

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

Red Mill Farms LLC 9/17/15



Department of Health and Human Services

Public Health Service
Food and Drug Administration
PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER
15-PHI-19

OVERNIGHT MAIL
RETURN RECEIPT REQUESTED

September 17, 2015

Mr. Arnold Badner, Owner/President
Red Mill Farms LLC
591 Rocky Glen Road
Moosic, PA 18507

Dear Mr. Badner:

We inspected your processing facility, located at 591 Rocky Glen Road, Moosic, PA on March 10, 2015 through March 12, 2015. During our inspection, FDA investigators collected finished product labels, to include your Jennies brand products. Some of those labels direct the consumer to the website, <http://www.jennies-macaroons.com>, and some direct the consumer to the website, <http://www.macaroonking.com>. Further, the website, <http://www.jennies-macaroons.com> automatically redirects the consumer to the website <http://www.macaroonking.com>. In addition, FDA also collected finished product labels for your Village brand products. The labels for these products direct the consumer to the website www.villagemacaroons.com, which automatically redirects the consumer to the www.onestopnaturenc.com website. Based on our review of your product labels and websites, we have concluded that your www.macaroonking.com website promotes your Jennies brand products for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claim on the website establishes that the products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Even if your Jennies brand products were not unapproved new drugs, your Jennies brand Chocolate Drizzle and Chocolate

Sugar Free Macaroon products would still be misbranded foods because they 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 in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). The introduction of a misbranded food into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)]. In addition, your Village brand Blueberry Macaroons, are also misbranded within the meaning of section 403. Further, during our inspection our investigators documented serious violations of the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding human food, Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). These violations cause the food products produced in your facility to be adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)], in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Specifically, our inspection of your facility revealed the following violations:

Unapproved New Drugs:

FDA reviewed your product labels and websites at the Internet addresses of <http://www.macaroonking.com> and <http://www.jeannies-macaroons.com> (which redirects to www.macaroonking.com), in September 2015. We determined that you take orders at the www.macaroonking.com website, for your Jennies brand products. These websites promote your products for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your websites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

From your webpage titled <http://www.macaroonking.com> under the "Health Benefits tab:

- "Coconut's lauric acid has unique anti-microbial qualities ..."

These products are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Misbranded Foods

Our review of your labeling revealed the following misbranding violations:

False or Misleading

1. Your Village brand Blueberry Macaroons product is misbranded under section 403(a)(1) of the Act [21 U.S.C. §343(a)(1)] in that the labeling is false and misleading. Specifically, the product label includes the statement "nut free." Further, the product label directs consumers to the website www.villagemacaroons.com, which automatically redirects to the www.onestopnaturenc.com website. That website also includes a "nut free" claim for the Village brand macaroon products under the "Products" page. However, the Village brand Blueberry Macaroons product is made with coconut, which FDA considers to be a tree nut for purposes of section 201(qq) of the Act [21 U.S.C. 321(qq)], which defines the term "major food allergen" to include "tree nuts."

Unauthorized Nutrient Content Claims

2. Your Jennies brand Chocolate Drizzle and Chocolate Sugar Free Macaroon products and your Village brand Blueberry Macaroons 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 and/or labeling 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. Your website at <http://www.macaroonking.com> bears an implied nutrient content claim, because it bears 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, your website states:

- Under the Home tab, “Delicious [sic] and healthy, the Jennies are rich in coconut, a nutritional powerhouse. They are gluten-free...and...have never contained...transfats. They are high in fiber and MCT’s...”
- Under the Health Benefits tab, “Jennies Macaroons are rich in coconut...Coconut contains the healthy fat the body needs ... The good fat in coconut is high in medium chain fatty acids (or MCT’s)...The Jennies also provide an important source of lauric acid...The Jennies are a superior functional food for improved health.”
- Under the About Us tab, “The Jennies not only taste great, but they are also a healthy energy boost loaded with coconut, a nutritional powerhouse! Rich in lauric acid and “medium-chain triglycerides,” or MCT’s, coconut is the best form of fat for cellular health... [a consumer] always packs a Jennie for a healthy, high energy snack.”

However, your Jennies brand Chocolate Drizzle and Jennies brand Chocolate Sugar Free Macaroon products do 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 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 Jennies brand Chocolate Drizzle product contains 8 g of saturated fat per 28.3 g of the food,
- The Jennies brand Chocolate Sugar Free Macaroons product contains 3.5 g of saturated fat per 16 g of the food (the serving size declared on your label).

