*Via Regulations.gov*

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

July 15, 2025

**Re: Docket No. FDA-2024-N-2910 for "Food Labeling: Front-of-Package Nutrition Information"**

To Whom It May Concern:

The undersigned organizations are members of the Food and Beverage Issue Alliance (FBIA), a coalition of food and beverage trade associations. We appreciate the opportunity to provide comments on the U.S. Food and Drug Administration (FDA or "the agency") proposed rule entitled "Food Labeling: Front-of-Package Nutrition Information."[1]

FBIA supports FDA's commitment to providing consumers with the information needed to make informed food choices. As an overarching comment, however, and as discussed in many of the undersigned organizations' prior comments, FDA has not adequately addressed its underlying statutory authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) to implement *mandatory* front-of-package nutrition labeling (FOPNL). Whereas the FFDCA grants express authority to FDA to mandate a *comprehensive* set of factual nutrition information including each of the elements dictated by Congress, the statute does not specifically grant the agency the authority to mandate a *selection* of nutrients to appear on food packages, nor any scheme requiring *interpretive* nutrition information (particularly given that the statute deems nutrient content claims such as "high" and "low" to be voluntary rather than mandatory information). Under the Supreme Court's 2024 decision in *Loper Bright*,[2] courts will not interpret silence in the underlying statute as a grant of rulemaking authority to the agency. In the event Congress were to provide the agency with express authority to implement FOPNL on a mandatory basis, we believe there are opportunities to improve upon FDA's proposed rule to ensure that any mandatory FOPNL scheme will be fact-based, practical, and effective. Moreover, any scheme must be evaluated under the First Amendment to ensure it passes constitutional muster.[3] We provide our comments below.

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[1] 90 Fed. Reg. 5426 (January 16, 2025).

[2] *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

[3] Specifically, because the proposed rule would require food manufacturers to add interpretive, government-mandated nutritional messages on the front of food packages, it could be found to be unconstitutional compelled commercial speech under the First Amendment. Applicable case law provides that, if FDA cannot demonstrate that the compelled speech is (1) purely factual and uncontroversial; (2) reasonably related to a substantial government interest; and (3) neither unjustified nor unduly burdensome, then the rule will be subject to intermediate scrutiny and found unconstitutional unless the agency shows the regulation "directly advances" a "substantial" government interest and is "not more extensive than is necessary to serve that interest." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). An interpretive FOP

### *1. FDA should ensure that any FOPNL scheme aligns with current FDA regulations.*

FDA should ensure that any FOPNL scheme aligns with current FDA labeling regulations and policies. Ensuring that any FOPNL scheme fits well within FDA's current regulatory framework and promotes consistency in labeling is essential for effectuating the purpose of FDA's proposed rule. Any mandatory FOPNL should work in concert with other FDA regulations to avoid consumer confusion and ensure that the scheme indeed helps consumers easily identify healthier foods and make healthier choices. To this end, and as discussed in the next section of our comments, there is an important opportunity for FDA to build upon existing voluntary industry schemes, which have been designed to align with current FDA regulations. Such an approach would help drive uniformity in labeling, and consumer understanding. With the importance of consistency in mind, we have the following comments:

- **Calories should be included in any FOPNL scheme.** Calories should be included in any FOPNL scheme. Such an approach is consistent with FDA's broader approach to nutrition labeling and its focus on caloric content as an essential piece of information for building a healthful, balanced diet and for putting into context the other nutrient information provided on the front-of-package. For example, one of the key changes FDA made as part of its final rule on the revision of Nutrition and Supplement Facts Panels in 2016 was to increase the prominence of the term "calories" on Nutrition Facts Panels (NFPs).[4] This was by design, as the public health community, FDA, and industry alike agree on the importance of calories. Including calories as part of a mandatory FOPNL scheme would also align well with FDA's vending machine calorie labeling requirements, which, at the direction of Congress, require calorie information – to the exclusion of all other nutrients – to be disclosed at the point of purchase.[5] FDA continues to prioritize the role of nutrition in affecting the risks of obesity and overweight, and the agency's own research has identified calories as "the most useful single piece of information in relation to managing weight."[6]

- **FDA should reconsider its focus on only three nutrients in the proposed rule.** Relatedly, we believe the agency should reconsider its approach to FOPNL in the proposed rule that focuses exclusively on only three nutrients: saturated fat, sodium, and added sugars. The focus on only three nutrients is inconsistent with current U.S. dietary guidance because it is too narrow to provide the consumer with the information needed for informed food choices and could lead to consumer confusion. The Dietary Guidelines for Americans (DGA) takes a holistic approach to dietary guidance, with an emphasis on both nutrients to limit and nutrients of public health concern (calcium,

scheme of the type under consideration, particularly when focusing in isolation on three nutrients only, could risk being considered controversial information.

