Via regulations.gov

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

July 17, 2023

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, FDA Docket No. FDA-2023-N-0155 (June 15, 2023)

Dear Sir or Madam:

The Consumer Brands Association (Consumer Brands) champions the industry whose products Americans depend on every day, representing nearly 2,000 iconic brands. From household and personal care to food and beverage products, the consumer packaged goods industry plays a vital role in powering the U.S. economy, contributing $2 trillion to the U.S. GDP and supporting more than 20 million American jobs. We advocate for uniform regulatory frameworks based on current science and risk that promote choice and build consumer trust across the sectors we represent.

Consumer Brands appreciates the opportunity to provide comments to the U.S. Food and Drug Administration (FDA or agency) regarding the procedural notice entitled, *"Quantitative Research on Front of Package Labeling on Packaged Foods."* We recognize that the agency is exploring the establishment of a standardized, science-based front of package (FOP) labeling scheme to help consumers, particularly those with lower nutrition literacy, to quickly and easily identify foods that are part of a healthy eating pattern. We look forward to collaborating with the agency to reach our shared goal of empowering consumers through informative labeling and tailored education.

FDA should issue an ANPRM or RFI to follow the expected, measured regulatory process to gain important stakeholder feedback and avoid unnecessary consumer confusion.

Development of a FOP labeling system will be the most significant nutrition labeling initiative since Nutrition Label Reform (NLR) which began in 2003 with the first of four Advanced Notice of Proposed Rulemakings (ANPRMs), followed by two proposed rules in 2014, and two supplemental proposed rules in 2015. The final rule was issued in 2016. Consumer Brands is unclear as to why this same transparent, measured, and deliberative approach is not being applied to FOP labeling. We are concerned that the agency's regulatory agenda includes the potential for the issuance of a proposed rule by the end of this year (December 2023), without any prior opportunities for stakeholder feedback, such as through an ANPRM or Requests for Information (RFI), or public hearing or meeting.

In addition to not leveraging the same transparent and methodical processes the agency has used for other recent, significant labeling initiatives (e.g., use of the term "healthy," and NLR),

Consumer Brands notes that the agency has included important information and process updates in Paperwork Reduction Act (PRA) procedural notices, which are only designed to control paperwork burdens imposed by agencies on the public and ensure information collection activities are conducted in an efficient and economical manner. We are concerned that FDA has not yet engaged in more formalized and traditional administrative procedures to obtain broader stakeholder input as part of an anticipated rulemaking. Consumer Brands recommends that the agency issue an ANPRM or RFI to follow the expected, measured regulatory process to gain important stakeholder feedback and avoid unnecessary consumer confusion.

Consumer Brands respectfully requests that the following comments are shared with the Office of Nutrition and Food Labeling within the Center for Food Safety and Applied Nutrition as the agency proceeds with this initiative.

We request that FDA hold a public meeting to provide interested stakeholders with additional information about its research and an opportunity to provide feedback.

Consumer Brands 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 its plans to use those results to inform the structure of its upcoming quantitative study. We specifically request that FDA hold a public meeting to share the findings from last year's focus group testing of FOP schemes that are now being used to inform the methodology and conduct of the upcoming quantitative study. FDA should provide clarity on how the agency decided to test the schemes that are intended to be included within the quantitative study. FDA should also provide a status update on where the agency is in the FOP process to date and how FDA foresees FOP labeling intersecting with nutrient content claims, dietary guidance statements, the use of a future "healthy" symbol, and how these various nutrition-related rulemakings, guidances and policies build upon one another. We recommend the agency explain its plans for consumer education for any final FOP scheme it implements. The public meeting should also provide interested stakeholders with an opportunity to provide feedback on FOP labeling including sharing of consumer testing/insights.

We specifically request that FDA share the following information during a public meeting prior to moving forward with the quantitative study:

- Results of the focus groups conducted in 2022 that tested FOPNL concepts and draft FOPNL schemes;
- The makeup of the 2022 focus group participants and how they were selected;
- The survey questions[1] for the proposed quantitative research;
- The agency's basis for choosing certain FOP schemes to test and not others for the proposed quantitative research; and
- A review of the quantitative study protocol.

Consumer Brands also requests that FDA respond publicly, preferably on its website and during the public meeting, to the following questions about the proposed quantitative FOP research:

[1] We are aware that FDA has referenced Appendix E for the study questionnaire, but we have been unable to locate this document.

