



6262 '03 SEP 23 02:00
SEP 15 2003

Ms. Jill Bunn
Technical Manager
Arkopharma, LLC
19 Crosby Drive
Suite 300
Bedford, Massachusetts 01730

Dear Ms. Bunn:

This is in response to your letter of March 15, 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 Arkopharma, LLC, dba Health From The Sun, is making the following claim, among others, for its product **Perilla Oil**:

“...contains flavonoids, anthocyanins and phenolic compounds: antioxidant nutrients which play a role in allergies...”

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, namely allergies. 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 20852.

975-0163

LET 723

Page 2 - Ms. Jill Bunn

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 flourish extending to the right.

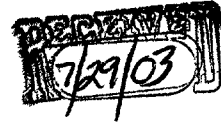
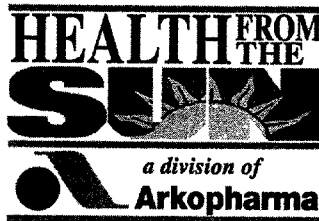
Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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



March 15, 2003

Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

Dear Sirs:

Pertinent letters of notification for each of the products listed below were submitted to the FDA's Office of Food Safety and Applied Nutrition on their respective dates. They each contained 3 copies of the name of the product being introduced, the text of claims made pertaining to the product and the ingredients subject to the claims made.

Products included:

Basikol (8 oz.)
The Woman's Oil (8 oz.)
Perilla Oil (8 oz.)

Notice was hereby given pursuant to the requirements of section 403(b) (21 U.S.C. 343r (6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma LLC, 22N. Main Street, Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the label:

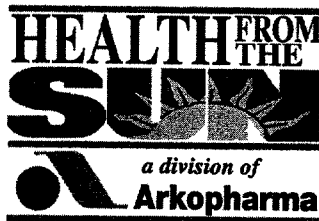
Please update your files accordingly with the information provided if they have not been done and do not hesitate to call me if you need further clarification.

Sincerely,

Bill Bunn
Technical Manager
Arkopharma, LLC
Phone: (781) 276-0505 x20
Fax: (781) 276-7335

8 5292

ARKOPHARMA, LLC dba HEALTH FROM THE SUN
SALES, MARKETING & FINANCE OFFICE
19 Crosby Drive, Suite 300, Bedford, MA 01730 Tel: 781•276•0505 Fax: 781•276•7334/7335
WAREHOUSE & DISTRIBUTION CENTER
22 North Main Street, Newport, NH 03773 Tel: 603•863•8075 Tel: 800•447•2229 Fax: 603•763•9159



March 20, 2003

Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403 (r) (6) (21 U.S.C. 343(r) (6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma LLC, 22N. Main Street, Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the label:

Text of Claims:

1. This special blend of omega-3 and omega-6 fatty acids from organic Flaxseed oil and Black Currant oil, plus immune-supporting flax lignans, vitamin E and rosemary, helps women maintain hormonal balance and promotes outward beauty that comes from inner harmony and health.
2. Fortify your diet with essential fats for overall health and vitality
3. Maintain glowing skin, shiny hair and strong nails
4. Promote hormonal balance

Name of Ingredients Subject to Claim: Organic Flaxseed Oil, Organic Flax Lignans, Black Currant oil, vitamin E and Rosemary.

Name of the Supplement: Health From The Sun The Woman's Oil (liquid and soft gel)

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that the statement is truthful and not misleading.

Sincerely

Jill Bunn

Technical Manager

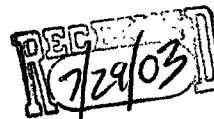
ARKOPHARMA, LLC dba HEALTH FROM THE SUN

SALES, MARKETING & FINANCE OFFICE

19 Crosby Drive, Suite 300, Bedford, MA 01730 Tel: 781•276•0505 Fax: 781•276•7334/7335

WAREHOUSE & DISTRIBUTION CENTER

22 North Main Street, Newport, NH 03773 Tel: 603•863•8075 Tel: 800•447•2229 Fax: 603•763•9159



March 15, 2003

Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(b)(6) (21 U.S.C. 343r (6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma LLC, 22N. Main Street, Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the label:

Text of Claims:

1. Omega-3 fatty acids are essential nutrients for you heart, brain, joints and skin, yet most people are not getting enough from their diet.
2. Perilla oil also contains flavonoids, anthocyanins and phenolic compounds: antioxidant nutrients which play a role in allergies and cardiovascular health.

