



October 11, 2018

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA-2018-N-238; The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the Food and Drug Administration's (FDA's) comprehensive, multi-year Nutrition Innovation Strategy. Overall, we appreciate the agency's stated commitment to align food labels with science-based dietary advice. The strategy offers a critical opportunity to create greater transparency for consumers in the service of public health and to foster innovation that drives reformulation and the availability of healthier foods. We encourage the FDA to use this opportunity both to promote healthful foods and to prevent misleading labeling that hampers Americans' ability to make healthier dietary choices.

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported primarily by the more than half million subscribers to its *Nutrition Action Healthletter*. CSPI provides nutrition and food safety information directly to consumers, and has long advocated for legislation, regulation, and judicial rulings to ensure that food labels and advertising be clear and transparent, and that they convey useful and relevant public health information.

I. General Principles that Connect Sound Labeling Policy to Public Health Goals

Despite the sound recommendations of the 2015 Dietary Guidelines for Americans (the Dietary Guidelines), Americans under-consume healthful foods, especially fruits and vegetables, low-fat dairy, seafood, and whole grains. We also over-consume unhealthy foods and beverages high in added sugars, refined grains, saturated fat, and sodium.

Labeling transparency is a valuable tool to help consumers achieve healthier dietary choices, and should assist us in following the best available dietary advice. Consumers should be confident that foods marketed as better for us are indeed more healthful. The stakes are high: 72 percent of

adults and 35 percent of children and teens are now overweight or obese.¹ Approximately 46 percent of adults have diabetes or prediabetes, and the Centers for Disease Control and Prevention has estimated that the total direct and indirect cost of diagnosed diabetes in the United States in 2012 was \$245 billion.²

Every time consumers go looking for healthier options and are sold foods or beverages that undermine their health is a missed opportunity to reduce diet-related disease. Even consumers who dutifully try to follow dietary advice nonetheless struggle with excess weight, high blood pressure, high cholesterol, diabetes, and other preventable diet-related health problems.

Labels provide actionable information at the point of decision, connecting broader health goals to concrete dietary choices. Yet rather than supporting our desire for healthier eating, too many manufacturers take advantage of our best intentions by creating a “health halo” to make foods and beverages appear more healthful than they truly are. Fruit snacks, bars, chips, and other foods carrying images of fruits or vegetables but made primarily of refined grains, juice concentrates, and other unhealthy ingredients are inadequate substitutes for whole, fresh fruits and vegetables.

It is critical that the FDA’s initiative foster truly beneficial innovation by correcting misleading or inaccurate labeling claims. As part of this effort, the agency should take care to ensure that it not create or permit new marketing claims that enable unhealthy foods to unfairly compete with fresh fruits and vegetables and other healthier options, which occupy too little space in Americans’ diets.

As the FDA designs its Nutrition Innovation Strategy, we encourage the agency to use an approach that will help clarify both what is *in* products and what is *not* in them. An effective regulatory strategy would encourage consumers to fill their grocery carts with healthy foods—including fresh fruits and vegetables that bear no labels at all. For these reasons, we believe that the FDA should focus on the following steps as part of its Nutrition Innovation Strategy. The FDA should:

- 1) Strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling.***
- 2) Improve labeling of whole grains to enhance transparency for consumers and encourage healthful reformulation of grain-containing foods.***
- 3) Support health and improve transparency by preventing other types of deceptive labeling.***
- 4) Improve standards of identity and ingredient lists.***
- 5) Complete critical work on nutrition education and sodium reduction.***

¹ Fryar CD, Carroll MD, Ogden CL. Prevalence of Overweight, Obesity, and Severe Obesity Among Adults Aged 20 and Over: United States, 1960–1962 Through 2015–2016. National Center for Health Statistics, September 2018. Accessed at: <https://stacks.cdc.gov/view/cdc/58670>; Fryar CD, Carroll MD, Ogden CL. Prevalence of Overweight, Obesity, and Severe Obesity Among Children and Adolescents Aged 2–19 Years: United States, 1963–1965 Through 2015–2016. National Center for Health Statistics, September 2018. Accessed at: https://stacks.cdc.gov/view/cdc/58669/cdc_58669_DS1.

² 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>.

We address each of these action steps in the specific comments below.

II. Specific Comments on the Nutrition Innovation Strategy

1) *Strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling programs*

As part of its interest in “modernizing claims,” the FDA is seeking public comment on the possibility of using an easy-to-find symbol to denote the claim “healthy” on food labels.³ Generally speaking, we support an effort to create a comprehensive, standardized, national front-of-package symbol system to help consumers quickly identify healthier and less healthy foods.

CSPI has long advocated for such a system for packaged foods. In 2006, we petitioned the FDA for a single front-of-package symbol system as a valuable supplement to the Nutrition Facts panel.⁴ One of the primary drivers behind our request was a lack of uniformity in the marketplace, which remains flooded by the proliferation of privately owned “stamp” programs with divergent nutrition criteria, public health goals, and consumer significance.⁵ Similarly, the Institute of Medicine has recommended a single, standard front-of-package symbol system for all grocery products, allowing consumers to scale or rank products using simple nutritional guidance and readily identifiable symbols.⁶

While an FDA-defined “healthy” logo holds potential to be useful for consumers, we are concerned that a standardized “healthy” symbol, available to manufacturers for voluntary use, would be less effective at addressing public health needs than a more comprehensive symbol system that conveys both the healthier and less healthy attributes of foods.

A voluntary “healthy” logo would compete with various private-sector certifications that convey similar or overlapping meaning, making it harder for consumers to identify, understand, and make use of the symbol. More fundamentally, while a voluntary “healthy” symbol may be able to guide some consumers to healthier choices *within* a food category, it would not allow them to discern which food categories should be eaten less often. Such information is key to following the Dietary Guidelines, which includes advice to limit foods that are high in saturated fat, added sugars, refined grains, and sodium.⁷ A “healthy” symbol that would be available primarily for use on packaged foods also could make these foods appear more attractive than unpackaged alternatives, including under-consumed fresh fruits and vegetables.

³ U.S. Food and Drug Administration. *FDA Nutrition Innovation Strategy*. 2015. Accessed at <<https://www.fda.gov/food/labelingnutrition/ucm602651.htm>>.

⁴ Center for Science in the Public Interest. *FDA Urged to Create New “Healthy Food” Labeling System*. The Center for Science in the Public Interest, 2006. Accessed at: <<https://cspinet.org/new/200611301.html>>.

⁵ *Ibid.*

⁶ Institute of Medicine of the National Academies. *Front-of-Package Nutrition Rating systems and Symbols: Promoting Healthier Choices*. Washington, DC: Institute of Medicine of the National Academies, 2011. Accessed at: <<http://www.nationalacademies.org/hmd/Reports/2011/Front-of-Package-Nutrition-Rating-Systems-and-Symbols-Promoting-Healthier-Choices>>.

⁷ 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>.

This problem would be exacerbated if the standard for “healthy” were too lax. Appropriately strengthening the definition of this term is critical for preventing unhealthy products from being mislabeled as “healthy,” upending public health goals. An FDA-endorsed “healthy” logo should not appear, for example, on potato chips, fruit and grain bars made with fruit juice concentrates, fruit juice smoothies, low-sugar bars made with whey protein and inulin or other processed fibers, or on the labels of similar foods that might meet the FDA’s current criteria defining “healthy.”

We therefore encourage the FDA to focus first and foremost on strengthening the definition of “healthy” prior to considering whether to design a logo for the term. We have previously commented, and reiterate here, that the “healthy” definition should include limits on added sugars and require that grain-containing foods be 100% whole grain.⁸ It should also consider both food and nutrient criteria but maintain the maximums for saturated fat⁹ and cholesterol, strengthen the maximum for sodium, and include a new maximum for added sugars.

If the FDA also requires that “healthy” foods must contain healthful ingredients (including whole grain, fruits, or vegetables), it should consider only ingredients that make up the core of a healthy eating pattern in their nutrient-dense forms. For example, if the FDA requires “healthy” foods to contain a minimum amount of fruits or vegetables, the agency should count only fruits and vegetables that are present in a whole or cut-up form, and *not* as concentrate, powder, paste, juice, or purée, since these forms are lacking in some of the healthful components of the original food, including the intact fiber, plant cell structure, and low calorie density that contribute to satiety.¹⁰ Additional considerations can be found in our comments on the docket for updating requirements for “healthy” claims.¹¹

Should the FDA proceed with developing a “healthy” logo, we encourage the agency to consider ways to coordinate the effort with existing labeling systems to provide more streamlined information to consumers about the nutrition content of foods. This could include issuing guidance on presenting the “healthy” logo in an integrated way with additional front-of-package elements, such as the information about calories, saturated fat, sodium, and sugars that is provided through the industry’s “Facts Up Front” system.¹²

⁸ Center for Science in the Public Interest. *CSPI Healthy Comment: Re: Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments; Docket No. FDA-2016-D-2335*. Center for Science in the Public Interest, 2017. Accessed at: <<https://cspinet.org/resource/cspi-healthy-comment>>.

