



OCT - 9 1997

Ms. De Lois L. Shelton
Regulatory Compliance
Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104-4836

0769 '97 DEC 16 P1:38

Dear Ms. Shelton:

This is in response to your letter of September 22, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Weider Nutrition International, Inc. is making claims for the products:

GAN 53130 Cold-Free Echinacea 30t

Everyday our bodies are burdened with a multitude of potential pathogens. In order to ward off these pathogens, give your immune system the support it needs. Cold-Free Echinacea features a unique blend of Echinacea pupurea and goldenseal root for enhanced effect and support.

GAN 51897 Cold-Free Lozenges

NOSE & THROAT FORMULA
FAST ACTING, BEST TASTING
MOST ACTIVE ZINC FORM

Make your life a little easier with COLD-FREE zinc acetate lozenges. Because they are made of zinc acetate, COLD-FREE is three times stronger than other zinc lozenges available on the market today. COLD-FREE is fast acting and has a terrific cherry flavor not to mention the fact that our formula is sugar-free. With COLD FREE great taste, sugar-free formula, and track record for effectiveness you can't go wrong.

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 and the inclusion of the term "cold-free" in the product name suggest that they are intended to treat, mitigate, or prevent a disease, namely the common cold. 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

975-0163

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Standish Place, Rockville, Maryland 20855.

You also submitted a notification pursuant to section 403(r)(6) of the act for the products "Weider Signature 50157 Dynamic Muscle Builder Chewables" and "GAN 52108 New Flavor Diet Fat Burner." However, these products are not dietary supplements within the meaning of section 201(ff) of the act. Weider Dynamic Muscle Builder Chewables is a conventional food because it is represented as an "easy, extra protein snack," as an item to use "for a quick snack," or as a part of "your regular meals to boost your protein consumption." GAN New Flavor Diet Fat Burner is a conventional food because it is represented as a "refreshing beverage" and the "perfect refresher anytime." Section 201(ff)(2)(B) states, in part, that the term dietary supplement means a product that "is not represented for use as a conventional food." Therefore, claims on the label or in the labeling for this product are not subject to section 403(r)(6) of the act.

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

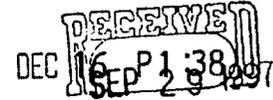
Copies:

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, Denver District, Compliance Office, HFR-SW240

DELOIS L. SHELTON
OFFICE OF REGULATORY AFFAIRS
WEIDER NUTRITION INTERNATIONAL, INC.
2002 SOUTH 5070 WEST
SALT LAKE CITY, UTAH 84104-4836
TELEPHONE (801) 975-5031
FACSIMILE (801) 972-2223



September 22, 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

Re: *Submission of Structure/Function Claims*

Dear Dr Tanner:

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

- | | | |
|-----|--------------------------|---|
| 1) | Phytosterols | Schiff Pre-DHEA |
| 2) | Diuretic Herbs | Schiff Water Balance |
| 3) | Vitamin C | Schiff 10320, 10321, Buffered 500 mg |
| 4) | Vitamin C | Schiff 10324, 10325, Vitamin C with Bioflavonoids, Rutin and Acerola |
| 5) | Vitamin C | Schiff 10346, 10347, 10348, Vitamin C 12-hour Sustained Release |
| 6) | Multiple Vitamin/Mineral | Schiff 11410, 11412 |
| 7) | Multiple Vitamin/Mineral | Schiff 11442, 11443, 11444 Chelated Mineral Formula with IRON and ZINC with Beta Carotene |
| 8) | Multiple Vitamin/Mineral | Schiff 11428 with Extra IRON and ZINC |
| 9) | Echinacea | GAN 53130 Cold-Free™ Echinacea with Echinacea pupruea and Goldenseal |
| 10) | Garlic | Schiff 10818, Super Garlic 10820 |
| 11) | Androstenedione | Weider 52397 Androstene 100 mg |
| 12) | <u>Creatine</u> | Science Foods 60030, 60031 Creatine |
| 13) | Multiple Vitamin/Mineral | Schiff 11514 Veggie Blend Multivitamin |
| 14) | Multiple Vitamin/Mineral | Schiff 11426 Mega High II |
| 15) | Multiple Minerals | Schiff 12424 Multi-Minerals Complex |