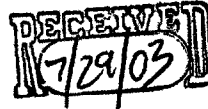
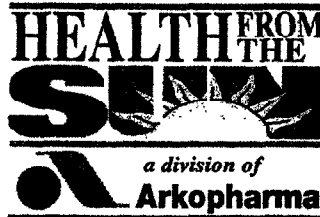
Name of the Supplement: Health From The Sun Perilla Oil 1000 (soft gel),
Health From The Sun Omega-3 Perilla Oil (liquid)
Name of Ingredients subject to claim: Perilla seed oil

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that statement is truthful and not misleading.

Sincerely,


Jill Bunn
Technical Manager

ARKOPHARMA, LLC dba HEALTH FROM THE SUN
SALES, MARKETING & FINANCE OFFICE
19 Crosby Drive, Suite 300, Bedford, MA 01730 Tel: 781•276•0505 Fax: 781•276•7334/7335
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March 15, 2003

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Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

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Text of Claims:

1. Omega-3 fatty acids are essential nutrients for you heart, brain, joints and skin, yet most people are not getting enough from their diet.
2. Perilla oil also contains flavonoids, anthocyanins and phenolic compounds: antioxidant nutrients which play a role in allergies and cardiovascular health.

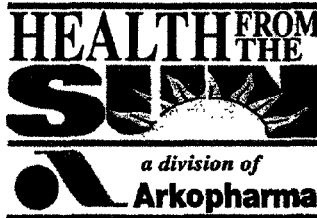
Name of the Supplement: Health From The Sun Perilla Oil 1000 (soft gel),
Health From The Sun Omega-3 Perilla Oil (liquid)
Name of Ingredients subject to claim: Perilla seed oil

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that statement is truthful and not misleading.

Sincerely,


Jill Bunn
Technical Manager

ARKOPHARMA, LLC dba HEALTH FROM THE SUN
SALES, MARKETING & FINANCE OFFICE
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March 15, 2003

Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

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Text of Claims:

1. Omega-3 fatty acids are essential nutrients for you heart, brain, joints and skin, yet most people are not getting enough from their diet.
2. Perilla oil also contains flavonoids, anthocyanins and phenolic compounds: antioxidant nutrients which play a role in allergies and cardiovascular health.

Name of the Supplement: Health From The Sun Perilla Oil 1000 (soft gel),
Health From The Sun Omega-3 Perilla Oil (liquid)
Name of Ingredients subject to claim: Perilla seed oil

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that statement is truthful and not misleading.

Sincerely,


Jill Bunn
Technical Manager

ARKOPHARMA, LLC dba HEALTH FROM THE SUN
SALES, MARKETING & FINANCE OFFICE
19 Crosby Drive, Suite 300, Bedford, MA 01730 Tel: 781•276•0505 Fax: 781•276•7334/7335
WAREHOUSE & DISTRIBUTION CENTER
22 North Main Street, Newport, NH 03773 Tel: 603•863•8075 Tel: 800•447•2229 Fax: 603•763•9159

- TRANS-FAT FREE
- INNER SEAL FOR LONG-LASTING FRESHNESS
- CHEMICAL-FREE EXTRACTION

Health From The Sun™ OMEGA-3 PERILLA OIL is cold expeller-pressed Perilla seed oil, one of nature's richest plant sources of omega-3 fatty acids. With a minimum of 55% omega-3 fatty acids, OMEGA-3 PERILLA OIL is an ideal vegetarian alternative to fish oil and an excellent alternative to flax seed oil. Omega-3 fatty acids are essential nutrients for your heart, brain, joints, and skin, yet most people are not getting enough from their diet.* Perilla oil also contains flavonoids, anthocyanins and phenolic compounds; antioxidant nutrients which play a role in allergies and cardiovascular health.* Perilla is derived from the plant *Perilla frutescens*, a member of the mint family.

INDEPENDENTLY TESTED TO GUARANTEE OIL QUALITY AND TRUTH-IN-LABELING.

MANUFACTURED FOLLOWING PHARMACEUTICAL GMPs (GOOD MANUFACTURING PRACTICES).