These amounts exceed 1 g of saturated fat per RACC (30g for cookies). These amounts also exceed the maximum of 15% of calories from saturated fat in the “low saturated fat” definition. Accordingly, your Jennies brand Chocolate Drizzle and Jennies brand Chocolate Sugar Free Macaroon products do not meet the requirements for use of the nutrient content claim “healthy” on food labeling [21 CFR 101.65(d)(2)]. Thus, these products are misbranded within the meaning of section 403(r)(1)(A) of the Act.

The “Health Benefits” page and “About Us” page on your website bears the claim “rich in lauric acid,” which is a nutrient content claim as defined by 21 CFR 101.13(b)(1) because it is a direct statement about the level of a nutrient in the food. FDA has issued a regulation specifying criteria for the use of the nutrient content claim “rich in” in food labeling (21 CFR 101.54(b)).

This regulation requires, in relevant part, that a food that bears this claim contain 20 percent or more of the Daily Value (DV) per RACC of the nutrient to which the term refers. However, this regulation does not authorize your claim because there is no DV for lauric acid. Therefore, the use of the term “rich in” to characterize the level of lauric acid for your products misbrands the products under section 403(r)(1)(A) of the Act. In addition, the label for your Jennies brand Chocolate Sugar Free Macaroon product bears the claim “BEST SOURCE OF: LAURIC AND CAPRIC ACID” and the “Health Benefits” page of your

www.macaroonking.com website bears the claim “important source of lauric acid.” These claims are also nutrient content claim as defined by 21 CFR 101.13(b)(1) because they are also direct statements about the level of a nutrient in the food. Under section 403(r)(2)(A) of the Act, nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has not defined the characterization “best source” or “important source” by regulation. Even if we determined that the term “best source” or “important source” could be considered synonymous with a term defined by regulation (e.g., “high” or “good source”), these claims do not comply with the requirements for use of those terms in 21 CFR 101.54(b) (“high” claims) or 21 CFR 101.54(c) (“good source” claims) because, as previously stated, there is no established DV for lauric acid, and there is similarly no established DV for capric acid.

The product label for your Jennies Chocolate Sugar Free Macaroons brand bears the claim “Loaded with Omega-3,” and this claim is also visible on the “Products” page of your www.macaroonking.com website. This claim is a nutrient content claim as defined by 21 CFR 101.13(b)(1) because it is a direct statement about the level of a nutrient in the food. Under section 403(r)(2)(A) of the Act, nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined by regulation. However, FDA has not defined the characterization “loaded with” by regulation. Even if we determined that the term “loaded with” could be considered synonymous with a term defined by regulation (e.g., “high” or “good source”), these claims do not comply with the requirements for use of those terms in 21 CFR 101.54(b) (“high” claims) or 21 CFR 101.54(c) (“good source” claims) because there is no established DV for lauric acid, and there is similarly no established DV for omega-3 fatty acids. Therefore, the use of the term “Loaded with Omega-3” to characterize the level of Omega-3 in your Chocolate Sugar Free Macaroons product misbrands this product under section 403(r)(1)(A) of the Act.

Your www.macaroonking.com website bears the following claims:

- Under the “Home” tab, “Jennies....They are high in fiber and MCT’s for a balanced diet...”
- Under the “Health Benefits” tab, “Coconut is high in dietary fiber...”

However, your Jennies brand Chocolate Drizzle Macaroons 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 DV per RACC. According to the Nutrition Facts panel, your Chocolate Drizzle Macaroons contain 3g of fiber per 28.3 g of the food (or approximately 3g of fiber or 10 percent of the DV per RACC of 30g) and your Chocolate Sugar Free Macaroons contain 1g of fiber per 16g of the food (or approximately 2g of fiber or 8 percent of the DV per RACC of 30g). This level of fiber is below the level that would qualify for a “high” claim under 21 CFR 101.54(b)(1).

