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FDA Issues Proposed Rule on Front-of-Package Nutrition Labeling

January 14, 2025

Food, Beverage, and Dietary Supplements

On January 14, 2025, the Food and Drug Administration (FDA) issued the long-awaited Proposed Rule on Front-of-Package (FOP) Nutrition Labeling. The proposed FOP labeling scheme is part of FDA's effectuation of the White House National Strategy on Hunger, Nutrition and Health to reduce diet-related diseases by 2030, and is also partially in response to a citizen petition filed by certain advocacy groups. FDA's proposal would require the inclusion of an FOP nutrition label, referred to as the Nutrition Info box, containing nutrient information for saturated fat, sodium, and added sugars on the principal display panel (PDP) for most foods that must bear a Nutrition Facts label. As discussed below, the Nutrition Info box must state whether these nutrients are at low, medium, or high levels, but no color coding would be required. FDA focused on saturated fat, sodium, and added sugars because they are directly linked with chronic diseases when consumed in excess. In announcing the proposal, FDA also notes that ultra-processed foods often contain high levels of these nutrients. FDA explains that the FOP nutrition labeling is intended to provide accessible, at-a-glance information to help consumers quickly and easily identify how foods can be part of a healthy diet. Deputy Commissioner for Human Foods, Jim Jones, also expressed that FOP labeling may lead manufacturers to reformulate products to be healthier.

Background and FDA's Statement of its Legal Authority

FDA sets forth its basis for the agency's statutory authority to mandate FOP labeling in the preamble to the proposed rule. FDA articulates its view that the proposal is consistent with its general food and nutrition labeling authorities in the Nutrition Labeling and Education Act of 1990 (NLEA), including as codified in the Federal Food, Drug & Cosmetic Act (FD&C Act). Notably, FDA cites the recent U.S. Supreme Court decision in *Loper Bright Enters. v. Raimondo* (144 S. Ct. 2244, 2263 (2024)), stating that in enacting the NLEA, Congress "expressly delegate[d]" the authority to FDA "to prescribe rules to 'fill up the details' of a statutory scheme." FDA asserts that, through section 403(q) of the FD&C Act, "Congress delegated discretionary authority to FDA to decide, as appropriately informed by its technical expertise," how to "fill up the details regarding the presentation of nutrition information to assist consumers in comprehending the information and maintaining healthy dietary practices."

FDA explains that, since the Nutrition Facts label was last updated in May 2016, the agency has tentatively determined that additional, interpretive nutrition information on the front of food packages is necessary to help consumers more easily observe and better understand and use this information when building their diets. Based on this conclusion, FDA also cites its authorities in sections 403(a)(1), 201(n), and 701 of the FDCA as a basis for mandating FOP labeling. While the Nutrition Facts label is a valuable tool to help consumers maintain healthy

dietary practices, FDA found that not all consumers rely on these labels and some consumers struggle to understand their meaning. Other countries have implemented FOP nutrition labeling, and FDA determined that such labeling could be beneficial for U.S. consumers.

FDA conducted a range of research in developing the Proposed Rule. Specifically, FDA conducted a literature review on nutrition labeling, two sets of focus group testing in 2022 and 2023, and a peer-reviewed experimental study to explore consumer reactions and responses to three FOP scheme categories with various features. FDA also sought public comment and feedback while developing the labeling scheme. In November 2023 FDA held a public meeting to discuss FOP labeling. FDA's findings indicate that interpretive FOP nutrition information is helpful for consumers and simpler schemes are easier for consumers to understand. For example, the experimental study, which included a diverse sample of participants, showed that all groups tested can use interpretive FOP nutrition information equally well; consumer research showed that using interpretive descriptions, such as "Low," "Med," and "High," put the percent daily value (DV) of a nutrient into context by helping consumers understand whether that number contributes a little or a lot of that nutrient to the daily diet; and scientific literature shows that making this information available on the front of food packages captures consumers' attention. These findings, among others, guided the design of the proposed FOP nutrition labeling.

FOP Nutrition Info box

The Proposed Rule would require the inclusion of a Nutrition Info box on the PDP of most foods that are required to display the Nutrition Facts label.

