



JUL 12 1999

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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 June 21, 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 the following claim, among others, for the product **Schiff PMS Nutritional System System [sic] Kit Product #11460**:

“Women with PMS have found it to be particularly helpful...”

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, including the use of “PMS” in the product name, suggests that it is intended to treat, prevent, or mitigate disease, namely premenstrual syndrome. 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.

Your submission also states that you are making claims of a relationship between calcium and osteoporosis for the product **Schiff Menopause Nutritional System Product #11470**. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements

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in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if you require further 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

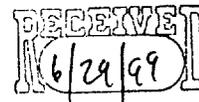
Copies:

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

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett)
f/t:HFS-456:rjm:7/12/99:docname:65874.adv:disc38

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® PMS Nutritional System System Kit Product #11460 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 **Vitamin A, D, E, C, B1, B2, B3, B6, B12, Folate, Biotin, Pantothenate, Calcium, Iron, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Potassium, Choline, Inositol, PABA, Sasparilla, Burdock & Ginger** is as follows:

(Statement 1)

The vitamin-mineral and herbal formulas are nutritional supplements formulated for women. Women with PMS have found it to be particularly helpful when used in a program of self-care including diet, exercise and stress reduction.

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 21st day of June, 1999.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

A handwritten signature in black ink that reads "Luke R. Bucci". The signature is written over a horizontal line.

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® PMS Nutritional System System Kit Product #11460 bearing the statements set out below:

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(Statement 1)

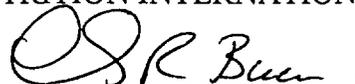
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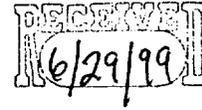
WEIDER NUTRITION INTERNATIONAL, INC.

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® Menopause Nutritional System Product #11470** 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 **Vitamins A, C, D, E, B1, B2, B3, B6, B12, Folate, Biotin Pantothenate, Calcium, Iron, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Boron, Fennel, Black Cohosh, Anise & Blessed Thistle** is as follows:

- (Statement 1) Provides the nutrients that may be important during midlife and menopausal years.
- (Statement 2) Proper nutrition and nutritional supplementation support healthy lifestyle practices during menopause.
- (Statement 3) Women have found them to be particularly helpful during menopause when used in a program of self-care including diet, exercise and stress reduction.
- (Statement 4) Proper nutrition and nutritional supplementation support healthy lifestyle practices during menopause.
- (Statement 5) For many women the use of a nutritional supplement is important in order to achieve optimal levels of certain essential nutrients.
- (Statement 6) Vitamin A - Vitamin A is necessary for the growth and support of the skin, mucous membranes, immune system, bones and eyes.
- (Statement 7) Vitamin B Complex - The whole complex works together to support metabolic functions, including glucose metabolism, homocysteine removal and stabilization of brain chemistry.
- (Statement 8) Vitamin D - Many medical studies have demonstrated the importance of vitamin D for bone support. It aids the absorption of calcium from the intestinal tract and in the assimilation of phosphorous. Adequate vitamin D is essential to maintain strong, sturdy bones through and beyond menopause.
- (Statement 9) Vitamin E - It protects vitamin A and polyunsaturated fats from oxidation and promotes cardiovascular health.
- (Statement 10) Calcium - Calcium is essential for maintenance of strong bones and

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teeth. Calcium intake throughout life is one risk factor for osteoporosis, or bone loss. Other risk factors are advancing age, being a woman, and being Caucasian or Asian. Menopausal women, and long-lived men and women are at greater risk for bone loss. An adequate intake of calcium throughout life is linked to a reduced risk of osteoporosis by the mechanism of optimizing peak bone mass during adolescence and early adulthood, and later, by slowing the rate of bone loss. However, a total dietary calcium intake of over 2000mg per day has no further known benefit to bone health. Regular exercise and a healthy diet with enough calcium helps high risk populations maintain good bone health and may reduce their risk of osteoporosis later in life. Calcium is also needed for blood clotting, enzymatic action, and the regulation of fluid passage through walls of tissues and cells.

(Statement 11)

Magnesium - Magnesium is involved in the function of numerous enzymes in all cells, especially those involved with production of cellular energy. Magnesium is essential for proper protein synthesis, fatty acid synthesis, neurotransmitter production, and for regulatory events between cells. Magnesium is also necessary for bone health.

(Statement 12)

Iron - Iron is important in transporting oxygen in red blood cells to tissue. Iron is absorbed better if taken with vitamin C.

(Statement 13)

Iodine - Iodine is essential for the development and functioning of the thyroid gland

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WEIDER NUTRITION INTERNATIONAL, INC.

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DR. LUKE R. BUCCI

Vice President of Research