⁹ With clarification to the enforcement discretion guidance, as noted in our “healthy” comment.

¹⁰ Haber GB, Heaton KW, Murphy D, Burroughs LF. Depletion and disruption of dietary fibre. Effects on satiety, plasma-glucose, and serum-insulin. *The Lancet*. 1977;2(8040):679-82; Mattes RD, Campbell WW. Effects of food form and timing of ingestion on appetite and energy intake in lean young adults and in young adults with obesity. *Journal of the American Dietetic Association*. 2009;109(3):430- 7. doi:10.1016/j.jada.2008.11.031; Bolton RP, Heaton KW, Burroughs LF. The role of dietary fiber in satiety, glucose, and insulin: studies with fruit and fruit juice. *American Journal of Clinical Nutrition*. 1981;34(2):211-7; Flood-Obbagy JE, Rolls BJ. The effect of fruit in different forms on energy intake and satiety at a meal. *Appetite*. 2009;52(2):416-22. doi:10.1016/j.appet.2008.12.001.

¹¹ Center for Science in the Public Interest. *CSPI Healthy Comment: Re: Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments; Docket No. FDA-2016-D-2335*. Center for Science in the Public Interest, 2017. Accessed at: <<https://cspinet.org/resource/cspi-healthy-comment>>.

¹² Grocery Manufacturers Association and the Food Marketing Institute. *Facts up Front*. Accessed at <<http://www.factsupfront.org>>.

We note that other countries have adopted more-uniform and consistent mandatory front-of-package labeling systems. The Health Star Rating in Australia and New Zealand¹³ combines interpretive guidance (a star rating score) with nutrition information for calories, saturated fat, sodium, and sugars (the same nutrients used in the food industry's Facts Up Front system in the United States). Presenting both types of elements in combination could also help distinguish the logo from other symbols and claims and clarify its connection to nutrition. The FDA's review should be guided by consumer testing of a range of systems, with reference to existing research and labeling rules on front-of-package systems around the globe, including the Health Star logo in New Zealand,¹⁴ the Keyhole logo in Sweden,¹⁵ and the Choices Logo in the Netherlands¹⁶ (now being phased out¹⁷). This review should include an evaluation of the impact of each type of system on both consumer choices and reformulation.

2) *Improve labeling of whole grains to enhance transparency for consumers and encourage healthful reformulation of grain-containing foods*

The FDA has requested feedback on the types of label claims that would be most helpful in facilitating product innovation and promoting healthy eating patterns consistent with the Dietary Guidelines.¹⁸ We encourage the agency to prioritize whole-grain claims. Most Americans consume packaged bread, crackers, pasta, and/or cereal, and do not produce these products at home, where they have clearer control over the whole-grain content. Clearer labeling of these and other grain-based packaged foods is needed, and would make it easier for consumers to eat healthier diets and incentivize industry to improve the healthfulness of these foods.

¹³ New Zealand Food Safety. *Health Star Ratings: Health Star Ratings are a quick and easy way for you to choose healthier packaged foods*. Accessed at <<https://www.mpi.govt.nz/food-safety/food-safety-for-consumers/food-labelling/health-star-ratings>>.

¹⁴ Mhurchu CN, Volkova E, Jiang Y, Eyles H, Michie J, Neal B, Blakely T, Swinburn B, Rayner M. Effects of interpretive nutrition labels on consumer food purchases: The Starlight randomized controlled trial. *American Journal of Clinical Nutrition*. 2017;105(3):695-704; Mhurchu CN, Eyles H, Choi YH. Effects of a voluntary front-of-pack nutrition labeling system on packaged food reformulation: The Health Star Rating System in New Zealand. *Nutrients*. 2017;9(8): e918; Herrera AM, Crino M, Erskine HE, Sacks G, Ananthapavan J, Mhurchu CN, Lee YY. Cost-effectiveness of product reformulation in response to the Health Star Rating food labeling system in Australia. *Nutrients*. 2018;10:614; Talati Z, Norman R, Pettigrew S, Neal B, Kelly B, Dixon K, Ball K, Miller C, Shilton T. The impact of interpretive and reductive front-of-pack labels on food choice and willingness to pay. *International Journal of Behavioral Nutrition and Physical Activity*. 2017; 14:171; Talati Z, Pettigrew S, Dixon H, Ball K, Hughes C. Do health claims and front-of-pack labels lead to a positivity bias in unhealthy foods? *Nutrients*. 2016;8(12):e787.

¹⁵ Larsson I, Lissner L, Wilhelmsen L. The 'Green Keyhole' revisited: Nutritional knowledge may influence food section. *European Journal of Clinical Nutrition*. 1999;53(10):776-780.

¹⁶ Vyth EL, Steenhuis IHM, Roodenburg AJC, Brug J, Seidell JC. Front-of-pack nutrition label stimulates healthier product development: A quantitative analysis. *International Journal of Behavioral Nutrition and Physical Activity*. 2010;7:65; Vyth EL, Steenhuis IH, Vlot JA, Hogenes MG, Looije DH, Burg J, Seidell JC. Actual use of a front-of-pack nutrition logo in the supermarket: Consumers' motives in food choice. *Public Health Nutrition*. 2010;13(11):1882-1889; Steenhuis IH, Kroeze W, Vyth EL, Valk S, Verbauwen R, Seidell JC. The effects of using a nutrition logo on consumption and product evaluation of a sweet pastry. *Appetite*. 2010;55(3):707-709.

¹⁷ European Commission. Minutes of the Joint Meeting on Front-of-Pack Nutrition Labeling between Working Group of the Standing Committee on Plants, Animals, Food and Feed. Brussels, 2018. Available at <https://ec.europa.eu/food/sites/food/files/safety/docs/comm_ahac_20180423_sum.pdf>.

¹⁸ U.S. Food and Drug Administration. FDA Public Meeting: FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy: Facilitated Breakout Session: Claims and Statements Used on Food Labels & Icon for "Healthy." Accessed at <<https://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM614173.pdf>>.

The Dietary Guidelines recommend that Americans “make at least half of grains whole grains.”¹⁹ Yet Americans in every age group are not following this advice, under-consuming whole grains and over-consuming refined grains.²⁰ Consumers are aware of this deficit and seek to increase their intake of whole grains. The International Food Information Council 2018 Food and Health Survey shows that whole grains are near the top the list of components considered to be healthful by consumers (following only vitamin D and fiber).²¹ The marketplace is responding dramatically to this interest with new “whole grain” products: market analysts predict that the global market for whole-grain and high-fiber foods will expand by nearly 50 percent over the next five years, reaching \$46.2 billion by 2022.²²

Unfortunately, labeling on whole grain-containing products often remains unclear or deceptive, obscuring refined-grain content and making it harder for consumers to select healthier options. While some companies are offering products that are rich in whole grains, incentives for such innovations are blunted by the fact that consumers often cannot tell how much of the grain in a product is whole and how much is refined. Hearty-looking (and sometimes artificially colored) “wheat” breads and “multigrain” breads add to the confusion, with label claims and images suggesting that they consist largely of whole grains when many are largely refined grain. (See Appendix, Fig 1: Nature’s Own Honey Wheat Bread.)

Whole-grain content is not disclosed in the Nutrition Facts panel, and the ingredient list is often uninformative—for example, if it includes both whole and refined grains, contains confusing names, or fails to specify which grains are whole grains. If a label lists a whole grain followed by multiple refined grains (which together could add up to more refined grain than whole grain), consumers would have no way of knowing that refined grain is the predominant grain, much less the percent of the total grain that is whole. This is commonplace in the bread aisle. Even voluntary declarations typically offer only “grams whole grain” without disclosing the refined grain content (unless the product is 100% whole grain). (See Appendix, Fig 2: Sara Lee White made with Whole Grain Bread.)

The lack of clarity on whole-grain claims has led to consumer confusion. A study published in 2016 by the FDA in collaboration with several academic institutions showed that older adults are confused by package information on whole-grain products.²³ The study used a structured interview protocol to test whether older adults (n = 89, age ≥ 65 years) could accurately identify three common food items as “whole grain” or “not whole grain,” with the option to indicate that they were unsure of the proper designation.

¹⁹ 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>.

²⁰ *Ibid.*

²¹ 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>>.

²² WhatTech. *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>>; 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>>.

