U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

July 15, 2025

VIA ELECTRONIC SUBMISSION

Martin A. Makary, MD, MPH
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: Food Labeling: Front-of-Package Nutrition Information (Docket No. FDA–2024–N–2910)

Dear Commissioner Makary:

On January 16, 2025, the U.S. Food and Drug Administration (FDA) published a proposed rule titled, *Food Labeling: Front-of-Package Nutrition Information*.[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule. The FDA complied with the Regulatory Flexibility Act (RFA) by drafting a preliminary initial regulatory flexibility analysis (IRFA). However, the document reflected the agency's intention to certify that the regulation will not have a significant impact on a substantial number of small entities in the final rule. The FDA justified this conclusion because the rule's projected costs would not exceed three percent of regulated small entities' annual revenue (FDA's measure of regulatory significance under the RFA).[2]

Stakeholders covered by the rule told Advocacy that the costs necessary to comply with the regulation will exceed the FDA's cost and revenue estimates, and therefore the assumptions contained in the agency's IRFA are inaccurate. This letter is meant to encourage the FDA not to certify the final rule, to more thoroughly assess the small business impacts and analyze regulatory alternatives associated with this regulation, and consider withdrawing the rule.

I. The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA) that seeks to ensure small business concerns are heard in the

[1] 90 Fed. Reg. 5426 (Jan. 16, 2025).
[2] U.S. FOOD & DRUG ADMIN., FOOD LABELING: FRONT-OF-PACKAGE NUTRITION INFORMATION: PRELIMINARY REGULATORY IMPACT ANALYSIS, INITIAL REGULATORY FLEXIBILITY ANALYSIS, INITIAL UNFUNDED MANDATES REFORM ACT ANALYSIS 51, https://www.fda.gov/media/185202/download?attachment (last accessed June 30, 2025).

federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.[4] If a rule is not expected to have a significant economic impact on a substantial number of small entities, agencies may certify it as such and submit a statement of the factual basis to Advocacy for such a determination that adequately supports its certification.[5]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[6] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the Federal Register, unless the agency certifies that the public interest is not served by doing so.[7]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[8]

II. The Proposed Rule

The FDA's objective with this rule is to reduce the burden of diet-related chronic diseases in the U.S. by prioritizing nutrition initiatives that can help improve dietary patterns in the country.[9] The proposed rule would require that most foods that must display a nutrition facts label to also bear a front of package (FOP) nutrition information box on the principal display panel of the food item.

The nutrition information box (Nutrition Info Box) would detail and interpret the relative amount of certain nutrients (i.e., saturated fat, sodium, and added sugars) in a serving of the food item. The regulation details how to determine the interpretive descriptions (i.e., "Low," "Med," and "High") of such nutrients for the Nutrition Info Box. It would also amend the nutrient content claim definitions for "low sodium" and "low saturated fat" to align with updated nutrition standards and to avoid within label inconsistencies.[10] The FDA suggests that the proposed rule would provide consumers, including those who have lower nutrition knowledge, with

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[3] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).
[4] 5 U.S.C. § 603.
[5] *Id.* § 605(b).
[6] Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).
[7] *Id.*
[8] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[9] 90 Fed. Reg. 5429.
[10] *Id.* at 5,427.

interpretive nutrition information that can help consumers quickly and easily identify how the food product can be part of a healthy diet.[11]

The FDA quantified costs to the packaged food industry for updating labeling to meet the proposed requirements. Annualized costs from relabeling would range from $66 million to $154 million over 10 years at a 2 percent discount rate, with a primary estimate of $105 million per year. The FDA also quantified the costs of reformulation, as the rule may result in some food manufacturers reformulating some food products. The FDA estimated that the annualized costs of reformulation over 10 years would range from $125 million to $377 million at a 2 percent discount rate, with a primary estimate of $227 million. Combined, the FDA estimated the annualized costs of the proposed rule over 10 years would range from $191 to $530 million at a two percent discount rate, with a primary estimate of $333 million.[12]

According to the FDA, the present value of costs over 10 years range from $1.7 billion to $4.9 billion at a two percent discount rate, with a primary estimate of $3.1 billion. On a per entity basis, the total discounted present value cost of the proposed rule per entity (including large firms) is approximately $100,253 ($3.049 billion / 30,413 establishments).[13] Additionally, the FDA estimated that the rule would impose $143 million in total one-time capital costs to complete information collection requirements under the Paperwork Reduction Act.

