

July 20, 2020

Stephen M. Hahn, MD
Commissioner of Food and Drugs
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period (Docket. No. FDA-1995-N-0062 (formerly 1995N-0294))

Dear Dr. Hahn:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to offer the following comments on the Food and Drug Administration’s (FDA’s) reopened proposed rule “Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period (Docket. No. FDA-1995-N-0062 (formerly 1995N-0294)). Representing over 107,000 registered dietitian nutritionists (RDNs),¹ nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals and is committed to a vision of the world where all people thrive through the transformative power of food and nutrition. Wherever Academy members work—in a variety of clinical and community settings preventing and treating chronic disease, in industry that is developing more healthful, reformulated food choices people want to eat, or providing consumers with the tools to make better food choices through nutrition education or public health campaigns—it is our singular mission to accelerate improvements in global health and well-being through food and nutrition.

A. OVERARCHING SUPPORT FOR THE FDA’S NUTRITION INNOVATION STRATEGY

The Academy enthusiastically shares the goal the FDA’s Nutrition Innovation Strategy is designed to attain; we wholeheartedly agree that “improvements in diet and nutrition offer us one of our greatest opportunities to have a profound and generational impact on human health.”² We support the FDA using its powers to harness market forces to incentivize the formulation of healthy products and better enable industry to effectively and truthfully promote them by aligning food labels and claims with validated, scientific dietary

¹ The Academy recently approved the optional use of the credential “registered dietitian nutritionist (RDN)” by “registered dietitians (RDs)” to more accurately convey who they are and what they do as the nation’s food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

² Scott Gottlieb, MD, “Reducing the Burden of Chronic Disease” (speech, Washington, DC, March 29, 2018), U.S. Food and Drug Administration website, <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>.

recommendations. Fostering innovation and sparking competition among industry has significant potential to reduce preventable death and disease related to poor nutrition.

The Academy supports the FDA's intent to "establish a set of general principles for food standards for FDA to use when considering whether to establish, revise, or eliminate a food standard," and offers comments below on specific aspects of the proposed rule.

B. ACADEMY'S LABELING PRINCIPLES

In 2014, the Academy adopted the following nine principles for labeling to guide development of our regulatory comments and policy stances, and we apply them to aspects of the proposed rule related to on-package communications, information, or marketing. We note and appreciate the similarity between and overlap of many of the Academy's labeling principles with those in the proposed rule.

1. Label claims should be clear and understandable to consumers; consumers' nutrition literacy is key to promoting understanding.
2. The label must be truthful and not misleading.
3. Content on the label should help consumers make informed decisions to build a healthy diet.
4. Labels should help to provide understanding about the nutrient density and overall healthfulness of the complete food context rather than a focus on particular nutrients.
5. Label content should have consistent type and format so products can be read and consumers can make product comparisons.
6. Labeling should enhance consistency among the various government nutrition recommendations.
7. All claims should include labeling of accurate quantitative information about the dietary substance, including percent of Daily Value in a single serving of the products, when known, or the daily dietary intake necessary to achieve the claimed effect.
8. Consumer research is imperative before making changes to the label.
9. The label is only a source of information, and thus sustained support for educational programs and individual counseling by registered dietitian nutritionists is essential.

C. GENERAL PRINCIPLES THAT CONNECT SOUND LABELING POLICY TO PUBLIC HEALTH GOALS

Contrary to the sound recommendations of the 2015 Dietary Guidelines for Americans, Americans under-consume healthful foods including fruits and vegetables, low-fat dairy, and whole grains. Americans also over-consume certain designated nutrients of concern such as added sugars, saturated fats, and sodium. Labeling transparency and simplicity are valuable tools for encouraging and empowering consumers to make more healthful choices

and should assist consumers in following dietary advice, as the Nutrition Labeling Education Act directs.

We are not presently a particularly healthy population. The previous FDA commissioner noted that, “Today, chronic diseases are the leading causes of death and disability in the U.S., and both chronic diseases and weight-related conditions raise health care costs, reduce productivity, and shorten lifespans.”³ Given these challenges, the American people and our government should expect and demand an all-hands-on-deck approach to finding effective, efficient, science-based solutions; there is no place for products or product marketing that intentionally or unintentionally mislead consumers. Consumers should be confident that foods marketed as ‘good for them’ or ‘better for them’ are indeed not simply more healthful choices, but are also objectively healthful choices. The stakes are high: 70 percent of adults and 33 percent of children and teens are now overweight or have obesity.^{4,5} Approximately 45 percent of adults have diabetes or prediabetes.⁶ Every sale of an unhealthy food or beverage item to a consumer seeking healthier choices represents another missed opportunity to reduce diet-related disease.

