425) 649-2075; Email: knaturecorp@msn.com

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

*Rec'd*  
JAN 21 2005

Jan 12th, 2005

**Notification letter for Statement on Dietary Supplement**

Dear FDA officers:

I am the president of Knature Corporation, who is, among other things, a manufacturer and distributor of dietary supplements, mostly herbal products in the United States. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

Knature Corporation

2489 173rd Pl. NE  
Redmond, WA 98052

Tel: (425)649-2075,

*907044*

6. Intended Use:

This product is intended to be used by person over the age of 14.

Dosage: As a dietary supplement, take 1-2 soft gel, twice daily after meal.

**Warning:** Keep out of reach of children. If you are pregnant or lactating, or taking a prescription medication, consult a physician before using this product. To be kept in a cool and dry place.

7. Statement of Affirmation:

We, as a distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement ( as shown in No. 4 above ) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8. Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to another statement called disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement, The disclaimer reads:

**The statement has not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure, or prevent any disease.**

Should there be any question or comment, please contact the Vendor through the information in No. 2 above.

Sincerely,



Dongning Wen  
President

Enclosure

## Evening Primrose Oil

**Source of GLA  
Hexane Free  
Naturally Cold Pressed  
Dietary Supplement**

500 mg, 180 softgels

Evening Primrose Oil is a natural source of Omega-6 fatty acids with a guaranteed level of Gamma Linolenic Acid (GLA).

EPO helps to promote women's well-being. It can provide nutritional support for woman with PMS, Menstruation, Menopause.\*

EPO helps regulate fat metabolism, inflammatory response, hormones, as well as cardiovascular, immune and central nervous systems.\*

EPO also maintain blood pressure, sustain healthy skin and support joints.\*

Vitamin E is added to enhance long term freshness and ensure a more stable product without artificial preservatives.\*

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Directions: 1-2 softgel, twice daily after meal.

**Warning:**

Not recommended for male; or female under the age of 15. Consult your physician if you are on any type of medication. Keep out of reach of children.

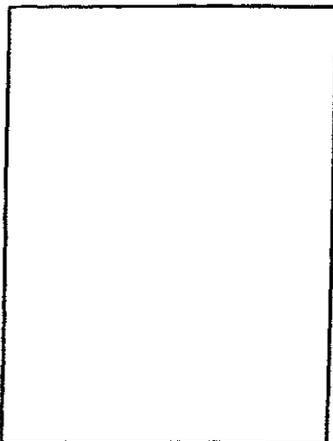
**Distributed by:**

Knature Corporation, Redmond, WA98052  
Tel: (425)649-2075.

Manufactured by: Sheng Sheng Pharmaceuticals Ltd., Co., China

Expire Date: Dec, 2009

### Nutrition Facts





DEC - 6 2004

Mr. Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Road  
Bloomington, Illinois 60108

Dear Mr. Roza:

This is in response to your letters of October 28, 2004 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 letters state that the following statements, among others, will be made for the product Hawthorne Extract: "[H]ealthy blood pressure."

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 claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

You also submitted a notification for the product Vein Supreme, which will use the claims "[P]roviding relief from the discomfort of symptoms associated with poor circulation, such as heaviness and swelling of the lower extremities" and "[M]inimize the occurrence of damaged, weakened blood vessels."

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 suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these product

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LET 799

Page 2 - Mr. Jim Roza

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 20855.

Please contact us if we may be of further assistance.

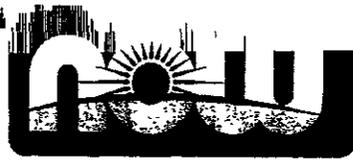
Sincerely yours,

*for Robert J. Moore*

Susan J. Walker, M.D.  
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, Chicago District Office, Office of Compliance, HFR-CE640



We Make Quality Affordable

October 28, 2004

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutritional Programs and Labeling  
200 C Street SW  
Washington, DC 20204

NOV 30 2004

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Vein Supreme, a dietary supplement.

