



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 30 2003

Delois L. Shelton
Director of Regulatory Affairs
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 June 12, 2003 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 **Schiff Move Free**:

“Unlike pain relievers that only offer temporary relief...”

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, because it is made in the context of other claims that the product is intended for use in the maintenance of joint flexibility and mobility, among other things, suggests that it is intended to prevent or treat joint diseases. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

LET 716

Page 2 - Mr. Delois L. Shelton

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', with a long horizontal stroke extending to the right.

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
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 Office, Office of Compliance, HFR-SW240

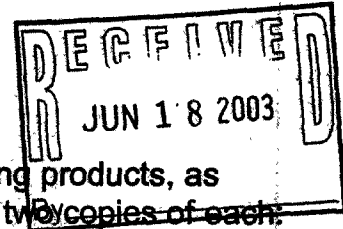
DELOIS L. SHELTON
OFFICE OF REGULATORY AFFAIRS
WEIDER NUTRITION INTERNATIONAL, INC.
2002 SOUTH 5070 WEST
SALT LAKE CITY, UTAH 84104-4836
TELEPHONE (801) 975-5031
FACSIMILE (801) 972-6532

June 12, 2003

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) Weider Dynamic Weight Gainer, product #50068 & #50069
- 2) Weider Whey Amino 6000, product #50031
- 3) Weider Cell Recovery Stack, product #50085 & #50086
- 4) Weider Muscle Volumizer, product #50041
- 5) Weider Alpha-GPC 250, product #50051
- 6) Weider Ultra Energy OB3, product #52610
- 7) Weider Whey Protein Isolate, product #50032 & #50033
- 8) Weider MSP-25, product #50087 & #50088
- 9) Weider Dynamic Body Shaper CLA Complete, product #50061 & #51061
- 10) Weider MSP-50, product #50076 & #50077
- 11) Weider Super Whey, product #50074 & #50075
- 12) Weider Dynamic Body Shaper Diet & Energy, product #52002
- 13) Weider Dynamic Body Shaper Metabolizer, product #50082 & #50037
- 14) Weider ZMA NT Plus, product #52608
- 15) Weider Megabolic Mega-Paks, product #50156
- 16) Weider Dynamic Body Shaper Transformation Kit, product #51040 & #50039
- 17) Weider Chromium 400 mcg, product #51965
- 18) Schiff DHEA, product #12767, #12768, #12773, S-3222
- 19) Spring Valley Vitamin B Complex, product #13614 & #13615/43575
- 20) Schiff Selenium, product #11231, #11268 & #11992


847E

- 24) Schiff PMS Kit, product #11303, S-3230 & S-3487
- 25) Schiff Lutein, product #12403, #12405, S-3222 & S-3488
- 26) Schiff Glucosamine, product #11029, #11030, #11034 & #11036
- 27) Schiff Breast Health, product #11971 & S-3230
- 28) Schiff SAME, product #10650
- 29) Schiff Move Free Plus SAME, product #12885
- 30) Schiff Joint Free Plus, product #11830 & #11833
- 31) Schiff Menopause Nutritional System, product #11479
- 32) Schiff Move Free, product #11751, #11752, #11753, #11749, #11760, #11755, S-3321 & S-3717
- 33) Schiff Move Free Plus MSM, product #10747, #10751, #12366, #12412, #12416, #12983, Brochure S-22, #12340, #12382 & #12384
- 34) Schiff Iron, product #11290 & Trade Ad S-65a
- 35) Schiff Move Free, product #10740, #1749, #12314, #12317, #12322, #12337, #12839, #12874, #12876, #12894, #12346, S-3222, S-3488, S-3321 & S-3329
- 36) Schiff ImmunAssure, product #11533, #11534 & #11535
- 37) Schiff ImmunAssure, product #11531 & #11532
- 38) Schiff ImmunAssure, product #11534, S-3378 & S-3465
- 39) Schiff Multi-Nutrient Pak Whole Food Based, product #11493

We welcome the opportunity to communicate with your office as we continue to submit structure/function claims as allowed by the Dietary Supplement Health and Education Act.

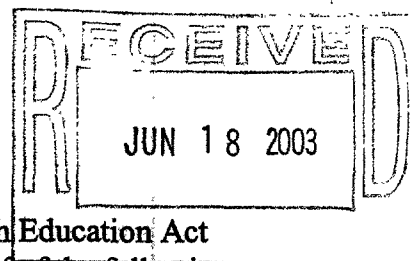
Please feel free to contact this office if you have further questions or comments regarding this submission.

Respectfully,



De Lois L. Shelton, Director of Regulatory Affairs

NOTIFICATION PURSUANT TO
SECTION VI OF DSHEA



In compliance with Section VI 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 Move Free, Product #10740, #10749, #12314, #12317, #13222 #12337, #12839, #12874, #12876, #12894, #47512346, #47612346, #47512893, 47612893, S-3488, S-3321 & S-3992 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 is as follows:

New Look Label:

(Statement 1) Schiff Move Free supports healthy joint function in active adults. Chondroitin helps to lubricate, cushion and support joints.

Carton:

(Statement 2) Unlike pain relievers that only offer temporary relief, Glucosamine and Chondroitin, (the ingredients in Schiff Move Free). Promote long term joint health. Glucosamine is a basic building block of joint cartilage, which helps to maintain structural integrity of joints and connective tissues. It [Chondroitin] is capable of binding water molecules to lubricate, cushion and support joints.

PDQ: S-3565 Headers S-3564 S-3566 S-3594:

(Statement 3) Cushion, lubricate and nourish your joints with Schiff Move Free. Schiff Move Free is still the brand you trust to deliver the joint health benefits you need.

Website:

(Statement 4) Chondroitin sulfates protect the structural integrity of joints and blood vessels.

Primary Use: Joint Health

S-3222 & S-3488

(Statement 5) Glucosamine helps to support healthy cartilage while Chondroitin helps lubricate your joints. Schiff Move Free promotes flexibility and mobility in your joints within weeks.

Unlike pain relievers that only offer temporary relief, glucosamine and chondroitin (the ingredients in Move Free) promote/support long term joint health and flexibility.

84758

S-3221 & S-3329

(Statement 6) These two nutrients work together to provide your joints with the elements they need to support healthy movement and flexibility. Glucosamine is a natural supplement that rebuilds joint cartilage and provides joint lubrication to support healthy joint movement and flexibility.

Pilfer Card: 47512893, 47612894

(Statement 7) Move Free helps support freedom of movement by providing the natural building blocks for joint fluid, cartilage and connective tissue.

Tray 12894

(Statement 8) Helps Support Healthy Joint Fluid & Cartilage
Maintains Joint Movement & Flexibility

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc., am authorized to certify this Notification on 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 10th day of June, 2003

WEIDER NUTRITION INTERNATIONAL, INC.

BY:



DR. LUKE R. BUCCI

Vice President of Research