Many consumers who dutifully try to follow dietary advice nonetheless struggle with excess weight gain, high blood pressure, prediabetes, and other preventable diet-related health problems. Data from the International Food Information Council show that health and weight loss are core considerations for most consumers in making food choices. Consumers pay attention to labels even if they do not always understand or utilize them fully or accurately: more than half of consumers look at the Nutrition Facts Panel or ingredient list “often” or “always” when making a purchasing decision, and approximately 40% say they consider other labeling statements about health or nutrition benefits.⁷

Labels thus provide actionable information at the point of decision, connecting dietary choices to health. Yet products across the marketplace attempt “permission” marketing, in which a health halo is intentionally created to make food and beverages appear more healthful than they are. Specifically, consumers should not be misled that processed foods touting images of fruits and vegetables or content label claims of fruit or vegetable content are necessarily adequate dietary substitutes for fresh fruits and vegetables. For this reason, it is critical that the FDA’s initiative should seek to correct misleading or inaccurate

³ *Ibid.*

⁴ Fryar CD, Carroll MD, Ogden CL. Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults Aged 20 and Over: United States, 1960–1962 Through 2013–2014. National Center for Health Statistics, July 2016. Accessed at: <https://www.cdc.gov/nchs/data/hestat/obesity_adult_13_14/obesity_adult_13_14.pdf>.

⁵ Fryar CD, Carroll MD, Ogden CL. Prevalence of Overweight and Obesity Among Children and Adolescents Aged 2–19 Years: United States, 1963–1965 Through 2013–2014. National Center for Health Statistics, July 2016. Accessed at: <https://www.cdc.gov/nchs/data/hestat/obesity_child_13_14/obesity_child_13_14.htm>.

⁶ National Center for Chronic Disease Prevention and Health Promotion. *National Diabetes Statistics Report, 2017: Estimates of Diabetes and Its Burden in the United States*. 2017. Accessed at: <<https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>>.

⁷ International Food Information Council Foundation. *2018 Food and Health Survey*. Washington, DC: International Food Information Council Foundation, 2018. Accessed at: <<https://www.foodinsight.org/2018-food-and-health-survey>>.

labeling claims and should not enable unhealthy foods to unfairly compete with fresh fruits and vegetables, which occupy too little space in Americans' diets.

As the FDA fleshes out the details of its Nutrition Innovation Strategy, the agency should consider the extent to which its labeling policies and new strategies encourage the promotion of products that are substantively better than an unhealthy substitute but remain suboptimal in its nutrient density or other relevant characteristics. In addition, the FDA should ascertain whether labeling initiatives may drive consumers not only towards more healthful products labeled as such and away from less healthful products, but also unintentionally away from optimally healthful whole foods that lack labels, such as fresh fruits and vegetables. For these reasons, we believe that the FDA should focus on the following initiatives as part of the Nutrition Innovation Strategy:

- **The FDA should improve labeling of whole grains to enhance transparency and clarity for consumers and encourage healthful reformulation of grain-containing foods.**
- **The FDA should support health and enhance transparency by addressing deceptive labeling.**
- **The FDA should modernize and improve standards of identity and ingredient lists and continue its efforts on sodium reduction.**

We address each of these in turn below. The FDA's initiative will be most effective if the agency limits misleading claims and undertakes other reforms in the service of a clear and powerful vision of a better marketplace for consumers and companies alike.

1) Improve Labeling of Whole Grains to Enhance Transparency and Encourage Healthful Reformulation

Virtually everyone eats packaged bread, crackers, pasta, and cereals, rather than preparing them from scratch at home, which means improved labeling of grains on processed foods is an important and promising area with added clarity for consumers and revitalized incentives to improve the healthfulness of these foods. Driving Americans to consume food patterns consistent with recommendations of the Dietary Guidelines is the heart of the FDA's Nutrition Innovation Strategy, and making these patterns affordable, and appealing, is also a priority to fight social inequalities in health.

