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February 16, 2023

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

Re: Docket No. FDA-2016-D-2335 (Food Labeling: Nutrient Content Claims; Definition of Term `Healthy.`)

Dear Dockets Management Staff,

On behalf of Oldways, a 501(c)3 educational nonprofit dedicated to inspiring people to embrace the healthy and sustainable joys of the old ways of eating, we applaud FDA for modernizing the definition of “healthy” to better reflect current nutrition science.

At Oldways and the Oldways Whole Grains Council, we interact with a large network of consumers, health professionals, and food professionals seeking more information about the foods they’re eating. We are writing in support of FDA’s move towards overall dietary patterns and food groups. Specifically, we’d like to express support for the following considerations:

- We strongly agree that the approach to focus on food groups (rather than individual nutrients) is better aligned with the food-based guidance in the 2020-2025 Dietary Guidelines for Americans. We also agree that nutrients to encourage should not be included as an addition to the food group criteria, as we fear that such an addition would spur indiscriminate fortification of foods that don’t otherwise make meaningful contributions toward a particular food group.
- We strongly agree that grain products must contain whole grains to bear the “healthy” claim, and that only whole grains should count toward the grain food group equivalent for the “healthy” claim.
- We agree with the approach to limit saturated fat, rather than cholesterol, as saturated fat is shown to have a more direct impact on LDL cholesterol and cardiovascular risk factors. We also agree that foods that are higher in cholesterol and lower in saturated fat (such as seafood) are to be encouraged, as recommended in the 2020-2025 Dietary Guidelines for Americans.
- We agree that raw, whole vegetables and fruits should be able to meet the “healthy” criteria without meeting a food group equivalent threshold.
- We agree that a compliance date that is 3 years after the effective date is ample time to update labeling.



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- We agree with allowing 100% oils and oil-based dressings that meet the proposed saturated fat, sodium, and sugar thresholds to use a “healthy” claim.
- We agree with allowing water (still and carbonated) and plain, unsweetened, calorie-free coffee and tea to use a “healthy” claim. Water is important for human health and there is strong and consistent research on the health benefits and antioxidant content of regular coffee and tea. We agree that the “healthy” claim should not extend to other calorie-free beverages (such as soft-drinks with artificial sweeteners) as those beverages do not contribute to nutrient needs.
- We agree that the saturated fat content of nuts and seeds should not contribute toward the overall saturated fat limit, and that even nuts and seeds with naturally higher levels of saturated fats should not be excluded from the “healthy” claim, given the strong body of research supporting nuts and seeds as nutrient-dense foods. For certain food groups (such as protein) there remain a few slight differences in our positioning, which we detail more clearly below.

Despite our broad support for the approach taken to modernize the definition of “healthy” foods, we still see opportunity to better align the definition of “healthy” with the Dietary Guidelines and better help the public navigate the noisy world of nutrition guidance. Specifically, we recommend that the following changes be made to the guidance:

- **Adjust the food group equivalent requirement for whole grains:** The 2020-2025 Dietary Guidelines for Americans recommends 6 ounce-equivalents of grain foods per day, with at least half of those being whole grain. The 2020-2025 Dietary Guidelines for Americans also explicitly recommend that one way to meet this recommendation is to choose foods with 8 grams of whole grain per ounce equivalent. However, under FDA’s proposed definition of healthy, foods with 8g whole grain per ounce equivalent and that meet all other established nutrient limits for saturated fat, added sugars, and sodium, would not qualify for a “healthy” claim as currently proposed. We wholeheartedly agree that only whole grains should count towards the grain food group equivalent for the “healthy” claim. However, we suggest that the whole grain threshold set by FDA align with the recommendations in the 2020-2025 Dietary Guidelines for Americans: 8g per ounce equivalent. Given the assumption of 4 eating occasions per day and the recommended 6 ounce-equivalents of grain foods, people will have to eat multiple ounce equivalents of grain foods at certain eating occasions. It is therefore not necessary for just four foods to deliver the full recommended 3 ounce-equivalents of whole grain. Rather, if each of the 6 ounce-equivalents of grain foods consumed per day was a source of at least 8g of whole grains, consumers would meet the recommendation. For clarity and consistency, FDA should expressly write this threshold into the final rule.

- **Expand Whole Grain Food Categories Eligible for a Healthy Claim:** We fear that the examples of whole grain foods in the proposed rule could be interpreted very narrowly, with only a short list of whole grain foods being able to qualify as a 1 oz. equivalent of grains. In the proposed rule FDA defined a 1 ounce-equivalent as: ½ cup cooked whole grain brown rice, whole grain pasta or cereal; 1 oz. dry whole grain pasta or rice; 1 medium (1 oz.) slice of whole grain bread, tortilla or flatbread; or 1 oz. of ready to eat whole grain cereal. This definition potentially excludes a wide variety of foods which are inherently whole grain (whole wheat flour, whole oat flour) or made from whole grains (whole wheat bagels, whole grain crackers, brown rice crisps etc.) Instead of limiting the grain equivalents to these few specific types of food, we recommend expanding the definition by utilizing language from the Dietary Guidelines and measuring compliance with the whole grain criteria in grams present per reference amount. This would ensure clarity and consistency and open up a variety of culturally relevant categories to be eligible for claims regardless of form.
- **Exclude Processed Meats and Red Meat from Using a Healthy Claim:** Regarding protein foods, we fear that processors will continue to “game the system” with highly processed, slightly reduced saturated fat and sodium sausages, hot dogs or bacon products that meet the proposed thresholds. Given that the [World Health Organization recognizes](#) processed meats (“meat that has been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavor or improve preservation”) as a carcinogen and red meats (“unprocessed mammalian muscle meat such as beef, veal, pork, lamb, mutton, horse and goat meat”) as a likely carcinogen, we suggest that these food categories be excluded from using the “healthy” claim, regardless of their saturated fat, sodium, or sugar content.

We thank the FDA for the opportunity to share our expertise.

Sincerely,



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