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Food and Drug Administration
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Comment on the FDA's Notice Regarding Quantitative Research on Front of Package Labeling (FDA-2023-N-0155)

The undersigned organizations and individuals support FDA's pursuit of research to help select a front-of-package (FOP) labeling scheme that will assist the U.S. population in making informed, healthy food choices. We believe it is critical that FDA conduct this research expeditiously so that consumers can promptly reap the benefits of interpretive FOP labels. We recommend that FDA test a label that states: "WARNING: HIGH IN [sodium/added sugars/saturated fat]" accompanied by a warning icon. We are disappointed that FDA did not provide enough information in this notice for the public to evaluate the suitability of its proposed sample size. We also think the FDA's proposed label designs could be substantially improved by limiting numerical information, emphasizing interpretive components, and adding attention-grabbing features. In the comments below, we provide additional input on the study's objectives, participants and procedures, measurements, and analysis.

Objectives

As FDA finalizes a protocol for its experimental, quantitative study, the agency should develop research objectives that precisely pair with the agency's policy objectives. In this notice, FDA states that its objectives for developing a FOP labeling system are to "giv[e] consumers a simple aid to provide additional context for making healthy food selections" and to "help[] consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy eating pattern."[1] We encourage FDA to recognize the following additional goal of FOP labeling: to help people quickly and easily identify foods that, when consumed, may lead people to exceed daily nutritional recommendations for nutrients of concern (sodium, added sugar, and saturated fat).

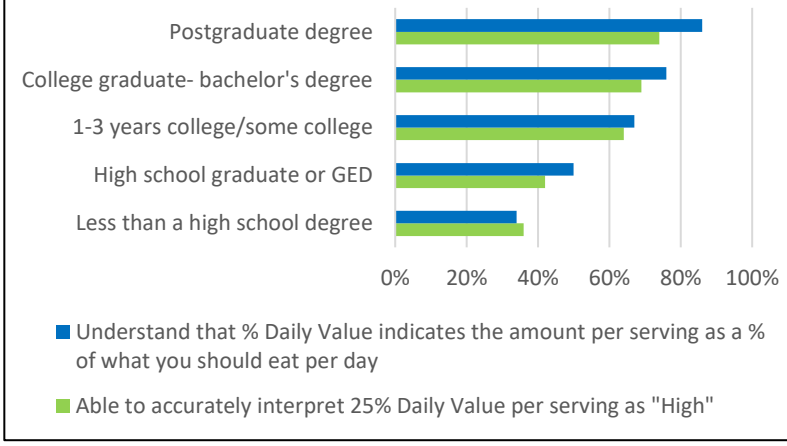
The average American adult consumes 50% more sodium, 40% more added sugars, and 40% more saturated fat than recommended daily,[2,3] contributing to high rates of hypertension, type 2 diabetes, and heart disease.[4] Reducing consumption of foods that are high in sodium, added sugars, and saturated fat could assist consumers in achieving healthy eating patterns and optimal health. However, many consumers—especially those with lower levels of education—are not able to identify such foods using only the Nutrition Facts labels. 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 percent of the Daily Value (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[6]). Only 36 percent of people with less than a high school degree and 42 percent of high school graduates with no college education were aware that this food is high in sodium, compared with 69 percent of college graduates and 74 percent of people with postgraduate degrees (Figure 1). 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 seven percent DV for Total Fat per serving. The association between comprehension of percent DV and educational attainment highlights the need for interpretive FOP labeling to help

consumers identify which foods may promote or undermine their ability to achieve nutritional recommendations.

The notice describes the agency's research objective as: "to further explore consumer responses to various FOP schemes." We recommend that FDA establish more specific research objectives, including:

- To assess which FOP scheme is most effective at encouraging healthier food selections.
- To assess which FOP scheme best enables consumers to identify foods that are part of a healthy eating pattern.
- To assess which FOP scheme best enables the identification of foods that, when consumed, may lead people to exceed daily nutritional recommendations for nutrients of concern (sodium, added sugar, and saturated fat).