- What are the anticipated milestones and timeline for the agency's FOPNL activities leading up to proposing a selected scheme?
    - Will there be additional studies following the quantitative study?
    - Before moving forward with a proposed FOP scheme, will the agency provide opportunities for stakeholder input/comments, including activities such as public meetings, industry roundtables and/or an ANPRM in the Federal Register with an opportunity for public comment?
- How will the agency measure the effectiveness of any voluntary or mandatory FOPNL scheme for consumer purchase behavior change or even health outcomes?

In addition to carefully researching any proposed FOP labeling scheme, we urge the FDA to establish appropriate baselines and metrics for assessing the success of implementing the selected scheme, and share such research, baselines and metrics publicly before moving forward.

To avoid stakeholder confusion, all FOP schemes the agency is testing/considering should align with and be consistent with the agency's existing regulatory and claims framework.

Based on the consumer testing information and graphics that have been shared, it appears the agency is basing FOP labeling on a "per serving" basis, which aligns with the Nutrition Facts panel. However, nutrient content claims, including "low in" and "high in" are based on the Reference Amounts Customarily Consumed (RACC), creating a significant discrepancy in the agency's application of these terms, compared to how they are defined under FDA regulations.[2] As highlighted in the marketplace assessment,[3] there are many instances where there are considerable differences in the serving size and the RACC. With the recently expanded definition of a single serving container as one with less than two times the RACC, these differences can be significant. As an example 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 in the FOP scheme is impacted by variations in serving size. Importantly, based on only the three nutrients to limit (NTLs) included in FDA's proposed nutrition labeling schemes (added sugars, sodium, and saturated fat), white bread and 100% whole wheat 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.

[2] 21 CFR 101.13(p).

[3] Please see Appendix 1 for a marketplace assessment that illustrates how the product's assessment in the FOP scheme are impacted by variations in serving size.

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

Product	***Labeled Serving Size / Weight***	**Added Sugars/ Serving**	**Sodium / Serving**	**Saturated Fat / Serving**
White Bread	1 slice 26 g	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	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 making food purchasing decisions based on a comparison of the same food product across various slice or package sizes. For example, a 15 oz. can of soup is labeled as one serving, but the RACC is one cup. The results of using the entire can versus one cup as a serving size changes the sodium from medium to high; see the example below.

Product	**Product Weight**	**Added Sugars/Serving**	**Sodium/Serving**	**Saturated Fat/Serving**
"Healthy" Lentil Veg Soup	1 can, 425g serving	0% 0g	31% 720mg	5% 1g
"Healthy" Lentil Veg Soup (same recipe as above)	1 cup RACC	1% <1g	18% 410mg	3% 0.5

Under current nutrient content claim regulations, Main dish and Meal products have different nutrient thresholds than Individual Foods; however, the agency has not yet acknowledged this difference in the FOP schemes it will test with consumers. Without category-specific thresholds, a meal product labeled as healthy could show a "high in" sodium and a "medium" in saturated fat, which could result in consumer confusion and cause claims to lose credibility; see the example below.

Product	**Product Weight**	**Added Sugars/Serving**	**Sodium/Serving**	**Saturated Fat/Serving**
"Healthy" Meal	283 g serving	6% 3g	26% DV 590mg	13% 2.5g

As shown in the above examples, the framework being tested does not align with FDA's own existing claims framework. Applying nutrient content claims of "high", "medium" and "low" to serving size irrespective of food category or other nutrient content claims will lead to mixed messages and consumer confusion. To avoid consumer confusion and align with FDA's own

regulatory framework, the best practical solution is to avoid using nutrient content claim language in FOP labeling schemes. Instead, when testing different FOP approaches, Consumer Brands recommends that the agency test using language such as "get less of" and "get more of"[4] (if nutrients to encourage are included) in a monochromatic scheme, which the agency included in earlier testing.[5]

FDA should include both nutrients to encourage and nutrients to limit in any proposed FOP scheme.

Consumer Brands acknowledges the importance of providing consumers with comprehensive and transparent labeling information to guide informed purchasing decisions to further nutrient rich dietary patterns. Thus, we wish to bring awareness to the limitations among the schemes that FDA intends to test. Research has shown that schemes with only nutrients to limit do not provide consumers with a full understanding of a food's complete nutritional profile.[6] With the current schemes being tested, consumers only gain greater understanding of nutrients to limit, but remain unaware of which nutrients they should consume more of as part of their overall diet.

