

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

KIND, LLC 3/17/15



Department of Health and Human Services

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

WARNING LETTER

MAR 17, 2015

VIA OVERNIGHT DELIVERY

Daniel Lubetsky, CEO
Kind, LLC
55 West 21st Street
New York, New York 10010-6809

Re: 437043

Dear Mr. Lubetsky,

The Food and Drug Administration (FDA) reviewed the labels for your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products in August, 2014. The labels for these products direct the consumer to your website at the Internet address www.kindsnacks.com. We examined your website in October 2014. Based on our review, we have concluded that these products are 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 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 Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product labels bear nutrient content claims, but the products do 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 labels of your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products bear an implied nutrient content claim, because they bear statements suggesting that the product may be useful in maintaining healthy dietary practices, and those statements are made in connection with claims or statements about nutrients. Specifically, the labels of the aforementioned products bear the claim "Healthy and tasty, convenient and wholesome" in connection with statements such as:

- "good source of fiber,"
- "no trans fats,"
- "very low sodium" [Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants],
- "low sodium" [Kind Plus Peanut Butter Dark Chocolate + Protein],
- "+ antioxidants" [Kind Plus Dark Chocolate Cherry Cashew + Antioxidants],
- "50% DV antioxidants vitamins A, C and E" [Kind Plus Dark Chocolate Cherry Cashew + Antioxidants],
- "+ protein" [Kind Plus Peanut Butter Dark Chocolate + Protein], and
- "7g protein" [Kind Plus Peanut Butter Dark Chocolate + Protein].

Additionally, your website at <http://www.kindsnacks.com/about/> states, "There's healthy. There's

tasty. Then there's healthy and tasty" and "all of our snacks are pretty much the nirvana of healthful tastiness." In addition, your webpage for the Kind Peanut Butter Dark Chocolate + Protein product at www.kindsnacks.com/products/kind-store/buy-kind-bars/kind-plus/peanut-butter-darkchocolate-protein.html states "KIND Peanut Butter Dark Chocolate + Protein is a healthy and satisfying blend of peanuts and antioxidant-rich dark chocolate. Each bar contains 7 grams of protein, which promotes satiety and strengthens bones, muscles and skin."

However, none of your products listed above 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 fat 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 panels:

- The Kind Fruit & Nut Almond & Apricot product contains 3.5 g of saturated fat per 40 g of the food,
- The Kind Fruit & Nut Almond & Coconut product contains 5 g of saturated fat per 40 g of the food,
- The Kind Plus Peanut Butter Dark Chocolate + Protein product contains 3.5 g of saturated fat per 40 g of the food, and
- The Kind Fruit & Nut Dark Chocolate Cherry Cashew + Antioxidants contains 2.5 g of saturated fat per 40 g of the food.

These amounts exceed 1 g of saturated fat per 40 g RACC. These amounts also exceed the maximum of 15% of calories from saturated fat in the "low saturated fat" definition. Accordingly, your products do not meet the requirements for use of the nutrient content claim "healthy" on a food label [21 CFR 101.65(d)(2)]. Your products are thus misbranded within the meaning of section 403(r)(1)(A) of the Act.

b. Your Kind Peanut Butter Dark Chocolate + Protein and Kind Dark Chocolate Cherry Cashew + Antioxidants product labels bear the term "+" (plus) as part of the product name but the products do not comply with the requirements governing the use of this term. The term "+" as part of the names of your Kind Peanut Butter Dark Chocolate + Protein and Kind Dark Chocolate

Cherry Cashew + Antioxidants read in conjunction with “7 g Protein” and “50% DV Antioxidant, vitamins A, C and E,” respectively, meets the definition for a nutrient content claim because it characterizes the product’s level of vitamins and minerals, which are nutrients of the type required to be in nutrition labeling [21 CFR 101.13(b)].

The term “plus” is defined in 21 CFR 101.54(e). This term may be used on the label or in labeling of foods to describe the level of nutrients (such as vitamins and minerals) in the food, provided that:

- (1) the food contains at least 10 percent more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) for the nutrient per RACC consumed than an appropriate reference food,
- (2) where the claim is based on nutrients that are added to the food, that the fortification is in accordance with the policy on fortification of foods in 21 CFR 104.20, and
- (3) the claim bears the required information for relative claims as described in 21 CFR 101.13(j)(2) and 101.54(e)(1)(iii).