²³ Violette C, Kantor MA, Ferguson K, Reicks M, Marquart L, Laus MJ, Cohen N. Package Information Used by Older Adults to Identify Whole Grain Foods. *Journal of Nutrition in Gerontology and Geriatrics*. 2016; 35:2; 146-160. Accessed at <<https://www.tandfonline.com/doi/abs/10.1080/21551197.2016.1168759>>.

The study found that approximately 35 percent of participants could not correctly identify two whole-grain products (cereal and crackers) as whole grain, and that approximately 80 percent of participants could not correctly identify that the refined-grain product (bread) was not whole grain, while nearly half (46 percent) misidentified the refined-grain bread as whole grain. Many participants also did not know where to look on labels for information about whole grains and consulted the Nutrition Facts panel almost as often as they did the ingredient lists, though only the latter displays (limited) information about the whole-grain content of foods.

These results accord with those of a national online survey commissioned by CSPI in 2011 that included more than 1,000 participants. The survey, which was sent to the FDA in 2012,²⁴ 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 the term “wheat” was accompanied by depictions of dark-colored crackers, heads of wheat, or the term “stone ground.”²⁵

CSPI previously urged the FDA to address this problem through a simple declaration of whole- and refined-grain content, by weight or percentage, which would prevent manufacturers from making misleading whole-grain claims.²⁶ In addition to these requests, which are still pending before the FDA, CSPI also supports the Food Labeling Modernization Act, which would amend section 403 of the Food, Drug and Cosmetic Act to require that whole-grain claims be accompanied by a conspicuous disclosure of whole-grain content, expressed as a percentage of total grains.²⁷

We therefore ask the agency to prioritize the issue of whole-grain labeling as part of its Nutrition Innovation Strategy. Specifically, to prevent misleading claims and encourage healthful innovation, we request that the FDA:

- Require a declaration of both whole-grain and refined-grain content for any label that makes a whole-grain claim. The declaration should appear on any food making a claim that includes (1) direct terms for whole grain like “whole wheat,” “whole grain,” or “made with whole grain,” (2) terms that imply whole grain in the minds of consumers, such as “multigrain,” (3) a declaration of the whole-grain content by weight, or (4) the term “wheat” on a wheat-based bread, pasta, cracker, muffin, or other product that is typically made from wheat. Implied whole-grain claims can be verbal or non-verbal depictions, including images of wheat or grains, or any similar descriptive phrases, terms, or representations suggesting that the product contains whole grains.

²⁴ Center for Science in the Public Interest. *2012 Letter on Whole Grain Labeling*. Center for Science in the Public Interest, 2012. Accessed at <<https://cspinet.org/sites/default/files/2012-letter-whole-grain-labeling.pdf>>

²⁵ *Ibid.*

²⁶ Center for Science in the Public Interest. *Petition to Prohibit Misbranding of Whole Wheat Products and to Promulgate Food Labeling Regulations Concerning Products Made with Whole Wheat*. Center for Science in the Public Interest, 1993. Accessed at <<https://cspinet.org/sites/default/files/1993-petition-misbranding.pdf>>; Center for Science in the Public Interest. *FDA’s Guidance on Whole Grain Label Statements [Docket No. 2006D-0066]*. Center for Science in the Public Interest, 2006. Accessed at <<https://cspinet.org/sites/default/files/2006-comment-whole-grain-guidance-fda.pdf>>; Center for Science in the Public Interest. *2012 Letter on Whole Grain Labeling*. Center for Science in the Public Interest, 2012. Accessed at <<https://cspinet.org/sites/default/files/2012-letter-whole-grain-labeling.pdf>>

²⁷ The Food Labeling Modernization Act of 2018 (H.R. 5425; S. 2647).

- Require that the declaration be uniform across products and that it prominently disclose *either* the percentage of whole grains in relation to refined grains (e.g., “80 percent of the grain is whole grain”) *or* the number of grams of both refined and whole grains per serving (e.g., “contains 8 g whole grain and 16 g refined grain per serving). The form of the disclosure should be based on the results of consumer testing that assesses the comparative understanding of these two options.

3) *Support health and improve transparency by preventing other types of deceptive labeling*

A. *“Meaningful Amount” of Healthy Ingredients*

In public remarks at the National Food Policy Conference on March 29, 2018, FDA Commissioner Scott Gottlieb expressed an interest in exploring new claims for products that offer fruits, vegetables, low-fat dairy, and healthy oils, for which American’s diets typically fall short of recommendations.²⁸ In particular, the commissioner suggested that claims related to healthful ingredients be structured in a way that signals that a product contains a “meaningful amount” of these foods.²⁹

We generally agree with the goal of increasing consumption of fruits, vegetables, and low-fat dairy. Fruits and vegetables are an important area of focus, since Americans in almost every age group consistently fail to consume the amounts recommended in the Dietary Guidelines.³⁰ The Centers for Disease Control and Prevention recently found that only one in ten adults meet the Dietary Guidelines’ fruit or vegetable recommendations.³¹ We question whether increasing intake of “healthy oils” should be a priority, given that Americans are close to the recommended intake and these oils often appear in foods that are not nutrient dense.³²

Yet we are concerned that an attempt by the agency to define “meaningful amounts” of fruit, vegetables, or other under-consumed healthful foods risks further validating potentially misleading claims that discourage Americans from following a healthy dietary pattern. Many food manufacturers take advantage of consumers by advertising “real fruit” products as healthy options. Yet the fruit in those products may be in the form of a juice, purée, paste, or concentrate, which are not as healthful as whole or cut-up fruits or vegetables because they lack the low calorie density, cell structure, intact fiber, and other factors that contribute to healthfulness and satiety.³³ Fruit snacks that depict images of whole berries are marketed to

²⁸ Gottlieb, S. “Reducing the Burden of Chronic Disease.” National Food Policy Conference, Consumer Federation of America, March 29, 2018, Capital Hilton, Washington, DC.

²⁹ *Ibid.*

³⁰ 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>. Children aged 1-8 consume enough fruit, but a higher proportion of this fruit comes from fruit juice, with fruit intake for the youngest children (aged 1-3) constituting nearly half their fruit intake. *Ibid.*

³¹ Lee-Kwan SH, Moore LV, Blanck HM, Harris DM, Galuska D. Disparities in State-Specific Adult Fruit and Vegetable Consumption – United States, 2015. *Morbidity and Mortality Weekly Report*. 2017; 66:1241–1247. Accessed at: <http://dx.doi.org/10.15585/mmwr.mm6645a1>.

³² Including snack chips, french fries, and doughnuts.

³³ See *supra*, note 10.

toddlers, when in fact those snacks are primarily made of concentrated apple juice or purée, which are both sources of added sugar.³⁴ (See Appendix, Fig 5: Plum Organics Teensy Fruits.)

Similarly, products that present themselves as containing a variety of nutritious vegetables are often made primarily of dyed refined flour or potato, a vegetable that tends to be over-consumed by Americans relative to other vegetables. (See Appendix, Fig 6: EatSmart Veggie Crisps and Mission Wraps.)³⁵ And the “yogurt” in many products is often sugar and palm oil, with little more than a touch of yogurt powder to support the claim. (See Appendix, Fig 7: Sun Maid Strawberry Greek Yogurt Raisins.)

CSPI alerted the FDA to the problem of deceptive fruit and vegetable ingredient claims as early as 1995, when we petitioned the FDA to require a disclosure for the actual amount of fruit or vegetables per serving on products making such claims.³⁶ More recently, similar steps were taken by an industry self-regulatory body run by the Council of Better Business Bureaus, the Children’s Advertising Review Unit (CARU), which “evaluates child-directed advertising...to advance truthfulness, accuracy and consistency.” In 2016, CARU recommended that Kellogg remove the “Made with Real Fruit” claim from its Fruit Flavored Snacks because the claim could be confusing to child consumers³⁷ when made on a product that contained very little fruit.³⁸ Similarly, CARU had advised Kellogg in 2010 that “Made with Real Fruit” claims were misleading on Pop-Tarts that contained only 6 percent fruit.³⁹

In light of the potential for serious consumer confusion with claims for fruits, vegetables, and other healthful ingredients, we urge the FDA to avoid defining a “meaningful amount” of these ingredients. Instead, we request that the agency:

- Require that foods making fruit and vegetable claims (e.g., “real fruit,” “made with real fruit”) disclose the quantity of fruits and vegetables per serving in household measures (e.g., “contains 1/8 teaspoon of strawberries per 1-cup serving”).
- Require that the declaration be specific to the type of fruit or vegetable used (e.g., “contains 1/8 teaspoon kale and ½ cup potatoes,” not “contains ½ cup vegetables”), and that it count only its whole or cut form toward the amount of fruit or vegetable in the

³⁴ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *Draft Guidance: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry*. U.S. Food and Drug Administration, January 2017. Accessed at <<https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm535372.pdf>>.