Despite the Dietary Guidelines' whole grains recommendation that Americans "make at least half of your grains whole"⁸ we know that Americans in every age group are not following this advice, and are instead under-consuming whole grains and over-consuming refined grains.⁹ Auspiciously, consumers are increasingly seeking to increase their intake of whole grains. The International Food Information Council 2018 Food and Health Survey

⁸ 2015–2020 Dietary Guidelines for Americans. 8th Edition. Washington, D.C.: U.S. Department of Health and Human Services and U.S. Department of Agriculture: December 2015. Accessed at: <https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf>.

⁹ 2015–2020 Dietary Guidelines for Americans. 8th Edition. Washington, D.C.: U.S. Department of Health and Human Services and U.S. Department of Agriculture: December 2015; 2:41-43. Accessed at: <<https://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/#figure-2-6-average-protein-foods-subgroup-intakes-in-ounce-equiv>>.

shows whole grains near the top the list of components considered to be healthful by consumers (following only vitamin D and fiber).¹⁰ The marketplace is responding: market analysts predict the global market for whole grain and high fiber foods will expand by nearly 50% over the next five years, reaching \$46.2 billion by 2022.^{11,12}

Labeling on grain-containing products remains afflicted by a lack of clarity. A study published in 2016 by the FDA in collaboration with several academic institutions showed that older adults are confused by package information about whole grain products. The study used a structured interview protocol to determine whether older adults (n = 89, age ≥ 65 years) are able to accurately identify whether three common food items were whole grain. The study found that approximately 35 percent of participants were not able to correctly identify the two whole grain products tested (cereal and crackers) as whole grain, and 80 percent of participants could not correctly identify that the refined grain product (bread) was not whole grain; nearly half of participants misidentified the refined grain bread as whole grain. Participants also did not know where to look on labels for information about whole grains and consulted the Nutrition Facts label almost as often as they did ingredient lists.

These results accord with those of a national online survey commissioned by the Center for Science in the Public Interest in 2011 that included more than 1,000 participants. The survey, which was sent to the FDA in 2012, showed that consumers overestimated the amount of whole wheat in a product when shown the front of product packages that emphasized the word “wheat,” including when “wheat” was accompanied by depictions of dark-colored crackers, heads of wheat, or the term “stone ground.”

A result of this confusion is that while some companies are innovating in the ovens and the marketplace to offer products with whole grains that appeal to consumers, incentives for these innovations are blunted by the fact that consumers often cannot tell which grain products are whole grain, and which are refined grains. Hearty-looking (and sometimes artificially colored) “wheat” breads and “multigrain” breads add to the confusion by containing labeling claims and images that suggest they contain whole grains when they may include none or negligible amounts. Whole grain content is not disclosed in the Nutrition Facts panel, and even the ingredient list may not be informative if it contains confusing names, fails to specify which grains are whole grains, or lists multiple refined grains after whole grain, which together could add up to make refined grain the predominant ingredient.

We therefore urge the agency to prioritize the issue of whole grain labeling to promote “incentives for food manufacturers to produce products that have more healthful

¹⁰ International Food Information Council Foundation. *2018 Food and Health Survey*. Washington, DC: International Food Information Council Foundation, 2018. Accessed at: <<https://www.foodinsight.org/2018-food-and-health-survey>>.

¹¹ WhaTech. *Research Details Developments in the Whole Grain Foods Market to Grow at 6.71% CAGR by 2021*. WhatTech, 2017. Accessed at: <<https://www.whatech.com/market-research/food-beverage/384820-research-details-developments-in-the-whole-grain-foods-market-to-grow-at-6-71-cagr-by-2021>>.

¹² Statistics Market Research Report. *Whole Grain and High Fiber - Global Market Outlook (2015-2022)*. Statistics Market Research Consulting, 2016. Accessed at: <<http://www.strategymrc.com/report/whole-grain-and-high-fiber-market>>.

attributes.” To prevent misleading claims and encourage healthful innovation, we request that the FDA:

- Define “whole grain claims” to clearly include use of the terms “whole wheat,” “whole grain,” “made with whole grain,” “multigrain,” a declaration of the whole grain content by weight; the term “wheat” on a wheat-based bread, pasta, or other product that is typically made from wheat, use of depictions of wheat or grains, or any similar descriptive phrases, terms, or representations suggesting the product contains whole grains; and
- Require that foods making such whole grain claims prominently and uniformly disclose *either* the percentage of whole grains and refined grains *or* the grams of both refined and whole grains per serving (for example, “Contains 8 g whole grain and 16 g refined grain”). The form of the disclosure should be based on the results of consumer testing.

