March 27, 2023

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

Re: Agency Information Collection Activities; Proposed Collection; 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) comment request 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 comment request, FDA discusses its continued prioritization of nutrition activities and empowering consumers with nutrition information to make healthier choices. Additionally, the Agency discusses maintaining flexibility to help facilitate and encourage industry innovation in the production of healthier foods. 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 for consumers and continuously strive to make nutrition information easily accessible to consumers.

Background on Facts Up Front Program

FDA notes in the comment request that the Agency seeks to help empower consumers with nutrition information, including both informative labeling and tailored education. One such tool to achieve these goals is the Facts Up Front (FUF) program. As a co-creator of the FUF program

– a widely-used, voluntary labeling program launched in 2011 – FMI believes the program facilitates consumer transparency and empowers informed choices. FDA also notes its objective that any front-of-pack nutrition labeling (FOPNL) scheme would "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.

Third-party research shows that consumers can easily understand the information provided through FUF icons. As summarized in a November 2021 International Food Information Council (IFIC) report, titled *Knowledge, Understanding and Use of Front-of-Pack Labeling in Food and Beverage Decisions*,[1] 74% of respondents found nutrition facts highlights, which summarize key nutritional content per serving, either very easy or somewhat easy to understand. Additionally, 67% of respondents believe that the front of product package has the right amount of information. The survey found that both front-and back-of-package labels are important. However, of those who have a preference, the labeling found on the back of packaging is nearly twice as impactful (21%) as the labeling on the front of the product packaging (12%). As such, it is a natural fit for the FUF program to complement the Nutrition Facts label. The research also found that Nutrition Facts highlights like those provided by the FUF program are the type of FOP labels that are most often considered by consumers, and the easiest to understand when compared to other FOP labels such as third-party certifications.

While the FUF program is a voluntary scheme, its implementers must follow defined conditions for program use. The FUF style guide outlines specific program requirements for FUF program implementers including aesthetic and technical guidelines that help ensure the program is implemented in a uniform and consumer-friendly way. Additionally, the FUF program is implemented to allow for updates to be made to the iconography to adapt to changes in consumer behavior. In fact, to align more closely with the *Dietary Guidelines for Americans*[2] (DGA) and the updates FDA made in 2016 to the nutrition labeling requirements, we have updated the FUF Style Guide to include an 'added sugars' icon, which is a dietary component to limit according to the DGA. We note that the FUF program does not apply to medical foods or dietary supplements because these products raise unique considerations when it comes to nutrition labeling; likewise, these products, as well as foods for special dietary use, should be exempt from any standardized FOPNL scheme adopted by FDA.[3]

Importantly, the FUF program has been widely adopted on food packaging and has been implemented on food labels in the market since 2011. Market penetration numbers provided by

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[1] International Food Information Council. Knowledge, Understanding and Use of Front-of-Pack Labeling in Food and Beverage Decisions: Insights from U.S. Shoppers. 16 November 2021. https://foodinsight.org/ific-survey-fop-labeling/

[2] https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf

[3] Medical foods are exempt from nutrition labeling and dietary supplements are subject to differing nutrition labeling rules than conventional foods. Foods for special dietary use are specifically formulated to meet a nutritional need for a specific population. FOPNL on these types of products could deter use by the very population they were designed for and/or cause consumer confusion.

Nielsen/Label Insights at the end of 2021 reflect over 207,000 products with Facts Up Front, accounting for $288 billion in sales in 2019. And note that these numbers understate market penetration of Facts Up Front, as they are based only on a FOP image search in the Label Insights database.

The program is also consistent with other voluntary industry programs, such as Clear on Calories (implemented for beverages since 2010), and Treat Right (implemented for confections since 2013). Companies implementing these three leading voluntary FOPNL programs represent over 80 percent of U.S. grocery sales (manufacturers) and over 80 percent of private label stock keeping units.

Initial Comments on FDA Legal Authority

1. **FDA must carefully assess its statutory authority before pursing mandatory FOPNL.**

The notice indicates that FDA may be considering both factual and interpretive schemes for FOPNL (such as a "high", "medium", or "low" label; or labels that identify nutrients of concern that are "high in" the product). We also understand the planned consumer research is only a first step in exploring FOPNL schemes and that FDA has not stated whether any standardized scheme it might adopt would be mandatory or voluntary. Before moving forward with a proposed mandatory approach, however, FMI urges FDA to carefully assess whether Congress has given the agency the legal authority to enact a mandatory FOPNL scheme of the type under consideration.

