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FEB 22 2001

Mr. Shawn Tiller
Manager, Product Development
Winning Combination
430 Parkson Road
Henderson, Nevada 89015

Dear Mr. Tiller:

This is in response to your letter dated June 9, 2000 to the Food and Drug Administration (FDA), which was received on February 13, 2001, 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 Winning Combination is making statements that its product "Andrew Lessman's Daily Inner Cleanse™" contains fiber from psyllium husk that "may help to maintain healthy blood cholesterol levels" and "reduce the risk of heart disease."

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between soluble fiber and 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 from psyllium and coronary heart 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 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, coronary heart disease.

Your submission also states that you are making a claim for this product that it "may also help to maintain healthy blood sugar levels."

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, namely, that it "may also help to maintain healthy blood sugar levels," suggests that it is intended to treat, prevent, cure, or mitigate a disease, diabetes. This

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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.

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

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

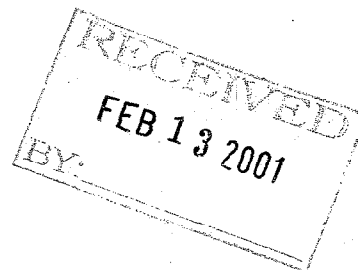
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HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-810 (r/f)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-607
GCF-1 (Nickerson)
HFV-228 (Benz)
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Andrew Lessman's
WINNING COMBINATION™
The Informed Choice for Nutritional Supplements

June 9, 2000

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

RE: DAILY INNER CLEANSE

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

Andrew Lessman's DAILY INNER CLEANSE™ is a comprehensive, all natural fiber and herb-based internal cleanser formulated for daily use. It is designed to support and maintain the health of several different internal systems. **Daily Inner Cleanse** is a unique blend of 5 different sources of fiber providing both soluble and insoluble (bulk) fiber. In addition to offering the benefits of fiber from Psyllium Husk, Oat, Apple, Grapefruit and Guar, it also contains Fructooligosaccharides (F.O.S.), Inulin, Lactobacillus sporogenes, Vitamin C and the herbs Cranberry and Milk Thistle, to provide additional benefits.

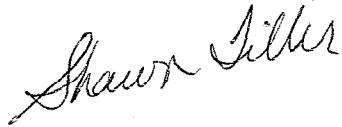
Dietary fiber provides a myriad of healthful benefits and is often overlooked as an important component in the American diet. It has been reported that soluble fiber may help to maintain healthy blood cholesterol levels. In fact, *diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from Psyllium Husk (the amount in 3 servings of Andrew Lessman's Daily Inner Cleanse) 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. Fiber can also provide a natural feeling of fullness to support most diet plans, while the Apple and Grapefruit pectins may also help to maintain healthy blood sugar levels.

We include L. sporogenes to support the beneficial proliferation of the healthy bacteria in your intestines. We also add Fructooligosaccharides (F.O.S.) and Inulin (which contains F.O.S.) because they are a preferred food of this healthy "good" bacteria, thus allowing them to multiply. The natural flora (good bacteria) in the GI tract also provides additional health benefits, which include supporting the absorption of certain vital minerals such as Calcium and Magnesium. We also include Cranberry for its antioxidant properties and because it helps naturally support the health of the bladder and the urinary tract. We add Milk Thistle because research has shown that Silymarin from the Milk Thistle plant is a potent antioxidant that can neutralize free radicals and has beneficial effects on the liver.

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

Daily Inner Cleanse not only provides the fiber that is so often too low in our modern diet, but also delivers a wide range of other components to support the health of the gastrointestinal tract and several other internal organs and systems.

Respectfully Submitted,



Shawn Tiller
Manager, Product Development