July 15, 2025

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

Re: Food Labeling: Front-of-Package Nutrition Information, A Proposed Rule by the Food and Drug Administration (Docket No. FDA-2024-N-2910)

Dear Dockets Management Staff:

The undersigned respectfully submit the following comments on the U.S. Food and Drug Administration's (FDA's) proposed rule to require front-of-package nutrition labels (FOPNL) on foods. We are a group of non-government organizations, public health advocates, and academics with extensive expertise and experience in nutrition science and policy who have collaborated to prepare this comment.

Providing and contextualizing basic nutrition information on the front of food packages improves the ability of consumers to make informed decisions in the marketplace. Seventeen countries around the world have already mandated FOPNL systems, and real-world evidence shows the potential of FOPNL to improve the nutritional quality of food purchases and spur industry reformulation.

In this comment, we convey the following feedback regarding FDA's proposed rule:

1. We strongly support the FDA's proposal for the U.S. to adopt a mandatory, interpretive FOPNL system that solely highlights key nutrients to limit.
    a. There is a clear need for FOPNL in the U.S. to address high rates of chronic disease.
    b. We support the FOPNL system being mandatory.
    c. We support the FOPNL system being interpretive.
    d. We support the FOPNL system only including key nutrients to limit and excluding positive nutrients.

2. We encourage FDA to consider the vast body of evidence showing "high in" labels are effective, and modifying the proposed FOPNL design to reflect that evidence.

3. FDA's FOPNL system should apply to foods marketed for infants and toddlers in addition to foods marketed for individuals aged 4 years and older.

4. FDA should mandate prominent disclosures on the front of products containing low-/no-calorie sweeteners (LNCS) to discourage industry reformulation with additives that are not recommended for children.

5. FDA should develop a consumer education campaign to accompany the release of the FOPNL system.

Our comments are as follows:

1. **We strongly support the U.S. adopting a mandatory, interpretive front-of-package nutrition labeling system that solely highlights key nutrients to limit.**

    a. **There is a clear need for FOPNL in the U.S. to address high rates of chronic disease.**

Diet and nutrition have a significant impact on health. Poor nutrition has contributed to the rise in U.S. obesity rates and the prevalences of heart disease, type 2 diabetes, cancer, stroke, and other chronic conditions. Nearly half of U.S. adults (47 percent) have high blood pressure, a major risk factor for heart disease and stroke, over half of U.S. adults have diabetes (14 percent) or prediabetes (46 percent), and 42 percent of U.S. adults have obesity.[1] The prevalence of diet-related chronic conditions among children and adolescents is also high.[2] The good news is that diet quality is a modifiable risk factor and improving diet and nutrition can reduce the burden of chronic disease and improve health.

Consumers want to buy healthy foods, but labels do not always make it easy for consumers to identify healthy choices and comply with dietary guidance. Nutrition Facts labels are important tools for helping people select healthy foods and limiting less healthy foods, and they display a % Daily Value (DV) that is meant to convey how a particular food can fit into the total daily diet. However, only 40% of U.S. adults report consistently using the Nutrition Facts label when deciding to buy a food product (*i.e.,* always or most of the time as opposed to sometimes, rarely, or never)[3] and regular use of the Nutrition Facts label varies across the U.S. population, with lower use among men, those with lower education levels, those with lower incomes, and those with limited English proficiency.[4,5,6] Furthermore, only 63 percent of adults understand how to interpret the % Daily Value and only 57 percent know how to tell when a food is "High" in a nutrient, with lower rates among those with less education.[7]

Additional nutrition labeling that is interpretive, prominently displayed on the front of food packaging, and provides a more accessible description of certain information contained in the Nutrition Facts label can empower consumers to make healthier choices. Dozens of countries have implemented FOPNL, and over one hundred experimental and real-world studies have tested the effects of different FOPNL systems.[8,9,10,11] These studies find that well-designed interpretive FOPNL can significantly improve the healthfulness of foods selected by consumers and prompt product reformulation. The U.S. should learn from experiences abroad and follow the science to select a system with optimal potential to promote equitable access to information, improve diets, promote reformulation, and advance public health.