The Federal Food, Drug, and Cosmetic Act (FFDCA) does not include express authority to mandate interpretive information about a selection of nutrients *outside* of the mandatory Nutrition Facts Panel. To the contrary, Congress was quite precise about the specific information FDA was authorized to require related to nutrition labeling.[4] And importantly, all of the regulatory authority provided to FDA related to mandatory nutrition information refers to factual information, rather than interpretation of it. FDA must carefully consider the limitations imposed by the current statutory framework when conducting research on FOPNL schemes.

The U.S. Supreme Court has recently made clear that Congress must provide *clear direction* to regulatory agencies – rather than a broad delegation of power – if the case implicates the "major question doctrine". The doctrine, invoked by a majority of justices in *West Virginia v. Environmental Protection Agency (EPA)* (2022), holds that courts should not defer to agencies on matters of "vast economic or political significance" unless Congress has explicitly given the agencies the authority to act in those situations. The doctrine is triggered here given the political significance that would be involved in moving from an approach that is information and

[4] In terms of mandatory nutrition information, FDA is authorized to require nutrition labeling that includes the following complete set of information: the serving size, the number of servings per container, calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein, and vitamins and minerals.

education-based, as provided for under the FFDCA, to one that effectively characterizing foods as "good" or bad" based on specific nutrient levels.

In light of this precedent, a court could conclude that FDA's authority to mandate nutrition labeling and to regulate voluntary nutrient content claims does not provide a broad, never-before-exercised authority to mandate separate front-of-pack nutrient labeling, particularly in an interpretive format. Essentially, a court could hold that if Congress had intended for FDA to have such unusual and broad authority it would have clearly provided it. In sum, as FDA considers various FOPNL schemes, including interpretive ones, it should critically assess its legal authority to mandate the use of FOPNL given that a requirement for such labeling has not been clearly provided for in the statute.

2. FDA must also assess potential Constitutional issues that would be raised by a mandatory labeling requirement.

It is also critical that FDA assess First Amendment considerations in weighing the potential for a mandatory FOPNL scheme. Commercial speech is entitled to First Amendment protections. *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980). Corporations cannot be compelled to speak except when that mandatory information is necessary to *avoid consumer deception*. There is a strong argument that, to the extent FDA were to impose the schemes it is testing as mandatory labeling requirements, they would be vulnerable to a constitutional challenge.

Under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), the Supreme Court upheld a compelled disclosure under the First Amendment when it was "reasonably related to the State's interest in preventing deception of consumers." 471 U.S.at 651. However, *Zauderer* involved compelled speech that is "strictly factual and uncontroversial." Many of the FOPNL schemes that FDA intends to test are not "strictly factual *and* uncontroversial." The test is phrased in the conjunctive; the speech sought to be compelled must be *both* "strictly factual" *and* "uncontroversial."

A number of the proposed schemes go beyond a strictly factual disclosure of the number of calories or other nutrients. Several of the schemes involve a subjective characterization of the perceived virtuousness ("high/medium/low" or "high in") of foods based on only three highlighted nutrients—and some would mandate that foods bear color-coded symbols (red/yellow/green, like a stoplight) in order to signal which foods are deemed to be preferred and which are not. Reducing a food's entire contribution to the diet to whether it is "high in" or "high", "medium," or "low" in one to three nutrients is overly simplistic and does not help educate consumers on how to improve their dietary pattern. And consumers have varying dietary requirements and preferences; purporting to assign foods a one-size-fits all

characterization to a food very well could prove confusing or even dangerous to consumers in such circumstances. None of this is "factual and uncontroversial."

Zauderer also suggests that it is not enough to show merely that the speech is "factual and uncontroversial"; the speech must be corrective of an omission that would otherwise be *deceptive*. Thus, unless FDA were to conclude, based on substantial evidence, that failure to require industry to include the relevant information on all product labels would result in *deception* of consumers, *and* that the compelled language is both "factual and uncontroversial," any attempt to mandate compelled speech may be susceptible to challenge.

