DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2024–N–2910]

RIN 0910–AI80

Food Labeling: Front-of-Package Nutrition Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) proposes to require front-of-package nutrition labels on most foods that must bear a Nutrition Facts label. This action, if finalized, would require the display of a compact informational box containing certain nutrient information on the principal display panel. The box would provide consumers, including those who have lower nutrition knowledge, with standardized, interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. We also propose to amend certain nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies.

DATES: Either electronic or written comments on the proposed rule must be submitted by May 16, 2025. Submit comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by May 16, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 16, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2910 for ''Food Labeling: Front-of-Package Nutrition Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents, the plain language summary of the proposed rule of not more than 100 words as required by the ''Providing Accountability Through Transparency Act,'' or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if your comments are received by May 16, 2025. Submit your comments on FDA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to FDA using the docket identified at the beginning of this rulemaking. FDA will respond to any information collection-related comments in the final rule. You may also send your information collection-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Food Labeling: Front-of-Package Nutrition Information.''

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Claudine Kavanaugh, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450; or Deirdre Jurand or Alexandra Beliveau, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the information collection: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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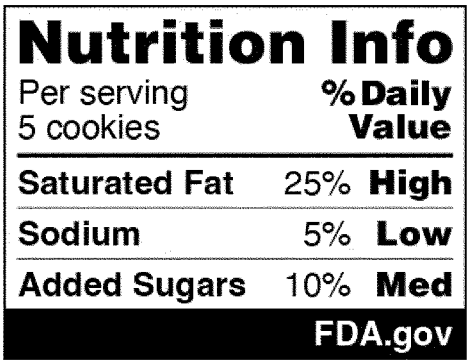
I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

This proposed rule, if finalized, would amend our regulations by adding a requirement for certain nutrition information to appear in a compact informational box on the principal display panel or bulk food labeling (for purposes of this document, referred to collectively as the front of the food package, principal display panel, or similar) of most foods bearing a Nutrition Facts label (by statute, ''food'' is defined as, among other things, articles used for food or drink for man (21 U.S.C. 321(f))). The scientific literature on nutrition labeling, including on the Nutrition Facts label, demonstrates that providing context for the levels of certain nutrients to limit that is interpretive rather than solely numeric—to communicate the relative significance in the context of a total daily diet—and requiring that interpretive information appear on the front of the package helps consumers notice and use the nutrition information presented on food packages. The box we are proposing would give consumers additional standardized context on the front of most food packages about certain nutrients that appear on the Nutrition Facts label and allow them to compare this nutrition information across foods. An example of the proposed front-of-package (FOP) nutrition information box (Nutrition Info box) that reflects all proposed requirements is as follows:



The proposed rule would provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. We also propose 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.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule, if finalized, would:

- Require most foods that must display a Nutrition Facts label to bear an FOP Nutrition Info box on the principal display panel that details and interprets the relative amount of certain nutrients to limit (*i.e.,* saturated fat, sodium, and added sugars) in a serving of the food;
- Detail how to determine the interpretive descriptions (*i.e.,* ''Low,'' ''Med,'' and ''High'') of such nutrients for the Nutrition Info box;
- Specify the required contents of the Nutrition Info box, such as the headings and nutrients;
- Specify the required format of the Nutrition Info box, such as placement, size, and use of dividing lines to separate information;
- Detail special labeling provisions for certain foods to modify or alternatively display the Nutrition Info box;
- Specify certain foods that are exempt from the requirement to display the Nutrition Info box;
- Provide examples of Nutrition Info boxes;
- Revise the low sodium and low saturated fat nutrient content claim definitions; and

• Establish a compliance date of 3 years after the final rule's effective date for businesses with $10 million or more in annual food sales, and a compliance date of 4 years after the final rule's effective date for businesses with less than $10 million in annual food sales.