Saturated Fat, Sodium, and Added Sugars

The Nutrition Info box would be required to detail and interpret the relative amounts of saturated fat, sodium, and added sugars in a serving of food and would appear on the package's front so that it is immediately visible when a consumer is deciding whether to buy, use, or eat the food. FDA chose to require information for these three nutrients because their excess consumption can increase the risk of chronic disease. The agency proposes to limit the required information to just these three nutrients because it concluded that this simpler scheme would provide consumers with important information without including additional information that could lessen the effectiveness of a nutrition label designed for quick, easy use.

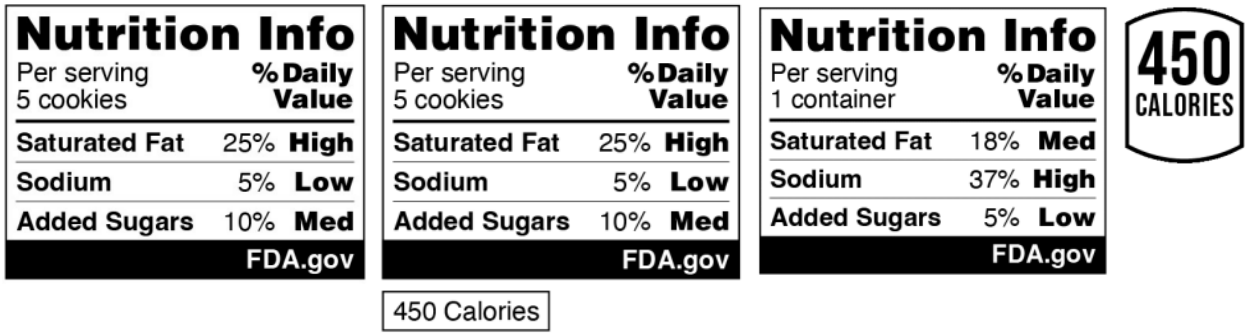
FDA explicitly chose to exclude a quantitative calorie disclosure on the Nutrition Info box because there is no established Daily Reference Value (DRV) for calories and a quantitative calorie statement would not provide consumers with new, interpretive information. However, FDA notes that the Proposed Rule would allow manufacturers to voluntarily include calorie information on the PDP.

Format and Information

The Proposed Rule specifies that the Nutrition Info box should be labeled as "Nutrition Info", include the subheading "per serving" alongside information on the servings size expressed in household measures, include the subheading "% Daily Value" below which the quantitative % Daily Value for the three nutrients and interpretive "Low," "Med," and "High" descriptions for the three nutrients should be included. FDA has proposed a range of 5% DV or less for "Low"; 6% to 19% DV for "Med"; and 20% DV or more for "High."

The Proposed Rule would also require the inclusion of a banner at the bottom of the Nutrition Info box that includes an "FDA.gov" attribution statement, as FDA found that inclusion of an attribution for the FOP nutrition label increases consumers' trust in and the credibility of the information.

The Proposed Rule specifies how the Nutrition Info box should be formatted, including guidelines for the box design, font size, easy to read font style, and black and white coloring. FDA has provided multiple examples for industry, including examples of the Nutrition Info box with a voluntary calorie declaration.



Application and Exemptions

The FOP nutrition labeling requirement would be applicable to food marketed to people ages 4 and older. FDA has declined to require proposed FOP nutrition labeling on foods marketed for infants and children ages 1 to 3 years or dietary supplements. Additionally, the Proposed Rule would exempt certain foods, including raw fruits and vegetables, foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, outer packaging for gift packages that contain a variety or assortment of foods, and unit containers in a multiunit retail food package.

Amendments to Nutrient Content Claim Regulations

FDA is also proposing to amend certain nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies. Specifically, FDA proposes to amend the nutrient content claim definitions for low sodium (which includes the terms "low sodium," "low in sodium," "little sodium," "contains a small amount of sodium," and "low source of sodium") and low saturated fat (which includes the terms "low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," and "a little saturated fat") to align with current nutrition science and to avoid within-label inconsistencies.

Proposed Effective/Compliance Dates

If finalized, the rule would have an "effective date" 60 days after publication of the final rule in the Federal Register. Then, businesses with $10 million or more in annual food sales would need to comply with the final rule three years after that effective date, and businesses with less than $10 million in annual food sales would need to comply four years after that effective date. FDA did not provide further direction on the meaning of "compliance" by the due date, i.e., whether products on store shelves or websites that did not comply by the stated date would

need to be removed or relabeled, or whether the compliance requirement would apply only to newly released product.

Public Comments

FDA is accepting public comments from industry and other interested parties until May 16, 2025.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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