Zauderer and its progeny also would require the agency to show, on top of the above, that the proposed compelled speech is reasonably related to a legitimate government interest and is not unduly burdensome. For all the reasons we've explained, it may 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.

We recognize the FDA has not proposed to mandate any FOPNL scheme, and FDA certainly has legal authority to conduct consumer research on such labeling options, but we would strongly recommend that the agency critically assess the types of schemes that would risk a statutory authority or First Amendment violation before moving forward with proposing any mandatory FOPNL scheme. The utility of the research would also be improved if FDA eliminates any schemes that pose a greater such risk, particularly the "High in" scheme and the schemes with color coding. With that comment in mind we next turn to the specific FDA requests for comments.

Responses to FDA Requests for Comments

1. **Topic 1: whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility**

    a. **It is necessary to conduct rigorous consumer research to understand the impacts of any FOPNL scheme, and the utility of the research will depend upon the study design and schemes tested, but the research will have important limitations.**

Generally speaking, FMI believes that completing rigorous consumer research to understand the impacts of any FOPNL scheme is necessary. The practical utility of the information will depend in part upon how the research is designed, and even a well-designed study will have certain limitations that need to be acknowledged. As an initial matter, FMI urges FDA to share the results of the previously completed qualitative focus groups so that this past work can help

shape the quantitative study design. This will provide stakeholders a better understanding of what has already been learned from the initial research compared to what may still need to be evaluated. Second, and as discussed further in response to topic 2, significantly more details are needed on the planned quantitative research in order to comment meaningfully on its potential practical utility.

FMI supports the inclusion in the quantitative consumer research of FOPNL schemes that are based on the Facts Up Front program. It is important to include this scheme in any consumer testing. It is the only one of the schemes that is currently used on package so FDA would be remiss not to test it.

Though quantitative consumer research is critical in order to understand consumer perceptions of the product, the label, and purchase/choice intent based on any FOPNL scheme used, it is also important for the agency to understand the limitations inherent in this type of research. The quantitative research does not measure consumer behavior; it only tests what participants say about how they will behave, which of course can differ. Further, the testing is proposed on a very small number of products that cannot possibly reflect the enormous range of foods and eating occasions represented across packaged food options. The research setting will also inherently lack a certain element of realism; for example, the mock labels used in the focus group research do not resemble packaged foods available in-market based on factors like the types of claims used, the text size and styles, and other factors. As discussed further below, the food industry is keen to work collaboratively with FDA to develop mock product labels that will improve the utility of the information collected. More broadly, though, it is important to recognize the limitations to the research under consideration.

Indeed, very few studies have been carried out in real-world supermarkets (let alone studies of consumption data rather than purchase data). The findings from those studies indicate that certain FOP labels or shelf labels may achieve a small degree of success at persuading shoppers to switch to healthier foods (maximum of 2.0% change).[5] Some FOP labels may assist shoppers in recognizing which foods are healthier. But there is little hard evidence that this enhanced knowledge has a *significant* impact on actual shopping behavior. There is a particular lack of evidence of any long-term behavioral changes, as discussed later in these comments.

Importantly, apart from the planned consumer research that is the subject of the notice, when reviewing the literature on FOP labeling and potential changes in consumer behavior, FDA needs to evaluate both the substantive significance (effect size) and statistical significance (P value) in its research. Not many studies or meta-analyses have undertaken a critical view of the effect sizes found from any real-life research. An effect may be statistically significant but much *smaller* than expected from "intention to purchase" studies, calling into question the reliability of consumers answers vs. real life consumer behavior. A recently published paper investigated whether four pre-selected front-of-pack nutrition labels improve food purchases in

[5] Norman J. Temple. Front-of-package food labels: A narrative review. *Appetite* (2020) 144:104485, https://doi.org/10.1016/j.appet.2019.104485.

real-life grocery shopping settings, using 1.9 million labels on 1266 food products in four categories in 60 supermarkets in France, and analyzed the nutritional quality of 1,668,301 purchases.[6] Overall, the authors found that the most effective nutrition label, Nutri-Score, increased the purchases of foods in the top third of their category nutrition-wise by 14 percent, but had no impact on the purchases of foods with medium, low, or unlabeled nutrition quality. Disappointingly, effect sizes were calculated as 17 times smaller (on average) than those found in comparable laboratory studies. The authors posit that potential reasons for this could include: laboratory studies are usually shorter, and the initial effect seen in these studies may not be sustained in time; it may also be that consumers pay stronger attention to the nutrition labels when they are participants of a study because they had just seen the labels minutes earlier and because each label was present on all the products that take part of the study; and finally, in the food domain, and especially for nutrition-related decisions, there can be a large difference between what people choose when they are being watched and when they are not.

b. There is a critical role for education in improving consumer understanding of nutrition information, and FDA should not discount this when considering FOPNL approaches.