C. Legal Authority

We are issuing this proposed rule consistent with the Nutrition Labeling and Education Act of 1990 (NLEA) (Pub. L. 101–535, 104 Stat. 2353, Section 2(b)(1) (21 U.S.C. 343 note (1990))) and sections 403(f) and 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). We are also issuing this proposed rule consistent with our authorities in sections 701(a), 403(a)(1), and 201(n) of the FD&C Act (21 U.S.C. 371(a), 21 U.S.C. 343(a)(1), and 21 U.S.C. 321(n), respectively).

D. Costs and Benefits

The proposed rule, if finalized, would require certain nutrition information to appear in a compact informational box on the front of most foods bearing a Nutrition Facts label. The proposed rule would also amend the low sodium and low saturated fat nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies. The proposed rule, if finalized, may result in industry reformulating products based on the interpretive label information or to maintain nutrient content claims, if some manufacturers choose to do so.

We quantify costs to the packaged food industry from updating labeling to meet the proposed requirements. Annualized costs from relabeling over 10 years would range from $66 million to $154 million at a 2 percent discount rate, with a primary estimate of $105 million per year. Although reformulation is not a requirement or goal of the proposed rule, we also quantify the costs of reformulation, as the rule may result in some food manufacturers reformulating some food products. We estimate 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, we estimate the annualized costs of the proposed rule over 10 years would range from $191 to $530 million at a 2 percent discount rate, with a primary estimate of $333 million. Note that, in general, this rule would impose few requirements on retailers. If a food that a retailer manufactures or packages either bears nutrition information or makes nutrition claims, and therefore is required to bear a Nutrition Facts label, the food would be subject to this rule's requirements.

Benefits of this proposed rule, if finalized, would come from the value consumers receive from the information provided by the interpretive FOP label on food packages. If some packaged food manufacturers chose to reformulate products to maintain current nutrient content claims or move into a ''Low'' or ''Med'' interpretive description, consumers whose nutritional intake changes accordingly would also benefit from a healthier food supply.

TABLE 1—SUMMARY OF THE BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

[Millions of 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes
Benefits:							
Annualized monetized benefits.							
Annualized quantified, but non-monetized, benefits.							
Unquantified benefits.	The benefits of this proposed rule would come from the value consumers receive from the information provided in the interpretive label on food packages.						
Costs:							
Annualized monetized costs.	$333	$191	$530	2023	2	2025–2034	Although reformulation is not a requirement or goal of the proposed rule, reformulation costs are estimated to be 68% of total quantified costs. Costs may, at least partially, be passed through to consumers in the form of price increases.
Annualized quantified, but non-monetized, costs.							
Unquantified costs.							
Transfers:							
Annualized monetized Federal budgetary transfers.							
Other annualized monetized transfers.							
Net Benefits:							
Annualized monetized net benefits.							

Category	Effects	Notes
Effects on State, local, or Tribal governments.		
Effects on small businesses	The total discounted cost of the proposed rule per entity (including large firms) is approximately $100,253. 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.	
Effects on wages.		
Effects on growth.		

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
Dietary Guidelines	Dietary Guidelines for Americans.
Dietary Guidelines, 2020–2025	*Dietary Guidelines for Americans, 2020–2025*.
DRV	Daily Reference Value.
DV	Daily Value.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOP	Front-of-package.
G	Gram(s).
GDA	Guideline Daily Amount.
HHS	U.S. Department of Health and Human Services.
IOM	Institute of Medicine (now NASEM).
Med	Medium.
Mg	Milligram(s).
NASEM	National Academies of Sciences, Engineering, and Medicine.
NLEA	Nutrition Labeling and Education Act of 1990.
OMB	Office of Management and Budget.
PRIA	Preliminary Regulatory Impact Analysis.
RACC	Reference Amount Customarily Consumed.
RDI	Reference Daily Intake.

