

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

0 4 3 2 '96 JUN 23 P2:16

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® PhenCal™ Product #12783** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure-function claim for **PhenCal** is as follows:

- (Statement 1)** The Natural Weight Loss Supplement
- (Statement 2)** Helps Reduce (Carbohydrate) Binging and Craving
- (Statement 3)** Helps Prevent Weight Regain
- (Statement 4)** PhenCal™ provides a patent-based combination of natural amino acids, vitamin B6, and chromium as part of a sensible diet and exercise program.
- (Statement 5)** PhenCal™ contains the amino acids DL-phenylalanine, L-Glutamine, L-Tyrosine, and L-5-Hydroxytryptophan, which are all precursors for formation of neurotransmitters in brain cells. Neurotransmitters control brain events by transmitting signals between brain cells. L-Carnitine is an amino acid derivative that helps transport fat inside of cells. Chromium is a trace mineral with roles in carbohydrate and fat metabolism. Pyridoxal-5-phosphate is the coenzymatic form of vitamin B6, which is important for function of enzymes that manufacture neurotransmitters.
- (Statement 6)** How PhenCal™ works: PhenCal™ normalizes the “Reward System” in your brain by maintaining levels of neurotransmitters involved in control of eating behavior. When normal neurotransmitter function is maintained, food intake can be controlled, and carbohydrate binging and craving can be reduced. In a preliminary human clinical trial, PhenCal™ promoted weight loss with a reduced calorie diet at levels comparable to those shown in other clinical trials, and subjects had reduced carbohydrate binging and craving. In another preliminary human trial, PhenCal™, when administered after a weight loss program, reduced the amount of weight regain in a two-year time period. PhenCal™ is safe, ephedra-free and available at you local pharmacy or health food store.

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 3rd day of June, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: 

DR. LUKE R. BUCCI
Vice President of Research

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5-Hydroxytryptophan, L-Carnitine, Chromium, Vitamin B6
[Revised Claims as per FDA agreement]

DATE: May 15, 1998

BY: Luke R. Bucci, PhD

Document Name: sf03pcal.wpd

BRAND, CODE # & PRODUCT NAME(S): Schiff 12783 PhenCal™ 120t

NUTRIENT AMOUNT:

Supplement Facts

Serving Size 6 capsules daily
Servings Per Container: 20

Amount Per Serving	% Daily Value*	
Vitamin B6 (as 80% pyridoxine hydrochloride and 20% pyridoxal-5-phosphate)	30mg	1500%
Chromium (as picolinate)	200mcg	170%
DL-Phenylalanine	2700mg	**
L-Tyrosine	300mg	**
L-Glutamine	150mg	**
L-5-Hydroxytryptophan	15mg	**
L-Carnitine (as tartrate)	60mg	**
* Reference Daily Intakes (RDI) ** Daily Value not established		

Other ingredients: Dicalcium phosphate, cellulose, stearic acid, silica, and magnesium stearate.

STRUCTURE/FUNCTION CLAIM:

Box & Bottle:

- The Natural Weight Loss Supplement
- Helps Reduce ±(Carbohydrate) Binging and Craving
- Helps Prevent Weight Regain

PHENCAL™ provides a patent based combination of natural amino acids, vitamin B6, and chromium as part of a sensible diet and exercise program. ±(See enclosed insert).

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

PHENCAL™ contains the amino acids DL-phenylalanine, L-Glutamine, L-Tyrosine, and L-5-Hydroxytryptophan, which are all precursors for formation of neurotransmitters in brain cells. Neurotransmitters control brain events by transmitting signals between brain cells. L-Carnitine is an amino acid derivative that helps transport fat inside of cells. Chromium is a trace mineral with roles in carbohydrate and fat metabolism. Pyridoxal-5-phosphate is the coenzymatic form of vitamin B6, which is important for function of enzymes that manufacture neurotransmitters.

Box:

HOW PHENCAL™ WORKS

PHENCAL™ normalizes the "Reward System" in your brain by maintaining levels of neurotransmitters involved in control of eating behavior. When normal neurotransmitter function is maintained, food intake can be controlled, and carbohydrate binging and craving can be reduced. In a preliminary human clinical trial, PHENCAL™ promoted weight loss with a reduced calorie diet at levels comparable to those shown in other clinical trials, and subjects had reduced carbohydrate binging and craving. In another preliminary human trial, PHENCAL™, when administered after a weight loss program, reduced the amount of weight regain in a two year time period. PHENCAL™ is safe, ephedra-free and available at your local pharmacy or health food store.