Therefore, your Jennies brand Chocolate Drizzle Macaroons and Chocolate Sugar Free Macaroons products do not meet these requirements to bear the nutrient content claim “high in fiber” and are therefore misbranded under section 403(r)(1)(A) of the Act.

b. In accordance with 21 CFR 101.60(a), a claim about sugar content of a food may only be made on the label or labeling of a food if, among other requirements, the claim uses one of the terms defined in 21 CFR 101.60 in accordance with the definition of that term. Under 21 CFR 101.60(c)(1)(i), the term “sugar free” may be used only if the food contains less than 0.5g of sugars, as defined in 21 CFR 101.9(c)(6)(ii), per RACC and per labeled serving. Your Jennies brand Chocolate Sugar Free Macaroons 8oz product is misbranded in that the label bears the claim “Sugar Free,” and this claim is also visible on the “Products” page of your www.macaroonking.com website. However, the product does not meet the criteria under 21 CFR 101.60(c)(1)(i) to make such a claim. According to your product label, your product contains 1g of sugar per serving of 16g (or 2g of sugar per RACC of 30g). Thus, your product is misbranded within the meaning of section 403(r)(1)(A) of the Act.

c. In accordance with 21 CFR 101.60(a), a claim about sugar content of a food may only be made on the label or labeling of a food if, among other requirements, the claim uses one of the terms defined in 21 CFR 101.60 in accordance with the definition of that term. Under 21 CFR 101.60(c)(2)(i), the term “no added sugar,” “without added sugar,” or “no sugar added” may be used only if no amount of sugars, as defined in 21 CFR 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally

substitute for added sugars is added during processing or packaging. Your Village brand Blueberry Macaroons 4oz product is misbranded because the label bears the claim “no added sugar,” and the “Products” page on the www.onestopnatureinc.com website bears the claim “no sugar added.” However, the Village brand Blueberry Macaroons 4oz product does not meet the criteria under 21 CFR 101.60(c)(2)(i) because the ingredient list on the product label states that the product contains tapioca syrup, a sweetener that functionally substitutes for added sugars. Thus, your product is misbranded within the meaning of section 403(r)(1)(A) of the Act.

We note that there are alternative ways to convey the amount of nutrients in your product to consumers. For example, the amount of a nutrient in a food may be stated on the product label or labeling in accordance with the requirements in 21 CFR 101.13(i). If you want to seek authorization to use your current claim, you may submit a petition requesting FDA to authorize a new nutrient content claim for amino acids (see 21 CFR 101.69). FDA’s review and authorization of a nutrient content claim prior to use in labeling ensures that the claim will provide consistent, meaningful information to consumers about the content of a product.

3. Your Chocolate Drizzle and Chocolate Sugar Free Macaroon products and your Village brand Blueberry Macaroons products are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. 343(q)] because the nutrition information on their labels does not comply with the format and content requirements in FDA’s regulations as follows:

a. Your Jennies brand Chocolate Drizzle Macaroons 10oz, Chocolate Sugar Free Macaroons 8oz, and Village brand Blueberry Macaroons 4oz products are misbranded within the meaning of Section 403(q)(2)(A) of the Act [21 U.S.C. § 343(q)(2)(A)] because the Nutrition Facts labels for these products do not include the amounts of polyunsaturated and monounsaturated fats present in the product, as required by 21 CFR 101.9(c)(2)(iii) and (iv) when claims about fatty acids are made. Because your products bear “Trans Fat Free” claims about fatty acids, they must declare the amounts of polyunsaturated and monounsaturated fats present in these products. Further, your webpages <http://www.macaroonking.com> and <http://www.jeannies-macaroons.com> make “Trans Fat Free” claims.

b. Your Village brand Blueberry Macaroons 4oz product is misbranded within the meaning of Section 403(q)(1)(A)(i) of the Act [21 U.S.C. § 343(q)(1)(A)(i)] because the serving size declared on the label of your product is incorrect, and consequently the nutrient values declared for the product are also incorrect. Serving sizes are determined based on the RACCs, as required by 21 CFR 101.9(b)(2), which are provided in 21 CFR 101.12(b). Your Village brand product label declares the serving size as 1 Piece (14 g), however, the RACC for “Bakery products: Cookies...” is 30 g.

For additional information on General Food Labeling requirements go to:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm>
(<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm>).

Adulterated Foods

Your firm failed to maintain equipment, containers, and utensils used to convey and hold food, in a manner that protects against contamination during manufacturing and/or storage, as required by 21 CFR 110.80(b)(7). Specifically,

On March 10, 2015, our investigators observed that the chocolate reservoir on the chocolate enrobing machine had no cover on it leaving it exposed and open. This is a repeat violation from our previous inspection conducted June 2013.

On March 10, 2015, the kettle used to melt and store the chocolate used in the chocolate enrobing machine, noted above, was observed with no cover on it, leaving the unused chocolate inside the kettle exposed and open.

