



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

NOV 6 2003 03 14 P3:16

Mr. Alan E. Huffington
Director of Regulatory Affairs
Body Wise International, Inc.
2802 Dow Avenue
Tustin, California 92780

Dear Mr. Huffington:

This is in response to your letter of October 6, 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 letter states that the following statement will be made for the product Essential Calcium™ : "Helps to maintain healthy blood pressure levels."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

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 a disease. 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 20855.

995-0163

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Page 2 - Mr. Alan E. Huffington

Please contact us if we may be of further assistance.

Sincerely yours,

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

Susan J. Walker, M.D.
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, Los Angeles District Office, Office of Compliance, HFR-PA240



Body Wise International, Inc.
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RECEIVED
OCT 21 2003
BY:

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

RE: Notification of statements on a dietary supplement known as, Essential Calcium™

October 6, 2003

Dear Ladies/Gentlemen;

Pursuant of 21 C.F.R. Subpart F, section 101.93, Body Wise International, Inc. ("Body Wise" the distributor, which is located at 2802 Dow Avenue, Tustin, CA 92780) wishes to notify the Food and Drug Administration that it has commenced marketing a dietary supplement known as Essential Calcium™ which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as Essential Calcium™

- Essential Calcium™ No bones about it-you need calcium!
- Essential Calcium™ provides 1,000 mg a day of calcium as calcium citrate, a very absorbable form of calcium, as well as vitamin D3 to optimize bone mineralization and to ensure proper calcium use. If you want a complete bone health formula, with all the important bone nutrients, try Essential Calcium today!
- Calcium Citrate. The most absorbable form of calcium. Helps support strong bones and normal bone density. Helps to maintain healthy blood pressure levels.
- Magnesium, Essential for maintaining strong bones and normal bone density.
- Hydrochloric Acid HCl, Helps to support calcium absorption.
- Essential Calcium™ helps support a healthy skeletal system. (Addressed by the materials: Vitamin D3 (as Cholecalciferol), Vitamin B6 (from Pyridoxine HCl), Calcium, Magnesium, Zinc, Copper, Manganese, Glucosamine Sulfate, Betaine HCl, Silica (from Magnesium Trisilicate), Boron, and Hyaluronidase.)

The above statements are accompanied by the required disclaimer, which is prominently displayed in a box in boldfaced type.

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The information contained in this notice is complete and accurate. Body Wise maintains on file substantiation that these statements are truthful and non-misleading.

An original and two copies of this notification are being submitted.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan E. Huffington". The signature is fluid and cursive, with the first name being the most prominent.

Alan E. Huffington
Director of Regulatory Affairs

dw/AEH

Enclosures: Two copies of this two-page letter.