A study published in the *American Journal of Preventive Medicine*[7], which compared Facts Up Front (FUF)[8] and multiple traffic lights, determined that the most beneficial scheme to increase consumer understanding of nutritional content included both nutrients to limit and nutrients to encourage. The presence of nutrients to encourage in the study for the multiple traffic light schemes, namely fiber and protein, did not impede consumers' comprehension of information related to nutrients to limit on various nutrition quizzes, suggesting that displaying nutrients to encourage might help participants better judge other nutrient levels. Therefore, there is evidence to demonstrate the presence of nutrients to encourage on FOP labeling will not only increase consumers' complete understanding of nutritional information but will also not interfere with their comprehension of information related to nutrients to limit.

For example, the FDA proposed cereal box mock-up with a "middle" level of sodium and a "more healthy" level of fiber, calcium and vitamin D might be viewed as "less healthy" if FOPNL only includes negative nutrients when, in fact it is a "more healthy" choice overall. Therefore, the addition of nutrients to encourage can fill this knowledge gap without impeding consumers' comprehension of information related to nutrients to limit.

Consumers deserve a comprehensive understanding of the nutrients in their foods to better their understanding of which product might be a "less healthy, "middle" or "more healthy" choice. It is

---

[4] The recommendation to include language such as "get less of" and "get more of" mirrors language used in the Dietary Guidelines for Americans.

[5] See https://www.reginfo.gov/public/do/DownloadDocument?objectID=121242801

[6] Christina A. Roberto, Marie A. Bragg, Marlene B. Schwartz, et al. Facts Up Front Versus Traffic Light Food Labels. A Randomized Controlled Trial. *American Journal of Preventive Medicine*, 2012. https://doi.org/10.1016/j.amepre.2012.04.022

[7] Same as above.

[8] The FUF program is a widely adopted, voluntary industry initiative to communicate key nutrition information to consumers on the front of food packages that has been in the marketplace for more than a decade. The FUF program is intended to be educational, allowing consumers to easily understand and use key product information to make informed food choices for themselves and their families. Additionally, the FUF program was designed to be consistent with U.S. labeling regulations including FDA's Nutrition Facts label, serving size and nutrient content claim regulations and reflect the FDA's 2016 revision of the Nutrition and Supplement Facts label.

important to provide consumers with readily accessible information about positive nutrients that the Dietary Guidelines for Americans (DGA) has determined to be short-fall nutrients. The ability to place positive as well as negative nutrients in context incorporates this important goal shared by both the U.S. Department of Agriculture (USDA) and FDA.

Consumer Brands favors the use of monochromatic FOP schemes.

FDA intends to test both color and monochromatic (black and white) schemes to understand consumers' preferences and ability to easily identify foods that are part of a healthy dietary pattern. A study[9] commissioned by Health Canada utilizing eye tracking technology concluded that monochromatic schemes captured attention equally as well as colorful schemes when measured in the total number of seconds needed to process information and make a successful selection. Consumers took an average of 2.3 seconds to make a successful selection for the black and white magnifying glass scheme, 2.5 seconds for the black and white exclamation scheme, 2.8 seconds for the black and white "high in" scheme, and 2.8 seconds for the red "high in" scheme. These results were not statistically significant from each other (p-value = .6) and thus, there was no evidence that the use of color added any benefit to the FOP labeling schemes when compared to the black and white schemes. Additionally, the monochromatic schemes were equally effective at increasing consumers understanding of nutritional information when compared to the colorful scheme in real-world conditions. Research findings suggest that consumers find it difficult to use traffic lights and compare products when multiple colors are utilized on one product. Studies that assessed the impact of the traffic lights on consumer purchasing behavior suggest limited efficacy which could be due in part to the "health halo" effect created by the presence of the green color on foods that are not consistent with dietary guidance.

Consumer Brands members are concerned with how the use of a colorful scheme may clash with current packaging designs and artwork as well as invoke significant complication for graphic packaging supplier equipment that can only use a certain number of colors (e.g., cans manufacturing is 6 colors, and most cartons are 6-7 colors). This may force food manufacturers and packaging suppliers to undertake expensive package redesigns, without any consumer benefit when compared to a monochromatic scheme. As mentioned above, we do not anticipate the use of color will increase consumer understanding and attention to nutrition information in a real-world setting when compared to a monochromatic FOP scheme.