2) Support Health and Transparency by Addressing Deceptive Labeling

A vast majority of health-related food label claims are not health claims at all, but are categorized as structure/function claims, nutrient content claims, or have no regulatory definition at all.¹³ Many consumers will presumably fail to draw meaningful distinctions between a structure/function claim like “calcium helps build strong bones” and a health claim like “calcium helps prevent osteoporosis.” Moreover, similar “health halo” effects can come from nutrient content claims (“contains calcium”), or claims for high-value ingredients that imply a health or nutrient benefit (“made with real yogurt”).

We urge the FDA to focus its reform efforts primarily on ensuring that healthful-sounding claims cannot be made on unhealthy products. Food stores are filled with sugary cereals, frozen novelties, and pastries carrying claims that they are “good” or “excellent” sources of vitamins and minerals. Cereals, candy, and salty snacks tout healthful ingredients like berries, fruit, or kale, even when they contain minuscule amounts of these healthful ingredients. When consumers purchase and consume these generally unhealthy products based on misleading claims, producers of truly healthy foods lose market share, undermining healthful innovation. More importantly, consumers may become increasingly confused why routine consumption of these products failed to improve their health status, or perhaps worsened it, thus further eroding consumer credibility of product labeling, dietary guidelines, and government health standards in general. Reforming deceptive labeling is likely to “promote industry innovation and provide flexibility to encourage manufacturers to produce more healthful foods.”

Existing rules to prevent such abuses are weak: health claims may not be made on products high in total fat, saturated fat, cholesterol, and sodium, but can be made on products made primarily of refined grain or high in added sugars.¹⁴ Regulation of nutrient content and structure/function claims is weaker still, as these claims generally can be made on

¹³ U.S. Government Accountability Office. *FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims*. GAO-11-102: Jan 14, 2011. Accessed at <<https://www.gao.gov/products/GAO-11-102>>.

¹⁴ 21 CFR § 101.14

unhealthy products with no more than a weak disclosure (“See nutrition information for __ content”) provided for nutrient content claims on foods high in total fat, saturated fat, cholesterol, or sodium (but there is no disclosure for products high in added sugars).

Moreover, structure/function claims do not require FDA approval, although for consumers such claims are often indistinguishable from health claims. The FDA has the authority to regulate structure-function claims under its general authority to prevent misleading labeling. Alternatively, the agency could deem at least some of these claims to be implied health claims, as it has done in the instance of labeling claims related to maintaining heart health.¹⁵

The FDA currently lacks a framework to prevent claims for healthy ingredients from being made on unhealthy products, such as claims that a product is “made with” whole grains, fruits, vegetables, nuts, and dairy made on products high in saturated fat, added sugars, and sodium. In addition to its general authority to prevent misleading claims, the agency has the authority to deem such claims to be implied nutrient content claims to the extent that they are known to contain a particular nutrient (*e.g.*, “contains oat bran” = “a good source of dietary fiber”).¹⁶ However, we are not aware of the FDA applying this authority to whole grains, fruits, vegetables, or other nutrient-dense ingredients associated with health benefits and for which the Dietary Guidelines encourage increased consumption.

The Dietary Guidelines recommend that consumers eat a variety of vegetables and increase their consumption of fruits, with a focus on whole fruit.¹⁷ Despite such advice, Americans in every age group consistently fail to consume the amount of fruit and vegetables recommended in the DGA.¹⁸ The Centers for Disease Control found that only one in ten adults meet the federal fruit or vegetable recommendations.¹⁹ More than half of consumers in the IFIC 2018 Food and Health Survey report eating less fruits and vegetables than what they believe experts recommend.²⁰

We therefore urge the FDA to review the most frequently utilized deceptive labeling claims with implications for public health, including “made with” and “contains real fruit” claims, the use of misleading images of whole fruits and vegetables when only minuscule amounts

¹⁵ U.S. Food and Drug Administration. *Hampton Creek Foods 8/12/15*. 2015. Accessed at <<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458824.htm>>.

¹⁶ 21 CFR 101.65(c)(2).