³⁵ 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; 2:44-46. Accessed at: <<https://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/#vegetables>>.

³⁶ Center for Science in the Public Interest. *Petition for Proposed Rulemaking and Regulatory Action to Prohibit Misleading Food Labeling*. Center for Science in the Public Interest, 1995. Accessed at <<https://cspinet.org/sites/default/files/1995-petition-prohibit-misleading-food-labeling.pdf>>.

³⁷ The decision did not address adult consumers, who are outside the scope of CARU’s review.

³⁸ Advertising Self-Regulatory Council. *CARU Recommends Kellogg Revise Product Packaging for ‘Fruit Flavored Snacks,’ Company Agrees to Do So*. Advertising Self-Regulatory Council, 2016. Accessed at <<http://www.asrcreviews.org/caru-recommends-kellogg-revise-product-packaging-for-fruit-flavored-snacks-company-agrees-to-do-so>>.

³⁹ Children’s Advertising Review Unit. *CARU Recommends Kellogg Discontinue Certain Claims on ‘Pop-Tarts’ Packaging*. New York, NY, 2010. Accessed at <<http://www.caru.org/news/2010/5165PR.pdf>>.

declaration.⁴⁰ Fruit or vegetable juices, concentrates, powders, purées, and other ingredients that are not whole or cut fruits or vegetables should not count toward the amount.

- Require that, if a food contains no whole or cut fruit or vegetables, it bear this disclosure: “Contains no whole or cut fruits/vegetables.”
- Require that, for fruit, the disclosure include that “The Dietary Guidelines for Americans recommends that at least half of your daily amount of fruit intake should be from whole fruits.”

The agency should consider similar quantitative disclosures in household measures for foods that make claims about other healthy ingredients, including yogurt and nuts. Again, these disclosures should count only the whole or unprocessed form (*e.g.*, yogurt, not yogurt powder).

Should the agency proceed with creating a new definition for a “meaningful amount” of fruits, vegetables, or other healthful yet under-consumed ingredients, we urge it to define these ingredients very narrowly. The FDA should not allow claims based on fruit or vegetable powders, juices, purées, pastes, or concentrates to count toward the “meaningful amount” threshold. Permitting “meaningful amount” claims for these ingredients could inflate the apparent healthfulness of unhealthy foods, and would undermine Americans’ efforts to identify more-healthful options, including whole or cut-up fruits and vegetables.

B. Health Halo Claims and other Labeling Deceptions

The FDA is also seeking input on other ways to modernize labeling claims related to healthier foods. In particular, the agency has solicited feedback on ways to streamline its procedures for approving qualified health claims.⁴¹ We urge the agency not to weaken the standards for reviewing health claims, since this category represents a very narrow subset of claims related directly to disease risk and should be subject to the highest review standards by the agency.

More broadly, while claims describing the health benefits of foods can be useful in some cases, the main problem with today’s food marketplace is not a paucity of label claims, but instead that too many packages bear misleading or deceptive claims touting health benefits for foods that are not healthy. Grocery stores are filled with sugary cereals, fruit snacks, frozen novelties, juice drinks, bars, and toaster 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, nuts, or kale, even when they contain minuscule amounts of these ingredients. When consumers purchase products based on misleading claims, producers of truly healthful foods lose market share, undermining healthful innovation.

Rather than focus agency resources on permitting additional dubious claims, we urge the FDA to focus on ensuring that all health-related claims are clear and transparent, and that they support consumers in making healthier choices. We hope that the FDA will expand its thinking beyond this narrow category of health claims to consider how to improve the value and truthfulness of

⁴⁰ If other, non-whole or cut forms of the fruit or vegetable are allowed to count toward the declaration, the manufacturer should be required to specify the form of the ingredient (*e.g.*, “Contains 1/8 teaspoon of strawberry purée and 1 teaspoon of apple juice concentrate per pouch”).

⁴¹ U.S. Food and Drug Administration. *FDA Nutrition Innovation Strategy*. 2015. Accessed at <https://www.fda.gov/food/labelingnutrition/ucm602651.htm>.

the many other types of claims that evoke health benefits. A majority of health-related food label claims are not considered health claims by the FDA, but instead are categorized as structure/function or nutrient content claims, or they lack any regulatory definition at all.⁴²

Many consumers will not draw meaningful distinctions between a structure/function claim like “calcium helps build strong bones” and a health claim like “calcium may reduce the risk of osteoporosis.” Moreover, similar “health halo” effects can occur from nutrient content claims (“good source of calcium”) or claims for high-value ingredients that imply a health or nutrient benefit (“made with real yogurt”).

Existing rules to prevent such abuses contain numerous weak points: health claims may not be made on products above a certain threshold of total fat, saturated fat, cholesterol, or sodium, but can be made on products that are made primarily of refined grain or that are high in added sugars. (See Appendix, Fig 3: Kellogg’s Smart Start Cereal.)⁴³ Nutrient content claims require no more than a weak disclosure (“See nutrition information for ___ content”) on foods that are high in total fat, saturated fat, cholesterol, or sodium, again with no disclosure for products that are high in refined grains or added sugars. Moreover, structure/function claims do not require FDA approval, although for consumers such claims are often indistinguishable from health claims.⁴⁴

In addition to these weaknesses in existing rules, the FDA lacks a regulatory structure to prevent manufacturers from making claims for healthy ingredients (*e.g.*, whole grains, fruits, vegetables, nuts, and yogurt) on unhealthy products that are high in unhealthy nutrients (saturated fat, cholesterol, sodium, or added sugars). For example, caramel popcorn can be labeled “whole grain” despite containing more than the entire Daily Value for added sugars per bag. (See Appendix, Fig 4: Gary Poppins Popcorn.)

In addition to flaws in the rules for advertising what is *in* products, there are flaws in the rules for advertising what is *not* in them. The FDA lacks any regulation defining “low added sugar” or “low sugar,” which means that these terms are prohibited nutrient content claims.⁴⁵ Yet the agency has not taken enforcement action against food and beverage manufacturers who make claims using synonyms for “low sugar” such as “lightly sweetened,” “just a tad sweet,” and “sorta sweet.” Manufacturers are responding to the agency’s inaction by labeling as “lightly sweetened” products that contain as much as 25 grams of sugar, or 50 percent of the Daily Value for added sugars. (See Appendix, Fig 8: Honest Tea, Half Tea & Half Lemonade.) Similarly, the agency has not updated its rules to prevent products from touting “0g *trans* fat per serving” even if they are high in saturated fat. (See Appendix, Fig 9: Pop Secret, Butter.)

⁴² 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>>.

⁴³ 21 CFR § 101.14.

⁴⁴ Lin CJ. How Do Consumers Interpret Health Messages on Food Labels? *Nutrition Today*. 2008;43:267-272. The study found that in many cases, consumers rate the believability and helpfulness of structure/function claims as similar to that of health claims.

⁴⁵ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *A Food Labeling Guide: Guidance for Industry*. College Park, MD : U.S. Food and Drug Administration, 2013. Accessed at <<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>>.

These and other deceptive claims should be considered as part of the FDA's Nutrition Innovation Strategy. We encourage the FDA to address the following areas:

- *Standards for health claims.* The FDA should maintain the current standards for reviewing new health claims, since this category represents a very narrow subset of claims related directly to disease risk and should be subject to the highest review standards. In addition, the agency should update 21 CFR § 101.14 (Health claims: general requirements) to include a disqualifying level of added sugars for health claims, as it indicated that it planned to do in the Nutrition Facts Panel rulemaking. The agency should also consider a disqualifying level for refined grains.
- *Review of structure/function claims.* The FDA should require premarket review and approval of structure/function claims and prevent those claims from being made on products that are high in nutrients that Americans are advised to limit under the Dietary Guidelines. This can be done through a rulemaking or by deeming such claims to be implied health claims because they purport to address a disease risk (as has been done with labeling claims related to maintaining heart health⁴⁶).
- *Disqualifying nutrients for “health halo” claims.* The FDA should prevent claims for healthful ingredients like fruits, vegetables, and whole grains from misleading consumers into believing that products that are high in saturated fat, cholesterol, added sugars, or sodium are healthy. This can be done by initiating a rulemaking under the FDA's general authority to prevent misleading claims.
- *Updating nutrient content claims.* The FDA should update nutrient content claim disclosures for unhealthful nutrients at 21 CFR § 101.13 to require a comparable disclosure for foods that are high in added sugars and to align the high level of sodium with the updated sodium Daily Value.
- *Low-sugar claims.* The FDA should take enforcement action against manufacturers using synonyms for “low sugar” such as “lightly sweetened,” “just a tad sweet,” and “sorta sweet.” These claims are illegal because “low sugar” is a nutrient content claim that has not been defined by regulation.⁴⁷ The FDA should also consider adopting regulations defining use of the term “low added sugar” and synonymous phrases, so that this nutrient content claim can be made appropriately in the future.
- *Disclosure for trans fat claims.* The FDA should require products bearing claims for “0 grams *trans* fat” or “no *trans* fat” that are high in saturated fat to disclose the level of saturated fat in the food in immediate proximity to the *trans* fat claim, with text no less than one-half the size or prominence of the *trans* claim.⁴⁸
- *Natural claims.* The FDA should define the term “natural,” and should require a prominent disclosure explaining what natural does, and does *not*, mean in terms of ingredients and manufacturing processes.