4. Your firm failed to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food-contact surfaces, to comply with 21 CFR 110.35(a). Specifically, on March 10, 2015 our investigators observed:

- a. A floor clean out trap in the cleaning room to be clogged and had stagnant water in it. This is a repeat violation from our previous inspection of June 2013.
 - b. A vent located directly above the open kettle in the mixing room to have excessive dirt and debris buildup on it. This kettle was used on March 10, 2015 to heat liquid sugar used to make sugar free and coconut macaroons. This is a repeat violation from the previous inspection conducted June 2013.
 - c. A loose ceiling tile which was not secured and was completely hanging over the kettle noted above, in the mixing room.
 - d. A section of metal cross bar in the ceiling directly above the same mixing kettle noted above in the mixing room, to have chipped and peeling paint on it.
5. Your firm failed to have smoothly bonded or well-maintained seams on food contact surfaces, to minimize accumulation of food particles and the opportunity for growth of microorganisms, as required by 21 CFR 110.40(b). Specifically, on March 10, 2015, our investigators observed the seams/welds on the inside of the large depositor in the mixing room were not smooth and had visible holes in the seams. In addition, at the bottom of the depositor, where the raw product exits and is formed, the edges of the metal were jagged with missing pieces.
6. Your firm failed to ensure that plant equipment and utensils are of such material and workmanship as to be adequately cleaned and properly maintained, as required by 21 CFR 110.40(a). Specifically, on March 10, 2015, our investigators observed peeling and chipped paint on the top edges of the large depositor in the mixing room.

The above violations are not intended 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 are in compliance with the Act and its implementing regulations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

In addition to the above violations, we also have the following comments:

- The label for your Jennies brand Chocolate Drizzle Macaroons includes the statement “Dairy Free.” In addition, the Health Benefits page on your www.macaroonking.com website states that “The Jennies are free of dairy” However, the chocolate ingredient used in this product, **(b)(4)**, is labeled with the following statement: “Allergy Information: Manufactured on cold shared equipment with milk-containing products. Milk may be present.” Under section 403(a)(1) of the Act, the use of false or misleading labeling causes a food to be misbranded. Although you stated during the inspection that your firm places an additional “Dairy” sticker on the product when it is manufactured, you did not provide an example of such a sticker during the inspection. We note that it is your responsibility to ensure that claims regarding your Chocolate Drizzle Macaroons are truthful and not misleading.
- Your label for your Village brand Blueberry Macaroons and your Jennies brand Chocolate Drizzle Macaroons bears the claim “Trans fat free,” and your www.macaroonking.com website bears the claim “free of...trans fat,” and we note that your ingredient statements do not include a partially hydrogenated oil as an ingredient in the ingredient lists. 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 terms “trans fat free” or “free of...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. 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. Your Jennies brand Chocolate Drizzle Macaroons contains 8 g of saturated fat per RACC and per labeled serving; your Jennies brand Chocolate Sugar Free Macaroons contain approximately 7.5 g of saturated fat per RACC; and your Village brand Blueberry Macaroons contain approximately 6 g of saturated fat per RACC but do not contain the disclosure statement "See nutrition information for saturated fat content." We intend to consider the exercise of our enforcement discretion for the use of these products provided the "trans fat free" and "free of . . . trans fat" claims include 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.

- Your Village brand Blueberry Macaroons product label does not properly declare the statement of your place of business as required by 21 CFR 101.5(c). Specifically, the label provides an address in Flushing, NY and the website www.villagemacaroon.com. It fails to state "Manufactured for _____," "Distributed by _____," or any other wording that expresses the facts. The label also does not include the actual company name. Additionally, we note that the name of the business declared on your Jennies branch Chocolate Sugar Free Macaroons and Chocolate Drizzle Macaroons products differs and that the street address is not included on either label.

Further, Section 743 of the Act, 21 U.S.C. § 379j-31, authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees, 21 U.S.C. § 379j-31(a)(2)(B). For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Please respond to this letter within fifteen (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 frame within which you will complete the corrections.

Your written response should be sent to Lynn S. Bonner, Compliance Officer at the address on this letterhead. If you have any questions about this letter, please contact Ms. Bonner at 215-717-3074 or email her at Lynn.Bonner@fda.hhs.gov (<mailto:Lynn.Bonner@fda.hhs.gov>).

Sincerely,
/S/
Anne E. Johnson
Acting District Director
Philadelphia District

cc:
Pennsylvania State Department of Agriculture
Bureau of Food Safety and Laboratory Services
Attention: Dr. Lydia Johnson, Assistant Director
2301 North Cameron Street
Harrisburg, PA 17110-9408

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