



FEB - 8 1999

5 3 0 5 '99 FEB 23 P1 :48

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 February 1, 1999 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 product "Metaform Pain Free (#52498)".

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 this product suggests that it is intended to treat, prevent, cure, or mitigate disease, in that the name of the product, by incorporating the term "Pain Free," evidences that it is intended to treat, prevent, cure, or mitigate pain. 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. 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,

Lynn A. Larsen, Ph.D.
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 Office, Office of Compliance, HFR-SW240

975-0163

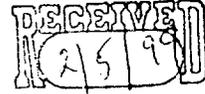
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DELOIS L. SHELTON
OFFICE OF REGULATORY AFFAIRS
WEIDER NUTRITION INTERNATIONAL, INC.
2002 SOUTH 5070 WEST
SALT LAKE CITY, UTAH 84104-4836
TELEPHONE (801) 975-5031
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6-35262

February 1, 1999

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) Nature's Valley™ **Melatonin**, Product #81482 & #81841
- 2) Nature's Valley™ **Pycnogenol®**, Product #81480
- 3) Schiff® **21 Grain Lecithin**, Product #11006
- 4) Weider Nutrition **Citrimax™**, Product # 52112
- 5) Metaform® **Pain Free**, Product #52498
- 6) Weider Victory **Mass 1000®**, Product #51492 & #51493
- 7) American Body Building Products® **Kick Some Mass™** Product #55477, #55478, #5597, #55483, #55484, #55488, #55489
- 8) Metaform® **Heat™** Product #52190 & #52208

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 **Metaform® Pain Free Product #52498** 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 **Glucosamine Complex & Shark Cartilage** is as follows:

- (Statement 1)**
- A.** Joint support
 - B.** Cartilage maintenance
 - C.** Athletes who must maintain the structural integrity of their bodies
 - D.** Active adults who want to have healthy joint function
 - E.** Well-documented combination for healthy connective tissue cartilage, blood vessels and to maintain structural integrity of joints
- (Statement 2)** Joint Health Formula
- (Statement 3)** Metaform's joint support formula combines the structural integrity characteristics of Purified Shark Cartilage with the cartilage manufacturing properties of Glucosamine to give you the ultimate joint health and support supplement
- (Statement 4)** Purified Shark Cartilage provides a natural source of minerals (including sulfate), and chondroitin sulfates (containing N-acetylgalactosamine and glucuronic acid), which help maintain healthy connective tissue.
- (Statement 5)** Glucosamine can help normalize cartilage production and provides support for joint function

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 1st day of February, 1999.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: 
DR. LUKE R. BUCCI
Vice President of Research