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Rec'd
5/12/97

May 9, 1997

James Tanner, PhD
Acting Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
HFS-450
200 C Street SW
Washington DC 20204

0150 '97 SEP 19 P1:43

Re: *Submission of Structure/Function Claims*

Dear Dr Tanner:

Enclosed are the structure/function claims for the following nutrients, as generated by Dr. Luke Bucci:

- 1) L-Glutamine -- American Body Building G FORCE Drink
- 2) NADH (Reduced Nicotinamide Adenine Dinucleotide) -- Schiff Enada NADH
- 3) DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5-Hydroxytryptophan, L-Carnitine, Chromium, P5P -- Gan PhenCal and Schiff SuperPhen
- 4) Chondroitin Sulfate -- Spring Valley Natural Chondroitin Sulfate

We welcome the opportunity to receive feedback from your office as we continue to interpret how to write structure/function claims as allowed by the Dietary Supplement Health and Education Act. There are some areas of overlap between nutrient functions or their effects on body structure and health claims. We anticipate that we will continue to fully comply with your interpretation of health claims.

Please feel free to contact me if you have further questions or comments.

Respectfully,



De Lois L. Shelton, Regulatory Compliance

cc: Dave Mastroianni, Luke R. Bucci

975-0162

5-2553
LET 656

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: L-Glutamine

DATE: April 30, 1997
Document Name: sf01gln.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): American Body Building 55560 GFORCE drink

NUTRIENT AMOUNT: 10 grams L-Glutamine, 2 grams L-Alanine, fructose, maltodextrin, dextrose, inositol, citric acid, tartaric acid, sodium citrate, monopotassium phosphate, manganese citrate

STRUCTURE/FUNCTION CLAIM:

L-Glutamine is the most abundant free form amino acid in lean muscle tissue and a critical nutrient for an anabolic and anti-catabolic environment. L-Glutamine has additional immune and digestive functions as a metabolic fuel. **GFORCE** utilizes a scientifically developed ratio of carbohydrates to create a delivery system for optimal absorption. Studies have shown that glutamine levels in muscle and blood can be depleted following severe workouts.

Just like creatine, L-glutamine is not completely stable in liquids. That is why American Body Building has created this great tasting instantized powder to consume following your workouts.

Anabolic: promotes protein synthesis, glycogen (energy) storage and muscle cell hydration.

Anti-Catabolic: protects against muscle breakdown (catabolism) due to workouts and other physiological forms of stress.

Digestive: primary fuel for digestive tract.

Immune: fuel for immune system cells.

Luke R. Bucci April 30, 1997
Approved by / Date

REFERENCES:

1. Varnier M, Leese GP, Thompson J, Rennie MJ. Stimulatory effect of glutamine on glycogen accumulation in human muscle. *Am J Physiol* 1995; 269(2 pt 1):E309-E315.
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14. Friedman JE, Neuffer PD, Dohm GL. Regulation of glycogen resynthesis following exercise. Dietary considerations. *Sports Med* 1991; 11(4):232-243.

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: NADH (Reduced Nicotinamide Adenine Dinucleotide)

DATE: April 28, 1997

BY: Luke R. Bucci, PhD

Document Name: sf01nadh.wpd

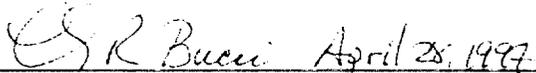
BRAND, CODE # & PRODUCT NAME(S): Schiff 12834 Enada NADH 30t

NUTRIENT AMOUNT: 2.5 mg per tablet

STRUCTURE/FUNCTION CLAIM:

Mind & Body Energizer

NADH is the coenzymatic form of vitamin B-3. NADH is involved in the production of energy in all cells. Patented NADH (Enada®) is stable, well-absorbed, and enters cells for use in energy production pathways. NADH helps maintain feelings of well-being by supporting healthy neurotransmitter functions.


Approved by / Date

REFERENCES:

1. Birkmayer JGD. Coenzyme nicotinamide adenine dinucleotide: new therapeutic approach for improving dementia of the Alzheimer's type. *Ann Clin Lab Sci* 1996; 26(1):1-9.
2. Birkmayer JGD, Vrecko C, Volc D, Birkmayer W. Nicotinamide adenine dinucleotide (NADH) - a new therapeutic approach to Parkinson's disease, comparison of oral and parenteral application. *Acta Neurol Scand* 1993; 87(Suppl 146):32-35.
3. Oduho GW, Baker DH. Quantitative efficacy of niacin sources for chicks: nicotinic acid, nicotinamide, NAD and tryptophan. *J Nutr* 1993; 123:2201-2206.
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5. Birkmayer JGD. Stable, ingestible and absorbable NADH and NADH therapeutic compositions. US Patent 5,332,727.
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STRUCTURE / FUNCTION CLAIMS

NUTRIENT: DL-Phenylalanine, L-Tyrosine, L-Glutamine, L-5-Hydroxytryptophan, L-Carnitine, Chromium, P5P

DATE: April 25, 1997
Document Name: sf01phen.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S):

GAN 52330 PhenCal 106™ 90t
GAN 52331 PhenCal 106™ 180t
Schiff 12845 SuperPhen™ 90t
GAN PhenCal 106™ Diet Plan Insert

NUTRIENT AMOUNT:

Supplement Facts

Serving Size 6 capsules daily
Servings Per Container: 15

Amount Per Serving	% Daily Value*	
Vitamin B6 (as 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, food glaze, silica and magnesium stearate.

STRUCTURE/FUNCTION CLAIM:

Safe Without a Prescription.
The Natural Alternative to Phen-Fen

- Helps Reduce Carbohydrate Binging & Craving
- As Effective as Prescription Treatment

Helps Reduce Weight Regain

PHENCAL 106™ provides a patented combination of amino acids, vitamins, and minerals as part of a sensible diet and exercise program (see enclosed insert).

PHENCAL 106™ 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 an essential 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.

HOW PHENCAL 106™ WORKS;

PHENCAL 106™ normalizes the "Reward System" in your brain by maintaining normal 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 human clinical trial, PHENCAL 106™ promoted weight loss at levels comparable to those shown in other clinical trials for prescription treatments, and subjects had reduced carbohydrate binging and craving. In another human trial, PHENCAL 106™, when administered after a weight loss program, reduce the amount of weight regain in a two year time period. PHENCAL 106™ is safe and available without a prescription.

 APR 28 1997

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, Trachtenberg MC, Garcia-Swan S, Holder J, Wood R, Braverman ER, Bucci LR. Amino acid loading and enkephalinase inhibition in familial overeating: clinical evidence for effectiveness of Carbotrol™ in maintaining weight loss in a open trial controlled two year study. *Curr Ther Res* in press, 1997.
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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STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Chondroitin Sulfate

DATE: April 23, 1997
Document Name: sf01cs.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): Spring Valley 32551 Natural Chondroitin Sulfate (60c)

NUTRIENT AMOUNT: 500mg per capsule

STRUCTURE/FUNCTION CLAIM:

Chondroitin sulfates are integral components of all connective tissues, especially cartilage in joints and blood vessels. Chondroitin sulfates help maintain structural integrity of joints and blood vessels.


Approved by / Date

REFERENCES:

1. Bucci LR. Glycosaminoglycans, Ch 12 in *Nutrition Applied to Injury Rehabilitation and Sports Medicine*, CRC Press, Boca Raton, FL, 1994, 177-203.
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9. Kerzberg EM, Roldan EJA, Castelli G, Huberman ED. Combination of glycosaminoglycans and acetylsalicylic acid in knee osteoarthritis. *Scand J Rheum* 1987; 16:377-380.
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