FDA should include calories in the FOP schemes tested and in any proposed FOP scheme.

Consumer Brands urges FDA to include calories in the FOP schemes to be tested. While FDA has stated that it is not testing any schemes that display calories because the revised Nutrition Facts panel (NFP) gives greater prominence to calories, we do not believe that providing additional nutrition information to ameliorate the "epidemic of diet-related chronic disease" – the stated goal of the research – can occur without including calories. FDA 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 prominently

[9] Mansfield, E. D., Ibanez, D., Chen, F., Chen, E., & de Grandpré, E. (2020). Efficacy of "high in" nutrient specific front of package labels—A retail experiment with canadians of varying health literacy levels. *Nutrients*, *12*(10), 3199. https://doi.org/10.3390/nu12103199.

on the front of pack. The information on calories provides a clearer picture of its contribution to the daily diet.

In the 2022 Food and Health Survey[10], 'calories' stand out as the most viewed information on the NFP followed by 'sodium,' 'total sugars,' and 'added sugars.' While FDA intends to test added sugars, sodium and saturated fats, we urge FDA to also include calories. Calories are an essential piece of information for consumers to ensure they have all the information they need to identify food choices quickly and easily as part of an overall healthy dietary pattern. Indeed, of all nutrients, calories were the *only* nutrient that Congress sought fit to require to be displayed at the point of purchase for both menu labeling and vending machine labeling.[11] It would be puzzling indeed if packaged foods were required to bear a wholly different set of nutrients, and not calories, in the most prominent location at the point of purchase.

Also of importance is that voluntary FOP schemes in use by industry today provide for "calories only" declarations on individual beverages, confectionery and small foods with limited packaging and labeling space.[12] Continuing to allow for calorie only FOP options where appropriate is of significant importance and should not be left out of FDA's consumer research.

Consumer Brands supports FDA testing a scheme that resembles FUF with an interpretive overlay.

Consumer Brands requests that FDA's quantitative research include the FUF[13] program and variations thereof given its widespread adoption on U.S. packages and existing consumer familiarity with the program and how to use it. Consumer Brands is concerned that FDA is only testing FOP schemes that are based on communicating negative nutritional attributes and excluding calories and positive nutritional attributes. We believe such limited FOP schemes will not accomplish the FDA's stated objectives of providing additional information that will allow consumers to quickly and easily identify foods that are part of a healthy dietary pattern.

As part of previous focus group testing, FDA tested several versions of a FUF-style scheme. However, we notice in FDA's current schemes to test, that the FUF-style scheme (referred to as the Guideline Daily Amount), is not interpretive (and as discussed above does not include calories or nutrients to encourage as FUF does). We understand some of the following FUF-style schemes were previously tested by FDA. Lacking visibility to results from FDA's 2022 focus groups testing, it is unclear how each of these schemes ranked in terms of consumer understanding. We encourage FDA to test the below FUF-style interpretive schemes in addition to those the agency has proposed. The simple interpretive schemes proposed below are more like the "Nutrition Information" and "High-In" schemes being tested. Without the inclusion of these FUF-style interpretive schemes, the study is flawed because it provides no comparison of GDA interpretive to the other interpretive schemes.

---

[10] International Food Information Council. 2022 Food & Health Survey. 18 May 2022. https://foodinsight.org/2022-food-and-health-survey/

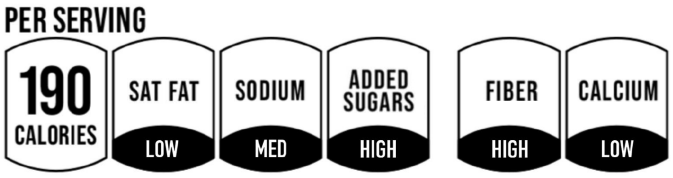
[11] FDA should ensure any proposed FOP scheme is in line with the current vending machine calorie requirements on front-of pack (21 CFR 101.8). The industry worked to implement the new requirements around type size by July 2021.

[12] Additionally, Consumer Brands urges FDA to carefully consider FOP scheme sizing requirements for various package sizes particularly as it relates to small packaging.

[13] As the owner of the FUF intellectual property, Consumer Brands encourages FDA to freely utilize the FUF graphics in their quantitative testing.