⁴⁶ 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>.

⁴⁷ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *A Food Labeling Guide: Guidance for Industry*. College Park, MD: U.S. Food and Drug Administration, 2013. Accessed at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>.

⁴⁸ Language for this proposal is included in the Food Labeling Modernization Act. The Food Labeling Modernization Act of 2018 (H.R. 5425; S. 2647).

- *Fortification policy.* The FDA should strengthen its fortification policy by conducting a market analysis to determine whether consumers are misled by the fortification of nutritionally minimal foods (including fruit snacks, frozen novelties, sugar-laden cereals, fruit drinks and other sugar-sweetened beverages, and bars). The agency should then clarify the guidance as warranted by the analysis and/or conduct appropriate enforcement as warranted.
- *Energy claims.* The FDA should prevent the unapproved use of the term “energy” on food labels, as CSPI requested in a petition to the agency on November 27, 1996.⁴⁹ These claims, made on bars, nuts, and breakfast cereal,⁵⁰ are implied to be “high in calories,” an unapproved nutrient content claim. These can also relate to caffeine, in beverages and foods where the levels are unregulated, and about which FDA has expressed health concerns.
- *Artificial colors.* The FDA should require a front-of-package declaration for artificial colors, as CSPI requested in a petition to the agency on December 8, 2011.⁵¹ Such disclosures are particularly important in cases where a product claims to use “all natural flavors,” since those claims, which often appear on the front of the package, create the misperception that all additives in the product are natural.

4) Improve standards of identity and ingredient lists

A. Modernizing Standards of Identity

The FDA has requested comment on whether the regulations governing standards of identity for foods can be modified to encourage and/or remove barriers to the production of more healthful foods. CSPI generally supports the modification of certain standards of identity in a manner that would benefit the public health, and we urge the FDA to finalize its proposed rule from 2005 expressing general principles for modernizing standards of identity and requiring that amendments to the standard be consistent with those principles.⁵²

However, in adopting its final rule, we urge the agency to clarify certain principles in the preamble to the rule. We generally support proposed principle #4, which states that “[t]he food standard should ensure that the food does not appear to be better or of a greater value than it is. The food standard may be used as a vehicle to improve the overall nutritional quality of the food supply.”

However, we are concerned that the preamble to the proposed principles appears to define “value” primarily in terms of historic economic value, which could lead principle #4 to be misread to prohibit changes to a food standard in instances where the more nutritious ingredient also happens to be more affordable. To address potential confusion on this point, we urge the FDA to amend the preamble to the rule to clarify that a food standard may be modified in ways

⁴⁹ Center for Science in the Public Interest. *Petition for Regulatory Action to Prevent the Unapproved Use of the Term “Energy” on Food Labels*. Center for Science in the Public Interest, 1996. Accessed at <<https://cspinet.org/sites/default/files/1996-petition-regulatory-prevent-use.pdf>>.

⁵⁰ For example, belVita Breakfast Biscuits, Cranberry Orange claim “4 hours of nutritious steady energy.”

⁵¹ Center for Science in the Public Interest. *Petition to Require Front Package Disclosure of Food Color Additives*. Center for Science in the Public Interest, 2011. Accessed at <<https://cspinet.org/resource/petition-require-front-package-disclosure-food-color-additives>>.

⁵² “Food Standards; General Principles and Food Standards Modernization,” 70 Fed. Reg. 29,214 (May 20, 2005).

that provide for the use of less expensive ingredients, provided that consumer expectations related to the overall economic and nutritional value of the final product are met.

With regard to amending particular standards, we encourage the agency to focus its consideration on the ways in which individual standards may be revised to better reflect public health priorities. Specifically, we support efforts to modify 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 (provided that claims such as “reduced fat” and “reduced sodium” remain reserved for products that comply with existing standards for these terms).

Possible changes to standards of identity could include:

- 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), and frozen desserts (21 CFR Part 135). In doing so, the FDA should prioritize elimination of milkfat minimums for the most commonly consumed products. The agency could start with mozzarella, cheddar, and American cheese.
- Modifying the standards of identity for cheese to allow potassium chloride to be used as a substitute for sodium chloride. The dairy industry has previously commented that such a change would allow companies to make modest reductions in sodium in keeping with the FDA’s voluntary sodium-reduction targets.⁵³

Other requests for modification of the standards of identity should be considered by the FDA on a case-by-case basis, as provided for in 21 C.F.R. Parts 10 and 130. In reviewing such petitions, the FDA should consider the principles laid out in its 2005 proposed rule. We encourage the agency to assess the technical and scientific information in support of the petition for any potential public health impact. 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. The FDA should require disclosure to facilitate further transparency when needed for consumer understanding of the distinctions among products.

The FDA has expressed an interest in revisiting the standard of identity for milk in light of the large number of non-dairy beverage products now being marketed as substitutes for milk,⁵⁴ and has opened a docket on this topic, to which CSPI intends to submit separate comments.⁵⁵ As the FDA considers how its standard of identity for milk applies to non-dairy milks, we urge the agency to prioritize public health, not the competitive or marketing concerns of a particular industry.

⁵³ National Milk Producers Federation, International Dairy Foods Association. *Docket No. FDA-2014-D-0055. Voluntary Sodium Reduction Goals: Target Mean and Recommended Maximum Concentrations for Sodium in Commercially Processed, Packaged and Prepared Foods*. 81 Fed. Reg. 35363 (June 2, 3536-35367). National Milk Producers Federation, International Dairy Foods Association, 2016. Accessed at <http://www.nmpf.org/files/Joint%20NMPF%20and%20IDFA%20comments%20on%20sodium%20reduction%20targets%20FINAL%2010%2017%2016.pdf>.

⁵⁴ U.S. Food and Drug Administration. *Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency’s standards of identity for dairy products*. U.S. Food and Drug Administration, 2018. Accessed at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm614851.htm>.

⁵⁵ Use of the Names of Dairy Foods in the Labeling of Plant-Based Products. 83 Fed. Reg. 49,103 (Sept. 28, 2018).

CSPI is unaware of any evidence that consumers who purchase almond milk, soy milk, rice milk, or other non-dairy beverages are confusing these products with cow's milk. However, we do believe that it is possible that some consumers may not know that some milk substitutes lack the key nutrients found in milk, or that milk substitutes may vary widely in nutrient content. We are particularly concerned with unfortified products that fall well short of milk in key nutrients, such as calcium and vitamin D, which the Dietary Guidelines has identified as "nutrients of public health concern" because they are generally under-consumed and because adequate intakes are necessary for acquiring and maintaining bone mineral density.

Rather than banning non-dairy milks from bearing the term "milk," we encourage the FDA to instead consider standards for key nutrients in non-dairy milks and in non-dairy beverages marketed as replacements for milk. Products that do not meet those nutrient standards should bear a disclosure on the front of the package that specifies which key nutrients they lack.

B. Modernizing Ingredient Lists

CSPI urges the FDA to take regulatory and enforcement action to ensure that ingredient lists be readable. CSPI petitioned the FDA on July 26, 2001, for a proposed rulemaking to establish format requirements for ingredient lists.⁵⁶ Specifically, we requested that the FDA establish a minimum type size, specify allowable type styles, require the use of upper- and lower-case letters, permit left justification only, institute contrast requirements identical to those required for the Nutrition Facts panel, and establish standard kerning (space between characters) and leading (space between lines).

The need for granting CSPI's 2001 petition has increased in recent years. The median age of U.S. residents is currently 38, up from 28 in 1970.⁵⁷ While more-readable ingredient lists benefit all consumers, lack of readability creates particular challenges for older adults.⁵⁸ In addition, as the FDA has noted, Americans today are more focused on ingredients than prior generations, seeking "clean labels" with fewer artificial ingredients and looking to consume more healthy ingredients like whole grains, fruits, and vegetables.

