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Food and Drug Administration
Department of Health and Human Services
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Comment on the FDA's Notice Regarding Quantitative Research on Front of Package Labeling on Packaged Foods
(Docket No. FDA-2023-N-0155)

We support FDA's pursuit of research to help select an interpretive front-of-package (FOP) labeling scheme that will let Americans make informed, food choices. We believe it is critical that FDA conduct this research quickly so that consumers can reap the benefits of interpretive FOP labels without delay. FOP labels can inform consumers, as shown by peer-reviewed research. We applaud the FDA for its efforts to investigate how best to design FOP labels to inform US consumers.

The average American adult consumes 50% more sodium, 40% more added sugars, and 40% more saturated fat than recommended daily, [1,2] contributing to high rates of hypertension, type 2 diabetes, and heart disease.[3] Reducing consumption of foods that are high in sodium, added sugars, and saturated fat could assist consumers in achieving healthy eating patterns and optimal health, as well as reduce the health care costs of obesity, estimated at more than 260 billion per year.[4] However, many consumers—especially those with lower levels of education or limited English language proficiency—are not able to identify such foods using only the Nutrition Facts labels, highlighting the need for interpretive FOP labeling to help.

The proposed study design has several strengths, including:

- Large sample of 9,000 participants sampled to mirror the US population with respect to gender, education, age, and ethnicity/race.[5]
- Focus on nutrients to limit (i.e., sodium, saturated fat, and added sugars), that are linked to health harms and are overconsumed by a majority of people in the US. The main type of saturated fat in packaged processed food is palm oil,[6-8] one of the unhealthiest of all edible oils.[9]
- Consistent definitions of "high," "medium," and "low" levels of nutrients, based on FDA's established criteria for interpreting the percent Daily Value (DV) of a nutrient (i.e., less than 5% DV is low, more than 20% DV is high, everything in between is medium).
- Use of a randomized experiment, allowing for causal inferences about the impact of labels on consumer beliefs and perceptions. Additionally, the agency has also incorporated qualitative research methods to inform the design of the labels.
- Assessment of demographic data such as nutrition knowledge, shopping habits, self-rated health, caregiver status, and nutrition literacy.
- Initial cognitive interviews to examine whether participants interpret the survey questions as intended.

We hope that FDA will keep each of these elements as they finalize the study.

We also have some recommendations that we believe could improve the study. Specifically, we recommend that FDA should make the following changes to the proposed study design.

Recommendation 1. Evaluate more versions of the "High in" FOP labels with visuals to increase comprehension. Use of visuals (such as icons, symbols, or illustrations) could facilitate better comprehension in general, and among populations with limited English proficiency and lower literacy. Examples of visuals to be included in FOP labels appear in Figure 1. Only one of the stimuli currently included in FDA's study uses an interpretive visual element (i.e., the label with the magnifying glass), despite evidence showing that including visual elements in labels makes the labels much more effective at changing a range of desirable outcomes.[10-15] For example, our experimental study (n=1,078, 48% Latino ethnicity, 13% limited English proficiency), which was not cited in FDA's literature review, evaluated FOP food labels with text and images compared to text-only labels, finding that labels with text and images out-performed text-only labels overall.[12] English proficiency moderated this effect such that the benefit of the images was larger for those with limited English proficiency. These findings suggest that visuals could make labels more effective, especially among people with limited English proficiency.[12] It is worth noting that, based on 2020 US Census data, 25.5 million people (8.2% of the population) in the US have limited English proficiency.[16] Labels without visuals could leave these 25.5 million people behind, and over time could widen the many disparities in obesity that already exist.[17,18] Similarly, an experimental study of prescription drug labels found that participants with marginal or low literacy were better able to correctly interpret drug warning labels with visuals and text, compared to labels with text alone.[14] Additionally, lower literacy predicted greater misinterpretation of drug labels in this study. Thus, including visuals in labels could be an important step for increasing comprehension of labels among lower literacy populations.[14] Additionally, FDA should consider using contrasting colors as another way of heightening attention to labels. Research demonstrates that black, yellow, and red are promising colors for FOP labels.[19-22]

