

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

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 **Excel™ Diet Formula Product #52499** bearing the statements set out below. 0406 '96 JUN 23 P2:14

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

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

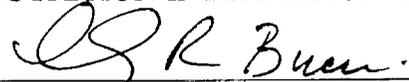
- (Statement 1) The Excel™ Diet Formula provides a patented combination of amino acids, vitamins, and minerals as part of a sensible diet and exercise program.
- (Statement 2) Excel™ Diet Formula contains the amino acids DL-Phenylalanine, L-Glutamine, L-Tyrosine, and 5-Hydroxytryptophan. Chromium is an essential trace mineral with roles in carbohydrate and fat metabolism. Pyridoxal-5-phosphate is the coenzymatic form of Vitamin B-6, which is important for function of enzymes
- (Statement 3)
- (Statement 4)
- (Statement 5)
- (Statement 6)

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: Diet Formula (DL-Phenylalanine, L-tyrosine, L-glutamine, L-5-hydroxytryptophan, L-carnitine, chromium picolinate, vitamin B6)

DATE: May 15, 1998
Document Name: sf02pcal.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): Excel 52499 Diet Formula

NUTRIENT AMOUNT: Per serving (4 tablets daily):

1800 mg dl-phenylalanine
200 mg L-tyrosine
100 mg L-glutamine
4 mg L-5-hydroxytryptophan
40 mg L-Carnitine
20 mg Vitamin B6 (80% pyridoxine HCL, 20% pyridoxal-5-phosphate)
133 mcg Chromium (as picolinate)

STRUCTURE/FUNCTION CLAIM:

Bottle:

The **EXCEL™ DIET FORMULA** provides a patented combination of amino acids, vitamins, and minerals as part of a sensible diet and exercise program.

EXCEL™ DIET FORMULA contains the amino acids DL-Phenylalanine, L-Glutamine, L-Tyrosine, and 5-Hydroxytryptophan. 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.


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, two 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.
4. Blum K, Sheridan PJ, Wood RC, Braverman ER, Chen TJH, Cull JG, Comings DE. The D2 receptor gene as a determinant of reward deficiency syndrome. *J Royal Soc Med* 1996; 89:396-400.
5. Blum K, Cull JG, Braverman ER, Comings DE. Reward deficiency syndrome. *American Scientist* 1996; 84:132-145.
6. DeFrance JF, Hymel C, Trachtenberg MC, Ginsberg LD, Schweitzer FC, Estes S, Chen TJH, Braverman ER, Cull JG, Blum K. Enhancement of attention processing by Kantroll™ in healthy humans: a pilot study. *Clin Electroencephalography* 1997; 28(2):68-75.
7. Wurtman RJ. Food consumption, neurotransmitter synthesis, and human behavior. *Experientia* 1983; 44:356-369.
8. Wurtman RJ, Hefti F, Melamed E. Precursor control of neurotransmitter synthesis. *Pharmacol Rev* 1981; 2:315-355.
9. Blum K, Briggs AH, Trachtenberg MC. Ethanol ingestive behavior as a function of central neurotransmission (review). *Experientia* 1989; 45:444-452.
10. Blum K, Allison D, Trachtenberg MC, Williams RW, Loeblich LA. Reduction of both drug hunger and withdrawal against advice rate of cocaine abusers in a 30-day inpatient treatment program by the neuronutrient Tropicamine. *Curr Ther Res* 1988; 43:1204-1214.
11. Trachtenberg MC, Blum K. Improvement of cocaine-induced neuromodulator deficits by neuronutrient Tropicamine. *J Psychoact Drugs* 1988; 20:315-331.
12. Cold JA. NeuRecover-SA™ in the treatment of cocaine withdrawal and craving: a pilot study. *Clin Drug Invest* 1996; 12:1-7.
13. Blum K, Trachtenberg MC, Elliot CE, Dingler ML, Sexton RL, Samuels AI, Cataldie L. Enkephalinase inhibition and precursor loading improves inpatient treatment of alcohol and polydrug abusers. Double-blind, placebo-controlled study of the nutritional adjunct SAAVE. *Alcohol* 1989; 5:481-493.
14. Blum K, Trachtenberg MC. Neurogenetic deficits caused by alcoholism: restoration by SAAVE™, a neuronutrient intervention adjunct. *J Psychoact Drugs* 1988; 20(3):297-313.
15. Blum K. A commentary on neurotransmitter restoration as a common mode of treatment for alcohol, cocaine and opiate abuse. *Integr Psychiatry* 1989; 6:199-204.
16. Brown RJ, Blum K, Trachtenberg MC. Neurodynamics of relapse prevention: a neuronutrient approach to outpatient DUI offenders. *J Psychoact drugs* 1990; 22(2):173-187.

Weider Nutrition International
2002 South 5070 West
Salt Lake City UT 84104

17. Douglass JM, Rasgon IM, Fleiss PM, Schmidt RD, Peters SN, Abelmann EA. Effects of a raw food diet on hypertension and obesity. *South Med J* 1985; 78(7):841-844.
18. Fullerton DT, Getto CJ, Swift WJ, Carlson IH. Sugar, opioids and binge eating. *Brain Res Bull* 1985; 14:673-680.
19. Dalvitt-McPhillips S. A dietary approach to bulimia treatment. *Physiol Behav* 1984; 33:769-775.
20. Mira M, Abraham S. L-Tryptophan as an adjunct to treatment of bulimia nervosa. *Lancet* 1989; 2:1162-1163.
21. Iwamoto ET, Way EL. Opiate actions and catecholamines. *Adv Biochem Psychopharmacol* 1979; 20:357-407.
22. Blum K, Briggs AH, Wallace JE. Enkephalinase and endorphinase inhibitors as anti-craving compositions. U.S. Patent 4,761,429, 1988.
23. Blum K, Trachtenberg MC. Treatment of cocaine addiction. U.S. Patent 4,189,064, 1993.
24. Umbdenstock AJ. Nutritional supplement for optimizing cellular health. U.S. Patent 5,308,627, 1994.