III. The FDA's Compliance with Section 603 of the RFA

The FDA determined that this rule would have a cost impact on the food and beverage manufacturing industries, comprised of large and small businesses, which would be required to update labeling to meet the proposed regulation's requirements. Pursuant to Section 603 of the RFA, if an agency determines that a rule will have a significant impact on a substantial number of small entities, it must prepare an IRFA.[14] The IRFA is designed to refine a rule's cost assumptions by specifically analyzing its impact on small businesses.

Advocacy acknowledges that the FDA appropriately prepared an IRFA in compliance with the RFA.[15] The IRFA provided the number of small entities likely to be impacted by this regulation broken out by North American Industry Classification System (NAICS).[16] The FDA analyzed the number of small businesses covered under this rule by identifying establishments in three classifications: Food Manufacturing (NAICS 311), Soft Drink Manufacturing (NAICS 31211) and Bottled Water Manufacturing (NAICS 312112). According to the FDA's analysis, the 2021 U.S. Census Bureau Statistics of U.S. Businesses (SUSB) data indicate that there are a total of 30,413 establishments within these manufacturing sectors, and Food Manufacturing (NAICS

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[11] *Id*.
[12] *Id.* at 5,428.
[13] U.S. FOOD & DRUG ADMIN., *supra* note 2, at 52.
[14] 5 U.S.C. §603.
[15] U.S. FOOD & DRUG ADMIN., *supra* note 2.
[16] *See* U.S. Census Bureau, *2021 SUSB Annual Data Tables by Establishment Industry* (Dec. 2023), https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html (choose U.S. & States, 6-digit NAICS); U.S. FOOD & DRUG ADMIN., *supra* note 2 at 51-52 tbl.20.

311) comprises 97 percent of these establishments.[17] The FDA concluded that, "Of these establishments, we estimate that at least 86 percent of these establishments qualify as a small business."[18]

Next, the FDA sought to identify the rule's compliance impacts as a function of annual revenue receipts and Universal Product Codes (UPC) owned by covered small businesses. The FDA noted substantial variability in the average annual receipts per establishment based on size category. Because of this variability, the FDA estimated the average annual receipts per small business establishment in NAICS 311 to be $9.1 million.

The FDA also provided costs for mandatory labeling as well as for product reformulation, "a cost some manufacturers may voluntarily choose to incur to avoid selling products labeled 'High' or 'Med' sources of saturated fat, sodium, or added sugars."[19] The FDA estimated that mandatory labeling and voluntary reformulation costs incurred due to the proposed rule would cost roughly $1,030 annually per UPC, or less than one percent of a manufacturer's estimated annual receipts. The FDA stated, "If firms choose not to reformulate, total costs annually per UPC are just $326 because voluntary reformulation makes up about 68 percent of total costs."[20]

In its IRFA the FDA stated, "We cannot estimate the exact cost per small entity because we do not know how many UPCs on average are owned by small entities as defined using the SBA definition. This number likely significantly overstates the cost per small entity, because the share of firms that are small businesses is typically large, and the share of sales controlled by small firms is typically small. This is evident from the above tables. On the other hand, brands owned by small entities may have relatively low sales and thus are not represented fully in our data."[21] Although the FDA did not provide a complete small entity compliance cost estimate in the IRFA, it sought public comment on these assumptions and conclusions.