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- | | | |
|-----|---|--|
| 16) | Grape Seed Extract
& Pycnogenol® | Schiff 12787, 12799, 12800 PCO+ |
| 17) | EPA (Eicosapentaenoic acid) | Schiff 11781 |
| 18) | Vitamin A | Schiff 10004 Vitamin A 10,000 IU |
| 19) | Siberian Ginseng | Excel 14079 Ultra Endurance Formula
800 mg Cwujia |
| 20) | Protein | Weider Signature 50157 Dynamic Muscle
Builder Chewables |
| 21) | New Diet Fat Burner Drinks | GAN 52108 with Chromium and Ginseng |
| 22) | UltraLean Herbal Supplement
& Weight Loss Plan | Schiff 12734 Super Ultra Lean |
| 23) | Zinc Acetate | GAN 51897 Cold-Free™ Lozenges |

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

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

STRUCTURE / FUNCTION CLAIMS

0771 '97 DEC 16 P1:38

NUTRIENT: Echinacea



DATE: September 11, 1997
Document Name: sf04echi.wpd

BY: Original

BRAND, CODE # & PRODUCT NAME(S): GAN 53130 Cold-Free™ Echinacea 30t

NUTRIENT AMOUNT: Echinacea puppurea (root) 500 mg/tab
Goldenseal 200 mg/tab

STRUCTURE/FUNCTION CLAIM:

IMMUNE SYSTEM SUPPORT WINTER SEASON FORMULA WITH GOLDENSEAL

Everyday our bodies are burdened with a multitude of potential pathogens. In order to ward off these pathogens, give your immune system the support it needs. Cold-Free™ Echinacea features a unique blend of Echinacea puppurea and goldenseal root for enhanced effect and support.

IMMUNE SYSTEM FORMULA

Q R Bucci 9/11/97
Approved by / Date

REFERENCES: ECHINACEA

1. Wildfeuer A, Mayerhoffer D, The effects of plant preparations on cellular function in body defense, *Arzneimittelforschung*, 1994; 44(3): 361-366.
2. Lersch C, Zeuner M, Bauer A, Siebenrock K, Hart R, Wagner F, Fink U, Dancygier H, Classen M, Stimulation of the immune response in outpatients with hepatocellular carcinomas by low-dose cyclophosphamide (LDCY), Echinacea purpurea extracts (Echinacin) and thymostimulin, *Arch. Geschwulstforsch*, 1990; 60(5): 378-383.
3. Roesler, J., Emmendorffer, A., Steinmuller, C., Luettig, B., Wagner, H., Lohmann-Matthes, M.L., Application of purified polysaccharides from cell cultures of the plant Echinacea purpurea to test subjects mediates activation of the phagocyte system, *Int. J. Immunopharm.*, 1991; 13(7): 931-941.
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5. Wacker, A., Hilbig, W., Virushemmung mit *Echinacea purpurea*, *Planta Med.*, 1978; 33(1): 89-102.

GOLDENSEAL

1. D'Amico ML. Investigation of the presence of substances having antibiotic action in higher plants. *Fitoterapia* 1950; 21:77-81.
2. Hay G, Willuhn G. Antiviral activity of aqueous extracts from medicinal plants in tissue cultures. *Drug Res* 1978; 28:1-7.
3. Amin AH, Subbaiah TV, Abbasi KM. Berberine sulfate: antimicrobial activity, bioassay, and mode of action. *Can J Microbiol* 1969; 15:1067-1076.

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Salt Lake City UT 84104

STRUCTURE / FUNCTION CLAIMS

0772 '97 DEC 16 P1:38
NUTRIENT: Protein



DATE: September 12, 1997
Document Name: sf02prot.wpd

BY: Original (reviewed by LRB)

BRAND, CODE # & PRODUCT NAME(S): Weider Signature 50157 Dynamic Muscle
Builder Chewables (225t)

NUTRIENT AMOUNT: 3 g protein/15 tabs

STRUCTURE/FUNCTION CLAIM:

THE EASY, EXTRA PROTEIN SNACK

Dynamic Muscle Builder Chewables are a quick, convenient and delicious way to increase your protein intake. Protein is important for energy and helps to repair muscle tissue. These chewables are also packed with essential and non-essential amino acids, vitamins and minerals for truly dynamic nutritional support. Take them along in your gym bag or backpack for a quick snack or enjoy them with your regular meals to boost your protein consumption.