III. Background

The United States faces a growing prevalence of preventable diet-related chronic diseases and conditions (for purposes of this document, we use the term ''diseases'' to cover both diseases and conditions), which can include hypertension, cardiovascular disease, type 2 diabetes, and certain forms of cancer. These diseases are leading causes of death and disability in the United States (Ref. 1). Data show that about one in 10 Americans has diabetes, and 90 to 95 percent of those have type 2 diabetes (Ref. 2); at least one in three people will have cancer in their lifetime (Ref. 3); and nearly half of American adults have high blood pressure, which is linked to leading causes of death for Americans: heart disease and stroke (Refs. 4 and 5). While these diseases can result from a mix of risk factors, such as genetic, biological, behavioral, socioeconomic, and environmental factors, unhealthy dietary patterns increase the risk of developing chronic diseases (Ref. 6). Diet-related chronic diseases are experienced disproportionately by certain racial and ethnic populations and those with lower socioeconomic status (Refs. 7 to 12).

The *Dietary Guidelines for Americans, 2020–2025* (*Dietary Guidelines, 2020–2025*) recommends, among other things, that Americans limit their intake of saturated fat, sodium, and added sugars to achieve healthy dietary patterns (Ref. 6). Under the National Nutrition Monitoring and Related Research Act of 1990 (Pub. L. 101–445, 104 Stat. 1034), the U.S. Department of Agriculture and the U.S. Department of Health and Human Services (HHS) must publish the Dietary Guidelines for Americans (Dietary Guidelines) at least every 5 years and must base them on the preponderance of the current scientific and medical knowledge. Development of the Dietary Guidelines entails a rigorous process and includes appointment of a federal advisory committee of external scientific experts, review of the scientific evidence by the committee, public meetings, issuance of a scientific report by the advisory committee, and a public comment process (Ref. 13). With those requirements and practices in place, the *Dietary Guidelines, 2020–2025* concludes that healthy dietary patterns are based on, among other things, ''consuming foods and beverages in their nutrient-dense forms—forms with the least amounts of added sugars, saturated fat, and sodium'' (Ref. 6).

FDA, as part of a whole-of-government approach, broadly seeks to help reduce the burden of diet-related chronic diseases. We are committed to accomplishing this goal by, in part, prioritizing nutrition initiatives that can help improve dietary patterns in the United States. Americans' choice of foods is influenced by, among other things, their knowledge about and understanding of the foods available to them. As consumers make their food purchases and daily food choices, food labeling provides them with valuable information about nutrients and how a particular food fits into their daily diet. Congress recognized this and passed the NLEA, which gave the Secretary of HHS, and by delegation, FDA, authority to require certain nutrition information to be conveyed in a manner that allows the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet (21 U.S.C. 343 note).

The NLEA, which added section 403(q) of the FD&C Act, specifies certain nutrients to be declared in nutrition labeling, including saturated fat and sodium, and authorizes FDA to require the declaration of other nutrients if we determine that the declaration will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices.

We have established various requirements under the NLEA related to nutrition information on food labels, such as the declaration of nutrients (including saturated fat and sodium), the format for nutrition labeling (including the Nutrition Facts label), reference values for use in declaring a food's nutrient content, and allowances for specified products to be exempt from nutrition labeling (§ 101.9 (21 CFR 101.9)). We first issued regulations related to the Nutrition Facts label in 1993 in a final rule entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (58 FR 2079, January 6, 1993) (1993 Nutrition Facts label final rule) and amended them in 1995 (60 FR 67164, December 28, 1995)) and in 2003 (68 FR 41434, July 11, 2003). In 2016, we again amended our regulations related to the Nutrition Facts label in a final rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742, May 27, 2016) (2016 Nutrition Facts label final rule) to, among other things, require the declaration of added sugars (codified at

§ 101.9(c)(6)(iii)). We took this action, in part, because of scientific evidence demonstrating a strong association between a healthy dietary pattern low in sugar-sweetened foods and a reduced risk of cardiovascular disease, evidence showing it is difficult to meet nutrient needs within calorie limits when added sugars consumption is high, and consumption data showing that Americans consume too many calories from added sugars (81 FR 33742 at 33759 and 33768 through 33770).

A. Need for the Regulation

In developing this proposed rule, FDA examined the scientific literature on nutrition labeling, including on the Nutrition Facts label. The Nutrition Facts label provides valuable, standardized nutrition information to consumers. Eighty-seven percent of U.S. consumers report ever looking at the Nutrition Facts label, and nearly 80 percent of U.S. consumers use it sometimes or often (Ref. 14). It focuses on numerical information: The quantitative amount per serving of each declared nutrient and the corresponding percent Daily Value (DV), when applicable, tell consumers how much a nutrient in a specified serving of food contributes to a total daily diet.