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

**HEALTH
FROM THE
SUN**

VEGETARIAN
**OMEGA-3
PERILLA
OIL**

OMEGA-3
ALTERNATIVE TO
FISH & FLAX OIL

Cold Expeller-Pressed

Unrefined

8 FL OZ

236 ML

Directions: One Tablespoon daily.

SUPPLEMENT FACTS

Serving Size 1 tbsp (15 ml)

Servings Per Container About 16

AMOUNT PER SERVING

Calories 125

Calories from Fat 125

% DAILY VALUE

Total Fat 14 g 22%*

Saturated Fat 1 g 5%*

Polyunsaturated Fat 11 g †

Monounsaturated Fat 2 g †

Alpha-Linolenic Acid (omega-3) 7700 mg †

Linoleic Acid (omega-6) 2100 mg †

Oleic Acid (omega-9) 1820 mg †

*Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.

INGREDIENTS: Perilla seed oil, rosemary extract, mixed tocopherols (vitamin E), ascorbyl palmitate (vitamin C) and citric acid to protect freshness.

May be taken by the spoonful or added to salad dressings, dips, yogurt, hot cereal, blender drinks or other foods. Do not apply direct heat.

REFRIGERATE AFTER OPENING.

Marketed by: Arkopharma, LLC

PO Box 179
Newport, NH 03773

www.healthfromthesun.com

800-447-2249

Product of Canada



- TRANS-FAT FREE
- INNER SEAL FOR LONG-LASTING FRESHNESS
- CHEMICAL-FREE EXTRACTION

Health From The Sun™ OMEGA-3 PERILLA OIL is cold expeller-pressed Perilla seed oil, one of nature's richest plant sources of omega-3 fatty acids. With a minimum of 55% omega-3 fatty acids, OMEGA-3 PERILLA OIL is an ideal vegetarian alternative to fish oil and an excellent alternative to flax seed oil. Omega-3 fatty acids are essential nutrients for your heart, brain, joints, and skin, yet most people are not getting enough from their diet.* Perilla oil also contains flavonoids, anthocyanins and phenolic compounds; antioxidant nutrients which play a role in allergies and cardiovascular health.* Perilla is derived from the plant *Perilla frutescens*, a member of the mint family.

INDEPENDENTLY TESTED TO GUARANTEE OIL QUALITY AND TRUTH-IN-LABELING.

MANUFACTURED FOLLOWING PHARMACEUTICAL GMPs (GOOD MANUFACTURING PRACTICES).

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

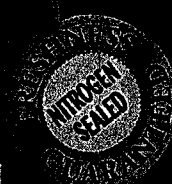
**HEALTH
FROM THE
SUN**

OMEGA-3 PERILLA OIL

OMEGA-3
ALTERNATIVE TO
FISH & FLAX OIL

Cold Expeller-Pressed

Unrefined



Directions: One Tablespoon daily.

SUPPLEMENT FACTS
Serving Size 1 tbsp (15 ml)
Servings Per Container About 16

AMOUNT PER SERVING	
Calories	125
Calories from Fat	125
% DAILY VALUE	
Total Fat	14 g 22%*
Saturated Fat	1 g 5%*
Polyunsaturated Fat	11 g †
Monounsaturated Fat	2 g †
Alpha-Linolenic Acid (omega-3)	7700 mg †
Linoleic Acid (omega-6)	2100 mg †
Oleic Acid (omega-9)	1820 mg †

*Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.

INGREDIENTS: Perilla seed oil, rosemary extract, mixed tocopherols (vitamin E), ascorbyl palmitate (vitamin C) and citric acid to protect freshness.

May be taken by the spoonful or added to salad dressings, dips, yogurt, hot cereal, blender drinks or other foods. Do not apply direct heat.

REFRIGERATE AFTER OPENING.

Marketed by: Arkopharma, LLC
PO Box 179
Newport, NH 03773
www.healthfromthesun.com
800-447-2249
Product of Canada



From Soil to Oil



8 FL OZ

236 ML

- TRANS-FAT FREE
- INNER SEAL FOR LONG-LASTING FRESHNESS
- CHEMICAL-FREE EXTRACTION

Health From The Sun™ OMEGA-3 PERILLA OIL is cold expeller-pressed Perilla seed oil, one of nature's richest plant sources of omega-3 fatty acids. With a minimum of 55% omega-3 fatty acids, OMEGA-3 PERILLA OIL is an ideal vegetarian alternative to fish oil and an excellent alternative to flax seed oil. Omega-3 fatty acids are essential nutrients for your heart, brain, joints, and skin, yet most people are not getting enough from their diet.* Perilla oil also contains flavonoids, anthocyanins and phenolic compounds; antioxidant nutrients which play a role in allergies and cardiovascular health.* Perilla is derived from the plant *Perilla frutescens*, a member of the mint family.

