



Consumer Federation of America

February 15, 2023

Commissioner Robert Califf
U.S. Food and Drug Administration

Submitted electronically

Re: Docket No. FDA-2016-D-2335, Proposed Rule on Nutrient Content Claims and Definition of Term “Healthy”

Dear Commissioner Califf:

Consumer Federation of America appreciates your consideration of these comments on the U.S. Food and Drug Administration’s proposed update to the definition for the implied nutrient content claim “healthy.” We agree that “healthy” claims should be consistent with the latest nutrition science and particularly with the Dietary Guidelines for Americans (DGA). The proposed changes will help to curb misleading marketing practices, but FDA can go further in making the healthier choice the easier choice. Specifically, FDA should prohibit “healthy” claims on 100% fruit juice and on artificially sweetened foods and beverages. Ultimately, to best assist consumers in maintaining healthy dietary practices, FDA should both revise the “healthy” definition for marketing claims purposes, and implement front-of-package (FOP) labeling requirements that alert consumers to high levels of sugar, salt and fat in foods.

As the proposed rule points out, diet-related disease imposes enormous costs on U.S. society. More than two-thirds of U.S. adults and nearly one-third of children and youth are overweight or obese, and obesity rates continue to trend upward. Medicare and Medicaid alone spend tens, if not hundreds, of billions of dollars each year to treat cardiovascular disease, type 2 diabetes, cancer, and other illnesses attributable to poor diet. Because diet-related diseases disproportionately affect people of lower socioeconomic status and certain racial and ethnic minority groups, improving how Americans eat is not just an economic and public health imperative, but also a matter of social justice.

According to the proposed rule, “claims like ‘healthy’ provide information to consumers that allow them to quickly identify foods that can be the foundation of a healthy dietary pattern.” This is undoubtedly true in some contexts. However, many of the healthiest foods, such as fresh fruit and vegetables, have no labels at all, or minimal labeling. So to the extent that “healthy” claims serve their intended marketing purpose, they may lead some consumers away from actually healthier foods. As the Proposed Rule points out, consumer and public health groups have raised concerns that “healthy” claims are too simplistic, that they may deter consumers

from looking further into a product’s nutritional content, and that they may lead to excessive consumption of “healthy”-labeled products. All of these concerns are well substantiated. FDA should therefore narrowly restrict the extent to which food manufacturers may employ the “healthy” claim. The agency should also halt development of a “healthy” icon in favor of FOP labels that call attention to potentially *unhealthy* foods, and thereby steer consumers to better alternatives, including whole foods that are often unlabeled.

The proposed rule makes appropriate accommodations to allow most whole foods to be labeled “healthy.”

A growing body of research shows that whole foods are healthier, in part because ultra-processed diets lead to excess calorie intake and weight gain.¹ The proposed rule correctly concludes that “raw, whole vegetables and fruits should be able to meet the ‘healthy’ criteria without meeting a food group equivalent threshold.” This preference for whole foods in turn supports the agency’s proposal to exclude the saturated fat content of nuts and seeds from the overall saturated fat limit for nut and seed products.

Sweetened beverages, including 100 percent fruit juice, should not be labeled “healthy.”

While FDA should expand the healthy definition to accommodate whole foods, the agency should otherwise restrict what foods qualify for the claim. What is “healthy” for one consumer may not be for another, and particularly where a food or beverage would not be recommended for many, if not most consumers, a “healthy” claim is inappropriate. Fruit juice provides an example. A small amount of fruit juice may supply some important vitamins and minerals to the diet of a consumer who is at a healthy weight and free of metabolic disease, particularly if she is not eating a lot of whole fruits and vegetables. But even 100% fruit juice contains sugar in amounts comparable to soda. Researchers have documented an association between excessive fruit juice consumption and increased risk for obesity in children.² Moreover, for the 38% of U.S. adults who are prediabetic, fruit juice is not a healthy option, and a label indicating so is misleading.³

The proposed rule does not allow “healthy” claims on fruit juices and other fruit products *if* they contain any added sugars. According to FDA, this is because the DGA “specifically recommends that juices should be 100 percent juice, without added sugars, and that individuals should choose canned fruits that are canned with 100 percent juice or options lowest in added sugars.” However, the DGA makes clear that, just as canned fruit and juice without added sugars are superior to sweetened varieties, whole fruits are superior to fruit juice, and indeed, that “at

¹ See, e.g., Kevin D. Hall et al, Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake, *Cell Metabolism*, Volume 30, Issue 1, 2019, Pages 67-77.e3, ISSN 1550-4131, <https://doi.org/10.1016/j.cmet.2019.05.008>

² Wojcicki JM, Heyman MB. Reducing childhood obesity by eliminating 100% fruit juice. *Am J Public Health*. 2012 Sep;102(9):1630-3. doi: 10.2105/AJPH.2012.300719. Epub 2012 Jul 19. PMID: 22813423; PMCID: PMC3482038.