Figure 1. Examples of visuals that could help draw attention to front-of-package food labels

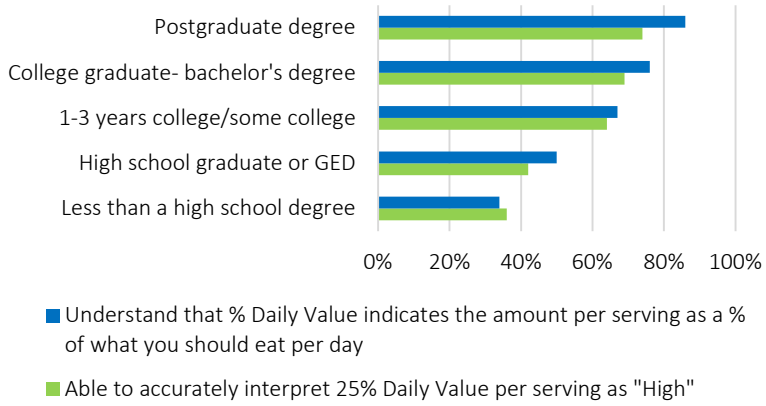
Recommendation 2. Test single-nutrient octagonal labels to maximize consumers' ability to quickly and accurately identify products high in nutrients of concern (Figure 2). As shown in Figure 2, this proposed octagonal design is similar to labels that are now required in Chile, Mexico, Peru, Argentina, and Uruguay.[23] Our assessment of the research literature is that octagonal labels have the strongest evidence base to date. Our team's evaluation found a 24% reduction in sugary drink purchases following the implementation of Chile's Law of Food Labeling and Advertising which included octagonal labels along with restrictions on child-directed marketing and a ban on sale of certain foods in schools.[24] Our team's experimental research manipulating shape (octagon vs. square) suggests that the octagon shape is more effective at making people think about the harms of the product than a square shaped label.[19] Several experimental studies have found that octagonal labels consistently out-perform competing label types[20,25-28] including magnifying-glass labels similar to those used in Canada and Brazil and proposed for testing by FDA.[20,27] We suggest testing at least one FOP labeling scheme with single, separated nutrient labels (instead of listing all of the nutrients in one label).

It is possible that single nutrient labels could facilitate better understanding among consumers by separating out the information and using more space on the packaging to communicate information to consumers. Testing this possibility would be useful to inform FDA's regulation. Moreover, because products that contain excessive amounts of several nutrients will have significantly more space taken up with these single-nutrient labels, it is expected that this approach will better encourage manufacturers to reduce the amount of such nutrients in their products to minimize the number of single-nutrient labels. We found evidence of this in the case of Chile for example.[29]

Figure 2. Example of single-nutrient octagonal labels

Recommendation 3. Remove the conditions that include information about the percent of the daily value (% DV). Dropping these conditions would allow for testing of new FOP label options that have a stronger evidence base. Despite the inclusion of a power calculation in the notice, we remain concerned about power because we would expect to see very small differences between similar label designs. Four of FDA's eight proposed labels include information about the % DV of nutrients, and only one of these four % DV labels includes any interpretive information (i.e., color coding). However, consumers generally struggle to understand numerical nutrition information, particularly those with lower education levels.[30-32] FDA's Food Safety and Nutrition Survey,[5] fielded in 2019, asked 4,398 respondents if they would consider one serving of a food with 25% DV of sodium to have a low, medium, or high amount of sodium (for reference, FDA defines "high" as 20% DV or more per serving). Only 36% of people with less than a high school degree and 42% of high school graduates with no college education were aware that this food is high in sodium, compared with 69% of college graduates and 74% of people with postgraduate degrees (Figure 3). These findings track closely with the results of another question in the survey assessing whether respondents could accurately interpret what it means if a product's Nutrition Facts label shows that the product contains 7% DV for Total Fat per serving. Based on these findings, and consistent recommendations from research to limit or avoid numerical information on warning labels,[33] we are concerned that labels focused on the % DV on a FOP label that is meant to be