¹⁷ 2015–2020 Dietary Guidelines for Americans. 8th Edition. Washington, D.C.: U.S. Department of Health and Human Services and U.S. Department of Agriculture: December 2015. Accessed at: <https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf>.

¹⁸ 2015–2020 Dietary Guidelines for Americans. 8th Edition. Washington, D.C.: U.S. Department of Health and Human Services and U.S. Department of Agriculture: December 2015; 2:41-43. Accessed at: <<https://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/#figure-2-3>>.

¹⁹ Lee-Kwan SH, Moore LV, Blanck HM, Harris DM, Galuska D. Disparities in State-Specific Adult Fruit and Vegetable Consumption – United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2017; 66:1241–1247. Accessed at: <<http://dx.doi.org/10.15585/mmwr.mm6645a1>>.

²⁰ International Food Information Council Foundation. *2018 Food and Health Survey*. Washington, D.C.: International Food Information Council Foundation, 2018. Accessed at: <<https://www.foodinsight.org/2018-food-and-health-survey>>.

are in a serving, the use of misleading titles for categories of foods that are unhealthy or are minimally nutritious foods (*i.e.*, “Veggie Sticks,” “Fruit Snacks”). The agency should consider whether, taken as a whole, such labels, images or claims are misleading or deceptive, and should use its full range of regulatory options, including enforcement, as well as developing new clarifying guidance or regulations where needed.

The FDA should proceed with caution, as creating a new definition for a “meaningful amount” of fruits, vegetables, or other healthful yet under-consumed ingredients on packaged foods is unlikely to result in appreciably better choices for consumers unless the term is defined very narrowly to include only those foods made of whole, largely unprocessed ingredients. The definition should not allow claims based on powders, juices, purees, pastes, and concentrates (except in select cases, such as tomato puree or paste), which are not as nutritious as whole fruits or fruit pieces because they lack the low-calorie density, cell structure, intact fiber, and other factors that contribute to the healthfulness and satiety of whole or cut up fruit. Permitting “meaningful amount” claims for these ingredients could appear to inflate the minimal nutritional value of options that are less nutritious than real fruits and vegetables, and therefore undermine Americans’ efforts to eat more healthful foods.

Instead, we urge the FDA to address this issue by:

- Requiring that foods making fruit and vegetable claims (through words or depictions) disclose the quantity of fruits and vegetables per serving in household measures (*e.g.*, “contains 1/8 teaspoon of strawberries per 1-cup serving”). The declaration should be specific to the type of fruit or vegetable depicted or mentioned in claims, to avoid creating a lack of transparency that unfairly depicts that more desirable or expensive ingredients (*e.g.*, “spinach” or “strawberries”) predominate in a food when they do not.
- Foods that contain fruit or vegetables that are not in their whole or cut form (without added sugar or sodium) should not be counted towards the amount of fruit in the declaration (for example, powders, concentrated fruit juice, or purees). A required disclosure should additionally indicate that the “The Dietary Guidelines for Americans recommends that at least half of your daily amount of fruit intake should be from whole fruits.”
- If a food is lacking in fruits and vegetables and contains only fruit or vegetable flavoring or coloring, it should bear a disclosure: “Contains no real fruits/vegetables.”

There are a number of specific additional steps that the FDA should take to update labeling requirements and address deceptions in the marketplace that currently impede healthful choices and fail to “encourage manufacturers to produce more healthful foods.” The FDA currently lacks a framework to prevent claims for healthy ingredients from being made on unhealthy products, such as claims that a product is “made with” whole grains, fruits, vegetables, nuts, and dairy made on products high in saturated fat, added sugars, and sodium. For example, caramel popcorn can currently be labeled “whole grain,” despite containing 30 percent of the Daily Value for added sugars per serving.