Given the rule's projected costs, the FDA indicated that it intends to certify in the final rule that this regulation will not have a significant impact on a substantial number of small entities, [22] stating "We estimate that the annual economic impact of this proposed rule is less than three percent of annual revenue."[23]

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[17] *See* U.S. Census Bureau, *supra* note 16.
[18] U.S. FOOD & DRUG ADMIN., *supra* note 2, at 51.
[19] *Id.* at 53.
[20] *Id*.
[21] *Id.*
[22] *Id*.
[23] The United States Department of Health and Human Services has adopted default numerical thresholds for "significant economic impact" and "substantial number." More specifically, "significant economic impact" is defined as an economic impact exceeding 3 percent of annual revenue (receipts) and "substantial number" is defined as 5 percent or more of the affected small entities within an identified industry.

IV. The FDA's RFA certification is improper

A. Stakeholders suggest that the regulation's costs have been underestimated.

Given the uncertainty associated with determining the per small entity cost of this regulation, the FDA cannot certify that this rule will not have a significant impact on a substantial number of small entities under the RFA. Without an accurate assessment, the FDA is unable to determine whether the costs amount to more or less than three percent of covered small entities' revenue, which defines the FDA's measure of significance under the RFA.[24] Advocacy's position is reinforced by small stakeholders who expressed to Advocacy that the FDA's cost assumptions were underestimated, and the rule should not have been certified.

Advocacy met with food industry representatives to receive their feedback on the estimated regulatory costs associated with this regulation. While the stakeholders are supportive of advancing public health goals, they believe that the FDA has underestimated the costs of compliance for FOP labeling, especially considering that an alternative labeling approach already exists.

In 2011, the Food Industry Association (FMI) and the Consumer Brands Association (CBA) created a voluntary label system for the food and beverage industry called Facts Up Front (FUF). Those groups suggested to Advocacy that the FUF system, which is located on the front of the package, addresses the needs of consumers as it highlights calories, saturated fat, sodium, and added sugars per serving size. They maintain that hundreds of thousands of products already carry FUF nutritional information that is useful to the consumer and significantly aligns with the FDA's regulatory framework. Adopting the FUF standard as an alternative would minimize the need and associated costs for some of the labeling requirements contained in this rule.

The rule estimates 322,000 products would undergo FOP labeling changes.[25] Based on their experience with the Canadian FOP labeling requirements, stakeholders reported that they anticipate that the costs necessary to implement the FDA's rule will be $4,000-$8,000 per label. They suggest that the higher end of the cost range will apply where there is a need to update photography and graphics due to the size of the Nutrition Info Box and depending upon the packaging material type. The FDA estimated labeling and reformulation costs at $1,030 per UPC,[26] significantly less than the costs estimated by FMI's members.

The FDA also estimates that covered entities would reformulate approximately 2,000 UPCs, which is only 0.5 percent of all covered UPCs. Further, the agency estimates the cost of reformulating a single formula at $1 million.[27] The FDA has potentially underestimated the number of reformulations likely caused by the rule. The FDA's estimate of the number of reformulations is based on the number of products with nutrient levels within one percent of

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[24] The 3 percent significance threshold is not set nor upheld by Advocacy but is of FDA's own design.
[25] U.S. FOOD & DRUG ADMIN., *supra* note 2, at 22.
[26] *Id*. at 53.
[27] *Id*. at 20.

FDA cutoffs. Products beyond that range are also likely to reformulate, especially if the FDA thinks customers will change their purchasing behavior in response to the labels, which is a central premise of the agency's regulatory endeavor. Additionally, the FDA assumes that dessert manufacturers will make no reformulations, which is unlikely given the rule is designed to prompt changes to food with similar low nutritional value.

Stakeholders also reported additional cost considerations they face when relabeling packages. These include:

- Modifying graphic design, which may include using an outside design service. Many small businesses do not have in-house designers and may be last in the queue for these design services.
- Updating printing plates for labels, possibly out of cycle.
- Unused packaging if there is no sell through provision in the rule.
- Internal company compliance resources to evaluate their product portfolio and appropriately apply the Nutritional Info Box to every individual product.