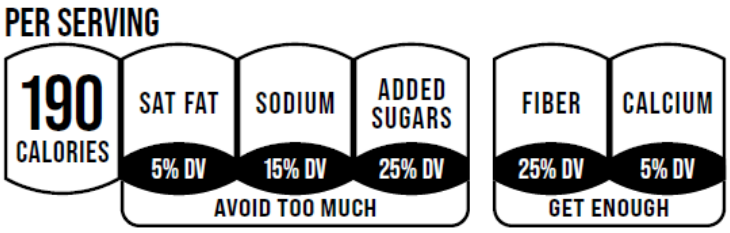
As indicated earlier in our comment, we are concerned with the discrepancy wherein the agency is basing the FOP schemes on a "per serving" basis while nutrient content claims, including "low in" and "high in," are based on the RACC. The discrepancy in RACC-based nutrient content claims versus "per serving" FOPNL needs to be reconciled. However, for the purposes of this test, the following schemes should be included in the quantitative test.

Calories and Interpretive Element



Get Less Of/Get More Of

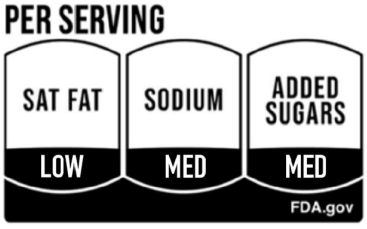
As stated earlier, avoiding the use of nutrient content claim language in FOP labeling schemes would reduce stakeholder confusion. FDA could test schemes that use language such as "Get Less Of" and "Get More Of" to replace "Avoid Too Much" and "Get Enough" as this aligns more closely with language used in the DGAs.



E1

The following reflects what FDA has suggested it is testing but includes an interpretive element. While we are suggesting this as a label to test, we continue to view calories and nutrients to encourage as critical elements of any labeling scheme.

No Calories and an Interpretive Element



FDA should consider testing FOP schemes that do not contain the "FDA.gov" text.

Finally, we note that the "FDA.gov" reference that is included in all of the schemes to be tested could cause consumer confusion considering there are both USDA and FDA-regulated products side by side on grocery store shelves. As an example, a frozen macaroni and cheese would be regulated by FDA and contain a FOP scheme, while next to that product could be a frozen buffalo chicken macaroni and cheese that is regulated by the USDA. The latter would not include an "FDA.gov" FOP scheme, but it would have the USDA seal on the front. Consumers are not likely to understand the differences in jurisdiction and why such similar products would contain different symbols. We also do not expect that FDA could accurately assess how consumers view the "FDA.gov" notation if the agency does not test a control (i.e., no reference to FDA or USDA) or other similar options that reference the FOP scheme as being government-developed (e.g., a reference to MyPlate or some other government source). As such, FDA could consider testing FOP schemes that do not contain the "FDA.gov" text.

FDA should be mindful of potential legal challenges to interpretive FOP labeling schemes.

As stated in previous comments[14] to the agency, Consumer Brands recommends that FDA carefully assess whether Congress has given the agency the legal authority to enact a mandatory, interpretive FOP labeling scheme. There is no express authority for such a requirement in the Federal Food, Drug, and Cosmetic Act (FFDCA) and such a requirement would impose burdens of clear First Amendment significance.

Section 403(q) of the FFDCA sets out the full scope of the agency's mandatory nutrition labeling authority, and the structure and history of the Nutrition Labeling and Education Act (NLEA) reinforce the limited scope of the agency's authority. When it passed NLEA, Congress could have directed the agency to require nutrition labeling in broad terms and left the details to the agency's judgment. It did not. It authorized the agency to require a highly specific, *complete set* of information consisting of serving size, 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 on all labels. Section 403(q)(1)(A-E).

Nothing elsewhere in Section 403 or in the history of the NLEA directly or indirectly supports the view that FDA is authorized to require a second set of nutrition information on all food labels consisting of a smaller subset of nutrients, with or without interpretive cues. The language immediately following the grant of authority to require the complete set of nutrients reinforces this point. It gives FDA authority to "require any information required to be placed on the label by this subparagraph . . . to be highlighted on the label . . . by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices." Section 403(q)(1). Thus, FDA has authority to use a limited set of tools – type size, bolding, and color in the full NFP – to emphasize some elements of the required set of nutrition information over others. If Congress had wanted to give FDA the authority to take steps beyond these to emphasize some subset of the complete set of required nutrients over others it could have done so by adding that authority to this enumerated list or through another provision. It did not.