We also wish to comment on the important role of educational efforts to increase consumer understanding and utilization of the Nutrition Facts label and its key positive and limiter nutrients. The FDA Food Safety and Nutrition Survey (FSANS) results from 2019 indicate that when respondents were asked if they ever look at the Nutrition Facts label on food packages, 87% said yes.[7] Sixty-four percent of respondents said they either somewhat agree or strongly agree that the Nutrition Facts label is easy to understand and 71% either somewhat agree or strongly agree that the Nutrition Facts label is useful to them. These results are encouraging but also support that with additional education, more consumers could understand and find value in the nutritional information offered to them through the existing Nutrition Facts label.

Relatedly, we applaud the agency for releasing the Nutrition Facts label education campaign as part of FDA's Nutrition Innovation Strategy. We acknowledge that the goal of the education campaign was to increase awareness of the new Nutrition Facts label and empower consumers with information to make informed food choices. Since its release was in March 2020 at the onset of the COVID-19 pandemic in the U.S., we feel that the important work of the agency was largely overlooked by consumers. As such, we encourage the agency to review its education efforts as it relates to the Nutrition Facts label. The agency should consider if a widespread multifaceted campaign is needed to disseminate the educational materials for the Nutrition Facts label. For instance, FDA could consider launching a social media campaign to share the educational materials. Additionally, another approach for the agency to consider is encouraging

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[6] Pierre Dubois et al. Effects of front-of-pack labels on the nutritional quality of supermarket food purchases; evidence from a large-scale randomized controlled trial. *Journal of the Academy of Marketing Science* (2021) 49:119–138.

[7] FDA's Food Safety and Nutrition Survey 2019 Survey (March 2021), https://www.fda.gov/media/146532/download.

the use of educational materials in school curriculums as a path forward for young consumers to become confident when making decisions about their diets.

2. **Topic 2: the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used**

The information that FDA has made available regarding the planned research does not provide enough information to fully respond to this question. FMI requests that FDA share more detailed information on the intended quantitative research proposal including:

- Survey questionnaire;
- Methodology for both the experiment pretests and the full-scale experiment;
- The different FOPNL schemes to be tested;
- The full details of each FOPNL scheme to be tested, based on the type of product (for example, the industry voluntary programs allow for calories only on individual beverages and small foods packaging due to the extremely limited space, but it is unclear whether any of the schemes to be tested involve modified options for smaller labels);
- The nutritional criteria behind each FOPNL scheme being tested (e.g., the criteria for high/med/low or red/yellow/green; whether all types of products will be subject to the same criteria or whether the criteria will differ by food or beverage category; whether the criteria be assessed on a per RACC or per serving size basis or some other metric. It is unclear how the criteria shown in the FOPNL schemes tested in the focus groups were determined, particularly given that "medium" nutrient content claims are not defined, and FDA has not defined "low in" as a nutrient content claim for nutrients like added sugars or calcium;
- Mock-ups of product images with FOPNL icons placement shown for each scheme;
- The specific objectives/goals for the research;
- The methodology:
    - A detailed sampling plan outlining how participants will be recruited and screening criteria for participation;
    - An explanation of how the survey will be administered;
    - Techniques used to show and assess reactions to the labels; and
    - An analysis plan including statistical approaches and techniques used to analyze the data.

Without the information above, it is not possible to fully assess whether FDA has accurately estimated the burden of the information collection, or whether the information obtained from the research will be of more or less practical utility.

Based on the information provided, we understand FDA is considering an experiment involving 3,000 participants. Consumer research to evaluate a program of this scale impacting the entire U.S. population should have at minimum of 3,000 and likely more like 5000+ participants. If a more robust participant sample size number is used, this would of course increase the estimated response burden, but would also increase the practical utility of the research.