B. Additional small business data exists that would allow the FDA to better assess the number of small businesses affected by this regulation.

The IRFA did not use available information from SUSB to its fullest extent, as it includes granular data that would allow the FDA to compare its cost estimates to the revenues of the smallest regulated firms. The smallest level of detail SUSB provides is for firms with between one and five employees. It is crucial for FDA to analyze the regulation's impact on this very small cohort because they are most likely to be severely affected by the high upfront costs of the rule. Furthermore, by limiting the small business analysis at 500 employees, the FDA has not properly accounted for all small businesses impacted by the proposed rule. The FDA only assessed impacts on small businesses with fewer than 500 employees. However, based on SBA size standards in an industry with extremely large entities, small businesses in all but one of the impacted industries can have more than 500 employees and still be considered "small." This artificial constraint imposed by FDA's methodology inappropriately excludes some of the small businesses that will face the highest costs. Lastly, the FDA should use the number of firms rather than the number of establishments in its analysis, as larger firms tend to own multiple facilities. Advocacy estimates that 96 percent of all firms impacted by the rule are small businesses rather than the 86 percent figure reported by the FDA.

The FDA should review the rule's impacts using each separate 6-digit NAICS within the Food Manufacturing subsector, rather than looking at the subsector as whole. This is important for two reasons:

1. Not all firms within the subsector are in scope of the rule. Dog and Cat Food Manufacturing (NAICS 311111) and Other Animal Food Manufacturing (NAICS 311119) were incorrectly included in FDA's analysis but are out of scope of this rule.

2. Different industries have different average receipt sizes. For example, using 2017 SUSB data, the industry with the lowest receipts per firm with less than 5 employees is Retail Bakeries (NAICS 311811), with $190,330 receipts per firm. This is just 27 percent the receipts of other impacted firms with less than five employees ($709,293). This particular subset of small firms is most at risk of being significantly impacted by this regulation, but this is obfuscated by grouping them with firms from other industries.

Advocacy encourages the FDA to use industry specific estimates of costs rather than using aggregate numbers. In the rule's Regulatory Impact Analysis (RIA), the FDA notes that different product classes have different numbers of UPCs and expected reformulation costs. This will lead to variability in costs across industries that should also be considered in the IRFA. The FDA should conduct outreach to inform its analysis on the number of UPCs used by small food and beverage manufacturers so it can provide an estimate of small entity compliance costs. The FDA has conducted a significant amount of research on this issue and Advocacy believes that reasonable estimates of small entity costs are obtainable through outreach and existing information. Notably, when the FDA prepares its FRFA, it should update its analysis to use the 2022 SUSB, which was released since this proposed rule was published in the Federal Register.

Based on Advocacy's calculations, 20 percent of small businesses would see a cost impact of at least three percent of receipts if they were subject to the average level of costs which exceeds the Department of Health and Human Services numerical thresholds for a "significant economic impact on a substantial number of small firms under the RFA.

V. The FDA should have considered additional alternatives in the proposed rule that were suggested by stakeholders.

Section 603(c) of the RFA requires agencies to describe any significant alternatives to the proposed rule which accomplishes the stated objectives of applicable statutes, and which minimize any significant economic impact of the proposed rule on small entities. In the proposed rule's IRFA, the FDA presented one alternative which extended the compliance period by one year.[28] This alternative was not adopted. Small business representatives suggest that other alternatives exist that could result in lowering the compliance costs of the regulation.