---

[14] See Consumer Brands and FMI Joint Comments to FDA Docket No. FDA-2022-P-1832, Appendix A, https://www.regulations.gov/docket/FDA-2022-P-1832.

Arguments that authority for mandatory FOPNL can be found in the FDA's authority under the NLEA to promulgate regulations that "require the required [nutrition] information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet" similarly fall short.[15] First, the cited language clearly relates to FDA's authority to mandate comprehensive nutrition information that includes *all* mandatory nutrients. Second, the language directs FDA to require that the authorized mandatory nutrition information be conveyed in a manner that enables consumers to understand "its relative significance in the context of a total daily diet." Selecting portions of the complete set of required information carefully chosen by Congress and requiring that they be presented separately, apart from the rest of the required information, is directly at odds with the goal of enhancing consumers' ability to evaluate relative significance. Without the complete set of required nutrients, the consumer does not have the context of the full daily diet necessary to understand or appreciate relative significance.

In short, FDA cannot rely on the mandatory nutrition labeling portions of the FFDCA to support additional mandatory FOP labeling requirements. And while we agree that FDA has authority to prohibit misleading labeling, there is no evidence to suggest that food labels across the board are categorically misleading in the absence of FOP labeling.

Even if FDA were able to identify statutory authority to create a mandatory, nutrient-specific, interpretive FOP labeling scheme, there would also be constitutional hurdles. 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 purely factual, non-misleading, and necessary to *avoid consumer deception*.

The First Amendment "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.,* 547 U.S. 47, 61 (2006). When the Government "compels individuals to speak a particular message," that compulsion "alters the content of their speech." *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018) (cleaned up). That is no less true in the commercial arena. As the Supreme Court has repeatedly instructed, speaker- and content-based speech mandates that target certain types of speakers or certain types of messages "are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests." *Reed v. Town of Gilbert, Ariz.*, 135 S. Ct. 2218, 2226 (2015); *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011) ("heightened judicial scrutiny is warranted" for laws imposing "a specific, content-based burden on protected expression.").

Even if the proposed rule were deemed to be subject to the standard announced in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), that standard applies only to "purely factual and uncontroversial information." 471 U.S. at 626. Disclosures that are "one-sided or incomplete," *Am. Meat Inst*. v. US Dep't of Agric. 760 F.3d 18, 27 (D.C. Cir. 2014) (en banc), as well as those that "might be misinterpreted by consumers" even if not "patently false," *R.J. Reynolds*, 696 F.3d 1205 at 1216–17, do not fall within *Zauderer*'s scope. *See CTIA-Wireless Ass'n v. City & Cty. of San Francisco, Cal.*, 494 F. App'x 752, 753–754 (9th Cir. 2012)

---

[15]/ 21 U.S.C. §343 note.

(affirming conclusion that compelled disclosure advising how to "reduce exposure to radiofrequency energy emissions" when using cellphones, without evidence that normal levels of "radiofrequency energy exposure" causes harm, fell outside *Zauderer*'s scope when it could be "interpreted by consumers" as suggesting "that using cell phones is dangerous").

For these reasons, any mandatory, nutrient-specific, interpretive FOP labeling scheme would be vulnerable to a constitutional challenge.

Both on statutory and constitutional grounds, it is highly unlikely that the array of interpretive labeling schemes the FDA appears to be considering would survive judicial review. As noted above, the only potentially relevant statutory authority available to FDA would be its ability to restrict misleading labeling—and the First Amendment similarly limits FDA's powers when affecting speech in a manner unnecessary to combat consumer deception. Accordingly, FDA certainly should not be considering FOP schemes which are *themselves* likely to be misleading or deceptive in many circumstances, because this is the exact opposite of what the agency is authorized to do.