Currently, FDA regulations require only that ingredient lists placed on the information panel be at least one-sixteenth (1/16) inch in height, and not be more than three times as high as they are wide.⁵⁹ The list must also appear with no intervening material between it and other required elements (*i.e.*, the Nutrition Facts panel). In addition, FDA regulation 21 CFR 101.15 lays out general requirements for information to be "prominent and conspicuous," including consideration for "[s]mallness or style of type in which such word, statement, or information

⁵⁶ Center for Science in the Public Interest. *Petition for Proposed Rulemaking to Establish Format Requirements for Ingredient Lists*. Center for Science in the Public Interest, 2001. Accessed at <<https://cspinet.org/sites/default/files/2001-petition-rulemaking-format-requirements-ingredient.pdf>>.

⁵⁷ Statista. *Median age of the resident population of the United States from 1960 to 2017*. Statista, 2018. Accessed at <<https://www.statista.com/statistics/241494/median-age-of-the-us-population>>.

⁵⁸ National Eye Institute. *Facts About Presbyopia*. National Eye Institute, 2010. Accessed at <<https://nei.nih.gov/health/errors/presbyopia>>.

⁵⁹ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *A Food Labeling Guide: Guidance for Industry*. College Park, MD: U.S. Food and Drug Administration, 2013. Accessed at <<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>>.

appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.”⁶⁰ The agency’s guidance on labeling further specifies that labels cannot be “crowd[ed]” by artwork and that “the lettering must contrast sufficiently with the background so as to be easy to read.”⁶¹

These regulations provide too much room for interpretation by manufacturers, and the result is that many labels fail to provide readable ingredient lists. In some cases, labels diverge so steeply from appropriate readability standards that they could be deemed to violate the “prominent and conspicuous” requirement, which would make them misbranded under 21 CFR 101.15. Some include obscuring designs. (See Appendix, Fig 10: Clif Bar Oatmeal Raisin Walnut.) Others have insufficient color contrast. (See Appendix, Fig 11: Hershey’s Syrup, Mission Wraps Garden Spinach Herb.) And many have small or densely spaced type, which makes them difficult to read. (See Appendix, Fig 12: Stouffer’s Classics Chicken Alfredo.)

In contrast, the format of the Nutrition Facts panel provides a clearer framework for ensuring readability. The panel must be set off in a box, and must conform to specific formatting requirements, including font type and size, minimum leading, and black or one-color type printed on a white or other neutral contrasting background whenever practical.⁶² The FDA also offers further specific guidance on Nutrition Facts formatting in its Food Labeling Guide, including font type (Helvetica) and minimum kerning (-4).⁶³ These regulations are largely effective. For example, most of the labels we have included in the Appendix that have unclear ingredient lists have much clearer and more-readable formatting for their Nutrition Facts panels.

Finally, the existing regulations covering ingredient declarations fail to include key information that is necessary to protect the health of specific populations. This includes allergen information for sesame, a top allergen that may be concealed as a “spice” or “natural flavor” on ingredient lists. In addition, quantitative information on caffeine content is not required to be declared in the ingredient list or elsewhere on the product label, which makes it harder for vulnerable groups (e.g., pregnant women, children) to control their intake.

We urge the FDA to consider the following actions to address ingredient lists under the Nutrition Innovation Strategy. The FDA should:

- Take enforcement action against the manufacturers of products with food labels that fail to conform to the “prominence and conspicuousness” requirements of 21 CFR § 101.15 and Section 403(f) of the Federal Food, Drug, and Cosmetic Act.

⁶⁰ 21 CFR § 101.15

⁶¹ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *A Food Labeling Guide: Guidance for Industry*. College Park, MD: U.S. Food and Drug Administration, 2013. Accessed at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>.

⁶² 21 CFR 101.9

⁶³ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *A Food Labeling Guide: Guidance for Industry*. College Park, MD: U.S. Food and Drug Administration, 2013. Accessed at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf>.

- Prevent future confusion by responding to CSPI’s petition with clear requirements for formatting of ingredient lists. Those requirements should be designed to harmonize the ingredient list with the formatting already required for the Nutrition Facts panel.
- Require allergen disclosures for sesame, as CSPI requested in a petition to the FDA on November 18, 2014.⁶⁴
- Require quantitative labeling of caffeine content adjacent to the ingredient list, as CSPI requested in a petition to the FDA on July 31, 1997.⁶⁵

5) The FDA should complete its critical work on nutrition education and sodium reduction

CSPI applauds the FDA’s commitment to moving forward with implementing the new Nutrition Facts panel and menu labeling requirements as part of the agency’s Nutrition Innovation Strategy.

A. Menu Labeling and Nutrition Facts Education

We applaud the agency’s support for consumer-awareness education campaigns for menu labeling and the updated Nutrition Facts panel, and we urge that it dedicate adequate funding and resources to the campaigns, which will help Americans make informed choices about what we eat and will encourage companies to provide healthier food options.

For menu labeling, we were pleased that the FDA conducted focus groups to help it develop consumer education materials. For instance, the FDA found that simple swaps—“Getting your sandwich with grilled chicken instead of fried helps cut the calories,” for example—are effective messages. We encourage the FDA to finalize and release its menu labeling materials. Other materials that would be useful could highlight the succinct statement on menus and menu boards that provides context about calories in a daily diet: that the ballpark target is 2,000 calories per day. The FDA should also highlight that additional nutrition information is available upon request.

For both the menu labeling and Nutrition Facts panel efforts, we encourage the agency to collaborate with major public health coalitions and organizations that represent constituencies like education, nutrition, and other health professionals. We encourage the FDA to hold a meeting with these stakeholders and to present at key conferences and to coalitions to maximize the dissemination of its menu labeling and Nutrition Facts panel materials.

For its Nutrition Facts panel public education efforts, we support the focus on calories, serving sizes, and added sugars, and encourage the agency to include sodium. As the commissioner stated in his March 29, 2018, speech at the National Food Policy Conference: “[t]here remains no single more effective public health action related to nutrition than the reduction of sodium in the diet.”⁶⁶ Education to enable consumers to evaluate whether a product is considered high in sodium is therefore critical.

⁶⁴ Center for Science in the Public Interest. *FDA Urged to Require Better Labeling of Sesame, an Allergen*. Center for Science in the Public Interest, 2014. Accessed at <<https://cspinet.org/new/201411181.html>>.

⁶⁵ Center for Science in the Public Interest. *1997 Petition Food Labeling Caffeine*. Center for Science in the Public Interest, 1997. Accessed at <<https://cspinet.org/sites/default/files/1997-petition-food-labeling-caffeine.pdf>>.

⁶⁶ Gottlieb, S. “Reducing the Burden of Chronic Disease.” National Food Policy Conference, Consumer Federation of America, March 29, 2018, Capital Hilton, Washington, DC.

We also encourage the FDA to conduct message testing through focus groups and/or polling to determine effective messages for educating consumers about the updated Nutrition Facts panel, as the agency has done with menu labeling. We recommend that the FDA test messages on low-income mothers as a priority population, given their influence over child and family health in purchasing decisions.

B. Single-Ingredient Sweeteners

Given the agency's public health progress in requiring a Daily Value for added sugars on the Nutrition Facts panel, it is critical that consumers continue to understand that the added sugars from single-ingredient sweeteners such as table sugar, honey, and maple syrup are part of their overall daily "budget" for sugars. The declaration of added sugars on the Nutrition Facts panel is of great public health importance, and small amounts of single-ingredient sweeteners can significantly contribute to daily added-sugars intake. For example, a one-tablespoon serving of honey contains about one-third of a day's worth of added sugars, and a two-tablespoon serving of maple syrup has more than half a day's worth.

We urge the FDA to ensure that the percentage "Daily Value" for added sugars remain listed for single-ingredient sweeteners regardless of whether the word "added" is retained on the label for these products. To facilitate consumer understanding, we urge the FDA to issue guidance that maintains clear and specific labeling requirements that apply only to single-ingredient sweeteners. That guidance should require that the percentage "Daily Value" for added sugars be provided as part of the current line for "Total Sugars" and should permit substitution of the term "Sugars" in lieu of "Total Sugars" to alleviate any consumer confusion.

C. Processed Fiber

As part of its Nutrition Facts panel update, the FDA reviewed the science underlying a range of processed (isolated or synthetic) fibers that are added to foods and has approved a number of them as dietary fiber for labeling purposes. While many consumers may expect dietary fiber to improve satiety or regularity and help them meet dietary recommendations for diets that are higher in fiber, most of the processed fibers approved thus far by the FDA have been approved on the basis of other benefits.