As discussed above in our comments on the agency's legal authority related to FOPNL, the utility of the research would be improved if FDA eliminates any FOPNL schemes that pose a greater risk of violating the First Amendment, particularly the "High in" scheme and the schemes with color coding.

3. **Topic 3: ways to enhance the quality, utility, and clarity of the information to be collected**

It is critical for any standardized FOPNL system to provide information in a way that is not misleading or confusing to consumers about the food's role in a healthy dietary pattern, and that is adequately flexible to apply across the wide range of foods in package form. In addition, any such system must be practical, reasonable, and technically feasible. To this end, FMI has a number of recommendations on how to enhance the quality, utility, and clarity of the information to be collected.

a. **Mock-ups of product labels should accurately represent product labels in market.**

The utility of the information collected would be enhanced if FDA ensures that the mocked-up product labels tested are accurate representations of product labels consumers are likely to see in market. It unclear if FDA proposes to use the mock labels used in the focus group research, or would use different labels in the quantitative research. The mock labels used in the focus groups have a number of elements that make them unrealistic and not accurately reflective of the products consumers would see in market, including that they have a smaller number of competing claims, and utilize small type size for voluntary claims, and font styles that are not commonly used on product labels. We would be pleased to work with the agency to provide further input or help develop mock product labels that are realistic in terms of graphics, text font and size, the number and type of labeling attributes used.

b. **The food products tested should reflect the range of product categories and nutrient profiles that would be subject to a standardized FOPNL scheme.**

The proposal to use only three different product categories (canned soup, breakfast cereal, and frozen meal) would not accurately represent the broad range of packaged products that would be subject to a standardized FOPNL scheme. Accordingly, it is unclear how the findings from the research could be applied across all types of the packaged foods and beverages available to consumers. The information collected would be more useful if FDA tests a range of nutrient profiles within each food category, and if FDA tests both products that the agency would like to encourage consumers to consume, and those that the agency would like to encourage consumers to limit. Testing a broader range of products from various food and beverage categories would better enable the research to serve FDA's goals of empowering consumers with nutrition information to make healthier choices and encouraging potential reformulation toward more healthful products.

The research should include very small package mockups to ensure fit and readability (e.g., soda bottle, candy bar, gum). An FOPNL scheme involving iconography that would not fit or would be too small to be readable would not be useful to consumers while imposing significant burdens on the entire food and beverage industry.

As noted above, FMI would like to partner with FDA to discuss products to test, package mock ups, and considerations for each.

c. FDA should publish additional information on, and carefully evaluate, the specific FOPNL schemes to be tested.

FDA has published images of the FOPNL schemes that the agency tested as part of its initial focus group research, and has stated that some smaller subset of these schemes will be the subject of the future quantitative research, but has not stated which schemes are to be tested. It is critical for FDA to share more information on the specific schemes to be tested, why those schemes were chosen, and why other approaches were not selected.

We urge FDA to carefully scrutinize the literature on the effectiveness (or more aptly, lack of effectiveness) of FOPNL schemes in changing consumer behavior, and to consider this literature when determining which schemes to test. We would particularly like to call the agency's attention to a literature review published in NUTRIENTS in January 2023 that reviewed 65 original studies exploring the performances of four widely use FOPNL schemes (traffic light, warning signs, Nutri-Score, and Health Star ratings).[8] The authors concluded that the magnitude of improvements in healthier food purchases "were modeled rather than observed" and the "magnitude of improvements was small". Further, there is a "significant research gap" on actual consumption changes (as opposed to purchase changes). The authors also discuss how the research does not bear out that any changes in consumer behavior would be sustained over longer periods of time. In order to justify imposing a burden as significant as mandatory FOPNL, it is critical that any beneficial effects on purchasing behavior be maintained over time. Finally, the authors commented on the potential unintended consequences of FOPNL schemes, where some individuals may anticipate that "unhealthy" products will be tastier, and accordingly make behavior changes toward consuming less healthful foods. FDA should assess and consider this research when determining which schemes to include in the quantitative research. To the extent FDA intends to propose any FOPNL scheme that is interpretive, the agency would need to clearly articulate any gap(s) identified through research in fact-based schemes such as Facts Up Front.