Unfortunately, all of the interpretive systems currently being considered are likely to be misleading and deceptive, particularly because none of them consider positive nutrients or food group contributions. Additionally, they purport to help address chronic disease risk while not including calories, the single most important nutrient to consider when addressing obesity. While Consumer Brands is supportive of dietary patterns that provide consumers with nutrients, the interpretive system here has the effect of assigning lower rankings to more nutrient dense foods. In the case of salads, canned vegetables and fruits, these food groups provide vitamins, minerals, and fiber while skim milk provides protein, vitamins and calcium. To cite an example, a product like maple syrup (which would get top marks for "healthiness" under these schemes, getting all "greens"/"lows" under these systems) would outperform salads, canned vegetables and fruits, and even skim milk (all of which would get one or more "yellows" or "reds"). Hard candies (which would bear one "red"/"high" designation) would typically appear comparably "healthy" to reduced-sodium soups under these labeling schemes, and they would also look as if they were significantly "healthier" than many whole grain cereals and low-fat chocolate milks. FDA would be hard-pressed to establish that these results are necessary to avoid consumer deception. Indeed, these results may themselves mislead consumers.

Moreover, the interpretive schemes FDA is testing are particularly vulnerable to challenge because they are not purely factual and uncontroversial. The decision to select only these three nutrients, to the exclusion of other information like calories or positive elements that is widely acknowledged to play an important role in diet and nutrition as well as chronic disease risk reduction, is indeed controversial. And calling a food "high in," "medium in," or "low in" nutrients, when that conflicts with FDA's own nutrient content claim definitions (which are based on the reference amount and not the labeled serving size), is also controversial.

The misleading and confusing results that would result from characterizing foods as the schemes to be tested would do, also raise serious questions as to whether the schemes could meet the First Amendment's requirement that the scheme must be reasonably related to a legitimate government interest. When the schemes do not help consumers to distinguish between more or less healthful foods, and in many cases assign rankings that could lead consumers to believe they should consume more of certain less "healthful" foods and less of certain more "healthful foods, serious questions are raised as to how the schemes could reasonably relate to the government interest of helping people to identify healthful foods more easily. Even if such a

system could help people to identify healthful foods more easily, there are significant questions as to whether there is any scientific evidence that it would result in the types of *sustained and meaningful* behavioral changes, as opposed to simply short-term changes, that would be needed to reduce the rates of chronic disease, one of the interests FDA has cited in this work.

These sorts of concerning results are an inherent problem with interpretive systems of the type FDA is considering, and this is a key reason why the FUF program has stuck to facts and avoided potentially misleading interpretive schemes like those FDA is considering. Legally and constitutionally, FDA has the power to restrict misleading labeling, but it quite clearly lacks the power to compel speech of the type under consideration here.

* * *

Consumer Brands believes a coordinated, strategic approach to establishing nutrition policies is crucial to achieving the federal government's goals of reducing diet-related chronic diseases and empowering consumers to make healthier choices more easily. Importantly, we believe all nutrition policy should be grounded in the most current recommendations of the DGAs and that robust engagement with stakeholders is a must. Consumer Brands strongly encourages the FDA to prioritize transparency in its evaluation and development of a FOP labeling scheme and establish more open engagement with stakeholders on its anticipated regulatory activities. We also reiterate that the agency should convene a public meeting to share and gather feedback on its FOP research activities and establish proper administrative procedures to ensure the public can effectively inform the development of any potential FOP rulemaking.

Consumer Brands thanks FDA for the opportunity to submit comments on this important issue, and we look forward to continued dialogue with the agency on this topic. Please do not hesitate to contact us to provide further information in support of our comments.

Sincerely,

Sarah Brandmeier

Sarah Brandmeier
Director, Regulatory & Technical Affairs
Consumer Brands Association