Figure 1. Comprehension of % Daily Value, by Educational Attainment (FSANS 2019)



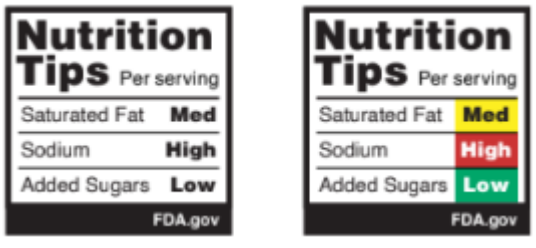
Participants and Procedures

FDA proposes to conduct a "controlled, randomized experiment that will use a 15-minute web-based questionnaire" with a sample that is "balanced to reflect the U.S. Census on gender, education, age, and ethnicity/race." We believe this study design is an appropriate and efficient way of comparing the efficacy of multiple label formats.[7,8,9]

The notice states that the sample will include "3,000 U.S. adult[s]" but does not include a power analysis or other information that would allow the public to evaluate the suitability of the proposed sample size. The notice omits the number of label conditions that will be tested, the number of food choices respondents will have in each comparison question, and whether there will be a separate control group or if the same participants will serve as their own controls by viewing both control labels and FOP labels. The notice also does not identify a primary study outcome. Without these details, the public cannot determine whether the sample size is likely to be large enough to achieve the study goals.

As discussed below (see Measurement and Analysis), we recommend that FDA evaluate a behavioral outcome. Large sample sizes are typically needed to detect the effect of a food label compared to a control condition on a behavioral outcome, so it will be important to ensure the sample size is large enough to detect small effects that may still be meaningful at a population level. We encourage the investigators to anticipate an effect size for the primary analysis (*e.g.*, a 5% difference between conditions for the primary outcome) and then conduct a formal power analysis to

Figure 2. Example of two similar labels that FDA may compare in the study



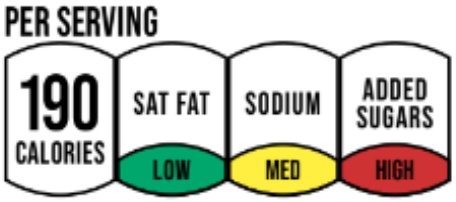
help ensure that the sample size is adequate for detecting the expected effect size. The study should also be powered to detect the smallest difference expected among all of the planned comparisons between label types. For example, if the investigators seek to assess differences in the effects of nearly-identical labels that differ in only one attribute, e.g., black and white versus color, the investigators should be confident that the sample size will be sufficient to detect a statistically significant difference between these similar label types (Figure 2). If the primary outcome is a behavioral choice between two products, it is likely that very large samples are needed to detect an effect. In general, we are concerned that 3,000 people may not be sufficient to test differences between multiple label types. If a key goal of the study is to determine optimal label design, the sample size should be sufficient to achieve that goal.

While FDA did not specify in its notice the number of labels that will be tested, or their designs, it did share publicly a set of 41 different label designs that were used in earlier FDA focus groups.[10] The agency will presumably select a few of these labels to test in the experimental study. Based on existing tobacco and food label research, we recommend testing labels that are simple and easy-to-understand (*i.e.,* that rely on symbols, colors, or icons rather than numbers or text).[11]

We recommend against designing and testing labels that highlight nutrients to encourage (e.g., fiber and calcium) because companies already promote the healthy aspects of their products and do not need a government mandate to incentivize doing so. Labels that combine both nutrients to limit and nutrients to encourage create an unnecessary challenge for consumer education (*i.e.*, instead of simply advising consumers to limit consumption of products with "High in" labels, communications would need to explain when "High" means "Consume less" versus when it means "Consume more"). Avoiding inclusion of the additional information will make the messaging easier to understand and more actionable. This is the approach taken in all countries that have so far implemented mandatory FOP.

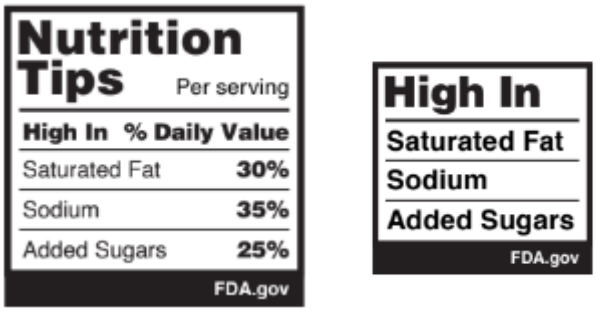
As previously mentioned, many consumers have difficulty interpreting the percent DV. We do not recommend testing Guideline Daily Amount (GDA) labels with numeric information (e.g., amount per serving or percent DV) without an additional interpretive component (e.g., traffic light colors and the terms High, Medium, and Low), as previous research shows these labels do not influence consumer behavior and are less effective than other FOP label formats at improving consumers' knowledge and understanding of the healthfulness of foods.[12,13] If FDA tests one of its 14 proposed GDA designs, it should test design B2 (*see* Figure 3) because this version focuses only on nutrients of concern and includes interpretive aids (red/yellow/green colors and high/med/low text) rather than numbers.