We urge the FDA to strengthen the rules for health, nutrient content, structure-function, and other “health halo,” claims to ensure these claims are not made on unhealthy products, by:

- Updating 21 CFR § 101.14 to include a disqualifying level of added sugars for health claims that comport with its Daily Value for added sugars, as the FDA indicated that it plans to do in its Nutrition Facts Panel Final Rule.
- Updating nutrient content claim disclosures for unhealthful nutrients, at 21 CFR § 101.13, to require a comparable disclosure for foods high in added sugars.
- Preventing claims for healthful ingredients like fruits, vegetables, and whole grains from misleading consumers into believing products high in saturated fat, added sugars, or sodium are healthy. This can be done either by initiating a rulemaking under the FDA’s general authority to prevent misleading claims, or by deeming such claims to be implied nutrient content claims.
- Issue regulations or take enforcement actions to define use of the term “low sugar” as a nutrient content claim. Because the FDA has not defined “low sugar” by regulation, the use of this term (or similar phrases like “lightly sweetened,” “just a tad sweet,” “sorta sweet”) that imply low sugar content should therefore be prohibited under 21 C.F.R. §101.13(b). A reasonable consumer would likely believe that a product labeled with any variation of the term ‘lightly sweetened’ contains a small amount of sugar and is a healthier option. Yet products labeled “lightly sweetened” sold today may contain as much as 20 grams of sugar, or 40 percent of the Daily Value for added sugars.
- Relatedly, the FDA should require a specific disclosure if a product boasts “0 grams” or “no” trans fat but is above a certain threshold for saturated fat, added sugars, or sodium, as most artificial trans fat is now gone from foods and this can create an unwarranted health halo on some unhealthful foods.
- IFIC consumer survey data indicate that “natural” is the most influential of all label claims and is used by nearly 40% of consumers when making purchasing decisions. The FDA should move forward to clarify the definition of “natural” and require a prominent disclosure defining the meaning of the term natural from a consumer perspective and clarifying what it does, and does not, mean in terms of ingredients and manufacturing processes.

3) Modernize and Improve Standards of Identity and Ingredient Lists and Continue its Efforts on Sodium Reduction

i. Modernizing Standards of Identity

We support modification of certain standards of identity in a manner that would benefit public health and support the FDA’s proposal to finalize its proposed rule from 2005 expressing general principles for modernizing standards of identity.²¹ In particular, we support principle #4, stating that the standards of identity “[m]ay be used as a vehicle to improve the overall nutritional quality of the food supply.” FDA should focus its consideration of standards of identity on the ways in which individual standards may be revised to better reflect public health priorities. Specifically, we support efforts to modify

²¹ Food Standards; “General Principles and Food Standards Modernization,” 70 FR 29214 (May 20, 2005).

the standards of identity to provide flexibility to manufacturers to implement modest reductions in saturated fat and sodium without changing the name of their products, such as:

- Eliminating milkfat minimums where they appear as part of a standard of identity, including for certain cheeses (21 CFR Part 133), cacao products (21 CFR Part 163), frozen desserts (21 CFR Part 135), and milk and cream (21 CFR Part 131). In particular, consistent with any forthcoming 2020-2025 Dietary Guidelines recommendations regarding types of dietary fats, FDA should prioritize milkfat minimums for the most commonly consumed cheeses (mozzarella, cheddar, and American), as cheese is a major contributor of saturated fat to the American diet and a calorically dense food.

Other requests for modification of the standards of identity should be considered by the FDA on a case-by-case basis with considerable input from stakeholders who would be impacted by the modification, in a manner similar to that applied to the petition for potassium chloride use. In considering such petitions, the FDA should consider the principles laid out in its proposed rule. The agency should also consider evidence of consumer acceptance of the ingredient in the given product, and any likelihood of consumer confusion that might result from the changes. As it has for “low-sodium” cheeses and similar products, FDA should require disclosures when needed to facilitate consumer understanding of distinctions among products.

ii. Modernize and Simplify Ingredient Lists Without Losing or Obfuscating Material Information

The Academy supports efforts to modernize ingredients lists to make them more readable and consumer-friendly. We urge the agency to take regulatory and enforcement action to ensure the readability of ingredients lists. The FDA should establish a minimum type size and allowable type styles, require use of upper- and lower-case letters, and include contrast requirements similar to those required for the Nutrition Facts panel, and other conspicuity measures.