ESL Bucci 9/12/97
Approved by / Date

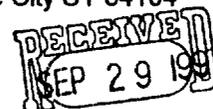
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1. Lemon PWR, Proctor DN. Protein intake and athletic performance. *Sports Med* 1991; 12:313-323.
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5. Bazzare TL. Nutrition and strength, Ch 17 in *Nutrition in Exercise and Sport*, 2nd ed, Wolinsky I, Hickson JF, Eds., CRC Press, Boca Raton, FL, 1994, 417-445.

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

STRUCTURE / FUNCTION CLAIMS



NUTRIENT: NEW DIET FAT BURNER DRINK

DATE: September 11, 1997
Document Name: sf02fatb.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): GAN 52108 New Flavor Diet Fat Burner

NUTRIENT AMOUNT: Chromium (50 mcg) & Ginseng (*Eleutherococcus senticosus*) (part of 67 mg proprietary herbal blend)

STRUCTURE/FUNCTION CLAIM:

Whether you're on a diet or simply need a refreshing beverage, **FAT BURNER™** may be perfect for you. **FAT BURNER™** contains hard-working diet and energy ingredients such as Chromium Picolinate and Ginseng to give you a boost of energy. With zero calories and no carbonation, **FAT BURNER™** is the perfect refresher anytime. **FAT BURNER™** beverages are available in a variety of great tasting fruit flavors.

ESR Bucci 9/11/97

Approved by / Date

REFERENCES:

CHROMIUM

1. Anderson RA. Chromium, in *Trace Minerals in Foods*, Smith K, Ed., Marcel Dekker, New York, 1988, 231-247.
2. Mertz W. Chromium - an overview, in *Chromium in Nutrition and Metabolism*, Shapcott D, Hubert J, Eds., Elsevier/North Holland Biomedical, Amsterdam, 1979, 1-14.
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4. Stoecker BJ. Chromium, in *Present Knowledge in Nutrition*, 6th ed., Brown ML, Ed., International Life Sciences Foundation, Washington, DC, 1990, 287-293.
5. Glinsmann WH, Mertz W. Effect of trivalent chromium on glucose tolerance. *Metabolism* 1966; 15:510-520.
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 10. Anderson RA, Cheng N, Bryden N, Polansky M, Cheng N, Chi J, Feng J. Beneficial effects of chromium for people with type II diabetes. *Diabetes* 1996; 45(Suppl 2):124A.
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 14. Evans GW, Pouchnik DJ. Composition and biological activity of chromium-pyridine carboxylate complexes. *J Inorg Biochem* 1993; 49:177-187.
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 17. Kaats GR, Fisher JA, Blum K. The effects of chromium picolinate supplementation on body composition in different age groups. *Age* 1991; 14:138.
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GINSENG (Siberian Ginseng, *Eleutherococcus senticosus*)

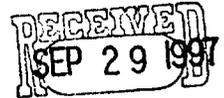
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2. Asano K, Takahashi T, Miyashita M, Matsuzaka A, Muramatsu S, Kuboyama M, Kugo H, Imai J. Effect of *Eleutherococcus senticosus* extract on human physical working capacity. *Planta Med* 1986; (3):175-7.
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4. McNaughton L, Egan G, Caelli G. A comparison of Chinese and Russian ginseng as ergogenic aids to improve various facets of physical fitness. *Int Clin Nutr Rev* 1989; 90:32-5.

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Salt Lake City UT 84104

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STRUCTURE / FUNCTION CLAIMS

0774 '97 DEC 16 P1:38
NUTRIENT: Zinc Acetate



DATE: September 12, 1997
Document Name: sf01cold.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): GAN 51897 Cold-Free Lozenges

NUTRIENT AMOUNT: 9 mg Zinc (as acetate) per lozenge

STRUCTURE/FUNCTION CLAIM:

NOSE & THROAT FORMULA
FAST ACTING, BEST TASTING
MOST ACTIVE ZINC FORM

Make your life a little easier with **COLD-FREE™** zinc acetate lozenges. Because they are made of zinc acetate, **COLD-FREE™** is three times stronger than other zinc lozenges available on the market today. **COLD-FREE™** is fast acting and has a terrific cherry flavor not to mention the fact that our formula is sugar-free. With **COLD-FREE™** great taste, sugar-free formula, and track record for effectiveness you can't go wrong.


Approved by / Date

REFERENCES:

1. Eby GA, Davis DR, Halcomb WW. Reduction in duration of common colds by zinc gluconate lozenges in a double-blind study. *Antimicrob Agents Chemother* 1984; 25(1):20-24.
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- Antimicrob Agents Chemother* 1988; 32:606-607.
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