



NOV 24 1997

0559 '98 MAR 24 P2:43

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

Dear Ms. Shelton:

This is in response to your letter of November 5, 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 you are making the following statement, among others, for the product "Muscle Tribe Pain Free with Purified Chondroitin Sulfates and glucosamine #52432," manufactured by Weider Nutrition International, Inc.: "Pain Free dietary supplement combines the best of science and nature and was developed to support healthy joint function in active adults."

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 statement that you are making for this product suggests that it is intended to treat or mitigate a disease, in that the name "PAIN FREE" evidences that it is intended to treat or mitigate pain. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim 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 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

975-0163

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Page 2 - Ms. De Lois L. Shelton

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

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (Williams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

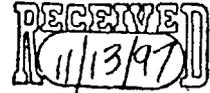
GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:11/18/97

f/t:HFS-456:rjm:11/18/97:docname:55723.adv:disc24



DELOIS L. SHELTON
 OFFICE OF REGULATORY AFFAIRS
 WEIDER NUTRITION INTERNATIONAL, INC.
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 SALT LAKE CITY, UTAH 84104-4836
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November 5, 1997

James Tanner, PhD
 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

55723

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) Schiff® Veggie Blend Multi Vitamin, product #11514
- 2) American Body Building Products® XXL 1100, product #55370
- 3) Joe Weider Chromium Picolinate, product #51965
- 4) Muscle Tribe Pain Free™ with Purified Chondroitin Sulfates and Glucosamine, product #52432
- 5) Muscle Tribe™ St. John's Wort, product #52434
- 6) Schiff® Children's Chewable Vitamins and Minerals, products #11406 & #11407
- 7) Great American Nutrition™ Time Release CITRIMAX™, product #52111
- 8) Great American Nutrition™ Complete Diet System, products #51105 & #50200

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

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NOV 13 1997

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 **Muscle Tribe Pain Free™ with Purified Chondroitin Sulfates and Glucosamine #52432** 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 is as follows:

- (Statement 1)** Pain Free™ dietary supplement combines the best of science and nature and was developed to support healthy joint function inactive 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.

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 5th day of November, 199 7.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:



DR. LUKE R. BUCCI
Vice President of Research

55723

Weider Nutrition Group
1960 South 4250 West
Salt Lake City UT 84104

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Glucosamine Complex & Chondroitin Sulfate

DATE: September 26, 1997
Document Name: sf01pain.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): Muscle Tribe 52432 Pain Free 60t

NUTRIENT AMOUNT: 500 mg glucosamine complex & 400 mg chondroitin sulfates per capsule (3 caps/serving)

STRUCTURE/FUNCTION CLAIM:

Pain Free dietary supplement combines the best of science and nature and was developed to support healthy joint function in active adults.

Purified Chondroitin Sulfates help to maintain structural integrity of joints and blood vessels. **Glucosamine** is used by the body to manufacture cartilage components necessary to facilitate joint health.

L. R. Bucci 10/6/97
Approved by / Date

REFERENCES:

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