As discussed above, FMI supports the inclusion in the quantitative research of Facts Up Front given its widespread adoption and the fact that consumers are already familiar with the program

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[8] Veronique Braesco and Adam Drewnowski. Are Front-of-Pack Nutrition Labels Influencing Food Choices and Purchases, Diet Quality, and Modeled Health Outcomes? A Narrative Review of Four Systems. *Nutrients* 2023 *15*(1): 205; https://doi.org/10.3390/nu15010205.

and understand how to use it. We also encourage FDA to test (1) positive interpretive schemes and (2) schemes that would build upon the existing voluntary Facts Up Front program. First, we encourage FDA to include within its research positive interpretive schemes, such as star or checkbox approaches, to evaluate such approaches against the more negative interpretive schemes FDA is considering testing (e.g., the "High In" option and others). This would be consistent with the recommendations of the 2012 report of the National Academies entitled *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices*, which focused on positive schemes such as checkbox approaches or stars.[9] We also encourage FDA to conduct research on schemes that would build on the existing voluntary Facts Up Front program by providing a positive interpretive approach that layers on top of the Facts Up Front icons. This would help to build upon existing industry efforts to provide nutrition information in an accessible way.

FMI is concerned that a number of the schemes tested with focus groups, such as the "High in" scheme or the schemes with color coding, are overly simplistic and would reduce a food's entire nutritional profile to between one and three nutrients – notably, none of which are calories. We do not view many of these interpretive schemes as being at all likely to accomplish FDA's stated objectives of providing additional information that will allow consumers to quickly and easily identify foods that are part of a healthy eating pattern. For example, a product with some added sugars could be viewed negatively by the consumer if "high in" or "red" was marked on the FOP while in fact this product may also provide substantial positive nutrition overall. Examples are too numerous to detail, but could include key nutritional staples such as flavored low fat milk, whole grain/high fiber cereal, or any number of other types of foods and beverages recommended in the DGA and MyPlate. By taking a negative, reductive approach, these approaches will not enable consumer education or understanding. And as noted, these approaches could raise heightened First Amendment concerns.

d. FDA should limit the schemes tested to ones that would be reasonable, practical, and technically feasible.

As discussed above, we believe that Facts Up Front should be one of the schemes tested in the quantitative research. We recommend that FDA include Facts Up in the research to ensure there is a balance in the types of schemes tested, including a scheme that is currently used in market.

To improve the usefulness of the data collected, FDA should assess considerations related to the ability to implement any schemes tested, including the size, color, costs, and other factors. The agency should limit the schemes tested to ones that would be reasonably implementable without excess cost and burden to industry. A number of the schemes that were included in the focus group research require significant label real-estate and are unlikely to be technically feasible given current package layouts. As one example, the Nutrition Tips have a more vertical layout and will be a significant challenge compared to smaller horizontal approaches like Facts

[9] Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices |The National Academies Press.

Up Front. FDA also should consider that any product bearing a scale label, such as foods packaged in a retail store environment, would not be able to accommodate the same types of graphics as a pre-printed label, as the capacity for graphics on scale labels is very limited.

Several of the possible FOPNL schemes would impose significant regulatory burdens due to the use of multiple colors, which add enormous cost due to the need for multiple plates for printing. We strongly encourage FDA to avoid schemes with mandatory colors because the burden imposed by such schemes will be outsized. We also note that the use of colors in characterizing nutrient content is overly simplistic and is unlikely to achieve the goal of meaningfully educating consumers on nutrition. Taking just one example from the schemes FDA tested with focus groups, the use of red color to signal that a product is "low" in calcium at 5%DV would attribute significantly outsized importance to that one nutrient and could lead consumers to think calcium is a "negative" nutrient, causing them to avoid what may be a healthy product because of the red icon when in fact all sources of calcium consumed throughout the day are valuable. This could therefore be both confusing and misleading to consumers.

When considering any scheme, we encourage FDA to assess the extent to which having a number of different FOP information systems could be potentially confusing to consumers. FDA also needs to consider how a standardized FOPNL scheme would fit together with the voluntary "healthy" symbol FDA is considering developing, as well as all other regulated elements that may be on the principal display panel, such as whether a new FOPNL scheme would replace the existing ability to satisfy the requirements of the vending machine labeling rule when a front-of-package calorie icon is used.

e. The quantitative research should be designed with a sufficient sample size and in a way that avoids introducing bias.