    b. **We support the FOPNL system being mandatory.**

Mandatory labeling policies are more effective than voluntary policies, which tend to have inconsistent uptake by food manufacturers. For example, Australia adopted a voluntary FOPNL policy in June 2014. Five years later, the voluntary Health Star Rating label appeared on less than half of eligible products (41%).[12] France adopted a voluntary Nutri-Score label in 2017, and the label only appeared on brands accounting for 50 percent of sales volume in 2020.[13] Endorsement logos (i.e., labels that endorse a particular food as healthy) such as the Scandinavian Keyhole and Choices logo have also faced low uptake by industry, leading the World Health Organization Regional Office for Europe to recommend that countries implementing FOPNL "explore ways to overcome issues with uptake of the FOPL system in the marketplace, including through mandatory implementation."[14]

FOPNL is inherently less useful when inconsistently applied across the food supply. When voluntary FOPNL is missing from some products, consumers cannot be certain of the reason behind the absence of a label, and thus cannot use the FOPNL information to compare products and guide their decisions.

Furthermore, when front-of-package summary rating systems are voluntary, companies may selectively apply labels to products that will look more appealing with the label. In Australia, products displaying the voluntary Health Star Rating label had a significantly higher average rating compared to products not displaying the label (3.4 stars versus 2.6 stars, $p<0.001$).[15] In France, 73 percent of products from national brands using a voluntary Nutri-Score label had Nutri-Score ratings of A or B (as opposed to C, D, or E) compared with only 37 percent of products from retailer brands.[16] Given the critical goal of addressing overconsumption of sodium, added sugars, and saturated fat in the United States, FOPNL should not appear on only the healthiest foods.

c. We support the FOPNL system being interpretive.

The FDA's 2023 food labeling literature review and focus group findings showed that interpretive labels (e.g., those that indicate when foods are "high" in added sugar, sodium, and/or saturated fat) are helpful for consumers, because they provide context for how consumers should interpret the numbers on the Nutrition Facts panel in the context of a total daily diet.[17,18] This finding is consistent with a multi-year review by the National Academy of Medicine (formerly the Institute of Medicine), which recommended the adoption of interpretive FOPNL and concluded: "an approach that provides nutrition information only and is not interpretive would have limited success in encouraging healthier consumer food choices and purchase decisions."[19] Non-interpretive labels that exclusively use numbers and text require greater nutritional knowledge, English proficiency, literacy, and numeracy skills to interpret and are infrequently used by consumers. As previously described, only 40% of U.S. adults report consistently using the Nutrition Facts panel when deciding to buy a food product, and individuals with lower levels of educational attainment, income, or English proficiency are even less likely to regularly use the labels.[20] All that a non-interpretive label would accomplish would be to repeat some of the same information that is already available on the Nutrition Facts Panel.

Studies also show that interpretive FOPNL systems are more effective than non-interpretive systems like Facts Up Front, an industry-developed voluntary label that repeats information from the Nutrition Facts label on the front of package without any additional interpretive signals. Facts Up Front-style labels—including the Guideline Daily Amounts label that FDA tested in its experimental study—have significantly weaker effects on consumer knowledge, including the ability to identify products that are more healthful, compared to nutrient warnings or traffic light labels.[21,22,23,24,25] And studies of Facts Up Front-style labels show they have no effect on consumer behavior.[26,27,28,29]

d. We support the FOPNL system only including key nutrients to limit and excluding positive nutrients.

We support FDA in its assertion that saturated fat, sodium, and added sugars should be the only nutrients highlighted in the FOPNL system, because the Dietary Guidelines for Americans recommends limiting foods and beverages higher in saturated fat, sodium, and added sugars as a key strategy for building healthy dietary patterns. When consumed in excess, these nutrients can increase risk for chronic diseases like heart disease, type 2 diabetes, and cancer. For example, saturated fat increases LDL or "bad" cholesterol, a major cause of atherosclerosis and cardiovascular disease.[30] Excess sodium consumption has been linked to high blood pressure, which leads to increased risk for coronary heart

disease, stroke, heart failure, and kidney failure.[31] Added sugars are a major source of excess calories and are associated with greater overall calorie intake and higher body weight, [32] which can contribute to increased risk of type 2 diabetes,[33,34,35] cardiovascular disease,[36,37,38] and many types of cancer.[39] Added sugars are also linked to several metabolic abnormalities.[40] Unfortunately, most people in the U.S. exceed the recommended intake limits for all three of these nutrients.[41] U.S. adults consume 40 percent more sodium, 40 percent more added sugars, and 40 percent more saturated fat per day than the Dietary Guidelines for Americans recommend,[42,43] in significant part because the U.S. packaged food supply is far too high in these harmful nutrients.