Statements being made in the labeling of Vein Supreme:

(1) Vein Supreme is an herbal supplement containing the patented ingredient, Trunorin, which has been shown to support healthy vein function. In combination with Butcher's Broom (*Ruscus aculeatus*), Horse Chestnut Seed Extract (*Aesculus hippocastanum*), and Grape Seed Extract, NOW's Vein Supreme formula protects vascular integrity, [providing relief from the discomfort of symptoms associated with poor circulation, such as heaviness and swelling of the lower extremities. NOW Vein Supreme is a safe and natural way to enhance vascular tone, as well as to minimize the occurrence of damaged, weakened blood vessels.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Rd.  
Bloomington, IL 60108



We Make Quality Affordable

October 28, 2004

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutritional Programs and Labeling  
200 C Street SW  
Washington, DC 20204

NOV 30 2004

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Hawthorne Extract, a dietary supplement.

Statements being made in the labeling of Hawthorne Extract:

(1) Hawthorne leaves, flowers, and berries have been used for generations by herbalists as a cardiovascular tonic. Hawthorne supports cardiovascular health by enhancing cardiac muscular tone and vascular integrity. NOW Hawthorne Extract provides powerful antioxidant flavonoids, including standardized Vitexin that, along with other components in Hawthorne, have been found to support healthy blood flow and healthy blood pressure.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Rd.  
Bloomington, IL 60108

90292



7836 '03 NOV -3 P1:25

OCT 15 2003

Mr. Michael Schwartz  
President  
Michael's Naturopathic Programs  
6203 Woodlake Center  
San Antonio, Texas 78244

Dear Mr. Schwartz:

This is in response to your letters of August 26, 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)).

The product Michael's Naturopathic Programs Blood Pressure Factors uses the claim "maintain proper blood pressure." 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 claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

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 suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 20855.

975-0163

LET730

Page 2 - Mr. Michael Schwartz

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker".

Susan J. Walker, M.D.

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, Dallas District Office, Office of Compliance, HFR-SW140

**MICHAEL'S®**  
NATUROPATHIC PROGRAMS

6203 Woodlake Center • San Antonio, Texas 78244

August 26, 2003

Office of Nutritional Products, Labeling  
and Dietary Supplements (HFS-810)  
Center for Food and Safety and Applied Nutrition  
Food and Drug Administration  
5100 Point Branch Pkwy  
College Park, MD 20740

SEP 05 2003

Re: 21 U.S.C. Section 343(r)(6),  
Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the provisions of 21 CFR §101.93(a), your Agency is hereby notified that Michael's Naturopathic Programs has made statements of nutritional support for its dietary supplement(s) as follows:

**Product Name**

**Label Statement(s)**

Michael's Naturopathic Programs Vision Factors

Contains essential nutrients for proper support and maintenance of eye function

Michael's Naturopathic Programs Joint Mobility Factors

Contains essential nutrients for proper joint function & integrity

Michael's Naturopathic Programs Blood Pressure Factors

Nourishes & supports "feedback" system body uses to maintain proper blood pressure

Michael's Naturopathic Programs Estrogen Factors

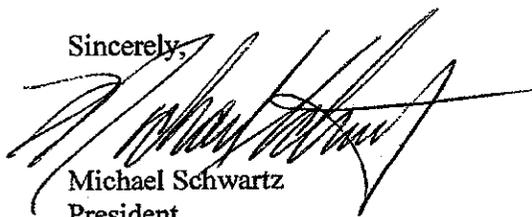
Provides essential nutrients to support the body in maintaining estrogen levels

PHONE: 210-661-8311 • FAX: 210-661-9145

8 5759

To the best of my knowledge and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete and that Michael's Naturopathic Programs possesses substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Schwartz", written over a horizontal line.

Michael Schwartz  
President  
Michael's Naturopathic Programs