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

Re: FDA-2021-N-0336; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim ‘‘Healthy’’ on Packaged Foods[1]

The Center for Science in the Public Interest (CSPI) respectfully submits this comment to FDA on the agency's proposed submission to the Office of Management and Budget regarding collection of quantitative information on a voluntary symbol depicting the nutrient content claim "healthy" on packaged foods.

We are disappointed that FDA has not incorporated our previous feedback into its updated research proposal. In July, CSPI urged the agency to examine additional front-of-package nutrition labeling (FOPNL) formats besides a "healthy" logo, and to examine the labels' effects on purchasing behavior. Instead, the agency still proposes to narrowly define the scope of its present initiative to preclude consideration of other FOPNL systems and to carry out research aimed at assessing consumer perceptions, not consumer behaviors.

Including additional FOPNL systems in the research would be better for U.S. consumers. However, if FDA opts to continue with its plans for the current study, we hope the agency will shift course by designing studies to explore behavioral outcomes and to assess the new label's effects on populations left behind by previous food labeling policies. We also urge the agency to carefully examine how agency activities contribute to the goal of advancing health equity.

I. FDA Should Include Front-of-Package Labels in Addition to a "Healthy" Logo in its Research

CSPI submitted comments on FDA's first notice of proposed information collection activities on a voluntary "healthy" logo in July 2021.[2] In our comments, we urged FDA to take a more ambitious, evidence-based approach to FOPNL. We objected to the agency's present approach as unduly focused on "healthy"-style logos, arguing that 1) the agency's literature review did not systematically evaluate the relative efficacy of endorsement logos compared to other FOPNL options, 2) had the agency thoroughly reviewed the evidence, it would have found that other FOPNL systems have greater effects on diet quality, 3) a "healthy" logo could lead to a price premium on products bearing the logo, making these foods less accessible, whereas other FOPNL systems would be unlikely to cause increases in prices of healthier foods, and 4) FDA has the authority to establish a mandatory (as opposed to voluntary) FOPNL system. We recommended that, to the extent that FDA moves forward with its information collection activities on a "healthy" symbol, the agency should expand its studies to include additional FOPNL systems, such as nutrient warnings and traffic lights.

II. FDA's Research Should Assess Behavioral Outcomes

We urge FDA to reconsider its decision not to examine behavioral outcomes. FDA states in the present notice that the development of a "healthy" logo is intended to contribute to its goals to "improve dietary patterns," "reduce the burden of diet-related chronic diseases," and "advance health equity." However, the agency has not thoroughly assessed whether voluntary endorsement logos on packaged foods have the potential to affect any of these outcomes.

In this notice, FDA clarifies several times that the purpose of its proposed research activities is strictly to test "consumer perceptions" about the proposed "healthy" symbols and that "[t]he studies are not designed to test purchasing behavior." FDA asserts that inclusion of variables such as purchase intent and behavior change would be "premature" because the present studies are only designed to explore consumer responses to the draft symbols. The agency goes on to state that it "intend[s] to use 'believability' and 'trustworthiness' as outcome measures because well-established scientific literature has shown that consumers' attitudes and perceptions affect their behavior." If the justification for measuring perceptions is their correlation with behavior, why not just measure true behavioral outcomes?

CSPI disagrees that assessing the effects of a "healthy" logo on purchasing behavior would be premature. This should have been a fundamental consideration in FDA's decision to expend resources on developing a "healthy" logo from the start. Studying behavioral outcomes is critical to determining whether the agency's efforts to develop a "healthy" symbol will advance the agency's stated public health goals.

III. FDA's Research Should Prioritize Subpopulations with Barriers to Achieving Healthy Diets

The FDA has stated that a goal of its efforts to develop a "healthy" logo is to "advance health equity," but has not described plans to measure differences in the effects of the labels between social strata.

People in the United States with less education, lower incomes, and lower levels of English use are less likely to understand or utilize current nutrition labels[3,4,5,6] and have greater barriers to achieving healthy diets (*e.g.*, less financial resources for food, lack of physical access to supermarkets,[7] and difficulty accessing nutrition assistance programs[8]) compared to people with higher incomes, educational attainment, and levels of English use. As a result of these barriers, people with less education and lower incomes have, on average, lower quality diets[9] and higher rates of diet-related disease. [10]

Existing food labeling policies have disproportionately benefited groups that already had more social privilege and superior diet and health outcomes. A food labeling intervention that provides less benefit to people with less education, income, or English use could further widen the gap in access to nutrition information and potentially even exacerbate health disparities. To avoid these unintended consequences, there should be concerted efforts to ensure that groups left behind by previous food labeling policies benefit at least as much from future policies. This means conducting research that is adequately powered to detect differences in understanding and utilization of labels between groups.

In this notice, FDA notes that:

> *Some comments also stated that FDA should consider oversampling from certain groups at highest risk for dietary-related disparities, asserting that it is important to ensure that any proposed healthy symbol works well among all populations. One comment noted this is especially*

important for lower-education groups who, the comment asserted, may be less likely to use or understand the package's nutrition label.

In response to such comments calling for special attention to populations that are less likely to use or understand existing labels, the agency asserts:

> *We designed our studies to test consumer responses to draft symbols in a randomized controlled setting, with participants drawn from a general population. Our research collection is not intended to produce population estimates. However, we intend to select the samples in each study to be reflective of the general U.S. population (e.g., sex, race/ethnicity). We believe our approach is reasonable because any ''healthy'' symbol we finalize will be available to the general U.S. population.*

This response provides no assurance that FDA plans to assess differences by education, income, and English use.

Likewise, the agency's response to comments that "recommended that the studies be adequately powered to enable FDA to do appropriate statistical analysis" does not indicate specifically whether the studies will be adequately powered to detect differences between subpopulations by level of education, income, or English use. The agency states:

> *Our studies are designed to have the appropriate statistical power to conduct all necessary statistical analysis. We will test hypotheses related to between-label differences. We will impose no a priori direction of differences, if any (i.e., we assume all tests are two-tailed). The target sample size (5,000 for the experimental study and 2,000 for the survey) will yield enough observations to provide adequate power to identify 4- way interactions of a medium size.*

The agency has not communicated whether it considers subpopulation analyses to fall under "necessary statistical analysis" and only specifies that its studies are powered to detect differences between groups assigned different label conditions, not between different demographic subgroups.

The focus on the general population without an additional, pre-specified complementary focus on subpopulations with the greatest barriers to healthy diets does not reflect an equity-centered approach. We strongly urge FDA to center the populations left behind by current food labeling policies in any future research and rulemakings (see below).

IV. FDA Should Carefully Examine How Food Labeling Policies Can Advance Health Equity

Especially given its lack of specific attention to subpopulations with the greatest barriers to healthy diets, we caution FDA to avoid overstating the potential for food labeling interventions to advance health equity and recommend that the agency adopt a clear theoretical framework for assessing the potential of agency activities to address disparities. Health disparities are, by definition, related to the unequal distribution of social, political, economic, and environmental resources.[11] Therefore, interventions that meaningfully address health disparities must address the social, political, economic, and environmental determinants of health, as opposed to targeting only individual-level factors such as food choices.

Food labeling interventions cannot remove the structural barriers that produce dietary differences and health disparities. They are important tools for advancing population health but have limited potential to advance health equity.[12] FDA should avoid overstating the potential for food labeling interventions to address health disparities.

References

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