DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

5170 '02 MAY 29 P2:38

MAY 16 2002

Mr. William F. Francis
President
Sweet Aloha Farms
PO Box 918
Kahuku, Hawaii 96731

Dear Mr. Francis:

This is in response to your letter received by the Food and Drug Administration (FDA) on April 30, 2002. 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 Sweet Aloha Farms is making the claims identified below for the product **SoooLITE!™** which it intends to market as a dietary supplement:

> SoooLITE!™ is a natural supplement extracted from a very special stevia plant that imparts a good taste. The stevia plant has been used for centuries as an all-natural and healthy way to enhance the healthiness of food and drinks. Combined with Hawaaian [sic] Natural Sugar, SoooLITE!™ provides the health conscious person with a better, more wholesome way to enjoy meals.

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 SoooLITE!™ is, in part, as a food flavoring. You state that this product, among other things, is to be added to other foods in order to impart a good taste to the food. Given this representation for the products intended use, SoooLITE!™ 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, SoooLITE!™ is a conventional food.. 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 market SoooLITE!™ as a flavor ingredient for use in food, it must be an approved food additive or it must be GRAS. Any questions

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regarding the marketing of your product as a conventional food should be directed FDA's Office of Food Additive Safety (HFS-200), 200 C St., SW, Washington, DC 20204.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

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

GM/t 5-1-02

Office of Special Nutritional Products, Labeling,
And Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., SW
Washington, DC 20204

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BY:

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NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

Sweet Aloha Farms, LLC files this notification pursuant to section 403(r)(6) of the Food, Drug and Cosmetic Act. This notification also includes the certification required by 21 CFR Part 101.93(a)(3)

1. Name and Address of Distributor: Sweet Aloha Farms, PO Box 918, Kahuku, Hawaii, USA 96731.

2. Brand Name: SoooLite!™

3. Name of dietary ingredient (s): Rebaudoside A, an extract of Stevia rebaudiana [with natural sugar as a bulking agent.] See attached labeling.

3. Text of Nutritional Support Statement being Made: (Labeling Attached.)

SoooLITE!™ is a natural supplement extracted from a very special stevia plant that imparts a good taste. The stevia plant has been used for centuries as an all-natural and healthy way to enhance the healthiness of food and drinks. Combined with Hawaaian Natural Sugar, SoooLITE!™ provides the health conscious person with a better, more wholesome way to enjoy meals.

Reduced Calorie, only 4 calories per serving
SoooLITE!
Natural Supplement

5. Substantiation information is on file is the sponsor's office. The Corporate officer who can certify same is William F Francis, President.

Sincerely yours,

William F. Francis
President
Sweet Aloha Farms

CUT HERE & PRESS ZIPPER TO RESEAL
SoooLite
Sugar Company
Only 4 Calories Per Serving!
SoooLite!
Natural Supplement
Net Weight 14oz • 397g

SoooLite Sugar Company

SoooLITE!™ is a natural supplement extracted from a very special stevia plant that imparts a good taste. The stevia plant has been used for centuries as an all-natural and healthy way to enhance the healthiness of food and drinks. Combined with Hawaiian Natural Sugar, *SoooLITE!™* provides the health conscious person with a better, more wholesome way to enjoy meals.

Supplement Facts

Servings Size 1/4 tsp (1g)
Servings Per Container About 448

Amount per Serving	
Calories 4	Calories from Fat 0
	% Daily Value*
Total Fat 0g	0%
Sodium 0mg	0%
Total Carbohydrates 1g	25%
Sugars 1mg	
Protein 0g	0%
Rebaudioside-A 1mg	0%

Not a significant source of cholesterol, dietary fiber, vitamin A, Vitamin C, calcium, iron

*Daily Value not established

Percent Daily Values (DV) are based on 2,000 calorie diet.

Ingredients: Natural Sugar(Bulking Agent), Rebaudioside-A (an extract from the Stevia plant)

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

SoooLite

SoooLITE! is a registered trademark of
Sweet Aloha Farms, LLC
PO Box 918 Kahuku, HI 96731
Comments: 1-800-555-1234

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