 5/15/98
Approved by / Date

REFERENCES:

1. Blum K, Trachtenberg MC, Cook DW. Neuronutrient effects on weight loss in carbohydrate bingers: an open clinical trial. *Curr Ther Res* 1990; 48(2):217-233.
2. Blum K, Cull JG, Chen TJH, Garcia-Swan S, Holder JM, Wood R, Braverman ER, Bucci LR, Trachtenberg MC. Clinical evidence for effectiveness of PhenCal™ in maintaining weight loss in an open-label, controlled, 2-year study. *Curr Ther Res* 1997; 58(10):745-763.
3. Kaats GR, Wise JA, Blum K, Morin RJ, Adelman JA, Craig J, Croft HA. The short-term therapeutic efficacy of treating obesity with a plan of improved nutrition and moderate caloric restriction. *Curr Ther Res* 1992; 51(2):261-274.
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 23. Blum K, Trachtenberg MC. Treatment of cocaine addiction. U.S. Patent 5,189,064, 1993.

STRUCTURE / FUNCTION CLAIMS

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NUTRIENT: PhenCal™ DIET & EXERCISE PLAN INSERT DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5- Hydroxytryptophan, L-Carnitine, Chromium, Vitamin B6 [Revised Claims as per FDA agreement]

DATE: May 15, 1998

BY: Luke R. Bucci, PhD

Document Name: sf04pcal.wpd

BRAND, CODE # & PRODUCT NAME(S): Schiff PhenCal™ Diet & Exercise Insert

NUTRIENT AMOUNT:

Supplement Facts

Serving Size 6 capsules daily
Servings Per Container: 20

Amount Per Serving	% Daily Value*	
Vitamin B6 (as 80% pyridoxine hydrochloride and 20% pyridoxal-5-phosphate)	30mg	1500%
Chromium (as picolinate)	200mcg	170%
DL-Phenylalanine	2700mg	**
L-Tyrosine	300mg	**
L-Glutamine	150mg	**
L-5-Hydroxytryptophan	15mg	**
L-Carnitine (as tartrate)	60mg	**

* Reference Daily Intakes (RDI)
** Daily Value not established

Other ingredients: Dicalcium phosphate, cellulose, stearic acid, silica, and magnesium stearate.

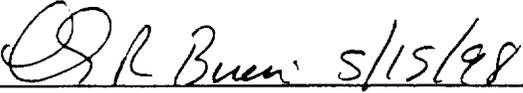
STRUCTURE/FUNCTION CLAIM:

The Natural Weight Loss Supplement

The PHENCAL™ Plan incorporates the steps needed to achieve the lean hard body you've always wanted. By following the complete program, you will have a positive change in your appearance, increased energy, and a greater sense of well-being.

HOW PHENCAL™ WORKS

PHENCAL™ normalizes the "Reward System" in your brain by maintaining levels of neurotransmitters involved in control of eating behavior. When normal neurotransmitter function is maintained, food intake can be controlled, and carbohydrate binging and craving can be reduced. In a preliminary human clinical trial, **PHENCAL™** promoted weight loss with a reduced calorie diet, and subjects had reduced carbohydrate binging and craving. In another preliminary human trial, **PHENCAL™**, when administered after a weight loss program, reduced the amount of weight regain in a two year time period. **PHENCAL™** is safe and available at your local pharmacy or health food store.


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Diet & Exercise:

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 17. Zuti WB, Golding LA. Comparing diet and exercise as weight reduction tools. *Phys Sportsmed* 1976; 4:49-53.

