



July 1, 2024

VIA EMAIL - Kathleen.tormey@fda.hhs.gov

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Compliance Officer
Office of Human and Animal Food Operations – West Division 4
U.S. Food and Drug Administration
6th Ave. & Kipling St, DFC Bldg. 20
Denver, CO 80225-0087

Re: Response to Warning Letter CMS Case #672140

Dear Mr. Harris:

I am writing on behalf of Tony Gavin, President of Bimbo Bakeries USA (BBU), in response to your warning letter dated June 17, 2024, regarding the labeling of certain BBU products. I am the Vice President of Quality and Food Safety at BBU, responsible for regulatory compliance and overall food safety. As the nation's largest commercial baking company, BBU is proud to deliver fresh, high-quality baked products to consumers throughout the U.S. Our products are a staple at mealtime for so many families. Because of that, we deeply understand our role in assuring the safety of our consumers, particularly those with allergen sensitivities. We remain committed to providing consumers with access to clear information about our products. Our goal is to help every consumer make informed choices for themselves and their families.

We address each of the charges and comments in the Warning Letter below, and append documents to demonstrate the label changes we are making.

1.SESAME LABELING:

The warning letter asserts that Sara Lee brand Artesano Brioche, Delightful Multigrain, Artesano Golden Wheat, and Artesano Smooth Multigrain bread loaf products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the product labels are false or misleading because they include sesame seeds in the ingredient and "Contains" statements; however, sesame seed is not an ingredient in the product formulations.

Response:

BBU takes very seriously our role in protecting sesame-allergic consumers, through good manufacturing practices (GMPs) and preventive controls in our facilities and informative labeling on our packages. Our declaration of sesame on the labels of the four products FDA identified in its letter – Sara Lee brand Artesano Brioche, Delightful Multigrain, Artesano Golden Wheat, and Artesano Smooth Multigrain – is made in order to have nationally uniform labels for these products, because at some of our bakeries they are formulated with sesame and at others they are not. We think it very important that sesame allergic consumers who may purchase these products at various locations throughout the country see consistent labeling of sesame so they can avoid these products where they truly contain sesame. This labeling approach is not employed to avoid the application of rigorous GMPs and preventive controls to address potential sesame cross-contact, nor do we believe that allergen advisory labeling is a suitable alternative under our circumstances. We explain below in greater detail why we think our approach is the most protective of sesame-allergic consumers.

The four products referenced above are produced by different facilities with different formulations. At some of our facilities, these products are formulated with sesame; in other facilities, including our Phoenix, AZ facility that FDA inspected, these products are not formulated with sesame. The reason for this approach is that in the wake of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act that added sesame as a major food allergen, BBU conducted extensive analyses of its facilities, production lines, GMPs and allergen cross-contact preventive controls, and made significant changes to reduce the risk of sesame cross-contact as much as possible. We moved the production of certain products to other locations and created dedicated production lines where feasible. But as BBU and other baking company stakeholders have explained in our dialogue with FDA on this issue since the passage of the FASTER Act, sesame presents unique challenges in the baking sector, both because of the nature of sesame seeds used as a topping, and because of the regional distribution model needed to get fresh bread to consumers, which limits the industry's ability to use dedicated facilities and production lines. We found that despite best practices for rigorous GMPs and stringent preventive controls, we could not eliminate the risk that potentially significant traces of sesame could be found on a regular basis in products not intended to contain sesame that were produced on the same lines.

We therefore determined that the most protective approach for sesame-allergic consumers is that for BBU products that are baked on the same line as products that contain sesame, we formulate those products to include sesame and declare it in the ingredient list and "Contains" statement. BBU products that are baked in a facility that uses sesame but are not baked on the same production lines as sesame are labeled with the allergen advisory statement "Made in a bakery that may also use sesame." Our Phoenix facility does not use sesame in the bread line, but it produces the four breads at issue that are also produced in other facilities on lines that also produce sesame-containing products. The only difference between the products is the small amounts of sesame included in the formulas of the same products produced at those other facilities. Accordingly, the product names and principal display panels are identical for the four products in national distribution, and we use a nationally uniform ingredient list and "Contains:" statement to prevent confusion and protect sesame-allergic consumers.

