



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

9693 '00 OCT 25 P2:22

Food and Drug Administration
Washington, DC 20204

OCT 12 2000

Shawn Tiller
Manager
The Winning Combination
430 Parkson Road
Henderson, Nevada 89015

Dear Ms. Tiller:

This is in response to your letters of August 30, 2000 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 submissions state that The Winning Combination is making the following claims, among others, for the following products below:

"Andrew Lessman's Ipriflavone Plus™:"

"...help support and maintain a healthy skeleton and bone mass for women at all stages of life..."

"...help support bone mass..."

"...boron suggests that it may help reduce calcium loss from bones..."

"Andrew Lessman's Calcium-Magnesium Intensive Care™

"...help support and maintain healthy bone mass for women..."

"...may reduce the risk of osteoporosis later in life."

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). FDA has not authorized a health claim on the relationship between, boron, magnesium, vitamin D, or Ipriflavone 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 under 21 U. S. C.321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis. 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.

978-0163

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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "John B. Foret". The signature is written in a cursive style with a long horizontal flourish extending to the right.

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-PA150

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cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-811:afp:9/27/00:72276:disc1

72276a



**THE WINNING
COMBINATION**

The Informed Choice

430 Parkson Road
Henderson, Nevada 89015
702-564-9000 FAX 702-564-7829

August 30, 2000

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

RE: IPRIFLAVONE PLUS

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 Ipriflavone Plus**. The structure / function claims on all sizes and configurations of this product are identical. They are as follows:

Andrew Lessman's Ipriflavone Plus™ is designed to help support and maintain a healthy skeleton and bone mass for women at all stages of life by providing ingredients that support the delivery and retention of calcium in your bones. Ipriflavone is an isoflavone derived from Soy and has been shown to have beneficial effects on bone health. It has been widely used, studied and recommended in Europe for over 10 years and its support of bone health has been demonstrated in several clinical studies. Ipriflavone supports calcium utilization and bone mineralization and can also slow the cells which break down bone. In so doing, Ipriflavone can help support bone mass and contribute to overall skeletal integrity. **Andrew Lessman's Ipriflavone Plus** further supports a healthy skeleton by combining Ipriflavone with Calcium and Magnesium, plus Vitamin D and Boron, to maximize availability, solubility, absorption and utilization. Preliminary research on Boron suggests that it may help reduce calcium loss from bone when combined with other nutrients such as Vitamin D, which is essential for the absorption of Calcium.

Respectfully Submitted,

Shawn Tiller
Manager, Product Development



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COMBINATION**

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702-564-9000 FAX 702-564-7829

August 30, 2000

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

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 an all natural formula designed to help support and maintain healthy bone mass for women, by providing superior forms of the two most abundant minerals found in your bones, Calcium and Magnesium. Despite Calcium and Magnesium being essential for building healthy bone, inadequate quantities are often found in the American diet. Accordingly, this formula is particularly useful for women, who need to consume extra calcium to build and maintain a healthy skeleton. Especially for teens and young adult women, adequate calcium in a healthful diet may reduce the risk of osteoporosis later in life. Preliminary research on Boron suggests that it may help reduce calcium loss from bone when combined with other nutrients such as Vitamin D, which is essential for the absorption of Calcium.

Respectfully Submitted,

Shawn Tiller
Manager, Product Development

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