Consumers have no way of knowing that these fibers do not contribute to satiety or laxation. Moreover, the marketplace is rife with fiber claims on cookies, candies, bars, ice creams, and other foods that compete with more-nutritious fruits, vegetables, beans, and whole grains that are rich in intact, unprocessed fiber and that are linked to a lower risk of several chronic diseases.⁶⁷

As fiber claims proliferate, consumers cannot discern how much of the "Dietary Fiber" listed on the Nutrition Facts panel is intact and how much is isolated or synthetic. Given that foods with

⁶⁷ In its 2002 report on fiber, the Institute of Medicine notes that "it should be kept in mind that although high *Dietary Fiber* intake is associated with decreased risk or improvements in several chronic diseases, a report of the National Academy of Sciences states 'there is no conclusive evidence that it is dietary fiber rather than the other components of vegetables, fruits, and cereal products that reduces the risk of those diseases.'" National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients)*. Washington, D.C.: National Academies Press. 2002; 362.

isolated fibers may not provide the same benefits as the mix of intact fibers in a healthy diet and that consumers may be eating these foods as substitutes for fiber-rich foods, we ask the FDA to require a food that makes a fiber claim and that contains synthetic or isolated fibers to clearly disclose on the front of the package that it “Includes X grams of processed fiber per serving.”

Moreover, many processed fibers are simply poorly absorbed carbohydrates that have significant adverse gastrointestinal effects, including abdominal discomfort, flatus, and diarrhea.⁶⁸ Some fibers, such as fructooligosaccharides and isomaltoligosaccharides, can provide sweetness and yet are declared on Nutrition Facts panels as fibers instead of added sugars. That creates large incentives to add these ingredients to foods as sugar replacements, since doing so will allow manufacturers to reduce the apparent added sugar and boost the apparent dietary fiber in their products. The FDA should consider whether warnings are needed to inform consumers, where relevant, that these fibers may cause gastrointestinal symptoms and discomfort when present above a certain level, in a manner similar to the warnings that the agency requires for some sugar alcohols that trigger similar effects.⁶⁹

D. Sodium Reduction

We strongly support inclusion of sodium reduction in the FDA’s Nutrition Innovation Strategy. Americans’ typical sodium intake—about 4,000 milligrams per day⁷⁰—substantially exceeds the maximum intake recommended by scientific and public health agencies and organizations. Sodium intake is a major cause of high blood pressure, which increases the risk of heart disease and stroke. An estimated 46 percent of U.S. adults⁷¹ suffer from high blood pressure, a condition estimated to cause more than 78,000 deaths annually in this country.⁷²

There is a strong positive correlation between increased levels of sodium intake and the risk of cardiovascular disease. Researchers estimate that reducing our average sodium intake to 2,200 mg/day could prevent at least 280,000 premature deaths over a 10-year period.⁷³ Even a more modest reduction to 2,300 mg/day (the daily upper intake level recommended by the Dietary Guidelines) could translate into more than \$18 billion in savings in healthcare costs annually.⁷⁴

⁶⁸ Grabitske HA, Slavin JL. Gastrointestinal effects of low-digestible carbohydrates. *Critical Reviews Food Science and Nutrition*. 2009; 49:327–60.

⁶⁹ See, e.g., 21 CFR § 180.25: Mannitol.

⁷⁰ 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>>.

⁷¹ 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, Ovbigele 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>>.

⁷² American Heart Association. Heart disease and stroke statistics—2018 update: a report from the American Heart Association. *Circulation*. 2018; 137:e67–e492.

⁷³ Coxson P.G., Cook N.R., Joffres M, Hong Y, et al. Mortality Benefits From U.S. Population-Wide Reduction in Sodium Consumption. *Hypertension*. March 2013; 61:564–570.

⁷⁴ Palar K, Sturm R. Potential Societal Savings from Reduced Sodium Consumption in the U.S. Adult Population. *Am J Health Promot*. 2009; 24(1):49–57.

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 eminently feasible and could even be strengthened. We urge the agency to finalize its modest two-year sodium-reduction targets, as promised, by 2019. The FDA should also continue its work toward finalizing the 10-year sodium-reduction targets as soon as possible, since far more significant reductions could be accomplished, and the 10-year timeframe gives companies ample time to plan and reformulate products.

III. Conclusion

The Center for Science in the Public Interest appreciates the opportunity to comment on the FDA's Nutrition Innovation Strategy. We are encouraged by the possibilities for supporting the public's health through the issues addressed above, and we look forward to working with the FDA on public education efforts and greater transparency on food labels in service of that end.

APPENDIX



Fig 1: Nature's Own Honey Wheat Bread. "Whole wheat flour" is the 6th ingredient in this bread, after honey and sugar.



Fig 2: Sara Lee White made with Whole Grain Bread. This bread has 8g whole grain, but an estimated 20 grams refined grain, per serving.¹

¹ Estimated based on a serving size of 57 grams. CSPI estimates refined grain content by assuming that the weight of total grain (whole grain plus refined grain) in bread is $\frac{1}{2}$ the total serving weight.



Nutrition Facts		
Serving Size	1 Cup (50g)	
Servings Per Container	About 10	
Amount Per Serving	Cereal	with 1/2 cup skim milk
Calories	190	230
Calories from Fat	5	10
% Daily Value**		
Total Fat 1g*	2%	2%
Saturated Fat 0g	0%	0%
Trans Fat 0g		
Polyunsaturated Fat 0g		
Monounsaturated Fat 0g		
Cholesterol 0mg	0%	1%
Sodium 200mg	8%	10%
Potassium 90mg	3%	8%
Total Carbohydrate 43g	14%	17%
Dietary Fiber 3g	11%	11%
Sugars 14g		
Protein 4g	3%	11%

Ingredients: Rice, whole grain wheat, sugar, whole grain rolled oats, brown sugar syrup, contains 2% or less of corn syrup, rice flour, salt, malt flavor, honey, yellow 5, artificial flavor, cinnamon, BHT for freshness.

Fig 3: Kellogg's Smart Start Cereal. The "Heart Healthy" claim is permitted on this product, which contains about 14 grams of added sugar,² more than 25 percent of the daily value.

² We estimated that all of the sugar in the product was added sugar, based on the fact that "sugar," brown sugar syrup, and corn syrup appeared to be the only ingredients in the product that contributed significant amounts of sugar.



Fig 4: Gary Poppins Popcorn, Classic Caramel. This popcorn advertises “whole grain” but contains more than 30 percent of the daily value for added sugar per $\frac{1}{3}$ bag serving.



Fig 5: Plum Organics Teensy Fruits, Berry. These fruit snacks advertise “a full serving of fruit” with images of berries but are made of mostly concentrated apple puree and juice.



INGREDIENTS: Potato Flour, Potato Starch, Expeller Pressed Sunflower Oil, Salt, Tomato Paste, Sea Salt, Spinach Powder, Potassium Chloride, Turmeric, Beet Powder.



INGREDIENTS: ENRICHED BLEACHED FLOUR (FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), WATER, VEGETABLE SHORTENING (INTERESTERIFIED AND HYDROGENATED SOYBEAN OILS), SEASONING (SPINACH POWDER, ONION POWDER, SPICES, GARLIC POWDER, SUNFLOWER OIL, YELLOW 5 LAKE, BLUE 1 LAKE, AND NATURAL FLAVOR), CONTAINS 2% OR LESS OF: SALT, BAKING SODA, SODIUM ACID PYROPHOSPHATE, FUMARIC ACID, CALCIUM PROPIONATE AND SORBIC ACID (TO MAINTAIN FRESHNESS).
CONTAINS: WHEAT

Fig 6: EatSmart Veggie Crisps, Sea Salt and Mission Wraps, Garden Spinach Herb. These products are made mainly of potato flour or refined wheat flour, with pastes, powders, and (in the wraps) artificial dyes used to give the appearance of more varied or higher vegetable content.



Fig 7: Sun Maid Strawberry Greek Yogurt Raisins. These raisins are coated primarily in “Greek style yogurt flavored coating” made of sugar, palm kernel oil, and nonfat dry milk, with only a small amount of “greek yogurt powder” included.

Just a tad sweet®

Honest® tea



**100
CALORIES
PER BOTTLE**

16.9 FL OZ
(1.06 PT) 500 mL

organic

Half Tea & Half Lemonade

CONTAINS 2% JUICE

Nutrition Facts

Serving Size 1 Bottle

Amount Per Serving

Calories 100

	% Daily Value*
Total Fat 0g	0%
Sodium 35mg	1%
Total Carbohydrate 25g	8%
Sugars 25g	
Protein 0g	

Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, dietary fiber, vitamin A, vitamin C, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: BREWED TEA (FILTERED WATER, FAIR TRADE ORGANIC BLACK TEA LEAVES), ORGANIC CANE SUGAR, ORGANIC LEMON JUICE FROM CONCENTRATE, ORGANIC LEMON EXTRACT, CITRIC ACID, ASCORBIC ACID (TO PROTECT TASTE), ORGANIC STEVIA LEAF EXTRACT.