We understand that our consumers may purchase the same product at various locations throughout the United States, and in doing so would expect that the labels, including allergen information, are consistent for all of the same products. Food allergic consumers in particular are encouraged to read the labels of every food product before purchasing to avoid their allergen(s) of concern. We are aware, however, that in practice, allergic consumers often just continue to purchase a product and brand they have determined is safe for them to consume. For example, a sesame-allergic consumer who reads the label and purchases a product that does not contain sesame will likely determine that this particular product is safe for them to consume. If they are traveling to another part of the country, they may be likely to purchase that same brand without checking the ingredient list and allergen statement, and would not see that the product sold in that part of the country is made with sesame and is labeled as such, and thus could risk an allergic reaction. Our current nationally uniform labeling approach for these products protects sesame-allergic consumers from this scenario because the consumer will know to avoid a particular product after discovering the product declares sesame in the ingredient list and bears a "Contains: Sesame" statement, irrespective of where the consumer purchases the product in the country and the product's formula. If BBU were to adopt FDA's stance and have different ingredient lists and allergen statements for the same product, it would create confusion among sesame-allergic consumers and put them more likely at risk of adverse reaction(s).

We hope the foregoing explanation makes clear that BBU has not chosen to label these four breads produced at our Phoenix facility as containing sesame out of an effort to avoid GMPs or preventive controls for sesame cross-contact, and we note there is no sesame in the bread line at all. Moreover, the facts set forth above also demonstrate that allergen advisory labeling such as "may contain sesame" would not be suitable here, because a sesame-allergic consumer might be comfortable purchasing products with such advisory labeling but might still suffer an adverse reaction if they unwittingly consumed the same product formulated to contain sesame that was made at a different one of our facilities. While BBU recognizes that we are declaring sesame on breads produced in Phoenix that do not contain this allergen, this approach helps ensure that sesame-allergic consumers avoid inadvertently consuming sesame from these same breads produced in facilities that do formulate them to contain sesame. Accordingly, we believe our

nationally uniform labeling approach serves the interests of the public health by protecting sesame-allergic consumers from adverse reactions.

2. NUTS DECLARATION:

The warning letter asserts that our Brownberry brand Whole Grains 12 Grains and Seeds bread loaf products are misbranded because the product label includes walnuts, almonds, and hazelnuts in the ingredient and “Contains” statements; however, these nuts are not ingredients in the formulation of the product.

Response:

We have updated our ingredient declaration and corresponding “Contains” statement to reflect the only nut that is included in the product formula, hazelnut. Attached please find our updated bag label, which we will start using in our Topeka facility in early August 2024 (Attachment A).

3. INGREDIENTS NOT DECLARED ON THE LABEL

The warning letter asserts that our Brownberry brand Whole Grains 12 Grains and Seeds product is misbranded because we use citric acid for (b) (4), (b) (4) as (b) (4), and (b) (4) for (b) (4), but do not list these ingredients on the product label. FDA states that these ingredients all provide technical functions in the finished product and thus do not meet the definition of processing aids exempt from ingredient labeling.

Response:

CITRIC ACID:

We have updated our ingredient deck to declare citric acid in the ingredients list as shown in our new bags that we will start using in our Topeka facility early August 2024 (Attachment A).

(b) (4) :

(b) (4) is used as an (b) (4) during the (b) (4) as a (b) (4) of (b) (4) is (b) (4) and

(b) (4) During our (b) (4) resulting in (b) (4) of (b) (4) in the finished product. Moreover, the (b) (4) has no continuing effect in the bread after it serves its function during the (b) (4). Therefore, it is exempt from labeling as a processing aid in accordance with 21 CFR 100.100(a)(3)(ii)(c) (substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food).

(b) (4) :

(b) (4) are (b) (4) in the form of (b) (4). (b) (4) have no continuing functional effect on the bread once that (b) (4) has been completed. Like (b) (4) are (b) (4) and thus are present at insignificant levels in the finished bread. Accordingly, the (b) (4) we use during our (b) (4) are processing aids exempt from labeling under 21 CFR 100.100(a)(3)(ii)(c).