[4] 81 Fed. Reg. 33742 (May 27, 2016).

[5] 21 CFR § 101.8(c).

[6] Food and Drug Administration, *Calories Count: Report of the Working Group on Obesity* (2004).

potassium, dietary fiber, and vitamin D) to promote balanced, nutrient-dense diets.[7] The proposed rule's focus on only three nutrients to limit could lead to confusing results for consumers that are not in line with the DGA. For example, FDA's proposed scheme could suggest to consumers that they should avoid certain foods and beverages that are nutrient-dense, provide important recommended food groups, and are encouraged by dietary guidance, but that may have higher levels of saturated fat, added sugars, and/or sodium.

- **Products with insignificant amounts of the nutrients to limit should not be labeled as "low" in the FOPNL scheme.** Requiring a "Low" interpretive marker for products that contain insignificant amounts of the nutrients to limit – i.e., amounts that may be declared in the NFP as "0" – would be wholly inconsistent with current FDA regulations, which specifically define "low" and "zero" as conveying different messages to consumers.[8] Under FDA's proposed rule, a product's NFP could declare 0 g and 0% DV added sugars and the label could bear a "no added sugar" nutrient content claim, but the FOPNL would indicate the product is "low" in added sugars. This would result in consumer confusion and we ask the agency to reconcile this inconsistency.

- **FDA should conduct additional research to understand how "medium" would be understood by consumers.** Although "high" and "low" are defined terms in FDA's nutrient content claim regulations,[9] "medium" is a new term not currently used in the regulations. It is unclear how a "medium" designation would be understood by consumers and how it would fit into FDA's well-established nutrient content claim framework. We note that the term "medium" is not used to advise consumers on dietary choices and there is reason to think information on nutrients present at "medium" levels would not be helpful to consumers in creating a healthy dietary pattern, and worse, could create confusion. We would support additional research and consideration on this issue.

- **FDA should ensure that any interpretive terms included in any FOPNL scheme are defined consistently with other FDA frameworks.** In order to align with existing regulations and to ensure the nutrition information provided to consumers is not confusing, FDA should ensure that any mandatory FOPNL scheme uses terminology and definitions that are consistent with the agency's broader labeling framework. For example, the proposed rule would require that interpretive markers, including "high" and "low," be applied based on the product's serving size. This approach is inconsistent with FDA's nutrient content claim regulations, which already establish legal definitions for

[7] U.S. Department of Agriculture and Department of Health and Human Services, *Dietary Guidelines for Americans, 2020-2025* (December 2020), available at: https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.
[8] *See generally,* 21 CFR Part 101 Subpart D.
[9] *Id*.

"high" and "low" claims on a per-RACC basis.[10] This inconsistency means that some products that currently qualify as low in a nutrient, such as low sodium, could be identified as medium for purposes of FOPNL. And some products that do not qualify as "low" in a nutrient, will be identified as low for purposes of FOPNL. Specifically, foods with small RACCs must evaluated on a "per 50 gram" basis for "low" nutrient content claims, and therefore could be identified as "low" in the FOPNL scheme but would not qualify for a "low" nutrient content claim. We recognize that FDA has endeavored to address the inconsistency by requiring that to bear a "low" nutrient content claim the food must also bear a "low" interpretive marker in the FOPNL scheme. However, a number of inconsistencies remain, including the discrepancy in the per RACC vs. per serving approach for "high" claims, as well as inconsistencies in how the terms are applied to different foods. This issue illustrates one of the challenges with an interpretive approach, and this challenge can be avoided with strictly factual schemes.

- **Use of interpretive descriptions in FOPNL could misalign with other nutrient content claims.** In certain cases, the use of the interpretive descriptions "high," "medium," and "low" could misalign with a consumer's understanding of a product's nutritional profile due to the use of other authorized nutrient content claims on the label. For example, FDA regulations permit meal products to bear "healthy" claims when, in relevant part, the product contains no more than 30% DV of sodium per labeled serving.[11] This approach makes sense because meal products have larger serving sizes and comprise a significant percentage of a daily diet. However, under FDA's proposed rule, a meal product that contains between 20-30% DV sodium and bears the authorized claim "healthy" would bear FOPNL designating the product is "high" in sodium. In this case, the product could be labeled as "healthy" in compliance with FDA requirements but the FOPNL information would be confusing for consumers, who would be unsure how to consider the product as part of a healthful dietary pattern. Accordingly, we urge FDA to take a more nuanced approach to FOPNL, taking into account differing serving sizes and contributions to the overall diet, to ensure that any scheme is fully aligned with existing requirements.

