



[Home](#) > [Inspections, Compliance, Enforcement, and Criminal Investigations](#) > [Enforcement Actions](#) > [Warning Letters](#)

Inspections, Compliance, Enforcement, and Criminal Investigations

Ken's Foods, 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

Frank A. Crowley III, CEO and President
Ken's Foods, Inc.
1 D'Angelo Dr.
Marlborough, MA 01752-3066

Re: CFSAN-OC-10-17

Dear Mr. Crowley:

The Food and Drug Administration (FDA) has reviewed the labels for your Ken's Healthy Options™ Parmesan & Peppercorn, Sweet Vidalia® Onion Vinaigrette, and Raspberry Walnut Dressings. Based on our review, we have concluded that these products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, **Code of Federal Regulations**, Part 101 (21 CFR 101). These products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 USC § 343(r)(1)(A)] because the product labels bear the nutrient content claim "healthy" but do not meet the requirements to make the claim. You can find copies of the Act and FDA regulations through links in FDA's home page at <http://www.fda.gov>

Under section 403(r)(1)(A) of the Act [21 USC § 343(r)(1)(A)], 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 in food labeling 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 [21 USC § 343(r)(1)(A)].

The labels of your Ken's Healthy Options™ Parmesan & Peppercorn, Sweet Vidalia® Onion Vinaigrette, and Raspberry Walnut Dressing products bear a nutrient content claim as defined by 21 CFR 101.13(b)(2)(ii) because they bear a statement suggesting that the products, because of their nutrient content, may be useful in maintaining healthy dietary practices, and those statements are made in association with claims or statements about a nutrient. Specifically, your product labels bear the brand name "Healthy Options™", in association with statements about the amounts of calories, fat, and sodium in the products. However, these products do not meet the requirements for the use of the nutrient content claim "healthy" that are set forth in 21 CFR 101.65(d)(2).

To bear the nutrient content claim "healthy," a food such as a salad dressing: (1) must be "low fat" as defined in 21 CFR 101.62(b)(2) (total fat content of 3 g or less per Reference Amount Customarily Consumed (RACC) and per 50 g of food); (2) must be "low saturated fat" is defined in 21 CFR 101.62(c)(2) (saturated fat content of 1 g or less per RACC and no more than 15 percent of calories from saturated fat); (3) must not exceed the disclosure level for cholesterol set forth in 21 CFR 101.13(h) (60 mg cholesterol per 50 g of food); (4) must contain no more than 480 mg sodium per 50 g of food (21 CFR 101.65(d)(2)(ii)(B)); and (5) must contain at least 10 % of the Daily Value per RACC of one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, and fiber (21 CFR 101.65(d)(2)(i)).

The label of your Ken's Healthy Options™ Parmesan & Peppercorn Dressing claims that the product is a "Healthy Option[]" in connection with the claims, "70 calories per serving, 6 g of fat, 230 mg of sodium." According to the Nutrition Facts panel, this product contains 6 g of fat per 30 g of food. Thus, the product's fat content exceeds the 3 g of fat per 50 g of food maximum in the "low fat" definition (21 CFR 101.62(b)(2)). Further, the product does not contain 10% of the Daily Value of at least one of the nutrients listed in 21 CFR 101.65(d)(2)(i) (vitamin A, vitamin C, calcium, iron, protein, and fiber). Accordingly, this product does not meet the requirements for the use of the nutrient content claim "healthy" on a food label (21 CFR 101.65(d)(2)).

Similarly, your Ken's Healthy Options™ Sweet Vidalia® Onion Vinaigrette and Raspberry Walnut Dressings bear the claim "Healthy Options" in connection with the claims, "60 calories per serving, 4 g of fat, 210 mg of sodium" and "60 calories per serving, 3.5 g of fat, 180 mg of sodium," respectively. According to the Nutrition Facts information for these products, the Sweet Vidalia Onion Vinaigrette contains 4 g of fat per 30 g of food, and the Raspberry Walnut Dressing contains 3 g of fat per 30 g of food. Thus, the fat content of each product exceeds the 3 g of fat per 50 g of food maximum in the "low fat" definition (21 CFR 101.62(b)(2)). Further, neither product contains 10 % of the Daily Value of at least one of the nutrients listed in 21 CFR 101.65(d)(2)(i). Accordingly, these products do not meet the requirements for the use of the nutrient content claim "healthy" on a food label (21 CFR 101.65(d)(2)).

This letter is not intended to be an all-inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to do so may result in regulatory action without further notice. Such action may include, but is not limited to, seizure or injunction.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and also prevent similar violations. You should include in your response documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your written response should be directed to Latasha Robinson, 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 207403835. If you have any questions, you may contact Ms. Robinson at 301-436-1890.

Sincerely,
/S/
Roberta Wagner
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: New England District Office

Links on this page: