



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

SEP 21 1998

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

Dear Ms. Shelton:

This is in response to your letter of September 8, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Weider Nutrition International, Inc. is making various claims for the maintenance of healthy joints for the products "Schiff Pain Free (#10740)" and "Great American Nutrition Cold-Free Zinc Acetate Spray Product (#50127)," "Great American Nutrition Cold-Free Zinc Lozenges Product (#51100 and #59000)," and "Great American Cold-Free Zinc Lozenges Product (#50231, #50232, #50253, #50251, #52519, #50255, #50256, and #52531).

21 U.S.C. 343(r)(6) 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 suggest that they are intended to treat, prevent, cure, or mitigate disease, in that the names of the products by incorporating the terms "Pain Free" and "Cold-Free" evidence that they are intended to treat, prevent, cure, or mitigate pain and the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. We have forwarded the notifications submitted for the aforementioned products to 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 any assistance

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

978-0163

LET223

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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 Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

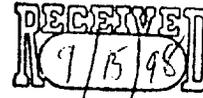
GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:9/21/98:docname:61186.adv:disc32



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 8, 1998



James Tanner, Ph.D.  
Acting Director, Division of Programs and Enforcement Policy  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
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, one original signature and two copies of each:

- 1) Schiff® **Ipriflavone**, Product #12841
- 2) Great American Nutrition® **UltraAC™**, Product #52506 & #52517
- 3) Great American Nutrition® **UltraAP™**, Product #50215 & #50216
- 4) Schiff® **Homocysteine Protection**, Product #11401
- 5) Regenex™ **Cardio Formula**, Product #12890
- 6) Muscle Tribe™ **Tribestan®**, Product #52447
- 7) Muscle Tribe™ **Tribe Gainer™**, Product #52438
- 8) Muscle Tribe™ **Neuro One**, Product #52435
- 9) Muscle Tribe™ **St. John's Wort**, Product #52434
- 10) Muscle Tribe™ **Creatine HMB**, Product #52370
- 11) Muscle Tribe™ **Creatine**, Product #50000 & #51895
- 12) Muscle Tribe™ **Creatine L3**, Product #52346
- 13) Schiff® **JointFree Plus™**, Product #11821
- 14) Excel® **Korean Ginseng**, Product #14202
- 15) Schiff® **Liverall Powder**, Product #11106
- 16) Schiff® **Liverall**, Product #11108
- 17) American Body Building Products® **Extreme Ripped Force**, Products #55495, #55496 and #55523
- 18) Schiff® **5-HTP**, Product #12844
- 19) Schiff® **JointFree™**, Product #11822

- 20) Fred Meyer, **Selenium**
- 21) Schiff® **Selenium**, Product #11261
- 22) Schiff® **Selenium**, Product #11261 & #11238
- 23) Fred Meyer, **Yeast Selenium**, Product #71867
- 24) Great American Nutrition® **Cold-Free™**, Products #50231, #50232, #50251, #52519, #50255, #50256 and #52531
- 25) Great American Nutrition® **Cold-Free™**, Products #51100 and #59000
- 26) Great American Nutrition® **Cold-Free™**, Product #50127
- 27) Schiff® **JointFree Plus™**, Product #11821 and Sales Sheet
- 28) Schiff® **Pain Free™**, Product #10740
- 29) Great American Nutrition® **PhenCal™**, Products #52489, #52312, #52330, #52335, #52336, #52337, #52344 and #52345; also Schiff® **PhenCal™**, Product #12783
- 30) Great American Nutrition® **NuStart™ Women's Breast Health Formula**, Products #52504 #50470 and #50472
- 31) Great American Nutrition® **NuStart™ Glucarate**, Products #52446, #50417 and #50473

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, Dan Thomson

**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 **Great American Nutrition® Cold-Free Zinc Lozenges Product #50231, #50232, #50253, #50251, #52519, #50255, #50256 and #52531** bearing the statement(s) set out below:

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

The text of each structure-function claim for **9 mg Zinc (as acetate) per lozenge** is as follows:

**(Statement 1)**      **Cold-Free's** potent zinc acetate formula provides nutritional support to improve overall health and immune function during the cold and flu season. A healthy immune system can keep your customers at peak performance all season long.

**(Statement 2)**

**(Statement 3)**

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 8th day of September, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:



DR. LUKE R. BUCCI  
Vice President of Research

**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 **Great American Nutrition® Cold-Free Zinc Lozenges Product #51100 and #59000** bearing the statement(s) set out below:

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

The text of each structure-function claim for **9 mg Zinc (as acetate) per lozenge** is as follows:

**(Statement 1)**      **Cold-Free's** potent zinc acetate formula provides nutritional support to improve overall health and immune function during the cold and flu season. A healthy immune system can keep your customers at peak performance all season long.

**(Statement 2)**

**(Statement 3)**

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 8<sup>th</sup> day of September, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:



DR. LUKE R. BUCCI

Vice President of Research

**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 **Great American Nutrition® Cold-Free Zinc Acetate Spray Product #50127** bearing the statement(s) set out below:

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

The text of each structure-function claim for **9 mg Zinc (as acetate) per three (3) sprays** is as follows:

- (Statement 1)**            **Cold-Free's** potent zinc acetate formula provides nutritional support to improve overall health and immune function during the cold and flu season. A healthy immune system can keep your customers at peak performance all season long.
- (Statement 2)**
- (Statement 3)**

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 8th day of September, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

  
\_\_\_\_\_  
DR. LUKE R. BUCCI  
Vice President of Research

**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 **Schiff® Pain Free™ Product #10740** bearing the statement(s) set out below:

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

The text of each structure-function claim for **500 mg Glucosamine Complex and 500 mg chondroitin sulfates per capsule (3 caps/serving)** is as follows:

- (Statement 1)** Pain Free dietary supplement combines the best of science and nature and was developed to support healthy joint function in active adults.
- (Statement 2)** Purified Chondroitin Sulfates help to maintain structural integrity of joints and blood vessels.
- (Statement 3)** Glucosamine is used by the body to manufacture cartilage components necessary to facilitate joint health.
- (Statement 4)** **Schiff® Pain Free™** is an advanced dietary supplement designed to help maintain and support joints and connective tissues. **Schiff® Pain Free™** is a simple and natural way to prevent body breakdown.
- (Statement 5)** **Pain Free™** combines 500 mg Glucosamine Complex and 400 mg Chondroitin Sulfate in a single caplet. This high-potency formula combines the best of science and nature and is designed to support and maintain joints.
- (Statement 6)** Glucosamine is the precursor for a group of compounds called glycosaminoglycans (GAGs) found in all connective tissues, especially cartilage in joints and joint fluid. Glucosamine helps normalize cartilage production to provide the support your joints can use.
- (Statement 7)** Chondroitin Sulfates are integral components of all connective tissues, especially cartilage in joints and blood vessels. Chondroitin Sulfates give cartilage its resilience and cushioning properties by binding with water. Chondroitin Sulfate is easily absorbed into the bloodstream after oral ingestion and is retained by connective tissues to help maintain joint integrity.

**(Statement 8)**            Glucosamine helps normalize cartilage production while  
Chondroitin Sulfate gives cartilage its resilience and cushioning  
properties.

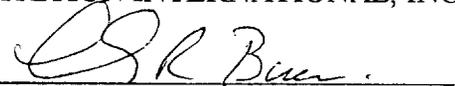
**(Statement 9)**            A simple and natural way to help support and maintain joint  
function in active adults.

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 8th day of September, 1998.

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BY:



DR. LUKE R. BUCCI  
Vice President of Research