However, neither product label states the identity of the reference food and the percentage (or fraction) that the nutrient is greater relative to the RDI or DRV declared in immediate proximity to the most prominent such claim. Accordingly, these products are misbranded within the meaning of section 403(r)(1)(A) of the Act because they bear the nutrient content claim “plus” but do not comply with the regulations governing the use of this claim.

c. The product page for your KIND Peanut Butter Dark Chocolate + Protein product on your website at www.kindsnacks.com/products/kind-store/buy-kind-bars/kind-plus/peanut-butter-darkchocolate-protein.html includes the nutrient content claim “antioxidant- rich dark chocolate”; however, the product and its labeling do not meet the requirements for the use of such claim that are set forth in 21 CFR 101.54(g).

The phrase “antioxidant-rich” characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim under 21 CFR 101.13(b). Nutrient content claims using the term “antioxidant” must 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)]. In addition, in order to qualify for a “rich” or “high antioxidant” claim the product must contain 20 percent or more of the RDI for nutrients that have recognized antioxidant activity, such as vitamin C, vitamin E, or beta carotene (when 10% or

more of the RDI for vitamin A is present as beta carotene) in accordance with 21 CFR 101.54(b). Based on the information in the Nutrition Facts label, this product contains 15% of the Daily Value (DV) of vitamin E and 0% of vitamin C and vitamin A. Therefore this product does not qualify for a “rich in” claim and the product is misbranded under section 403(r)(2)(A)(i) of the Act.

2. Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products are misbranded within the meaning of section 403(r)(2)(A)(v) of the Act [21 U.S.C. § 343(r)(2)(A)(v)] because the labels include the nutrient content claim “Good Source of Fiber” without including the required statement disclosing that the food is not low in total fat in immediate proximity to the claim. Under 21 CFR 101.54(d), if a product label makes a claim with respect to the level of dietary fiber (e.g., that the product is a good source of fiber) and the food is not “low” in total fat as defined in 21 CFR 101.62(b)(2), then the label must disclose the level of total fat per serving.

According to the Nutrition Facts panels:

- the Kind Fruit & Nut Almond & Apricot product contains 10 g of total fat per 40 g of the food,
- the Kind Fruit & Nut Almond & Coconut product contains 12 g of total fat per 40 g of the food; the Kind Plus Peanut Butter Dark Chocolate + Protein product contains 13 g of total fat per 40 g of the food, and
- the Kind Fruit & Nut Dark Chocolate Cherry Cashew + Antioxidants contains 9 g of total fat per 40 g of the food.

These amounts exceed the maximum of 3 g of total fat per 40 g RACC in the “low fat” definition. Therefore these products are not “low” in total fat and you are required to disclose this fact on the labels in immediate proximity to the claims that the products are a “good source of fiber.”

3. Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products are misbranded within the meaning of section 403(q)(2)(A) of the Act [21 U.S.C. § 343(q)(2)(A)] in that nutrition information is not disclosed in accordance with 21 CFR 101.9. Specifically,

- a. Your labels bear a claim about fatty acids (i.e., “no trans fat”) but fail to include the levels of monounsaturated fatty acids and polyunsaturated fatty acids in the nutrition information as required by 21 CFR 101.9 (c)(2)(iii) and (iv).

- b. Your Kind Plus Peanut Butter Dark Chocolate + Protein product label includes the nutrient content claims: “+ protein” and “plus 7 g protein” on the principal display panel; however, the nutrition label fails to include the percent DV for protein as required when the label bears a nutrient content claim for protein as required by 21 CFR 101.9(c)(7)(i).
4. Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products are misbranded within the meaning of section 403(e)(1) of the Act because the statement of the name and the place of business fails to completely or accurately declare the place of business as required by 21 CFR 101.5(d). Specifically, the statement “Kind, LLC, P.O. Box 705 Midtown Station, NY, NY 10018” which is provided on the label does not include the street address and the street address of your business does not appear in a current city or telephone directory. FDA is unable to determine the physical location of your firm using a city or telephone directory and the address listed on the label.

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 regulatory action without further notice, including seizure and/or injunction.

In addition, we offer the following comments:

- Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants product labels bear the claim “No Trans Fats,” and we note that your ingredient statements do not include a partially hydrogenated oil as an ingredient. Under section 403(r)(1)(A) of the Act, a nutrient content claim in food labeling must be made in accordance with a regulation authorizing the use of the claim in order for the food bearing such claim not to be misbranded. Although FDA has not defined the term “Contains No Trans Fat” by regulation, we announced in the *Federal Register* dated July 11, 2003 (68 FR 41507 at 41509) that we would likely consider exercising enforcement discretion for a trans-fat nutrient content claim that is demonstrably true, balanced, adequately substantiated, and not misleading.

