

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Laughing Giraffe Organics 5/12/15



Department of Health and Human Services

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

MAY 12, 2015

WARNING LETTER

VIA OVERNIGHT MAIL

Chelsea Marshall, CEO
Laughing Giraffe Organics
3340 Mount Diablo Blvd, Suite E
Lafayette, CA 94549

Re: 449449

Dear Ms. Marshall,

The Food and Drug Administration (FDA) reviewed the labels for your Pineapple Snakaroons product in November 2014. Based on our review, we have concluded that this product is in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343] and its implementing regulations found in Title 21, Code of Federal Regulations, Part 101 (21 CFR Part 101). You can find the Act and FDA regulations through links on FDA's home page at <http://www.fda.gov> (<http://www.fda.gov>).

The significant violations are as follows:

1. Your Pineapple Snakaroons 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 label bears nutrient content claims, but the product does not meet the requirements to make such claims.

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 authorizing the use of such a claim. Characterizing the level of a nutrient on the food labeling of a product without complying with the specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act. Specifically:

a. The label of your Pineapple Snakaroons product bears an implied nutrient content claim, because it bears a statement suggesting that the product may be useful in maintaining healthy dietary practices, and that statement is made in connection with claims or statements about nutrients. Specifically, the label of the Pineapple Snakaroons product bears the claim “HEALTHY EVERYDAY SNACK!” in connection with statements such as:

- “nutrient-rich...,”
- “high in fiber,” and
- “great source of healthy fats”

However, your product does not meet the requirements for use of the nutrient content claim “healthy” that are set forth in 21 CFR 101.65(d)(2).

In accordance with 21 CFR 101.65(d)(2), you may use the term “healthy” as an implied nutrient content claim on the label or in the labeling of a food provided that the food, among other things, is “low saturated fat” as defined in 21 CFR 101.62(c)(2) [i.e., the food has a saturated fatty acid content of 1 g or less per Reference Amount Customarily Consumed (RACC) and no more than 15 percent of the calories are from saturated fat].

According to the Nutrition Facts panel on the label of your Pineapple Snakaroons product, the product contains 7 g of saturated fat per 22 g of the food. This amount far exceeds the maximum of 1 g of saturated fat per 30 g RACC. This amount also exceeds the maximum of 15% of calories from saturated fat in the “low saturated fat” definition. Accordingly, your product does not meet the requirements for use of the nutrient content claim “healthy” on a food label [21 CFR 101.65(d)(2)]. Your product is thus misbranded within the meaning of section 403(r)(1)(A) of the Act.

b. Your Pineapple Snakaroons product label bears the claim “high in fiber.” However, your

product does not meet the requirements for use of the nutrient content claim “high in fiber” that are set forth in 21 CFR 101.54(b). In accordance with 21 CFR 101.54(b)(1), you may use the term “high” on the label of foods provided that the food contains 20 percent or more of the RDI or the DRV per RACC. According to the Nutrition Facts panel, your Pineapple Snakaroons product contains 2 g of fiber per 22 g of the food (or 3 g fiber per RACC of 30 g). This level of fiber equates to 12 percent of the DRV for fiber per RACC. This level of fiber is below the level that would qualify for a “high” claim under 21 CFR 101.54(b)(1). Accordingly, this product does not meet the requirements to bear the nutrient content claim “high in fiber.” [21 CFR 101.54(b)]. Your product is thus misbranded within the meaning of section 403(r)(1)(A) of the Act.

c. Your Pineapple Snakaroons product label bears the claim “nutrient-rich,” but the product does not contain any nutrients that would meet the definition of “rich in” in accordance with 21 CFR 101.54(b). In accordance with 21 CFR 101.54(b)(1), “rich in” claims may be used if the food contains at least 20% of the RDI/DRV per RACC of fiber, protein, or an identified vitamin or mineral. Based on information in the nutrition label, the level of neither protein, fiber, nor any of the declared vitamins and minerals is at 20 percent or more of the RDI or the DRV per RACC. Accordingly, this product does not meet the requirements to bear the nutrient content claim “nutrient-rich.” [21 CFR 101.54(b)]. Your product is thus misbranded within the meaning of section 403(r)(1)(A) of the Act.

Your Pineapple Snakaroons product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] because it is fabricated from two or more ingredients and the label fails to declare the common or usual name of each ingredient, as required under 21 CFR 101.4(a)(1). Your Pineapple Snakaroons product lists “Organic agave nectar” as an ingredient; however, “Organic agave nectar” does not accurately describe the ingredient because the ingredient is actually hydrolyzed inulin syrup, and not juice. We note that this may be misleading to consumers under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)].

The above violations are not meant to be an all-inclusive list of violations that may exist in connection with your products or their labeling. It is your responsibility to ensure that your products comply with the Act and its implementing regulations. You should take prompt action to correct the violations. Failure to promptly correct the violations may result in enforcement action without further notice, including seizure and/or injunction.

In addition, we offer the following comments:

- The statement of the place of business on your Pineapple Snakaroons product label does not

include the street address of your firm. According to 21 CFR 101.5(d), the statement of the place of business must include the street address, unless the street address is shown in a current city directory or telephone directory.

Please respond to this letter within 15 working 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 15 working days, state the reason for the delay and the time within which you will complete the corrections.

You should direct your written reply to Carrie Lawlor, 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. If you have any questions regarding this letter, you may contact Ms. Lawlor via email at carrie.lawlor@fda.hhs.gov (<mailto:carrie.lawlor@fda.hhs.gov>).

Sincerely,

/S/

William A. Correll, Jr.
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:

FDA LOS-DO District

Justin Baumgartner, General Manager
1606 E. University Drive, Ste. 108
Phoenix, AZ 85034

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