



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

9 6 9 9 '00 OCT 25 P2:22

Food and Drug Administration
Washington, DC 20204

OCT 24 2000

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

Dear Ms. Tiller:

This is in response to your letters of September 3, 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 product below:

"Andrew Lessman's Psyllium:"

"...may reduce the risk of heart disease."

This statement is a claim of a relationship between soluble fiber and the risk of coronary heart disease. 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 soluble fiber and the risk of coronary heart disease (see 21 CFR 101.81). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between soluble fiber and the risk of coronary disease. 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 101.81 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 101.81 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, coronary heart disease.

975-0163

LET 410

Page 2 - Ms. Shawn Tiller

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Page 3 - Ms. Shawn Tiller

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

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)

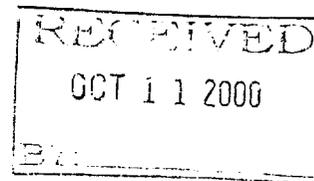
HFS-605

HFV-228 (Benz) - -

GCF-1 (Nickerson, Dorsey)

f/t:HFS-811:afp:10/20/2000:72798:disc1

Andrew Lessman's
WINNING COMBINATION™
The Informed Choice for Nutritional Supplements



October 3, 2000

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

RE: PSYLLIUM

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

Dietary fiber provides a myriad of healthful benefits and is generally considered the most overlooked component in the American diet. Moreover, it has been reported that the unique properties of the soluble fiber in this product can help to maintain and support healthy blood cholesterol levels. In fact, *diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from Psyllium Husk (the amount in 1 serving of Andrew Lessman's Psyllium) may reduce the risk of heart disease.* Also, the insoluble (bulk) fiber in this product helps to "scour" the digestive tract removing undigested food, debris and other by-products. Fiber also speeds gastrointestinal (GI) transit time (the time it takes for food to pass through you) and as a result can help remove digestive by-products sooner. Scientific research studies consistently demonstrate the long-term health benefits of a high fiber diet. It is also well established that adequate fiber intake is vital for maintaining the health of the digestive system. Moreover, when taken with meals, fiber can also provide a natural feeling of fullness to support most diet plans.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Shawn Tiller".

Shawn Tiller
Manager, Product Development