Using the Nutrition Facts label frequently is associated with healthier dietary patterns (Ref. 15). However, while many consumers use and benefit from the Nutrition Facts label, fewer people who ever look at the Nutrition Facts label look at nutrients to limit (including sodium, saturated fat, and added sugars) in that label (Ref. 14). Use of the Nutrition Facts label use also differs by sex, race/ethnicity, education level, and household income. Specifically, regular use of the Nutrition Facts label is lower among men, those with lower education levels, and those with lower incomes (Refs. 15 to 17). Additional nutrition labeling that is interpretive and prominently displayed on the front of food packaging could help improve consumer awareness of nutrients to limit by providing a more accessible description of certain information contained in the Nutrition Facts label.

The scientific literature on nutrition labeling also demonstrates that some consumers struggle to understand the numerical values used to represent the nutrient content of the food or use the information in the labeling to make their food selections (Refs. 18 and 19). Additionally, information FDA has collected shows that providing context for the levels of certain nutrients to limit that is interpretive rather than solely numeric—to communicate the relative significance of the nutrients in the context of a total daily diet—and requiring that interpretive information appear on the front of the package helps consumers notice and use the nutrition information presented on food packages (Refs. 20 and 21). Based on this data and other information referenced in this document, we have tentatively determined that an interpretive FOP nutrition label is needed to help consumers readily observe and comprehend information about certain nutritional attributes of a food at the point of decision-making (*i.e.,* when a consumer is deciding whether to buy, use, or eat the food) that will assist them in maintaining healthy dietary practices.

B. Regulatory and Research History

FDA has considered the possible use of FOP nutrition labeling under its NLEA and FD&C Act authorities since at least 2007. In the **Federal Register** of July 20, 2007 (72 FR 39815), we issued a notice of public hearing and request for comment about symbols then in use to communicate nutrition information on food labels. In the **Federal Register** of December 1, 2009 (74 FR 62786), we announced that we had submitted two experimental studies for Office of Management and Budget (OMB) review and clearance under the Paperwork Reduction Act of 1995, with the intent to quantitatively assess consumer reactions to various FOP nutrition labeling schemes. We discussed how we completed a focus group study in April 2008 to obtain comments and information about many consumer issues related to FOP nutrition labeling schemes (id.). We noted that the information available to us left gaps in our understanding of the impacts of FOP nutrition labeling schemes on U.S. consumers and commented that there was a lack of publicly available quantitative consumer research on the relative effectiveness of existing and alternative nutrition labeling schemes (id.).

In a **Federal Register** notice entitled ''Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information'' (75 FR 22602, April 29, 2010), we established a docket to ask questions and obtain data and other information about ways to enhance the usefulness of point-of-purchase nutrition information, such as through FOP nutrition labeling. We stated that we were working with interested parties to develop a voluntary FOP nutrition label that was driven by sound nutrition criteria, consumer research, and design expertise (id. at 22603). In 2011, we issued a letter (Ref. 22) to the Grocery Manufacturers Association (now the Consumer Brands Association) and the Food Marketing Institute (now the Food Industry Association) announcing our intent to exercise enforcement discretion with respect to certain FDA nutrition labeling regulations so that the associations could introduce and use their Facts Up Front (FUF) FOP nutrition labeling program (Ref. 23). We recognized in the letter that the standardized, non-selective presentation of calories, saturated fat, sodium, and total sugar content on a company's entire product line, if widely adopted by the food industry in a uniform manner, could contribute to FDA's public health goals by fostering awareness of the nutrient content of foods in the marketplace and helping consumers in making quick, informed, and healthy food choices (Ref. 22).