We also agree with FDA that FOPNL should not include information about beneficial "nutrients to get enough of" (e.g., dietary fiber, vitamin D, calcium, iron, and potassium). FDA's focus groups found that participants were confused about how to interpret FOPNL schemes that included both nutrients to limit and nutrients to get enough of.[44] Additionally, food companies already use the front of food packages to convey positive information about their products—such as nutrient-content claims (e.g., "good source of Vitamin D")—with the ultimate goal of convincing consumers to purchase them. Food companies will continue to pursue this practice voluntarily; there is no need to make this mandatory. Conversely, requiring food companies to highlight information they may prefer not to directly communicate to consumers on the front of the package (saturated fat, sodium, and added sugar content) is a transparent way to provide consumers with more complete information about the products they are purchasing while maintaining a level playing field for industry.

2. We encourage FDA to consider the vast body of evidence showing "high in" labels are effective, and modifying the proposed FOPNL design to reflect that evidence.

There is a large body of experimental and real-world evidence demonstrating that "High In"-style labels, which appear solely on products that are high in nutrients of concern and are already mandated in nine countries in the Americas,[45] can improve the nutritional quality of selected/purchased foods.[46,47] There is also evidence that High In labeling systems can encourage industry to reformulate products to be healthier, in part to avoid having to label their products.[48] A 2025 modeling study estimated that "High In"-style FOPNL would prevent between 96,926 and 137,261 deaths from diet-related chronic disease in the United States.[49]

FDA's proposed "Nutrition Info" design, which would appear on nearly all products regardless of their nutrient content and notify consumers whether products are high, medium, or low in nutrients of concern, is less studied. It may also decrease industry's incentive to reformulate to provide healthier products, because reformulation would not allow them to avoid labeling their products at all. Additionally, FDA's Nutrition Info box system could have the unintended consequence of making unhealthy foods that are only high in one nutrient of concern—like sugar-sweetened beverages and candy—appear healthier than they actually are, because their labels will display only one "high" nutrient with two "low" nutrients instead of just the "high-in" label for added sugar. FDA's quantitative study notably did not test any Nutrition Info labels that had this type of mixed label, in which at least one nutrient was "high" and at least one nutrient was "low."[50]

To avoid confusion and maximize efficacy, FDA should consider shifting to the more straightforward, evidence-based "High In" labeling system, or, less desirably, making design changes to the Nutrition Info box to more clearly highlight "High In" products for consumers. This could be accomplished, for example, by adding a prominent exclamation mark icon to any Nutrition Info label that contains "high" levels of at least one nutrient of concern, and drawing attention to any "high" designations with a red background

and white text to ensure consumers notice it. We recognize that FDA's experimental study found that the inclusion of the magnifying glass icon did not meaningfully affect U.S. consumers' attention to or use of the Nutrition Info box,[51] and that FDA therefore chose not to include an icon in its proposed label. However, a recent experimental study suggests that exclamation mark icons are significantly more effective than magnifying glass icons at improving consumers' perceived message effectiveness of FDA-style "High In" labels.[52] Another recent experimental study found that "Nutrition Info" labels drawing attention to "high" designations with the color red were significantly more effective at promoting correct identification of healthiest and least healthy options compared to black-and-white-only "Nutrition Info" labels.[53] However, in this study, participants who viewed high sodium and high added sugar items (beef jerky, candy, and soda) with "Nutrition Info" labels perceived them as being significantly healthier compared with participants who viewed the same products with "High In" labels. A modified version of FDA's "High In" label, where each nutrient was separated into a separate black box, also outperformed "Nutrition Info" labels at encouraging healthier hypothetical purchases in a shopping task and enabling quicker label assessments, leading to the conclusion that the modified "High In" label should be prioritized for mandatory FOPNL.

3. FDA's FOPNL system should apply to foods marketed for infants and toddlers in addition to foods marketed for individuals aged 4 years and older.

We disagree with the exclusion of foods marketed for children under 4 years old from FDA's proposal. In the proposal, FDA notes that the Daily Reference Values (DRVs) for children 1 through 3 years codified at 21 CFR 101.9(c)(9) are currently not aligned with the 2020-2025 DGA. These should be updated, and FDA should require FOPNL on products marketed for children ages 1 to 3 years based on the DRVs for children 1 through 3 years and resultant %DVs that are required on the Nutrition Facts labels of such foods. FDA should apply the same %DV cutoffs for determining when a food is high in (or high, medium, and low in) added sugars, sodium, and saturated fat as apply for foods marketed for individuals aged 4 years and older.

