



NOV 24 1997

0561 '98 MAR 24 P2:43

Mr. Klee M. Irwin
President
Irwin Naturals
10549 W. Jefferson Boulevard
Culver City, California 90232

Dear Mr. Irwin:

This is in response to your letters of November 3, November 4, and November 5, 1997 making submissions to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submissions state that you are making the following statements, among others, for the products:

PhenSafe

“A formula that safely mimics the non-drug effects of Phen Fen.”

Cat's Claw

“...this amazing plant has been the subject of recent scientific research with cancer, A.I.D.S., arthritis and virtually very other ailment that the immune system combats.”

St. John's Wort

“...naturally improves symptoms of mild to moderate depression, sadness, hopelessness, anxiety, headaches and exhaustion with rare to no reported side effects.”

Shark Cartilage

“Resistant to cancer and a myriad of diseases, shark cartilage tissue has been the subject of countless research studies.”

975-0163

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Page 2 - Mr. Klee M. Irwin

Section 403(r)(6) of the act 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 do not meet the requirements of section 403(r)(6) of the act.

The claims state that one product (i.e., PhenSafe) is intended for use as an alternative to approved prescription drugs and, therefore, the product is intended for the same purposes as the drugs; that is, to diagnose, mitigate, treat, cure, or prevent a disease. A claim that an article is an alternative to an approved drug is a claim that the article is intended to diagnose, mitigate, treat, cure, or prevent the disease that the drug is approved for. Therefore, your product makes claims that indicate that it is for other than food use within the meaning of section 201(g) of the act, and that it is subject to regulation under the drug provisions of the act. Thus, it appears that this product is intended for drug use within the meaning of section 201(g)(1)(B) of the act.

The statements that you are making for the products shark cartilage, cat's claw, and St. John's Wort suggest that they are intended to treat, prevent, cure, or mitigate a number of diseases, namely cancer, AIDS, arthritis, immune system disorders, depression and other behavioral disorders, and headaches. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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, Los Angeles District, Compliance Office, HFR-PA240

Page 3 - Mr. Klee M. Irwin

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (r/f, Moore)

HFS-450 (r/f)

HFD-310 (Williams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

f/t:HFS-456:rjm:11/15/97:docname:irwin.adv:disc24

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

RECEIVED
11/12/97

This notification is being filed on behalf of Irwin Naturals which is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 10549 W. Jefferson Blvd., Culver City, CA 90232. 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 PhenSafe.

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

(Statement 1): Lose Weight

(Statement 2):

(Statement 3): See Attached

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 that is the Subject of the Statement</u>
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1. L-Glutamic Acid; B-6 Pyrodoxine; Niacinamide;
2. Zinc; Folic Acid; Chromium Polynicotinate; B-12; Selenium;
3. Sida Cordifolia Extract; Licorice Root Powder; Ginger Root Powder; Cayenne Powder; Mustard Seed Powder; Bioperin

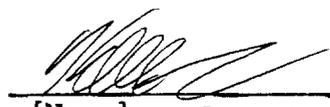
The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
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- 1.
- 2.
- 3.

I, Klee M. Irwin, am authorized to certify this Notification on behalf of Irwin Naturals. I certify that the information presented and contained in this Notification is complete and accurate, and that PhenSafe has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: November 4, 1997

By: 

[Name] Klee M. Irwin
[Title] President

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STATEMENTS

Statement 2 A formula that Safely mimics the non-drug effects of Phen Fen

Statement 3 Feel Good

Statement 4 St. John's Wort, the "feel good" herb, enhances the effects of
PhenSafe

Statement 5 Energize

Statement 6 Naturals Metabolic Herbs and Amino nutrients

Statement 7 With increased energy, calorie burning is dramatically
enhanced while exercise and activity become more enjoyable.

DIETARY INGREDIENT(S)

Statement 2 L-Glutamic Acid; B-6 Pyrodoxine; Niacinamide; Zinc; Folic
Acid; Chromium Polynicotinate; B-12; Selenium; Sida
Cordifolia Extract; Licorice Root Powder; Ginger Root Powder;
Cayenne Powder; Mustard Seed Powder; Bioperin

Statement 3 St. John's Wort

Statement 4 St. John's Wort

Statement 5 L-Glutamic Acid; B-6 Pyrodoxine; Niacinamide; Zinc; Folic
Acid; Chromium Polynicotinate; B-12; Selenium; Sida
Cordifolia Extract; Licorice Root Powder; Ginger Root Powder;
Cayenne Powder; Mustard Seed Powder; Bioperin

Statement 6 L-Glutamic Acid; B-6 Pyrodoxine; Niacinamide; Zinc; Folic
Acid; Chromium Polynicotinate; B-12; Selenium; Sida
Cordifolia Extract; Licorice Root Powder; Ginger Root Powder;
Cayenne Powder; Mustard Seed Powder; Bioperin

Statement 7 L-Glutamic Acid; B-6 Pyrodoxine; Niacinamide; Zinc; Folic
Acid; Chromium Polynicotinate; B-12; Selenium; Sida
Cordifolia Extract; Licorice Root Powder; Ginger Root Powder;
Cayenne Powder; Mustard Seed Powder; Bioperin

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

RECEIVED
11/24/97

This notification is being filed on behalf of Irwin Naturals which is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 10549 W. Jefferson Blvd., Culver City, CA 90232. 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 Cat's Claw.