- **We support the flexibility in the proposed rule for small packages.** We are supportive of FDA's exemption in the proposed rule for FOPNL on small packages that have a total surface area available to bear labeling of less than 12 square inches. This approach aligns well with existing regulations, which exempt such packages from Nutrition Facts labeling.[12]

[10] *See, e.g.,* 21 CFR 101.13(p).
[11] 21 CFR § 101.65(d)(3)(v).
[12] 21 CFR § 101.9(j)(13)(i).

2. ***FDA did not adequately consider alternatives, including schemes with which consumers are already familiar, like Facts Up Front.***

FDA's proposed rule did not adequately consider FOPNL schemes that have already been widely implemented in the marketplace and with which consumers are already familiar, such as the Facts Up Front (FUF) program as well as others such as Clear on Calories for beverages.[13] Since 2011, FDA has exercised enforcement discretion with respect to certain nutrition labeling regulations in order to facilitate the voluntary FUF nutrition keys program, which has since been widely adopted by the food industry. The FUF nutrition keys, which include four basic icons displaying information on calories, saturated fat, sodium, and sugars per serving, are familiar to consumers after over a decade of use on grocery shelves. Importantly, the FUF program was developed to complement the information in the Nutrition Facts panel, and also is fully consistent with FDA's nutrient content claim framework by avoiding interpretive terms. Indeed, in its 2011 letter of enforcement discretion, the agency characterized FUF as a "positive effort to provide consumers more ready access to information about the nutrient content of packaged foods" and stated that FUF, "if widely adopted by the food industry in a uniform manner, may contribute to FDA's public health goals by fostering awareness of the nutrient content of foods in the marketplace and assisting consumers in making quick, informed, and healthy food choices."[14] However, FDA's experimental study on FOPNL schemes did not include FUF as one of the schemes tested.[15] Instead, FDA tested eight newly-developed FOPNL schemes (one of which incorporated attributes of FUF but importantly did not include calories or voluntary nutrients to encourage).[16] The experimental study is therefore limited in its usefulness because it was not designed to assess consumers' pre-existing understanding of voluntary FOPNL schemes already in use.

Additionally, the experimental study did not test schemes with calorie information, nor did it fully assess consumer understanding of "high," "medium," and "low" interpretive markers or the effectiveness of alternative FOPNL placement options (i.e., on the bottom one-third of the PDP). The "medium" interpretive marker in particular is a new concept in nutrition labeling, and there is insufficient evidence as to how consumers interpret the marker, and therefore whether it will indeed help consumers identify healthier foods. These are crucial details that must be fully fleshed out before FDA implements any mandatory FOPNL scheme. Other alternatives not fully considered include voluntary schemes, consumer education efforts, and use of QR codes, to name just a few.

Accordingly, there is an opportunity for FDA to conduct additional research into consumer understanding of Facts Up Front, and to more fully consider alternatives that would be less costly

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[13] *See* U.S. Food & Drug Administration, *Letter of Enforcement Discretion to GMA/FMI re "Facts Up Front"* (Dec, 13, 2001), available at: https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/letter-enforcement-discretion-gmafmi-re-facts-front.

[14] *Id*.

[15] U.S. Food & Drug Administration, *Quantitative Research on Front of Package Labeling on Packaged Foods (OMB No. 0910-0920)* (May 2024), available at: https://www.fda.gov/media/185007/download?attachment.

[16] Although the experimental study report concludes that consumers were less likely to correctly identify product healthfulness when using the scheme resembling FUF when compared to some other schemes, the report also states that consumers "reacted positively" to this scheme when compared to other options. *Id*.

and burdensome to implement, so that the agency has the information necessary to implement a FOPNL scheme that is well-understood and effective.

***3. FDA should provide additional flexibility on FOPNL placement.***

The undersigned organizations strongly support additional flexibility on FOPNL placement requirements. The proposed rule would require FOPNL to appear in the upper third of the principal display panel (PDP). FDA stated in the proposed rule that the agency reviewed consumer research studies showing that FOPNL is most effective when placed in the upper left or right of the PDP.[17] However, the agency only tested one FOPNL scheme that appeared in the lower portion of the PDP when conducting its experimental study.[18] Indeed, the experimental study report stated that this is a limitation of the research.[19] Additionally, consumers are accustomed to seeing FOPNL in the lower portion of the PDP under the Facts Up Front scheme, which is the same location where consumers typically find other mandatory information like the net quantity of contents and the statement of identity. Moreover, mandatory placement in the upper third of the PDP would pose significant design challenges for manufacturers, as the upper third of the PDP is traditionally reserved for logos and other key brand imagery. We therefore would encourage the agency to conduct additional research on FOPNL placement or provide greater flexibility for manufacturers to place the information in other areas of the PDP. Additionally, we would encourage the agency to consider the way in which any changes to the proposed mandatory elements of FOPNL, such as the addition of calories, could increase the footprint of FOPNL, which would prove further challenging for industry. Indeed, this is one of the benefits of existing voluntary FOPNL schemes, which use a horizontal presentation such that additional nutrients do not occupy significant added space on the label.