4. KAMUT® KHORASAN WHEAT DECLARATION

FDA states that the ingredient list declares “Kamut®” which is not part of the common or usual name of Khorasan wheat because it is a brand name. Furthermore, Khorasan is misspelled as “Khorsan.”

Response:

Based on the information we received from our supplier and elsewhere and the general labeling of this ingredient in the marketplace, “Kamut®” does appear to be part of the common or usual name of this ingredient. FDA’s regulations at 21 CFR 102.5(a) provide that:

The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

We understand that Kamut® Khorasan wheat does have specific characterizing properties that are unique to it. The trademark guarantees certain attributes of this particular wheat, such as its protein and selenium content and several quality specifications related to growing conditions, including that the grain must always be grown certified organic and never hybridized or genetically modified.¹ Moreover, the ingredient appears to be labeled consistently in the marketplace with the Kamut® brand name. Accordingly, because Kamut® appears to be part of the description of the ingredient’s characterizing properties and is used consistently in similar products, the coined and trademarked term “Kamut®” is part of the common or usual name of this ingredient.

We have corrected the minor spelling mistake for Khorasan and will include the missing “a” in the next packaging redesign. We have made the correction in our Regulatory Sheet (Attachment B), which provides direction for our label changes that will be implemented in our next packaging redesign, which will occur in September.

5. FDA COMMENTS

In addition to the charges above, FDA made the following comments, to which we respond below:

VOLUNTARY ALLERGEN DECLARATION

FDA adds a comment in the warning letter noting that firms may choose to voluntarily place allergen advisory statements on products to alert consumers to the possible presence of major food allergens due to cross-contact.

Response:

BBU appreciates FDA’s recognition that voluntary allergen advisory statements can be an appropriate means to alert allergic consumers to the possible presence of major food allergens due to cross-contact risks that may inevitably remain after implementation of strong preventive controls and GMPs. Indeed, BBU employs such allergen advisory statements to address the risk of cross-contact for products produced in facilities that also produce sesame-containing products on different lines such as is the case for the Brownberry label shown in Attachment A. But for the reasons detailed in our response above, we have determined that sesame allergen advisory labeling is not suitable for our Sara Lee brand Artesano Brioche, Delightful Multigrain, Artesano Golden Wheat, and Artesano Smooth Multigrain breads.

¹ (b) (4)

(b) (4)

BROWN SUGAR POWDER AND (b) (4) NOT DECLARED

FDA noted that during the inspection of our Topeka facility, the Kansas state inspector questioned why the Brown Sugar Powder and (b) (4) - Flavor were not declared on the label, and BBU responded that the Brown Sugar Powder and the (b) (4) ingredients meet the definition of "Natural Flavors" and are considered to be included as that on the label. FDA's comment in the warning letter restates the definition of "natural flavor" and notes that ingredients that do not meet this definition may not be declared as such on the label.

Response:

BBU has labeled this ingredient appropriately, in accordance with FDA's regulatory definitions of "natural flavor" and incidental additives. Our supplier provides us with a compound ingredient labeled as NATURAL FLAVOR. It is comprised of (b) (4) natural flavors, and brown sugar. The only functional ingredient in this compound is natural flavors, which we declare on our finished product label. The (b) (4) is a carrier that is present at insignificant levels and without a technical or functional effect in our finished breads, and accordingly is exempt from labeling as an incidental additive under 21 CFR 100.100(a)(3)(i). Similarly, the brown sugar is present in our formula at the insignificant level of (b) (4) %, at which level it does not have a sweetening effect in our breads, and is thus likewise exempt from labeling on our breads.

* * *

BBU is committed to the safety and appropriate labeling of our products. We hope the foregoing satisfies FDA's concerns, and that the agency will understand that our nationally uniform sesame labeling is the most protective approach for sesame-allergic consumers. BBU welcomes continued dialogue with FDA on this issue.

Respectfully submitted,



Arturo Carrillo
Vice President of Quality and Food Safety