Figure 3. One of 14 versions of the Guideline Daily Amount label used in FDA's focus groups



FDA should prioritize testing the label formats with an additional interpretive component, such as the phrase "High in," and the phrase should be sufficiently prominent to ensure consumers will notice it. We are concerned that certain versions of the Nutrition Tips design are too crowded with information, and "High in" appears in such small text, that it will not be noticed or understood by consumers (see Figure 4). We recommend testing simpler formats, such as FDA's proposed "High in" designs, that use space efficiently to convey a clear and simple message to consumers.

Figure 4. Crowded Nutrition Tips label design (left) and simpler High In design (right), both from FDA's focus groups



Research also demonstrates that labels are likely to be more effective if they have attention-grabbing features such as the word "WARNING" or accompanying icons or imagery.[14,15,16,17] FDA should be testing formats that comply with these observations. We recommend that FDA test a label that states: "WARNING: HIGH IN [sodium/added sugars/saturated fat]" accompanied by a warning icon.

Finally, the notice states that FDA's study will include "a 'no-information' condition where no explanation of the FOP scheme is provided." We understand this to mean that, in this condition, participants will not receive any information, *e.g.*, about the purpose of FOP labeling or how the FOP labels should be used to help evaluate or select foods. However, the notice does not state that the agency plans to test a condition *with* an explanation. FDA should consider testing the effects of different FOP label designs both with and without additional information provided to aid in interpretation of the labeling system. This would help more closely mimic the real-world environment, where consumer education efforts will assist consumers with using the new labels.

Measurement and Analysis

The notice states that "Product perceptions (e.g., healthfulness and contribution to a healthy diet), label perceptions (e.g., believability, trustworthiness, and effects perceptions), and purchase/choice questions will constitute the measures of response in the experiment." It provides no additional details on plans for measurement or analysis.

We agree that FDA should measure purchase/choice and recommend this as the primary outcome measure for the experiment, assuming the study is adequately powered to detect an effect for the primary outcome. Measuring actual selection of products or intentions to purchase products would best predict long-term behavior change and allow FDA to identify which label has the greatest potential to improve the healthfulness of consumers' purchases. Participants' ratings of believability and trustworthiness are not generally strong predictors of how people will respond to labels in the real world,[18] and we recommend against using these outcomes to determine which labeling scheme would be most likely to encourage healthy food choices.

When evaluating responses to purchase/choice questions, we encourage FDA to assess changes not only in likelihood of purchase but also in calories and nutrients selected (*e.g.,* grams of added sugar and milligrams of sodium) in response to the FOP schemes. We also encourage FDA to consider evaluating

which FOP scheme best encourages selection of foods that meet the FDA's proposed definition of "healthy" and which scheme best discourages selection of foods that are high in added sugars, sodium, or saturated fat.

In addition, we encourage FDA to assess consumer understanding of product healthfulness using objective measures (*i.e.*, questions with factual answers). For example, previous studies have asked participants to rank products from the lowest to highest nutritional quality,[19,20,21] to identify the most healthful product in a set, [22] or to assess whether a product's content of sugar, saturated fat, or sodium was higher than recommended levels.[23] Some of the label formats FDA is considering rate levels of nutrients of concern as high, medium, and low. It is possible that labels disclosing "low" for one of these nutrients and "high" for another could be confusing for consumers trying to understand the overall healthfulness of products. Objective measures of consumer understanding of the overall healthfulness of foods will be especially important if FDA's experiments include such labels.

We encourage FDA to use survey measures with strong psychometric properties. For example, to assess "effects perceptions" (i.e., perceived potential for behavioral impact of the labels), FDA should consider using the UNC Perceived Message Effectiveness Scale.[24,25] Originally designed for use in assessing perceived effectiveness of messages about the harms of cigarette smoke, the scale includes three items that have already been adapted for studies evaluating the perceived effectiveness of messages about nutrients in foods (*e.g.*, "This message makes me concerned about the health effects of drinking beverages with added sugar"; "This message makes drinking beverages with added sugar seem unpleasant to me"; and, "This message discourages me from wanting to drink beverages with added sugar").[26,27] A potential single-item measure adapted for this context is "This label discourages me from wanting to buy this product."

Finally, we strongly recommend that FDA pre-register a protocol for the proposed experiment including the primary outcome and all secondary outcomes, any hypotheses or predictions, the analytic plan, and the power calculations used to arrive at the target sample size. Options for submitting this plan include AsPredicted.org, ClinicalTrials.gov, or Open Science Framework.

Time is of the essence, and despite the shortcomings of this research proposal, we do not think FDA should delay the process by issuing an updated notice. Thank you for considering these recommendations, and for your commitment to developing an evidence-based FOP system for packaged foods in the United States.

Sincerely,

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