



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 16 2000 0195 '00 DEC -7 P3:07

Mr. Daniel R. McFarland
President
Fitness Labs Nutrition Corporation
P.O. 3896
Torrance, California 90510-3896

Dear Mr. McFarland:

This is in response to your letter of October 25, 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 submission states that Fitness Labs Nutrition Corporation is making the following claim for the product **Soy Protein Isolate**:

“It’s theorized that soy isoflavones are a major contributing component in soy providing major health benefits.” “This is the soy used in many of the research studies beginning in 1996 demonstrating its effect on cholesterol levels. Researchers have found that soy protein, in conjunction with naturally occurring isoflavones, is most effective in lowering cholesterol levels.”

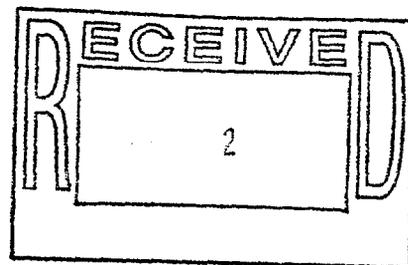
This statement appears to be a claim of a relationship between soy protein and risk of coronary heart disease. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between soy protein and risk of coronary heart disease (see 21 CFR 101.82). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between soy protein and risk of 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 101.82 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 101.82 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.

However, in so far as this claim appears to attribute its affect on blood cholesterol levels and the risk of coronary heart disease to soy isoflavones rather than soy protein, it is a claim that suggests that this product is intended to treat, prevent, or mitigate a disease. 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

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FITNESS LABS™
NUTRITION CORPORATION



October 25, 2000

Linda S. Kahl, Ph.D.
Office of Special Nutritionals (HFS-450)
Center of Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W.
Washington, D.C. 20204

Dear Dr. Kahl:

Fitness Labs Nutrition Corporation wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Soy Protein Isolate, Certified and Original. The dietary ingredient that is the subject of the statements is Soy Protein Isolate. The statements read as follows.

"It's theorized that soy isoflavones are a major contributing component in soy providing major health benefits." "This is the soy used in many of the research studies beginning in 1996 demonstrating its effect on cholesterol levels. Researchers have found that soy protein, in conjunction with naturally occurring isoflavones, is most effective in lowering cholesterol levels."

These statements are accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,
Fitness Labs Nutrition Corporation

A handwritten signature in black ink, appearing to read "D. McFarland".

Daniel R. McFarland
President

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