July 17, 2023

Submitted electronically via regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods; Docket No. FDA-2023-N-0155

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) procedural notice regarding quantitative research on front of package labeling on packaged foods. As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

In its notice, FDA reiterates concerns related to diet-related chronic diseases and the continued prioritization of nutrition activities and empowering consumers with nutrition information to make healthier choices. FMI and our members share these important goals and appreciate FDA's use of quantitative research to guide the Agency's work and understanding related to this labeling initiative. Health and nutrition is of the utmost importance to the food industry and for years, FMI and its members have recognized the need to help consumers navigate the varying labeling attributes on today's products. We remain committed to transparency and continuously strive to make nutrition information easily accessible to consumers. The FDA notice also responds to comments submitted in response to the Agency's January 26, 2023 request for public comment, and provides more information related to the schemes to be tested and the research FDA plans to undertake. FMI provides feedback on these responses and the schemes to be tested, below.

Comments on Schemes to be Tested

Facts Up Front is an Important Tool to Achieve FDA's Public Health Objectives

FDA states in the notice that the Agency seeks to empower consumers with nutrition information. As we discussed in our March 27, 2023 comments, one important tool to achieve this goal is the Facts Up Front (FUF) program. FMI believes this widely-adopted program facilitates consumer transparency and empowers informed choices by making important information – calories, added sugars, saturated fat, and sodium – easy to find in a simplified format. FDA also notes that any front-of-pack nutrition labeling (FOPNL) scheme should "complement the Nutrition Facts label." The FUF program was designed to be consistent with U.S. labeling regulations and allows consumers to easily understand and use key product information directly from the Nutrition Facts panel to make informed food choices.

FMI was disappointed to see that a scheme resembling the FUF program, including calories and positive nutrients, is not among the FOP labeling schemes being proposed as the subject of further testing. Given the significant foundation of industry adoption and consumer familiarity with and understanding of FUF, we ask that FDA to continue to consider the role the FUF program could play in helping consumers to select healthful products. Additionally, the FUF program is fully aligned with the FDA's regulatory and claims framework; in contrast, the interpretive schemes being tested do not align in this way, as discussed below.

The Schemes Tested Should Include Calories

FMI urges FDA to include calories in the FOP schemes to be tested. The agency explains in its response to comment 32 that it is not testing any schemes that display calories because the revised Nutrition Facts panel (NFP) format gives greater prominence to calories. The agency concludes that consumers have "adequate access to calorie information, while the purpose of our research on FOP is to determine the usefulness of providing consumers with additional factual context for making healthy food selections."

Respectfully, we do not believe any fulsome discussion of providing additional nutrition information to ameliorate the "epidemic of diet-related chronic disease" – the stated goal of the research – can take place without including calories. Indeed, calories is the *only* nutrient that Congress sought fit to require to be declared at the point of purchase for both menu labeling and vending machine labeling, reflecting its importance in relation to obesity. It would be puzzling indeed if this nutrient was left off of the most prominent position of packaged food labeling, while being featured prominently for restaurant and vending machine foods.

As noted, the agency explains that the FOP labeling scheme is intended to complement the NFP. If that is the case, we question why the scheme would not include calories. Given the increased type size and bolding of calories in the NFP, it would be fully consistent and complementary to also highlight this information again on the front of pack. The information on calories provides a clearer picture of its contribution to the daily diet.

Including calories in any scheme tested is, in our view, necessary from a public health perspective. The changes to the NFP to increase the prominence of the calorie information were based on a 2004 FDA report finding that caloric balance is the single most important factor in weight control.[1] At the time the report was issued, FDA cited statistics finding that 64% of U.S. adults were overweight or obese. This number has only gone up in the past 20 years. According to 2017-2018 data from the National Health and Nutrition Examination Survey (NHANES), 73% of adults are overweight or obese. FDA has continued to make obesity a priority of its nutrition initiatives, citing obesity rates at historic levels.[2] Likewise, the 2023 National Strategy on Hunger, Nutrition, and Health focuses significantly on obesity in its recommendations. Simply, obesity cannot be addressed without a focus on calories. For that reason, we urge FDA to include at least one, and ideally multiple, schemes with calories in its research.