³ See <https://www.cdc.gov/diabetes/data/statistics-report/prevalence-of-prediabetes.html#:~:text=Among%20US%20adults%20aged%2018%20years%20or%20older%2C.level%20%28%20Appendix%20Table%206%20%29.%20More%20items>

least half” of the recommended amount of fruits “should come from whole fruit, rather than 100% juice.” The DGA also points out that 100% fruit juice is “lower in dietary fiber than whole fruit” and warns that “the amount of fruit juice in the USDA Food Patterns ranges from 4 fluid ounces at the lower calorie levels and no more than 10 fluid ounces at the highest calorie levels.”⁴ The same rationale applied in the proposed rule to (correctly) disallow “healthy” claims on fruit juices with added sugars should similarly operate to exclude 100 percent fruit juices.

Foods and beverages made with artificial or “high-intensity” sweeteners should not be labeled “healthy.”

Low-calorie sweeteners have become ubiquitous in the food supply, with over 25 percent of children now estimated to be consuming these ingredients as part of their normal diet.⁵ However, a growing body of research has raised concerns about the long-term impacts of low-calorie sweetener consumption. Allowing a “healthy” claim on foods and beverages with low- and no-calorie sweeteners creates a misleading impression for many consumers, including many parents, about the health risks associated with these products.

The proposed rule explains that “high-intensity sweeteners are not a factor in this proposed rule,” because the DGA “does not consider high-intensity sweeteners to be added sugars and do not make any recommendations for those 2 years of age and older on the intake of high-intensity sweeteners.” However, for children younger than 2, the DGA makes clear that “high-intensity sweeteners are not recommended” because “[t]aste preferences are being formed during this time period, and infants and young children may develop preferences for overly sweet foods if introduced to very sweet foods during this timeframe.” If for no other reason, artificially sweetened foods and beverages should not carry a “healthy” claim because children under 2 are commonly fed foods marketed to adults.

These foods also should not fall under the “healthy” definition because they are linked to health problems in adults. Researchers have documented an association between sweetener consumption and elevated incidence of overweight/obesity, hypertension, metabolic syndrome, diabetes, kidney dysfunction, heart attack, and hemorrhagic stroke.⁶ Last year, a large scale prospective cohort study of over 100,000 adults in France found “a potential direct association” between higher artificial sweetener consumption (especially aspartame, acesulfame potassium, and sucralose) and increased cardiovascular disease risk.” According to the study, sweetener consumption was linked to a 9% increase in risk of cardiovascular disease, and an 18% risk of

⁴ https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf at 87.

⁵ Sylvestsky AC, Jin Y, Clark EJ, Welsh JA, Rother KI, Talegawkar SA. Consumption of Low-Calorie Sweeteners among Children and Adults in the United States. *J Acad Nutr Diet.* 2017 Mar; 117(3):441-448.e2. doi: 0.1016/j.jand.2016.11.004.

⁶ Fowler SP, Williams K, Hazuda HP. Diet soda intake is associated with long-term increases in waist circumference in a biethnic cohort of older adults: the San Antonio Longitudinal Study of Aging. *J Am Geriatr Soc.* 2015 Apr;63(4):708-15. doi: 10.1111/jgs.13376.

stroke.⁷ Growing evidence suggests that sweeteners cause these ill health effects by interfering with the metabolic process. In a randomized-controlled trial encompassing 120 healthy adults, also conducted last year, subjects who were administered various sweeteners for 2 weeks—in doses lower than the acceptable daily intake—had “impaired glycemic responses” compared with controls given sugar or nothing at all.⁸ The concerns surrounding these chemicals have led some public health authorities to reexamine policies on sweeteners. New York City, for example, has banned low-calorie sweeteners from all food and beverages at “sites serving a majority of children age 18 or younger.”⁹

Conclusion

In general, FDA’s proposed changes to the “healthy” definition will assist consumers to make healthier choices by making clear that whole foods are the key building blocks of a healthy diet, and that consumers should avoid foods with high levels of added sugars, sodium, and saturated fat. But FDA should go further in restricting the definition, and exclude any foods that pose a credible threat of causing diet-related disease among significant segments of the population, including fruit juice, and foods and beverages made with artificial or “high intensity” sweeteners. Ultimately, “healthy” claims are marketing claims, and FDA should take a conservative stance in protecting consumers from misleading and deceptive marketing.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

⁷ Debras C, Chazelas E, Sellem L, Porcher R, Druenes-Pecollo N, Esseddik Y et al. Artificial sweeteners and risk of cardiovascular diseases: results from the prospective NutriNet-Santé cohort BMJ 2022; 378 :e071204 doi:10.1136/bmj-2022-071204;

⁸ Suez et al. “Personalized microbiome-driven effects of non-nutritive sweeteners on human glucose tolerance.” Cell, Vol. 185: 18, (Aug. 19, 2022), DOI: <https://doi.org/10.1016/j.cell.2022.07.016>

⁹ See New York City Food Standards, available at: <https://www.nyc.gov/site/foodpolicy/governance-initiatives/nyc-food-standards.page>