Scientific evidence suggests that trans-fat acts in a similar manner to saturated fat with respect to raising LDL cholesterol. 68 FR 41445 at 41456 (July 11, 2003). Higher total and LDL cholesterol levels are associated with increased risk of developing coronary heart disease. 68 FR 41445 (July 11, 2003). Under 21 CFR 101.13(h), if a food bears a nutrient content claim and also contains more than 13.0 grams of fat, 4.0 grams of saturated fat, 60 milligrams cholesterol, and 480

milligrams of sodium per reference amount customarily consumed (RACC), per labeled serving (or for a food with a RACC of 30 grams or less or 2 tablespoons or less, per 50 grams), then the food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: “See nutrition information for _____ content” with the blank filled in with the identity of the nutrient exceeding the specified level.

We intend to consider the exercise of our enforcement discretion for the use of the “Contains No Trans Fat” claim on your products provided the claim includes a disclosure statement, in accordance with the requirements in 21 CFR 101.13(h). We will review such claims on a case-by-case basis. We note that your Kind Fruit & Nut Almond & Coconut product contains 5g of saturated fat per 40g but does not contain the disclosure statement “See nutrition information for saturated fat content.”

- Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, and Kind Plus Peanut Butter Dark Chocolate + Protein products labels include the statement beginning “Allergen information: Contains...”; however, this allergen statement is not declared correctly. We note that these product labels correctly declare the allergen information in the ingredients lists in accordance with section 403(w)(1)(B)(i) of the Act, so a separate “Contains” statement is not required. However, if a separate “Contains” declaration is used, it must include all of the major allergens in the food and must use the names of the food sources as defined in sections 201(qq) and 403(w)(2) of the Act. The ingredient lists for Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, and Kind Plus Peanut Butter Dark Chocolate + Protein declare soy lecithin as an ingredient; however, soy is not declared in the “Contains” statement. In addition, the term “milk” must be used instead of “dairy” and the generic term “tree nuts” cannot be used in place of the names of the specific tree nuts such as almonds, coconuts, and cashews.
- Your Kind Plus Dark Chocolate Cherry Cashew + Antioxidants product ingredient list does not meet the requirements in 21 CFR 101.4(b), which requires that the name of an ingredient shall be a specific name and not a collective (generic) name. This product lists the collective terms “mixed nuts,” “dried fruits,” and “vitamins” as multicomponent foods and declares the specific nuts, fruits, and vitamins as sub-ingredients. The regulations do not allow the collective listing of nuts, fruits, or vitamins.
- Your Kind Plus Peanut Butter Dark Chocolate + Protein product ingredient list does not meet the requirements in 21 CFR 101.4(b)(2) because the label declares the standardized multicomponent food, peanut butter, but does not declare the sub-ingredients as required in 21 CFR 101.4(b)(2)(i). In accordance with 101.4(b)(2)(ii), if the ingredients of the standardized food are incorporated in the finished food ingredient list, then the name of the standardized ingredient must not be listed.

- The required information that appears on the information panels of your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants product labels does not meet the requirements in 21 CFR 101.2(e) because all of the information does not appear in one place without intervening material. The paragraph describing your brand that comes between the ingredient list and the name and place of business is an example of intervening material.
- Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants ingredient statements declare “non GMO glucose.” This is not an appropriate common or usual name for glucose syrup or dried glucose syrup in accordance with 21 CFR 101.4 and 168.120 or 168.121.
- The name and place of business declaration on your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants products does not include the street address as required in 21 CFR 101.5(d). The street address may only be omitted if it is shown in a current city directory or telephone directory. An online 411 search for your firm yielded several different street addresses in New York City; therefore, it is not clear which address is correct and should be considered your place of business.
- Your Kind Fruit & Nut Almond & Apricot, Kind Fruit & Nut Almond & Coconut, Kind Plus Peanut Butter Dark Chocolate + Protein, and Kind Plus Dark Chocolate Cherry Cashew + Antioxidants product labels do not include an appropriate statement of identity as required in 21 CFR 101.3.

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
Center for Food Safety
and Applied Nutrition

cc: FDA New York District

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