The Schemes Tested Should Include Nutrients to Encourage

We also encourage FDA to test schemes that include positive attributes/nutrients to encourage. For some consumers, these positive elements may be the more important factor in selecting healthful foods. Products that are "high" in the three nutrients FDA plans to test may still provide substantial positive nutrition overall. Consumers not only overconsume nutrients to limit, they also underconsume the positive nutrients listed on the Nutrition Facts panel, several of which are identified as nutrients of public health concern by the Dietary Guidelines for Americans (fiber, calcium, vitamin A and potassium). It is just as important for consumers to increase consumption of these nutrients as it is for them to decrease consumption of nutrients to limit. For these reasons, including positive nutrients provides a more complete picture of the food's nutritional contribution. Indeed, FDA explains that the goal of the schemes is to help consumers "put a food, as a whole, into the context of their daily (or longer-term) diets." Information on the positive elements of nutrients would do just this, while helping consumers make healthful choices.

The Schemes Tested Should Align with FDA's Regulatory and Claims Framework

Based on the consumer testing information and graphics that have been shared, the agency is basing the FOP labeling schemes to be tested on a "per serving" basis, which aligns with the Nutrition Facts Panel – an approach FMI supports. However, nutrient content claims, including "low" and "high" are based on the RACC, creating a significant discrepancy in the agency's application of these terms, compared to how they are defined under FDA regulations.[3] As highlighted in the marketplace assessment of four different breads below, there are considerable differences in the labeled serving sizes and the RACC. With the recently expanded

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1 FDA, Calories Count: Report of the Working Group on Obesity (2004).

2 See https://www.fda.gov/news-events/fda-voices/improving-nutrition-turn-tide-diet-related-chronic-disease.

3 21 CFR 101.13(p).

definition of a single serving container as one with less than two times the RACC, these differences can be significant. As noted below, the serving size for bread ranges from 25g to 49g, while the RACC for sliced bread is 50g. The chart illustrates how the product's assessment under the FOP scheme is impacted by variations in serving size. Importantly, based on only the three nutrients to limit included in the FOP schemes to be tested (added sugars, sodium, and saturated fat), white bread and 100% wheat whole bread appear to be equivalent nutritional choices. Further, a 100% whole wheat bread with a different serving size would rate differently even though it might be nutritionally identical to the first whole wheat bread on a per RACC basis.

Low (per serving): ≤5% DV	Medium (per serving): 6-19% DV	High (per serving): ≥20% DV

Product	***Labeled Serving Size / Weight***	**Added Sugar / Serving**	**Sodium / Serving**	**Saturated Fat / Serving**
White Bread	1 slice 26g	2%DV 1g	5%DV 120mg	0%DV 0g
100% Whole Wheat Bread	1 slice 26 g	2%DV 1g	5%DV 110mg	0%DV 0g
100% Whole Wheat Bread	1 slice 43 g	6%DV 3g	5%DV 110mg	0%DV 0g
Hearty White Bread	1 slice 49g	8%DV 4g	10%DV 230mg	0%DV 0g

These significant differences between the RACC and serving size could result in confusion for consumers when trying to compare the same food product across various slice or pack sizes. To avoid consumer/stakeholder confusion and align with the FDA's own regulatory framework, the best practical solution is to avoid using nutrient content claim language in FOP labeling schemes. Strictly informational schemes like FUF do not raise this discrepancy. To the extent FDA tests interpretive schemes, we recommend testing more positive approaches (e.g., checkboxes and stars), consistent with the IOM report on such schemes discussed in our earlier comments.

In Addition to Testing Facts Up Front, FDA Should Also Test a Hybrid Informational/ Interpretive Scheme

The Agency states the study will test a variety of schemes reflecting those currently found in the marketplace. But this is not so. The list of schemes that FDA plans to test do not include any that reflect current schemes on the marketplace. The first scheme to be tested includes information on only three nutrients in a format similar to FUF, but most significantly, *not* on calories, and with no ability to voluntarily include information on positive nutrients. As discussed above, we recommend that FDA test a scheme that does in fact mirror the existing FUF scheme, as opposed to one that simply takes "attributes" of that scheme but omits critical other elements like calories.

