



Natural Factors Nutritional Products Inc.

August 18, 2004

Susan J. Walker, M.D., Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
And Dietary Supplements
Center for Food Safety and Applied Nutrition

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Dear Dr. Walker:

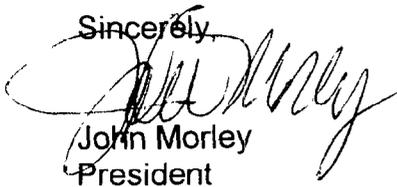
Thank you for your letter regarding Natural Factors June 23, 2004 notification to the Food and Drug Administration (FDA) for our **SlimStyles™ Weight Loss Drink Mix with PGX™** marketed as a dietary supplement.

The information that was sent to you saying we were using the words "Meal Replacement Program" was an error. It was apparently taken from some original artwork that was never used for the reasons you have stated. We printed the PDP with the following information:

Dietary Supplement
SlimStyles™ Weight Loss Drink Mix with PGX™

I hope this corrected information will meet with your approval.

Sincerely,



John Morley
President

Enclosed: Your letter for reference

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Mr. John Morley
President
Natural Factors Nutritional Products, Inc.
1111 80th Street S.W.
Suite 100
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 23, 2004. Your letter was submitted 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 Natural Factors Nutritional Products, Inc. is making the following claim, among others, for the product **SlimStyles™ Weight Loss Drink Mix with PGX™** which it intends to market as a dietary supplement:

“The revolutionary new SlimStyles Meal Replacement Program....”

21 U.S.C. 321(ff) defines the term “dietary supplement.” As defined by the Act, dietary supplements do not include products represented for use as conventional foods, 21 U.S.C. 321(ff)(2)(B). In your submission, you state that the intended use of this product is, in part, as a drink mix intended for use as a component of a meal replacement. Therefore, this product appears to be represented for use as a conventional food and is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to

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market this product as a conventional and you have any questions about the status of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan W. Walker". The signature is fluid and cursive, with a long horizontal stroke at the end.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340