Figure 3. Comprehension of % Daily Value, by Educational Attainment (FSANS 2019)



interpretive would only be truly informative for individuals with higher education levels, thus widening existing disparities in comprehension of nutritional information and ultimately contribute to disparities in obesity.[17,18]

Recommendation 4. Eliminate the placement condition proposed in the single product evaluation task. FDA proposes that one tenth of participants will be randomized to view the Nutrition Info label in black and white but placed in the lower right corner of a food package. We encourage FDA to remove this condition because it will reduce the study's power and is arbitrarily applied to only one FOP scheme. We also note that existing research suggests that top right placement of nutrition information is optimal for capturing consumers' attention,[34,35] and other countries including Canada and Peru require their FOP labels to be placed on the upper right part of the food package.[36,37]

Recommendation 5. Use the same nutritional profiles for the "healthiest," "middle," and "least healthy" labels across all FOP schemes tested in Part 1 of the study. Per Appendix F, it appears that the nutritional profile of the "healthiest," "middle," and "least healthy" labels will vary across some of the FOP schemes tested. For example, in the "Nutrition Information with % Daily Value Information and Color" condition, the "middle" label shows that the product is low in saturated fat, medium in sodium, and medium in added sugar. By contrast, the "middle" label for "High In" condition shows that the product is high in both saturated fat and sodium. This means that labeling scheme is confounded with the nutritional profile of the labels, and any differences between these two conditions could therefore be due to either differences in the label design or differences in the nutritional profile of the labels. Similar problems exist across other labeling conditions. The FDA should use the same nutritional profiles across labeling schemes to avoid this harmful confounding.

Recommendation 6. Make the study's primary outcome be "ability to identify whether a product is high in a given nutrient." FDA states that the study will have three primary outcomes: 1) participants' ability to identify the healthiest and least healthy products, 2) the speed at which participants make their decisions, and 3) whether or not participants search for more information to answer the question (i.e., whether they click a link to view the Nutrition Facts label). Only the first of these outcomes appears to be inherently tied to the agency's goals, but it is still problematic because the concept of healthfulness is inherently subjective and the proposed labels do not include any information about health. **We strongly suggest focusing on one primary outcome that is directly tied to FDA's goals and that is likely to change based on the labels: a measure such as "Does this product contain high amounts of [nutrient]?"**[28,38,39] Identifying products high in these nutrients is an objective measure that links to FDA's goals of helping consumers assess healthfulness, because as previously stated, most Americans overconsume these nutrients and they are all associated with increased risk of non-communicable diseases. Additionally, we recommend either dropping the other two outcomes or treating them as secondary outcomes because they are not independently and objectively desirable. The desirability of faster decision-making depends on whether the decision is correct. Additionally, searching for the Nutrition Facts label could be desirable (if the labeling scheme spurs consumers to learn more about the product's nutrition information and ingredients) or undesirable (if the labeling scheme is not noticeable or confusing and thus participants need to seek more information).

Recommendation 7. Participants should complete the between-subjects evaluation prior to the within-subjects evaluation. As proposed, it appears that participants will perform a within-subjects experiment prior to a between-subjects experiment. To avoid potential confounding of the between-subjects task (the strongest design for causal inference), we would

suggest reversing the order and having participants complete the between-subjects evaluation prior to the within-subjects comparison task.

Thank you for considering these recommendations and for your commitment to developing an evidence-based FOP labeling system for packaged foods in the US.