Requiring FOPNL on foods for children ages 1-3 is important because many products marketed as being healthy for young children are high in nutrients that need to be limited. For example, nutrition and public health organizations and experts across the United States have raised concerns over potentially misleading marketing of "toddler milks," which can contain high amounts of added sugars,[54,55,56,57] despite the 2020-2025 DGA recommendation that children aged 2-3 years consume less than 25 grams of added sugar per day (and children under 2 avoid added sugars entirely).[58]

If FDA is unable to quickly update the DRVs and DVs for children aged 1 to 3, rather than delay the release of the final rule, the Agency could expand the rule at a later date to include products marketed to this population.

4. FDA should mandate prominent disclosures on the front of products containing low-/no-calorie sweeteners (LNCS) to discourage industry reformulation with additives that are not recommended for children.

Mandatory FOPNL is likely to have the unintended consequence of increasing industry's use of LNCS across the food supply as food companies reformulate products that are "high" in added sugars. For example, following Chile's FOPNL implementation, the percentage of products containing LNCS in certain categories (including beverages, dairy-based beverages, yogurts, and desserts and ice creams) increased.[59] Furthermore, purchases of LNCS-containing products and LNCS consumption increased,

including among children.[60,,61] LNCS are not recommended for young children by leading nutrition and public health organizations because long-term health effects associated with consumption in childhood are still unknown, and it has been suggested that early exposure to LNCS may predispose children to prefer higher levels of sweetness in the diet and unfavorably influence their future dietary patterns.[62,63,64,65,66,67] Research has shown that many U.S. parents try to avoid purchasing products sweetened with LNCS for their children, but are largely unsuccessful due to confusing product labels.[68,69] In one simulated shopping study in a supermarket, parents indicated that they avoided LNCS for their children, but they failed to identify the majority (77%) of the foods and beverages that contained LNCS, and roughly one quarter of the foods and beverages they selected for their family contained LNCS.[70] Similarly, the majority of parents in another study (62%) could not identify beverages with LNCS, even when shown the ingredients lists.[71]

To prevent excess intake of LNCS among children as an unintended consequence of FOPNL, FDA should mandate clear disclosures for products that contain LNCS that explicitly state that they are not recommended for children. For products requiring FOPNL related to added sugars, these disclosures should appear immediately adjacent to such labels. These disclosures could alleviate confusion and aid parents in selecting healthier products for their children.[72] Mexico did this as part of its FOPNL policy and saw a reduction in LNCS in several food categories after the policy's implementation.[73] FDA should determine the best pathway for mandating this disclosure—either as part of the FOPNL rule or as a separate rule.

5. FDA should develop a consumer education campaign to accompany the release of the FOPNL system.

To help consumers understand the new FOPNL system, FDA should develop a consumer education and outreach campaign. The campaign should explain how to use the new FOPNL system, how the new system will complement the existing Nutrition Facts label, and the importance of limiting saturated fat, sodium, and added sugars in the diet.

In conclusion, we strongly support the FDA's proposal for the U.S. to adopt a mandatory, interpretive front-of-package nutrition labeling system that solely highlights key nutrients to limit, but we urge FDA to improve this rule in several ways to ensure it will maximally improve health for the entire U.S. population. We urge federal agencies to act quickly on these recommendations to enable consumers to access the information they need to make healthy choices for themselves and their families.

Sincerely,

Academy of Nutrition and Dietetics
Advocates for Better Children's Diets
American Cancer Society Cancer Action Network
American College of Cardiology
American Heart Association
American Nutrition Association
American Public Health Association
Association of SNAP Nutrition Education Administrators
Association of State Public Health Nutritionists
Center for Science in the Public Interest

Consumer Federation of America
Consumer Reports
Hattie Mae and Pals Foundation
Healthy Food America
Interfaith Center on Corporate Responsibility
Interfaith Public Health Network
International Fresh Produce Association
Kids In Nutrition
National Association of Pediatric Nurse Practitioners
National League for Nursing
National WIC Association
Partnership for a Healthier America
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Note: The views expressed in this comment letter are those of its authors only. This letter is not submitted on behalf of The University of North Carolina at Chapel Hill.

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