



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAR 30 2000

3 2 8 4 '00 APR 25 P 2 :39

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

Dear Mr. Shelton:

This is in response to your letter of March 15, 2000 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 the following claim, among others, for the product **Weider Signature chromium Picolinate, Product #50295**:

“...helps your body maintain normal blood sugar levels.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely diabetes or disorders of glucose tolerance. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 349

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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-800 (r/f, file)

HFS-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-811:rjm:3/28/00:docname:69858.adv:disc45

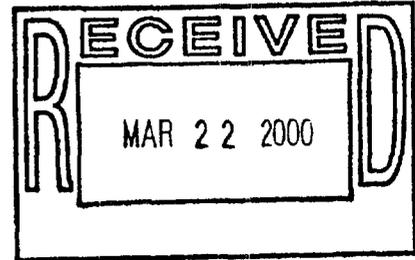
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# OFFICE OF REGULATORY AFFAIRS

WEIDER NUTRITION INTERNATIONAL, INC.

2002 SOUTH 5070 WEST  
SALT LAKE CITY, UTAH 84104-4836

DELOIS L. SHELTON  
TELEPHONE (801) 975-5031  
FACSIMILE (801) 972-6532



March 15, 2000

Lynne A. Larsen, 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 Larsen:

Enclosed are the structure/function claims for the following products, as generated by Dr. Luke Bucci, one original signature and two copies of each:

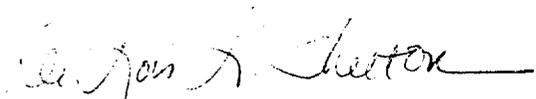
- 1) Science Foods® Extreme Size™, Product #60013
- 2) Science Foods® White Lightning™, Product #60024, #60025, #60026 & #60028
- 3) Science Foods® Muscle Shake™, Product #60106 & #62050
- 4) Science Foods® Ripped to the Max™, Product #60170, #60171 & #60172
- 5) Science Foods® Ion X™, Product #60180, #60181, #60182 & #60183
- 6) Science Foods® Diet Turbo Tea™, Product #62021
- 7) Science Foods® Turbo Tea™, Product #62020
- 8) Science Foods® Ripped Mass™, Product #62040 & #62041
- 9) Spring Valley® Vitamin B1, Product #13616
- 10) Spring Valley® Folic Acid, Product #13603
- 11) Science Foods® Carbo Pump™, Product #62126, #62127 & #62128
- 12) Weider Signature 90% Plus Protein, Product #50158 & #50159
- 13) American Body Building™ Pure Pro™, Product #55627 & #55628
- 14) Schiff® Fat Burners® Women's Formula, Product Insert
- 15) Schiff® Glucosamine, Product #12758, #12759, #12762 & #15206
- 16) Spring Valley® B-50, Product #13611
- 17) Weider Signature Creatine ATP™, Product #52403 & #52404
- 18) Weider Signature Creatine Monohydrate, Product #52485

- 19) Weider Signature Creatine Monohydrate, Product #52800
- 20) Weider Signature Pyruvate, Product #52399
- 21) Weider Signature Chromium 400mcg, Product #51965
- 22) Weider Signature Chromium Picolinate, Product #50295
- 23) Schiff® Fat Burners®, Product #12736, #12740 & #12739
- 24) Meataform® Androstenedione, Product #50615

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.

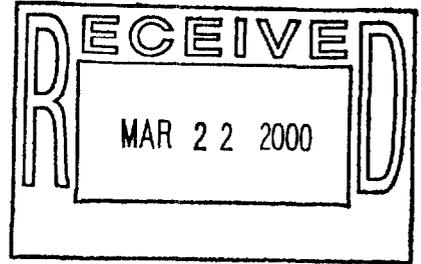
Please feel free to contact me if you have further questions or comments.

Respectfully,



De Lois L. Shelton, Regulatory Compliance

cc: Luke R. Bucci, Dan Thomson, Todd Crowley



**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 **Weider Signature Chromium Picolinate, Product #50295** 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 **Chromium picolinate** is as follows:

**(Statement 1)**

Chromium is an essential trace element that helps your body maintain normal blood sugar levels.

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 13<sup>th</sup> day of March, 2000.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: *LR Bucci*  
DR. LUKE R. BUCCI  
Vice President of Research

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