INDEPENDENTLY TESTED TO GUARANTEE OIL QUALITY AND TRUTH-IN-LABELING.

MANUFACTURED FOLLOWING PHARMACEUTICAL GMPs (GOOD MANUFACTURING PRACTICES).

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

**HEALTH
FROM THE
SUN**

OMEGA-3 PERILLA OIL

OMEGA-3
ALTERNATIVE TO
FISH & FLAX OIL

Cold Expeller-Pressed

Unrefined



Directions: One Tablespoon daily.

SUPPLEMENT FACTS

Serving Size 1 tbsp (15 ml)
Servings Per Container About 16

AMOUNT PER SERVING

Calories 125
Calories from Fat 125

% DAILY VALUE

Total Fat	14 g	22%*
Saturated Fat	1 g	5%*
Polyunsaturated Fat	11 g	†
Monounsaturated Fat	2 g	†

Alpha-Linolenic Acid (omega-3)	7700 mg †
Linoleic Acid (omega-6)	2100 mg †
Oleic Acid (omega-9)	1820 mg †

*Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.

INGREDIENTS: Perilla seed oil, rosemary extract, mixed tocopherols (vitamin E), ascorbyl palmitate (vitamin C) and citric acid to protect freshness.

May be taken by the spoonful or added to salad dressings, dips, yogurt, hot cereal, blender drinks or other foods. Do not apply direct heat.

REFRIGERATE AFTER OPENING.

Marketed by: Arkopharma, LLC

PO Box 179
Newport, NH 03773

www.healthfromthesun.com

800-447-2249

Product of Canada

8 FL OZ

236 ML

Health From The Sun™ **Perilla Oil 1000** is cold expeller-pressed Perilla seed oil, one of nature's richest plant sources of the omega-3 essential fatty acid, alpha-linolenic acid.

With 55% omega-3 fatty acids, perilla oil is an ideal vegetarian alternative to fish oil as well as an excellent alternative to Flax seed oil. In addition to omega-3 fatty acids which are so vital for your heart, brain, joints and skin, **Perilla Oil 1000** also contains flavonoids, anthocyanins and phenolic compounds, which are antioxidant nutrients that play a role in allergies and cardiovascular health.* Chemical-free extraction.

Independently tested to guarantee purity and truth-in-labeling.

Manufactured following pharmaceutical GMPs (Good Manufacturing Practices).

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

HEALTH
FROM THE
SUN

PERILLA OIL 1000

OMEGA-3 ALTERNATIVE
TO FISH & FLAX OIL

Cold Expeller-Pressed

Unrefined

90 SOFT GELS

1000 MG

Directions: Three to six capsules daily with food.

Supplement Facts

Serving Size 2 Capsules /
Servings Per Container: 45

Amount Per Serving	% Daily Value	
Calories	20	
Calories from Fat	20	
Total Fat	2g	3%*
Alpha-Linolenic Acid (Omega-3)	1100mg	†
Linoleic Acid (omega-6)	300mg	†
Oleic Acid (omega-9)	260mg	†

* Percent Daily Values are based on a 2000 calorie diet

† Daily Value not established

INGREDIENTS: Perilla seed oil, gelatin, glycerin and water.

Store in a cool dry place. Do not use if safety seal is broken or missing.

Marketed by: Arkopharma, LLC
PO Box 179, Newport, NH 03773
www.healthfromthesun.com
800-447-2249
Product of Canada

PROOF #6
10/30/02

Health From The Sun™ **Perilla Oil 1000** is cold expeller-pressed Perilla seed oil, one of nature's richest plant sources of the omega-3 essential fatty acid, alpha-linolenic acid.