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References

1. U.S. Department of Agriculture. Nutrient Intakes from Food and Beverages, by Gender and Age. *What We Eat in America, NHANES 2017-March 2020 Prepandemic,* https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1720/Table_1_NIN_GEN_1720.pdf.
2. U.S. Department of Agriculture. Food Pattern Equivalents. *What We Eat in America, NHANES 2017-2018* https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/FPED/tables_1-4_FPED_1718.pdf
3. Tsao CW, Aday AW, Almarzooq ZI, et al. Heart Disease and Stroke Statistics—2023 Update: A Report From the American Heart Association. *Circulation.* 2023;147(8):e93-e621.
4. Cawley J, Biener A, Meyerhoefer C, et al. Direct medical costs of obesity in the United States and the most populous states. *J Manag Care Spec Pharm.* 2021;27(3):354-366.
5. U.S. Food and Drug Administration. FSANS Explorer: FDA's Food Safety and Nutrition Survey (FSANS). https://fsans-explorer.fda.gov/. Accessed March 16, 2023.
6. Pease JJ. Confectionery fats from palm oil and lauric oil. *Journal of the American Oil Chemists' Society.* 1985;62(2):426-430.
7. Mba OI, Dumont M-J, Ngadi M. Palm oil: Processing, characterization and utilization in the food industry–A review. *Food bioscience.* 2015;10:26-41.
8. Voora V, Larrea C, Bermudez S. *Global market report: Palm oil.* Manitoba, Canada: International Institute for Sustainable Development;2019.
9. Kadandale S, Marten R, Smith R. The palm oil industry and noncommunicable diseases. *Bull World Health Organ.* 2019;97(2):118-128.
10. Brewer NT, Hall MG, Noar SM, et al. Effect of pictorial cigarette pack warnings on changes in smoking behavior: A randomized clinical trial. *JAMA Intern Med.* 2016;176(7):905-912.
11. Noar SM, Hall MG, Francis DB, Ribisl KM, Pepper JK, Brewer NT. Pictorial cigarette pack warnings: A meta-analysis of experimental studies. *Tob Control.* 2016;25(3):341-354.
12. Hall MG, Lazard AJ, Grummon AH, et al. Designing warnings for sugary drinks: A randomized experiment with Latino parents and non-Latino parents. *Prev Med.* 2021;148:106562.
13. Grummon AH, Ruggles PR, Greenfield TK, Hall MG. Designing effective alcohol warnings: Consumer reactions to icons and health topics. *Am J Prev Med.* 2023;64(2):157-166.
14. Wolf MS, Davis TC, Bass PF, et al. Improving prescription drug warnings to promote patient comprehension. *Arch Intern Med.* 2010;170(1):50-56.
15. Acton RB, Jones AC, Kirkpatrick SI, Roberto CA, Hammond D. Taxes and front-of-package labels improve the healthiness of beverage and snack purchases: a randomized experimental marketplace. *Int J Behav Nutr Phys Act.* 2019;16(1):46.
16. U.S. Census Bureau. Selected social characteristics, 2017-2021 American Community Survey 5-year estimates. 2021; https://data.census.gov/table?tid=ACSDP5Y2021.DP02&hidePreview=true.
17. Krueger PM, Reither EN. Mind the gap: race/ethnic and socioeconomic disparities in obesity. *Curr Diab Rep.* 2015;15(11):95.
18. Anekwe CV, Jarrell AR, Townsend MJ, Gaudier GI, Hiserodt JM, Stanford FC. Socioeconomics of Obesity. *Curr Obes Rep.* 2020;9(3):272-279.
19. Grummon AH, Hall MG, Taillie LS, Brewer NT. How should sugar-sweetened beverage health warnings be designed? A randomized experiment. *Prev Med.* 2019;121:158-166.
20. Goodman S, Vanderlee L, Acton R, Mahamad S, Hammond D. The Impact of Front-of-Package Label Design on Consumer Understanding of Nutrient Amounts. *Nutrients.* 2018;10(11).

