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SEP 22 2005

Mr. Michael Salaman
President/CEO
Creative Enterprises, Inc.
825 Lafayette Road
Bryn Mawr, Pennsylvania 19010

Dear Mr. Salaman:

This is in response to your letter of August 23, 2005 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 Creative Enterprises, Inc. is making several claims for the product **Skinny Water**.

You identify label your product using the term "water." As such, you appear to be representing your product to be a bottled water, which is a standardized food (see 21 CFR Part 165). 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). The product described above, in that it is being described as a water, is being represented as a bottled water, a standardized food. In doing so, this product is being represented for use as a conventional food. Therefore, in that it is represented for use as conventional food, it 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, and in particular those requirements that apply to bottled water (21 CFR Part 165). 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. 343(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.

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Please contact us if we may be of further assistance.

Sincerely yours,



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, Philadelphia District Office, Office of Compliance, HFR-CE140

August 23, 2005

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements
(HFS-810)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Pkwy
College Park, MD 20740

SEP 12

Dear Sir/Madam:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that **Creative Enterprises, Inc.**, 825 Lafayette Rd, Bryn Mawr, PA 19010 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

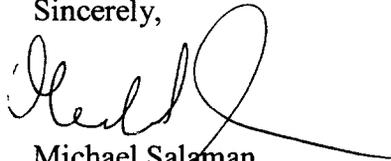
TEXT OF CLAIM(S) Reduce Body Weight, Curb Appetite, Increase fat burning

NAME OF INGREDIENT(S) THAT IS SUBJECT OF CLAIM
Artesian Water, Garcinia Cambogia, Hydroxycitric Acid, Natural Lemon Essence

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)
Skinny Water

The undersigned certifies that the information contained in this notice is complete and accurate and that **Creative Enterprises, Inc.** has substantiation that the statements are truthful and not misleading.

Sincerely,



Michael Salaman
President/CEO

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