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Inspections, Compliance, Enforcement, and Criminal Investigations

Sunsweet Growers Inc.



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Arthur Driscoll, President and CEO
Sunsweet Growers Inc.
901 North Walton Ave.
Yuba City, CA 95993

Re: CFSAN-OC-10-06

Dear Mr. Driscoll:

The Food and Drug Administration (FDA) has reviewed the label for your Sunsweet® Antioxidant Blend™ dried fruit mix. Based on our review of this label and your website at <http://www.sunsweet.com>, we have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Your Sunsweet® Antioxidant Blend™ dried fruit mix product is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product labeling bears nutrient content claims that do not meet the requirements to make these claims. Specifically, these claims include "high antioxidant" on the principal display panel of the product label and "full of nutritious antioxidants" in the labeling for this product on your website.

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the

nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

The claim "high antioxidant" is an unauthorized nutrient content claim. The term "high" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim is unauthorized and causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The claim "full of nutritious antioxidants" is also an unauthorized nutrient content claim. The term "full" characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "full" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "full of nutritious antioxidants" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure or injunction.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Felicia B. Williams, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,
/S/

Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety
And Applied Nutrition

cc: Los Angeles District

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