21. Cabrera M, Machín L, Arrúa A, et al. Nutrition warnings as front-of-pack labels: influence of design features on healthfulness perception and attentional capture. *Public Health Nutr.* 2017;20(18):3360-3371.
22. Acton R, Vanderlee L, Roberto C, Hammond D. Consumer perceptions of specific design characteristics for front-of-package nutrition labels. *Health Educ Res.* 2018;33(2):167-174.
23. Global Food Research Program at UNC Chapel Hill. Front-of-package labels around the world. 2023; https://www.globalfoodresearchprogram.org/wp-content/uploads/2023/02/GFRP-UNC_FOPL_maps_2023_02.pdf.
24. Taillie LS, Reyes M, Colchero MA, Popkin B, Corvalan C. An evaluation of Chile's Law of Food Labeling and Advertising on sugar-sweetened beverage purchases from 2015 to 2017: A before-and-after study. *PLoS Med.* 2020;17(2):e1003015.
25. Jáuregui A, White CM, Vanderlee L, et al. Impact of front-of-pack labels on the perceived healthfulness of a sweetened fruit drink: a randomised experiment in five countries. *Public Health Nutr.* 2022;25(4):1094-1104.
26. Jáuregui A, Vargas-Meza J, Nieto C, et al. Impact of front-of-pack nutrition labels on consumer purchasing intentions: a randomized experiment in low- and middle-income Mexican adults. *BMC Public Health.* 2020;20(1):463.
27. White-Barrow V, Gomes FS, Eyre S, et al. Effects of front-of-package nutrition labelling systems on understanding and purchase intention in Jamaica: results from a multiarm randomised controlled trial. *BMJ open.* 2023;13(4):e065620.
28. Mora-Plazas M, Aida Higgins IC, Gomez LF, et al. Impact of nutrient warning labels on choice of ultra-processed food and drinks high in sugar, sodium, and saturated fat in Colombia: A randomized controlled trial. *PLoS One.* 2022;17(2):e0263324.
29. Reyes M, Taillie LS, Popkin B, Kanter R, Vandevijvere S, Corvalan C. Changes in the amount of nutrient of packaged foods and beverages after the initial implementation of the Chilean Law of Food Labelling and Advertising: A nonexperimental prospective study. *PLoS Med.* 2020;17(7):e1003220.
30. Bhawra J, Kirkpatrick SI, Hall MG, Vanderlee L, Thrasher JF, Hammond D. Correlates of Self-Reported and Functional Understanding of Nutrition Labels across 5 Countries in the 2018 International Food Policy Study. *J Nutr.* 2022;152(Suppl 1):13s-24s.
31. Persoskie A, Hennessy E, Nelson WL. US Consumers' Understanding of Nutrition Labels in 2013: The Importance of Health Literacy. *Prev Chronic Dis.* 2017;14:E86.
32. Rothman RL, Housam R, Weiss H, et al. Patient understanding of food labels: the role of literacy and numeracy. *Am J Prev Med.* 2006;31(5):391-398.
33. Roberto CA, Ng SW, Ganderats-Fuentes M, et al. The influence of front-of-package nutrition labeling on consumer behavior and product reformulation. *Annu Rev Nutr.* 2021.
34. Bialkova S, van Trijp H. What determines consumer attention to nutrition labels? *Food quality and preference.* 2010;21(8):1042-1051.
35. Bopape M, Taillie LS, Frank T, et al. South African consumers' perceptions of front-of-package warning labels on unhealthy foods and drinks. *PLoS One.* 2021;16(9):e0257626.
36. Government of Canada. Nutrition labelling: Front-of-package nutrition symbol. 2023; https://www.canada.ca/en/health-canada/services/food-labelling-changes/front-package.html#a5.
37. U.S. Department of Agriculture Foreign Agricultural Service. Global Agricultural Information Network Report: Peru Publishes Warning Manual for Processed Product Food Labels. 2017; https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Peru%20Publishes%20Warning%20Manual%20for%20Processed%20Product%20Food%20Labels_Lima_Peru_9-27-2017.pdf.

38. Taillie LS, Hall MG, Gómez LF, et al. Designing an effective front-of-package warning label for food and drinks high in added sugar, sodium, or saturated fat in Colombia: An online experiment. *Nutrients.* 2020;12(10).
39. Singh SK, Taillie LS, Gupta A, Bercholz M, Popkin B, Murukutla N. Front-of-Package Labels on Unhealthy Packaged Foods in India: Evidence from a Randomized Field Experiment. *Nutrients.* 2022;14(15).