- In 2023, the FDA published an agency collection of information notice designed to garner industry comments on its plan to conduct additional studies on possible front of package labeling schemes.[29] CBA and FMI filed comments on the notice in March and July 2023, noting their disappointment that the FDA did not consider a scheme like the FUF program. Those groups told Advocacy that they continue to believe that the FUF program is a viable way to achieve FDA's goal of providing consumers with nutrition information that can help them quickly and easily identify how foods can be part of a

[28] The rule proposes that firms earning less than $10 million in annual food sales, which covers approximately 95 percent of all food manufacturers and 48 percent of all food UPCs, have a 4-year compliance period, while firms with $10 million in sales or more per year have a 3-year compliance period.
[29] 88 Fed. Reg. 5005 (Jan. 26, 2023).

healthy diet, while minimizing packaging and reformulation costs on the food industry. The FDA should have discussed and analyzed this suggested alternative in the IRFA.

- Advocacy also discussed this rule with representatives of small and independent craft brewers from the Brewers Association (BA). Over 99 percent of the breweries in the U.S. are small.[30] They noted that most of their products fall under Department of the Treasury's Alcohol and Tabacco Tax and Trade Bureau (TTB). However, two categories of alcohol beverage produced by their members are outside of TTB's Federal Alcohol Administration Act (FAA) jurisdiction and fall under the primary labeling jurisdiction of the FDA.[31] These are: (a) fermented grain products made without malted barley or without hops, a category that includes most "hard seltzer" products; and (b) wines containing less than 7 percent alcohol by volume (ABV), a category that includes most "hard cider" products.

  The BA believes that given the split jurisdiction between most alcohol beverage products and the relatively small subset of alcohol beverages subject to the FDA's primary labeling jurisdiction, requiring FOP labeling on products like hard seltzers and hard ciders would impose significant costs on brewers and would only serve to confuse the public about the nature of these products. The BA estimates that roughly 25 percent of craft breweries produce either hard seltzer and/or hard cider. They believe hard seltzer-type products represent the bulk of affected beverages produced by small breweries. This means that more than 2,400 small brewers are potentially impacted directly by the FOP labeling rule. Accordingly, the BA believes that the FDA should create an exemption of alcohol beverages from a final FOP labeling mandate.

  Should the FDA decide not to provide for the requested exemption, the BA believes the agency should not require FOP labeling on kegs. Kegs are generally sold for immediate consumption and the FOP labeling rule exempts restaurants and other sales of food for immediate consumption at the place of purchase.

The FDA should analyze alternatives requested by small businesses in the final rule as they may result in reducing unintended consequences of the regulation and eliminating the costs of compliance for entities that should not be covered by the rule. The FDA has a broader set of alternatives available for them to consider beyond changing compliance timetables. The FDA should consider the exemption of food manufacturers such as very small or young businesses with low revenues and volumes. Also, the FDA should give small entities the flexibility to provide nutrition information to their customers in other ways while still maintaining the rule's public health goals.

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[30] *See* U.S. Census Bureau, *supra* note 16.

[31] For an explanation of the interaction of the FAA Act and the Federal Food, Drug, & Cosmetic Act when it comes to beer products, see DEP'T OF THE TREAS., ALCOHOL & TOBACCO TAX & TRADE BUREAU, TTB RULING NO. 2008-3: CLASSIFICATION OF BREWED PRODUCTS AS "BEER" UNDER THE INTERNAL REVENUE CODE OF 1986 AND AS "MALT BEVERAGES" UNDER THE FEDERAL ALCOHOL ADMINISTRATION ACT (July 7, 2008), https://www.ttb.gov/media/72026/download?inline.

VI. Conclusion

Advocacy believes the proposed regulation will impose greater impacts on small entities than the agency accounted for in this regulation. Given the level of likely underestimation of costs on top of the $3.1 billion estimated cost of the rule on small businesses, Advocacy recommends the FDA withdraw the proposed rule. If FDA decides to issue a final rule, Advocacy encourages the FDA not to certify this regulation will not have a significant economic impact on a substantial number of small businesses because of the regulation's stated uncertainties and because the rule's RFA analysis could be improved.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Linwood Rayford at (202) 205-6533 or by email at linwood.rayford@sba.gov.

Sincerely,

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Copy to: Jeffrey B. Clark, Acting Administrator
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