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

- (Statement 1): Also called "Uncaria Tomentosa", this amazing plant has been the subject of recent scientific research with ~~(Statement 2)~~ cancer, A.I.D.S., arthritis and virtually every other ailment that the immune system combats.
(Statement 3): See Attached

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

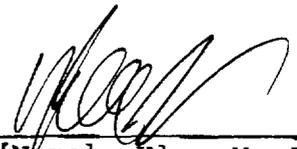
<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	Cat's Claw
2.	See Attached
3.	

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.		
2.		
3.		

I, Klee M. Irwin, am authorized to certify this Notification on behalf of Irwin Naturals. I certify that the information presented and contained in this Notification is complete and accurate, and that Cat's Claw has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: November 3, 1997

By: 
[Name] Klee M. Irwin
[Title] President

55698

STATEMENTS

- Statement 2 While still new in the U.S., many have found that Cat's Claw far surpasses the effectiveness of most herbs that are more well known.
- Statement 3 The Immune System Herb

DIETARY INGREDIENT(S)

- Statement 2 Cat's Claw
- Statement 3 Cat's Claw

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

RECEIVED
11/14/97

This notification is being filed on behalf of Irwin Naturals which is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 10549 W. Jefferson Blvd., Culver City, CA 90232. 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 St. John's Wort.

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

(Statement 1): St. John's Wort has shown to naturally improve symptoms of mild to moderate depression, sadness, hopelessness, ~~XXXXXX~~ anxiety, headaches and exhaustion with rare to no reported side effects.

~~XXXXXX~~ (Statement 2) See Attached

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 that is the Subject of the Statement</u>
1.	St. John's Wort
2.	
3.	

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.		
2.		
3.		

I, Klee M. Irwin, am authorized to certify this Notification on behalf of Irwin Naturals. I certify that the information presented and contained in this Notification is complete and accurate, and that St. John's Wort has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: November 3, 1997

By: 
[Name] Klee M. Irwin
[Title] President

55698

STATEMENTS

- Statement 2 In many cases, St. John's Wort has been known to elevate spirits
- Statement 3 In many cases, St. John's Wort has been known to improve sleep
- Statement 4 In many cases, St. John's Wort has been known to improve brain function
- Statement 5 In many cases, St. John's Wort has been known to promote a general sense of well-being
- Statement 6 17 Brain Nutrients

DIETARY INGREDIENT(S)

- Statement 2 St. John's Wort
- Statement 3 St. John's Wort
- Statement 4 St. John's Wort
- Statement 5 St. John's Wort
- Statement 6 Kava Kava Root Extract; Ginkgo Biloba Extract; Ginkgo Biloba Leaf Powder; Hops Flower Powder; PABA; Inositol; Choline; Magnesium; Vitamin C; Vitamin B-1; Bivitamin B-2; Niacin; Vitamin B-12; Folate; Biotin; Pantothenic Acid

11/12/97

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

This notification is being filed on behalf of Irwin Naturals which is the Distributor of the product (s) which bear the statements identified in this notification. Its business address is 10549 W. Jefferson Blvd., Culver City, CA 90232. 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 appears is SHARK CARTILAGE

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

- Statement 1: Resistant to cancer and a myriad of diseases, shark cartilage tissue has been the subject of countless research studies.
- Statement 2: The highest quality 100% pure shark cartilage and the most advanced processing and testing methods ensure purity, freshness and safety.
- Statement 3: We naturally process the cartilage into an ultra fine powder to enhance absorption.

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

Statement Number	Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement
1.	Shark Cartilage
2.	Shark Cartilage
3.	Shark Cartilage
4.	Shark Cartilage

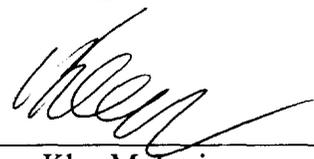
The following identifies the brand name of each supplement for which a statement is made:

Statement Number	Brand Name	Label or Labeling

I, Klee M. Irwin, am authorized to certify this Notification on behalf of Irwin Naturals. I certify that the information presented and contained in this Notification is complete and accurate, and that SHARK CARTILAGE has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: November 5, 1997

By:



Klee M. Irwin
President

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