With respect to the proposed aggregate FOPNL panels for variety packs, we ask the agency to consider alternative approaches that will be easier for consumers to understand and that take up less label space, such as a single box. The proposal to include a separate "Nutrition Info" box for each variety would be impractical, particularly considering that variety packs can contain between 2 and 10 different varieties, which would result in a significant proportion of the label being occupied by the FOPNL schemes; while consumers are unlikely to be able to quickly digest so much information.

***4. FDA should allow for an additional year for compliance.***

The proposed rule sets a compliance date of 3 years for businesses with $10 million or more in annual food sales and 4 years for businesses with less than $10 million in annual food sales. We would support an additional year for each of these compliance periods (i.e., 4 years for businesses with $10 million or more in annual food sales and 5 years for businesses with less than $10 million in annual food sales), to account for the significant design changes that would be required under the

[17] 90 Fed. Reg. 5426, 5446 (January 16, 2025).
[18] U.S. Food & Drug Administration, *Quantitative Research on Front of Package Labeling on Packaged Foods (OMB No. 0910-0920)* (May 2024), available at: https://www.fda.gov/media/185007/download?attachment.
[19] *Id*. at 19 ("Two limitations of the study were that it tested only eight scheme versions and only one of the eight schemes in the lower right corner of the mock products – all other tested schemes were in the upper right corner.").

rule. These design changes would need to be implemented across entire portfolios, which are resource- and time-intensive processes.

5. ***FDA must adequately consider whether the benefits of the proposed rule outweigh the costs.***

Finally, FDA must fully evaluate whether the benefits of the proposed rule would outweigh the costs imposed. Although the experimental study was designed to test consumer understanding of various schemes, there is insufficient evidence supporting that the proposed scheme would result in longer-term consumer behavioral changes or widespread product reformulations resulting in healthier dietary patterns. For example, the stated purpose of the proposed rule is to "provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet."[20] However, the results of the experimental study still reported consumer confusion when viewing products with "middle" nutrient profiles, a category of foods that could potentially be broad, and did not assess whether consumers actually change their behavior based on this information.[21] Indeed, the agency does not cite changes in consumer behavior as a potential benefit of the rule, which is particularly illuminating. Indeed, the current body of published literature demonstrates the limited effectiveness of FOPNL in impacting consumer behavior, and we believe the agency has missed an important opportunity to fully evaluate the implications of this and incorporate these findings into its consideration of potential regulatory approaches and alternatives. Nor did the agency fully consider whether implementation of FUF, which is already widely adopted across the industry, could accomplish its consumer education goals in a less burdensome manner.

We note that evaluating changes in health outcomes following previous FDA rulemaking to require nutrition information could be instructive. For example, in a 2025 retrospective evaluation of FDA's 1993 final nutrition labeling rule, Policy Navigation Group found that the rule did not cause reduced intakes of calories, saturated fats, and cholesterol, and that the costs of the rule were as large, "if not larger," than FDA's estimated health benefits. In light of this, it is critical that FDA ensure it has adequately assessed the costs of the rule against its potential benefits.

As discussed above, the proposed rule would result in substantial costs to the industry, as entire portfolios would require label redesigns. FDA should ensure that the costs of this undertaking are outweighed by expected improvements in consumer education and health. We would therefore support additional research and evaluation of alternatives to ensure that any mandatory FOPNL scheme is well-tailored to its goal of enabling consumers to easily identify how foods can be part of a healthy diet in a way that does not result in disproportionate costs to the food industry and, critically, is expected to result in improvements in consumer health.

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[20] 90 Fed. Reg. 5426, 5427 (January 16, 2025).
[21] *Id* at 18-19.

In conclusion, FBIA thanks FDA for the opportunity to comment. Please do not hesitate to contact our organizations if we can provide further information in support of these comments.

Sincerely,

American Bakers Association
American Frozen Food Institute
Corn Refiners Association
Council for Responsible Nutrition
FMI – The Food Industry Association
Independent Bakers Association
International Food Additives Council
National Automatic Merchandising Association
National Fisheries Institute
National Pasta Association
National Seasoning Manufacturers Association
North American Millers' Association
Refrigerated Foods Association
SNAC International
Soy Nutrition Institute Global