Honest Tea, Inc.
4827 Bethesda Ave., Bethesda, MD 20814 USA
CERTIFIED ORGANIC by Pennsylvania Certified Organic
Tea Leaves Certified by Fair Trade USA

HH-RF-1-15 / 172090



6 57622 53155 1

Fig 8: Honest Tea, Half Tea & Half Lemonade. This beverage describes itself as "Just a tad sweet," but contains about 25 grams of added sugar,³ half the daily value.

³ Estimated from ingredients list.

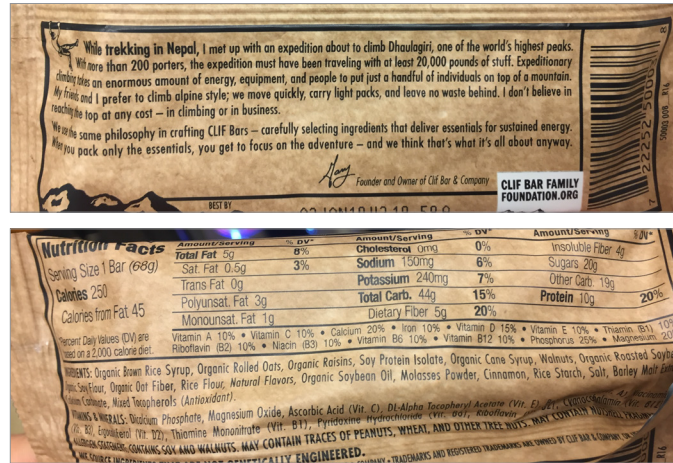


Fig 10: Clif Bar, Oatmeal Raisin Walnut. This obscuring design presents ingredients below a folded strip, with the space above the fold reserved for advertising copy.

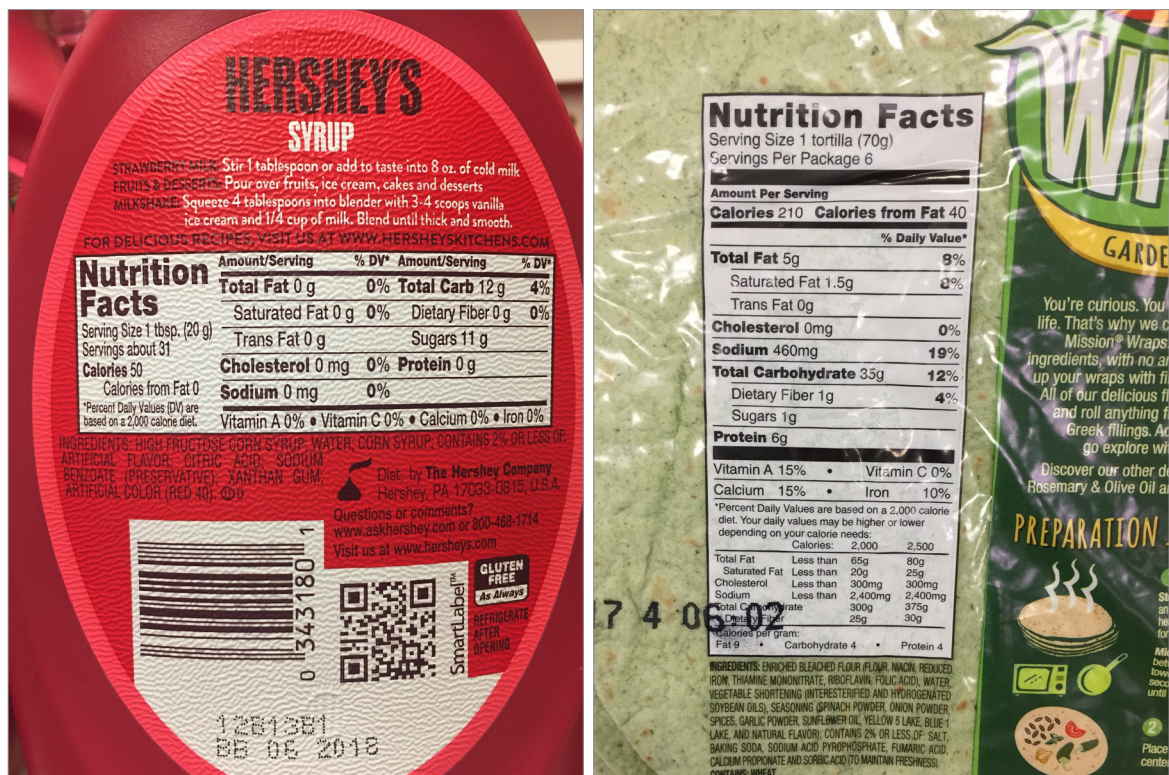


Fig 11: Hershey's Syrup, Delicious Strawberry Flavor and Mission Wraps, Garden Spinach Herb. These labels print the ingredients list in black or brown text against a red or clear background, reducing readability. By contrast, the Nutrition Facts label is printed against a white background, providing higher readability.



CLASSICS
CHICKEN ALFREDO
tender white meat chicken & penne pasta
in a creamy alfredo sauce
• no preservatives •

LARGE FAMILY SIZE

PER 1 CUP SERVING

270 CALORIES	3.5g SAT FAT 18% DV	890mg SODIUM 37% DV	5g SUGARS	16g PROTEIN 44% DV	CALCIUM 20% DV
------------------------	----------------------------------	----------------------------------	---------------------	---------------------------------	--------------------------

SEE NUTRITION INFORMATION FOR SODIUM CONTENT

ABOUT **7** SERVINGS

KEEP FROZEN • SERVING SUGGESTION
COOK THOROUGHLY

NET WT 57 OZ (3.189 02) 1.61 kg

Nutrition Facts
Serving Size 1 Cup (237 g)
Servings Per Container About 7

Amount Per Serving	
Calories 270	Calories from Fat 90
% Daily Value*	
Total Fat 10 g	15%
Saturated Fat 3.5 g	18%
Trans Fat 0 g	
Cholesterol 25 mg	8%
Sodium 890 mg	37%
Total Carbohydrate 30 g	10%
Dietary Fiber 1 g	4%
Sugars 5 g	
Protein 16 g	44%
Vitamin A 2%	Vitamin C 0%
Calcium 20%	Iron 6%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g
Protein	50g	65g

INGREDIENTS:
SAUCE & CHICKEN: SKIM MILK, WATER, COOKED WHITE MEAT CHICKEN, PARMESAN AND ASHADO CHEESE BLEND WITH FLAVOR (PARMESAN AND ASHADO CHEESES) (CULTURED MILK, SALT, ENZYMES), ENZYME MODIFIED PARMESAN CHEESE (CULTURED MILK, WATER, SALT, ENZYMES), WHEY (SALT), SOYBEAN OIL, MODIFIED CORNSTARCH, PARMESAN CHEESE PASTE (GRANULAR AND PARMESAN CHEESE (CULTURED MILK, SALT, ENZYMES), WATER, SALT, LACTIC ACID, CITRIC ACID), SALT, MODIFIED TAPIOCA STARCH, ROMANO CHEESE WITH FLAVOR (ROMANO CHEESE (CULTURED COW'S MILK, SALT, ENZYMES), ENZYME MODIFIED ROMANO CHEESE (ROMANO CHEESE (CULTURED COW'S MILK, WATER, SALT, ENZYMES), SALT), POTASSIUM CHLORIDE, DATEM, SPICES, CARRAGEENAN, CHICKEN FLAVOR (DRIED CHICKEN BROTH, CHICKEN POWDER, NATURAL FLAVOR), WHEY PROTEIN CONCENTRATE, CORN SYRUP SOLIDS, SODIUM PHOSPHATE, CULTURED WHEY, GARLIC POWDER, MALTODEXTRIN, NATURAL FLAVOR.

COOKED ENRICHED PASTA: WATER, SEMOLINA WHEAT FLOUR, NIACIN, FERROUS SULFATE, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID.

CHEESE: MOZZARELLA CHEESE AND MODIFIED CORNSTARCH (MOZZARELLA CHEESE (CULTURED MILK, SALT, ENZYMES), MODIFIED CORNSTARCH, SODIUM CITRATE, FLAVORS ANNATTO).

CONTAINS: WHEAT, MILK INGREDIENTS.
DISTRIBUTED BY: NESTLÉ USA, INC.
SOLOM, OH 44139 USA

Fig 12: Stouffer’s Classics Chicken Alfredo, Large Family Size. This ingredients list is printed in densely-spaced, all-caps type that is far more difficult to read than the clearly printed Nutrition Facts appearing on the same panel.