As discussed in our earlier comments, and reiterated later in these comments, we have significant concerns with the interpretive approaches that FDA is considering. With the

publication of the specific FOP schemes that will be tested, our concerns are heightened. The agency is testing one solely informational scheme, and the rest are interpretive. With this design, planned research could set the first (solely informational) scheme up for failure. Consumers will naturally find the words low, medium, and high to be easier to understand than numerical or quantitative values.

If FDA is going to test interpretive schemes, then we ask the agency to also test a hybrid approach that combines an interpretive and informational scheme; in addition to testing an informational scheme based on FUF. Specifically, we believe it is important for FDA to also test a hybrid approach that takes the existing Facts Up Front scheme (including calories and positive nutrients) and adds to it an interpretive element.

FDA Should Test A Variety of Options Related to the Governmental Reference ("FDA.gov") in the Schemes

Finally, it is not clear to us how FDA will evaluate the role of the "FDA.gov" reference in consumer perception of the FOP schemes if this statement is included on every scheme tested, with no control or alternative tested. We encourage FDA to at least test control versions without this information; and to also consider whether a reference to MyPlate or other governmental information might better achieve the Agency's objectives.

Legal Authority

As discussed in FMI's March 27, 2023 comments, a mandatory FOP nutrition labeling scheme would raise significant concerns under the First Amendment and as to the agency's statutory authority to impose such a scheme. [4] We incorporate our prior comments by reference here. These concerns are heightened when FDA is testing predominantly interpretive schemes. All but one of the schemes under consideration for consumer research involve an interpretive element that characterizes nutrient levels as high, medium, or low. This is not merely factual and uncontroversial information. The term low has not been defined for total or added sugars; nor has the term medium ever been defined by regulation. The term high has only been defined with the intention of allowing voluntary nutrient content claims about beneficial nutrients, such as "high in calcium" or "excellent source of iron," as opposed to using the term "high" in a broader manner that would apply to nutrients to limit and would characterize them as high, medium, or low as a mandatory matter, and not simply for purposes of a voluntary claim. As discussed above, in some cases, FDA would be testing uses of "high in" or "Low in" that conflict with FDA's definitions of these terms under its nutrient content claim regulations due to the difference in the RACC size vs. the serving size.

More broadly, it is deeply controversial to simplify a food's entire nutritional profile to three nutrients without inclusion of calories or any positive elements. A scheme that mandates speech that goes beyond factual and uncontroversial information must be reasonably

[4] See https://www.regulations.gov/comment/FDA-2023-N-0155-0021.

related to a legitimate government interest and not unduly burdensome. Assuming, for the sake of discussion, that helping consumers to identify more healthful foods and reducing risk of chronic disease are legitimate government interests, we have significant concerns about whether FDA could satisfy the requirement that mandating the schemes under consideration is "reasonably related" to this interest. To the contrary, presenting information for only three nutrients to limit would create misleading and confusing results. Instead of helping to educate consumers on the overall nutritional value of their food, and how foods might fit into a healthful diet, it would over-simplify the information and cause consumers to place excessive focus on three nutrients without receiving a more holistic picture of its nutritional profile as reflected by calorie and positive nutrient information.

Based on how various foods would be categorized as low/medium/high according to their added sugars, sodium, or saturated fat content, there are many instances where the interpretive schemes being tested will not help consumers to identify more healthful items. Examples include the following:

- White bread and 100% whole wheat bread score would have the same FOP labeling
- Diet soda and maple syrup would have all "Low in" numbers
- Foods such as candy would rank similarly (one "high" nutrient) as more healthful options like soup and canned fruit
- Regular and reduced sodium chicken soup would both bear "high in" labeling for soup; fruity cereal and oats and honey cereal with whole grains would both have the same ranking

As seen by these examples, in many cases, more healthful and less healthful options would score the same under the proposed schemes, meaning consumers would have no basis to distinguish them. At the same time, foods that are encouraged to consume under the Dietary Guidelines for Americans receive "high in" or the most negative scores, while foods that are meant to be consumed in moderation receive all "low in" or the most positive scores. These examples emphasize that in order to help consumers more quickly and easily identify healthful foods, more information is needed than just information on three nutrients to limit. As discussed above, information on calories and positive attributes should be a part of any front of pack scheme. For these reasons, we have significant concerns that the schemes being tested will not help consumers to identify more healthful products, and therefore that they would not satisfy the "reasonably related" prong of the First Amendment analysis.