With 55% omega-3 fatty acids, perilla oil is an ideal vegetarian alternative to fish oil as well as an excellent alternative to Flax seed oil. In addition to omega-3 fatty acids which are so vital for your heart, brain, joints and skin, **Perilla Oil 1000** also contains flavonoids, anthocyanins and phenolic compounds, which are antioxidant nutrients that play a role in allergies and cardiovascular health.* Chemical-free extraction.

Independently tested to guarantee purity and truth-in-labeling.

Manufactured following pharmaceutical GMPs (Good Manufacturing Practices).

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

HEALTH
FROM THE
SUN

PERILLA OIL 1000

OMEGA-3 ALTERNATIVE
TO FISH & FLAX OIL

Cold Expeller-Pressed

Unrefined

90 SOFT GELS

1000 MG

Directions: Three to six capsules daily with food.

Supplement Facts

Serving Size 2 Capsules /
Servings Per Container: 45

Amount Per Serving	% Daily Value
Calories	20
Calories from Fat	20
Total Fat	2g 3%*
Alpha-Linolenic Acid (Omega-3)	1100mg †
Linoleic Acid (omega-6)	300mg †
Oleic Acid (omega-9)	260mg †

*Percent Daily Values are based on a 2000 calorie diet

†Daily Value not established

INGREDIENTS: Perilla seed oil, gelatin, glycerin and water.

Store in a cool dry place. Do not use if safety seal is broken or missing.

Marketed by: Arkepharma, LLC
PO Box 179, Newport, NH 03773
www.healthfromthesun.com
800-647-2249
Product of Canada

PROOF #6
10/30/02

Health From The Sun™ **Perilla Oil 1000** is cold expeller-pressed Perilla seed oil, one of nature's richest plant sources of the omega-3 essential fatty acid, alpha-linolenic acid.

With 55% omega-3 fatty acids, perilla oil is an ideal vegetarian alternative to fish oil as well as an excellent alternative to Flax seed oil. In addition to omega-3 fatty acids which are so vital for your heart, brain, joints and skin, **Perilla Oil 1000** also contains flavonoids, anthocyanins and phenolic compounds, which are antioxidant nutrients that play a role in allergies and cardiovascular health. * Chemical-free extraction.

Independently tested to guarantee purity and truth-in-labeling.

Manufactured following pharmaceutical GMPs (Good Manufacturing Practices).

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**HEALTH
FROM THE
SUN**

PERILLA OIL 1000

OMEGA-3 ALTERNATIVE
TO FISH & FLAX OIL

Cold Expeller-Pressed

Unrefined

90 SOFT GELS

1000 MG

Directions: Three to six capsules daily with food.

Supplement Facts

Serving Size 2 Capsules
Servings Per Container: 145

Amount Per Serving	% Daily Value
Calories	20
Calories from Fat	20
Total Fat	2g 3%*
Alpha-Linolenic Acid (Omega-3)	1100mg †
Linoleic Acid (omega-6)	300mg †
Oleic Acid (omega-9)	260mg †

*Percent Daily Values are based on a 2000 calorie diet

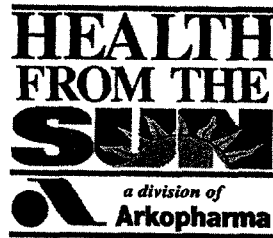
†Daily Value not established

INGREDIENTS: Perilla seed oil, gelatin, glycerin and water.

Store in a cool dry place. Do not use if safety seal is broken or missing.

Marketed by: Arkopharma, LLC
PO Box 178, Newport, NH 03773
www.healthfromthesun.com
800-447-2249
Product of Canada

PROOF #6
10/30/02



May 14, 2001

Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma/Health From The Sun, 22 N. Main St. Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

Text of Claims:

1. a natural way to help maintain a healthy heart system
2. 800 mg of phytosterols, shown to maintain cholesterol levels that are already in the normal range
3. high in the antioxidant vitamin E

Name of Ingredients Subject to Claim: phytosterols from soy, corn and canola oils
Name of Supplement: Basikol

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma/Health From The Sun has substantiation that the statement is truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "Christian Seyrig", is written over a horizontal line.

Christian Seyrig
Senior Vice-President

SALES, MARKETING AND FINANCE OFFICE
19 Crosby Drive, Suite 300
Bedford, MA 01730
Tel 781•276•0505
Fax 781•276•7334/7335