The Academy Labeling Principles 1 (“Label claims should be clear and understandable to consumers; consumers’ nutrition literacy is key to promoting understanding.”) and 3 (“Content on the label should help consumers make informed decisions to build a healthy diet.”) leads us to support a narrow carve out for dietary supplements to ensure the ingredients are labeled with the requisite detail to ensure consumers are able to identify subtle but important differences between versions of the same ingredient. We share the concerns expressed at the referenced public meeting by Keith Nelson from SmartyPants Vitamins “that the proposal to change ingredient labels will be detrimental to consumer transparency and our industries, specifically, with regards to dietary supplement labels, and believe[d] it will negatively impact consumers’ ability to make informed decisions about their health. For example, if companies only list B9 in their labels, versus listing folic

acid or methyl folate, this could lead to uninformed health decisions and consumer distrust as these two versions of B9 impact populations differently.”²²

It is useful and convenient for consumers to have clear and understandable labels. Clarity leads to informed decisions, but truly obtaining this clarity may sometimes require the FDA to choose a somewhat less simple, but ultimately more clear and informative, set of rules for conveying material information about the label to consumers. In short, we agree with Mr. Nelson’s assertion that the FDA should “continue providing the u[t]most transparency regarding dietary supplement ingredients so that consumers are able to supplement their diet with the specific nutrients they need.”²³

iii. Continue Sodium Reduction Efforts

We strongly support inclusion of sodium reduction included in the FDA’s Nutrition Innovation Strategy. As the FDA notes, “[r]educing sodium in the diet is the single most effective health action related to nutrition.”²⁴ The typical sodium intake—about 4,000 milligrams per day²⁵—is a major cause of hypertension. An estimated 46 percent of U.S. adults²⁶ suffer from that condition, which increases the risk of heart disease and stroke. Together, coronary heart disease and stroke kill about 500,000 people annually in the United States.²⁷

Given successful population-wide sodium-reduction efforts in several other countries and the variation in sodium concentration within similar types of foods, the FDA’s proposed sodium-reduction targets are feasible. The FDA should also continue its work toward finalizing the ten-year sodium-reduction targets, since far more significant reductions

²² Transcript of Public Meeting re FDA’s Comprehensive Multi-Year Nutrition Innovation Strategy. Page 80. U.S. Food and Drug Administration website. Accessed October 5, 2018, Available at <https://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM618412.pdf>.

²³ *Ibid.*

²⁴ U.S. Food and Drug Administration. *FDA Nutrition Innovation Strategy*. 2015. Accessed at <https://www.fda.gov/food/labelingnutrition/ucm602651.htm>.

²⁵ Cogswell ME, Loria CM, Terry AL, Zhao L, Wang CY, Chen TC, Wright JD, Pfeiffer CM, Merritt R, Moy CS, Appel LJ. Estimated 24-Hour Urinary Sodium and Potassium Excretion in US Adults. *JAMA*. 2018; 319(12):1209–1220. Accessed at <https://www.ncbi.nlm.nih.gov/pubmed/29516104>.

²⁶ Whelton PK, Carey RM, Aronow WS, Casey DE Jr, Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbiagele B, Smith SC Jr, Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA Sr, Williamson JD, Wright JT. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2018; 71(19):e127–e248. Accessed at: <https://www.ncbi.nlm.nih.gov/pubmed/29146535>.

²⁷ Benjamin EJ, Blaha MJ, Chiuve SE, Cushman M, Das SR, Deo R, de Ferranti SD, Floyd J, Fornage M, Gillespie C, Isasi CR, Jimenez MC, Jordan LC, Judd SE, Lackland D, Lichtman JH, Lisabeth L, Liu S, Longenecker CT, Mackey RH, Matsushita K, Mozaffarian D, Mussolino ME, Nasir K, Neumar RW, Palaniappan L, Pandey DK, Thiagarajan RR, Reeves MJ, Ritchey M, Rodriguez CJ, Roth GA, Rosamond WD, Sasson C, Towfighi A, Tsao CW, Turner MB, Virani SS, Voeks JH, Willey JZ, Wilkins JT, Wu JHY, Alger HM, Wong SS, Muntner P. Heart Disease and Stroke Statistics—2017 Update: A Report from the American Heart Association. *Circulation*. 2017; 135(10):e146–e603. Accessed at: <https://www.ncbi.nlm.nih.gov/pubmed/28122885>.

could be accomplished and ten years provides industry ample time to plan and reformulate its products.

D. CONCLUSION

The Academy appreciates the opportunity to comment on the reopened proposed rule and supports its promise to improve Americans' dietary choices by promoting healthful foods. We look forward to working closely with you as partners and as a resource whenever possible. Please contact either Jeanne Blankenship by telephone at 312-899-1730 or by email at jblankenship@eatright.org or Pepin Tuma by telephone at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,



Jeanne Blankenship, MS RDN
Vice President, Policy Initiatives and Advocacy
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