



JAN -7 2003 0573 '03 FEB 12 P1:49

Nancy Steely, ND
Research & Development Manager
Your Vitamins
430 Parkson Road
Henderson, Nevada 89015

Dear Dr. Steely:

This is in response to your letter of December 11, 2002 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 Your Vitamins is making the following claim, among others, for the product **Andrew Lessman's Calcium-Magnesium Intensive Care™**:

“Osteoporosis is a major health concern among American women and despite Calcium and Magnesium being absolutely essential for building health bone....”

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim 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 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

John B. Foret
Director
Division of Compliance and Enforcement
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

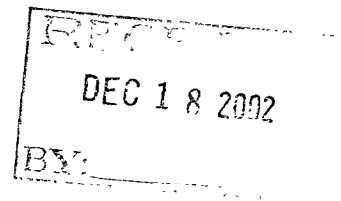
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140



December 11, 2002

Director
Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, DC 20204



SENT VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED
ARTICLE #: 7099 3400 0016 4139 9843

RE: CALCIUM MAGNESIUM INTENSIVE CARE

Dear Sir / Madam:

This is a 30-day notification of a statement of nutritional support for a dietary supplement. The product name is **Andrew Lessman's Calcium Magnesium Intensive Care**. The structure / function claims on all sizes and configurations of this product are identical. They are as follows:

Andrew Lessman's Calcium-Magnesium Intensive Care™ is a mild all natural formula designed to support and maintain bone health by providing superior forms of the two most abundant minerals found in your bones -- Calcium and Magnesium. Osteoporosis is a major health concern among American women and despite Calcium and Magnesium being absolutely essential for building healthy bone, the American diet consistently delivers amounts of these vital minerals far below those required for skeletal health and bone integrity. To ensure maximum benefits, **Calcium-Magnesium Intensive Care** combines two forms of both Calcium and Magnesium to maximize yield, solubility, absorption, availability and utilization. We also add Vitamin D since it is absolutely essential for Calcium utilization, as well as Boron, which plays a complementary role in supporting healthy bone. **Calcium-Magnesium Intensive Care** is designed to be a convenient and effective means of getting the Calcium and Magnesium you need without the chalky aftertaste and upset stomach associated with ordinary Calcium and Magnesium supplements.

Respectfully Submitted,

Dr Nancy Steely, ND
Research & Development Manager

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