Appendix 1
Consumer Brands Association FOP Marketplace Assessment

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**	**Potential positive nutrient**
White Bread	1 slice 26 g	2%DV 1g	5%DV 120mg	0%DV 0g	None
100% Whole Wheat Bread	1 slice 26 g	2%DV 1g	5%DV 110mg	0%DV 0g	None
100% Whole Wheat Bread	1 slice 43 g	6%DV 3g	5%DV 110mg	0%DV 0g	Fiber - 14% DV
Hearty White	1 slice 49g	8%DV 4g	10%DV 230mg	0%DV 0g	Iron - 10% DV
2% milk	1 cup 236 mL	0%DV 0g	5%DV 125mg	15%DV 3g	Potassium - 10% DV, Protein, 17% DV, Calcium - 30% DV, Vitamin D - 25% DV
Skim milk	1 cup 240mL	0% DV 0g	6% DV 130mg	0% DV 0g	Protein – 18%DV, calcium – 25% DV, Vit D – 10% DV,
Whole milk	1 cup 236 mL	0%DV 0g	5%DV 125mg	25%DV 5g	Protein - 16% DV, Calcium - 25% DV, Vitamin D - 10% DV
Low-fat Chocolate Milk	1 cup 236 mL	28%DV 14g	10%DV 220mg	8%DV 1.5g	Protein - 8g, Potassium - 10% DV, Calcium - 20% DV, Vitamin D - 10% DV
Frozen French Fries	12 Fries 84 g	2%DV 1g	13%DV 290mg	4%DV 1g	None
Chopped Salad Kit Sesame Asian	1 cup 100 g	8%DV 4g	13%DV 290g	5%DV 1g	30% DV Vit. C
Canned Sweet Peas, Drained	1/2 cup 125 g	2%DV 1g	11%DV 250mg	0%DV 0g	16% DV fiber
Dark Red Kidney Beans	1/2 cup 130 g	4%DV 2g	12%DV 270mg	0%DV 0g	19% DV fiber
Canned Peaches in Heavy Syrup - Drained	1/2 cup 128 g	28%DV 14g	0%DV 5g	0%DV 0g	none
Canned Peaches in 100% Juice - Drained	1/3 cup 82 g	8%DV 4g	0%DV 0g	0%DV 0g	None
Fruity-flavored Candy	27 pieces 28g	42%DV 21g	0%DV 5mg	5%DV 1g	None
Reduced Sodium Chicken Noodle Soup	1 cup 240 g	0%DV 0g	20%DV 470mg	3%DV 0.5g	25% DV potassium

Product	***Labeled Serving Size/ Weight***	**Added Sugar / Serving**	**Sodium / Serving**	**Saturated Fat / Serving**	**Potential positive nutrient**
Traditional Chicken Noodle Soup	1 cup 242 g	0%DV 0g	30%DV 680mg	4%DV 1g	15% DV potassium
Oats and Honey Granola	1/2 cup 53 g	24%DV 12g	0%DV 0g	3%DV 0.5g	11% DV fiber
Fruity Cereal	1 1/3 cup 39 g	24%DV 12g	9%DV 210mg	3%DV 0.5g	25% DV iron
Plain Oat Cereal	1 ½ cups 39g	4% DV 2g	8% DV 190mg	3% DV 0.5g	14% DV fiber
Maple Syrup	4 Tbsp 60 mL	0% DV 0g	0%DV 7mg	0%DV 0g	None

From a consumer perspective, it is difficult, if not impossible to discern what would truly be the better nutritional choice, based only on the "low, medium, high" (per serving) descriptors of the NTLs. The following key insights come to light:

- The FOPs for white bread and 100% whole wheat bread appear to be the same, or nearly the same, especially if viewed across the entire grocery aisle of breads, which will have a vast array of serving sizes (ranging from roughly 25g to 55g per slice/serving). How will consumers choose which is the "better" choice?
- Maple syrup, white bread (26g slice), and 100% whole wheat bread (26g slide) appear to score "best" with "low in/green" values for all 3 NTLs, yet these foods vary widely in their nutrient density.
- All fat levels of milk have at least 1 "medium in/yellow" or "high in/red" NTL compared to maple syrup which are "green/low in" for all NTLs.
- Whole milk has 1 "high in/red" NTL, yet milk, including whole milk, is one of the most nutrient dense choices a consumer can make.
- Low fat chocolate milk has 2 "medium in/yellow" and 1 "high in/red" NTL, yet a serving of chocolate milk contains a serving of dairy and significant amounts of protein, calcium, potassium and vitamin D.
- Both reduced sodium and "regular" chicken noodle soup are "high in/red" for sodium, making the "better" choice unclear.
- Most foods have at least one "medium in/yellow" or "high in/red" NTL, with many foods having a combination of more than one; the better nutritional choice is hard to discern.

How should consumers decide which food is the "better" choice, when faced with this confusing array of information? Is one food with a "medium" amount of sodium better than another food with a "medium" amount of saturated fat? Including at least 1 nutrient to encourage would provide consumers with an additional datapoint to help them consider the total contribution of a food, balance the "negatives," and decide which is the better nutritional choice for them.

Additionally, and as noted elsewhere in these comments, results would be different for many foods if thresholds were applied per RACC vs. per serving. Finally, an additional source of consumer confusion could arise if a food meets a nutrient content claim per RACC but not per serving.