Based on the information provided, we understand FDA is considering smaller "experiment pretests" on 180 and 25 participants, and a full-scale experiment involving 3,000 participants. Consumer research to evaluate a program of this scale impacting the entire U.S. population should have at minimum of 3,000 and likely more like 5000+ participants. FMI also recommends that FDA include data cuts on key demographics such as racial and ethnic minority groups, those with lower socioeconomic status, those living in rural areas, and parents (of minor aged children) vs. nonparents to ensure visibility on behavior changes across various demographic groups. Further, it is recommended that FDA include readable samples of category users for each of the categories being presented (e.g., cereal, frozen meals, etc.) and evaluate results among each relevant category user base.

We note that the web-based nature of the study could exclude the types of participants we understand FDA is seeking to engage with the research and with its FOPNL initiative. In particular, a web-based design could exclude participants from groups most at risk for diet-related chronic disease (i.e., individuals from racial and ethnic minority groups, lower socioeconomic status, and rural areas). These individuals may not have the resources for a computer or access to high-speed internet that would be necessary for participation in the web-

based questionnaire. According to Pew Research only 77% of adults in the U.S. have broadband internet. Even fewer adults (72%) in rural areas have access to broadband internet.[10] In addition, the design could inadvertently exclude individuals responsible for making purchasing decisions for their family because they have small children or reside in a shared living space. It is important, therefore, to assess whether a web-based study is the proper way to administer the study given the target population.

It would also be helpful to understand whether participants will be shown multiple schemes and provide input on their preferences, or whether each participant will only see and comment on one scheme. It is critical for FDA to design the study in a way that will ensure consumers will not be biased by the introduction of multiple schemes.

f. The survey should be designed in a way to thoroughly probe consumer perceptions of the product and label.

To optimize the utility of the information collected, it is important to fully probe consumer perceptions of the product bearing the label. For example, it would be important to understand whether consumers viewing an FOPNL scheme:

- Perceive the product as unhealthy, a "bad" food choice, or one that should be avoided, particularly for products that are healthful food choices recommended by the Dietary Guidelines for Americans or in MyPlate. For example, if a cereal is whole grain or high in fiber and other nutrients but contributes more than "low" amounts of sodium, added sugars, or saturated fat;
- Understand that the product, like all products, could fit into a healthy dietary pattern to a greater or lesser extent as recommended by the DGA or MyPlate;
- Intend to limit consumption of the item (either frequency or amount);
- Expect to change their likelihood of purchasing/consuming the item altogether, or would expect to change their purchase frequency or consumption amount/frequency;
- Are more or less likely to flip the package over to read the Nutrition Facts panel after viewing the FOPNL schemes; and
- Better understand the information in the Nutrition Facts panel after viewing the FOPNL schemes.

It is particularly important to understand this information for products that are identified in a FOPNL scheme as having one or more nutrients as "high in" or "medium in" or uses the colors red or yellow; or is identified as not having significant amounts of positive nutrients.

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[10] See https://www.pewresearch.org/internet/fact-sheet/internet-broadband/.

g. The survey should be designed in a way that seeks to understand purchasing behavior.

As discussed above, there are significant limitations to "intent to purchase" research. To optimize the utility of the information collection, FMI recommends that the study include a simulated grocery store shopping experience as part of the research to understand purchasing behavior and what impacts purchase decisions. For example, the survey could include a mock set of digital shelves accompanied by discrete choice questions that help understand purchase intent and purchasing behavior changes. While this would not perfectly replicate actual consumer behavior, we suspect it would mirror it more closely than research designed to merely measure consumers' stated intentions.

h. FDA should identify key metrics for success on label effectiveness prior to conducting the study.

In drafting the study protocol, FDA should identify the key metrics for success on FOPNL scheme effectiveness. FDA should also identify how product perception, label perception, and purchase or choice questions will be represented to the respondents.

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We greatly appreciate the opportunity to comment on the procedural notice on the planned quantitative consumer research on FOPNL schemes. We would welcome the opportunity to partner with FDA particularly on development of mock labels for the research, but also to dialogue on the agency's thinking on FOPNL approaches. We look forward to continuing to work collaboratively on this important topic.

Sincerely,

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