Moreover, we have serious doubts about the ability of the schemes under consideration to change consumer behavior, which would be required in order to have any impact on chronic disease rates in the U.S. As discussed below, our understanding of the scientific literature is that there is a lack of any study showing *long-term* (sustained) and *meaningful* behavioral changes resulting from mandatory FOP labeling schemes like the ones FDA is testing.

As discussed in our earlier comments, we expect it will prove difficult to convince a court that a compelled speech regime is reasonably related to a legitimate government interest when a wealth of *other* statutes and regulations further that interest in a balanced way. And there can

be no doubt that forcing manufacturers to comply with a mandatory FOPNL scheme would be unduly burdensome; compliance would likely cost manufacturers millions of dollars in many cases.

These concerns underscore our request that FDA carefully consider the schemes to be tested based on its First Amendment obligations. While an informational approach would still be subject to these significant restrictions on FDA's legal authorities, it would provide a somewhat more balanced approach that would not pose as great a risk of violating the First Amendment as the interpretive schemes.

Additional Comments on Study

FMI supports FDA's plans to increase the sample size to 9,000. We are disappointed, however, that FDA has only published the information on the survey methodology and schemes to be tested with a 30-day comment period, depriving stakeholders of a meaningful opportunity to comment on the planned research. For instance, it is not possible to provide meaningful comments on the Agency's planned methodology or literature review document in a 30-day period.

FMI encourages FDA to prioritize transparency and more open engagement with stakeholders on its FOP labeling activities. We are concerned that the agency is not adequately engaging with stakeholders on the results of its qualitative study on FOP labeling, or how it plans to use those results to inform the structure of its upcoming quantitative study. We encourage FDA to host a public meeting[5] to share the findings from last year's focus group testing that are now being used to inform the methodology and conduct of the upcoming quantitative study. FMI also requests that FDA be more forthcoming with regards to proposed milestones, the timeline for the Agency's FOPNL activities, and the ability of stakeholders to engage throughout the process.[6]

Moreover, FDA has dismissed many of the industry's legitimate concerns about the significant limitations of the planned testing, yet appears poised to use the forthcoming consumer research as its primary evidentiary basis for proposing a mandatory FOPNL scheme. Indeed, as indicated by the agency's Spring 2023 regulatory agenda, we understand FDA plans to issue a proposed rule at the end of 2023. We urge FDA to keep in mind the limitations of the planned consumer research, including that this type of intention-to-purchase research does not reflect, and is not a

[55] Specifically, a public meeting would be appropriate for sharing information that we think is important to transparency including, but not limited to, results of the 2022 focus groups, additional information on focus group participants and selection, survey questions, and the Agency's basis for choosing which FOP schemes to test.

[6] Many unanswered questions remain. For example, will there be additional studies following the quantitative study? Will the Agency provide opportunities to comment through public meeting, ANPR, etc. prior to moving forward with a proposed scheme? How will FDA measure the effectiveness of any FOPNL scheme?

good predictor of, actual consumer behavior; as well as the very small number of products to be tested. Further, we ask FDA to take a critical eye to its literature review, as the current body of literature fails to demonstrate that FOP labels have a *significant* impact on actual shopping behavior, or result in any *long-term* behavioral changes – i.e., what would be needed to result in meaningful health changes.

Finally, FDA continues to pursue two sets of labeling schemes – FOP nutrition labeling and a voluntary healthy symbol – on parallel paths without any discussion of how these two schemes might work together. If FDA continues to pursue a voluntary healthy symbol, the Agency must assess the interaction of this symbol with other information that FDA is seeking to mandate. We question why FDA would not utilize the present consumer research as an opportunity to evaluate this issue.

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Once again, we greatly appreciate the opportunity to comment on the planned quantitative consumer research on FOPNL schemes. We look forward to continuing to work collaboratively on this important topic.

Sincerely,

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