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STRUCTURE / FUNCTION CLAIMS

NUTRIENT: PhenCal™ DIET & EXERCISE PLAN INSERT DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5- Hydroxytryptophan, L-Carnitine, Chromium, Vitamin B6 [Revised Claims as per FDA agreement]

DATE: May 15, 1998

BY: Luke R. Bucci, PhD

Document Name: sf05pcal.wpd

BRAND, CODE # & PRODUCT NAME(S): GAN PhenCal™ Diet & Exercise Insert

NUTRIENT AMOUNT:

Supplement Facts

Serving Size 6 capsules daily
Servings Per Container: 20

Amount Per Serving	% Daily Value*	
Vitamin B6 (as 80% pyridoxine hydrochloride and 20% pyridoxal-5-phosphate)	30mg	1500%
Chromium (as picolinate)	200mcg	170%
DL-Phenylalanine	2700mg	**
L-Tyrosine	300mg	**
L-Glutamine	150mg	**
L-5-Hydroxytryptophan	15mg	**
L-Carnitine (as tartrate)	60mg	**
* Reference Daily Intakes (RDI) ** Daily Value not established		

Other ingredients: Dicalcium phosphate, cellulose, stearic acid, silica, and magnesium stearate.

STRUCTURE/FUNCTION CLAIM:

The Natural Weight Loss Supplement

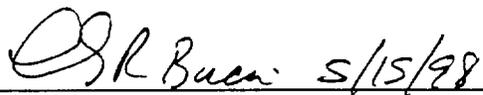
LOSE WEIGHT NATURALLY

The PHENCAL™ Plan incorporates the steps needed to achieve the lean hard body you've always wanted. By following the complete program, you will have a positive change

in your appearance, increased energy levels, and a greater sense of well-being.

HOW PHENCAL™ WORKS

PHENCAL™ normalizes the "Reward System" in your brain by maintaining levels of neurotransmitters involved in control of eating behavior. When normal neurotransmitter function is maintained, food intake can be controlled, and carbohydrate binging and craving can be reduced. In a preliminary human clinical trial, **PHENCAL™**, in conjunction with a reduced caloric diet, promoted weight loss, and subjects reduced carbohydrate binging and craving. In another preliminary human trial, **PHENCAL™**, when administered after a weight loss program, reduced the amount of weight regain in a two year time period.

 D.R. Bacon 5/15/98

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0436 '96 JUN 23 P2:17
STRUCTURE/FUNCTION CLAIMS

NUTRIENT: PhenCal™
DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5-
Hydroxytryptophan, L-Carnitine, Chromium, Vitamin B6
[Revised Claims as per FDA agreement]

DATE: May 15, 1998

BY: Luke R. Bucci, PhD

Document Name: sf06pcal.wpd

BRAND, CODE # & PRODUCT NAME(S): GAN PhenCal™ Brochure

STRUCTURE/FUNCTION CLAIM:

The Natural Weight Loss Supplement

What Is PhenCal™?

PhenCal™ is a patent-based weight loss dietary supplement containing amino acid and other nutrients that help regulate chemicals in the brain. These chemicals, called neurotransmitters, play a critical role in appetite.

PhenCal™ helps normalize levels of neurotransmitters, which are then utilized by the brain when needed. The body's normal "reward system" is then maintained, promoting feelings of satisfaction.

HOW DOES PHENCAL™ WORK?

The "Phen" in PhenCal's name is derived from one of the primary ingredients, the amino acid DL-Phenylalanine. This ingredient and the other amino acids contained in the formula are precursors to the neurotransmitters responsible for appetite.

Varying amounts of one neurotransmitter or too much of another have a profound effect on feelings of hunger and how much we eat. PhenCal™ actually helps normalize the levels of neurotransmitters and helps you resist the urge to overeat.

PhenCal™ enhances weight loss from diet and exercise by warding off cravings and impulses to binge, particularly on carbohydrates.

Who Can Benefit From PhenCal™?

PhenCal™ can benefit anyone on a weight loss program consisting of proper diet and exercise. PhenCal™ is designed to help normalize, rather than suppress, the appetite so that healthy eating habits may be established. PhenCal™ is not designed to help skip meals or "burn" fat. Like any weight-loss product, it will only work with an overall diet modification and exercise plan, as is included with PhenCal™.

How Does PhenCal™ Compare to Other Supplements?

- Reduces cravings & normalizes the "Reward System"

What Have the Studies Shown?

In a preliminary 90-day clinical trial, the patients who were taking PhenCal™ were 4.5 times more likely to comply with the prescribed diet plan compared to the patients not taking the supplement.

In addition, a preliminary two-year clinical study showed that PhenCal™ users were less likely to regain the lost weight than subjects who had not used PhenCal™.


Approved by / Date

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STRUCTURE/FUNCTION CLAIM:

The Natural Weight Loss Supplement

Helps Reduce Carbohydrate Binging & Craving


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