Congress has also demonstrated its interest in FOP nutrition labeling. In 2009, Congress directed the Centers for Disease Control and Prevention to commission a study by the Institute of Medicine (IOM) (now the National Academies of Sciences, Engineering, and Medicine (NASEM)) to examine and provide recommendations regarding FOP nutrition symbols (Refs. 24 and 25). In 2010, the IOM released a Phase I report (Ref. 26), which found, among other things, that FOP systems had been established internationally as far back as 1989, may have the greatest potential benefit if the nutrition components included are limited to those most closely related to prominent public health conditions, and that research was needed to determine the most effective way of presenting nutrition ratings to consumers so they could make food choices that contribute to a healthy diet. In 2012, the IOM released a Phase II report (Ref. 27), which addressed the potential benefits of a single, standardized front-label food guidance system regulated by FDA, assessed which systems are most effective with consumer audiences, considered which systems best promote health, and recommended ways to maximize the use of such systems. The IOM concluded that a single, standardized system that is easily understood by most age groups and appears on all products would be the best option (id.).

Further, in 2011, we commissioned a literature review (Ref. 28) to look at scientific studies, including, *e.g.,* experimental and real-world studies, on FOP and Shelf Label Nutrition Systems (*i.e.,* tags set on grocery store shelves rather than directly on food packaging) and learn which types of systems were most effective at informing consumers about the relative healthfulness of foods.

This literature review found that summary systems incorporating text and color worked better than those using only numeric information in attracting consumer attention and informing them about the relative healthfulness of foods (id.).

In 2016, FDA commissioned an update to our previous literature review (Ref. 29), which captured more recent scientific literature on FOP nutrition labeling from 2010 to August 2016. Like previous reviews, the update reported that, among other things, consumers, no matter their nutrition knowledge, preferred visually simple labels that were quick and easy to read over those that have more complex numerical information.

The White House released a National Strategy (Ref. 30) at the September 2022 Conference on Hunger, Nutrition, and Health that outlined the goal of ending hunger and increasing healthy eating and physical activity by 2030, so that fewer Americans experience diet-related diseases such as type 2 diabetes, hypertension, and certain cancers. The strategy highlighted several FDA initiatives to help empower consumers with information and help create a healthier food supply. The National Strategy included FDA's work to, among other things, conduct research on and propose a standardized FOP system for food packages to help consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy eating pattern.

C. Citizen Petition

On August 5, 2022, the Center for Science in the Public Interest, the Association of SNAP Nutrition Education Administrators, and the Association of State Public Health Nutritionists submitted a citizen petition asking that we amend our regulations to require an easy-to-understand, standardized system of nutrition labeling on the principal display panel of foods (Citizen Petition from Peter Lurie, MD, MPH, Executive Director and President, and Eva Greenthal, Senior Science Policy Associate, Center for Science in the Public Interest, Amy Branham, Immediate Past Co-chair, ASNNA Leadership Team, Association of SNAP Nutrition Education Administrators, and Jamie Stang, Ph.D., MPH, RDN, President, Association of State Public Health Nutritionists, to Dockets Management Staff, Food and Drug Administration, dated August 5, 2022, Docket No. FDA–2022–P–1832 (petition) at page 1). The petition requested that such a system be mandatory, nutrient-specific, inclusive of calories, and interpretive with respect to the levels of added sugars, sodium, and saturated fat per serving (id.).

The petition claimed that experimental and real-world evidence shows that policies that aim to give consumers information about the healthfulness of foods that is clear, quick, and easy to access and understand, such as interpretive FOP nutrition labeling, can improve consumer understanding and encourage healthier diets (id. at page 4). The petition provided various examples of FOP systems that would meet its criteria. We have considered this citizen petition in proposing this rule.

D. Updated FDA Literature Review and New Research Overview

We have seen rising global interest in FOP nutrition labeling schemes in recent years, and many countries have implemented, or are implementing, their own versions amid growing concern about the impact of diet-related chronic diseases, which can include cardiovascular disease, diabetes, and certain forms of cancer (Refs. 20 and 31). As of 2024, countries in North America, South America, Asia, and Africa have implemented, or are implementing, mandatory FOP nutrition label schemes, while several other countries in Africa, Europe, Asia, and Oceania have voluntary schemes (Refs. 32 to 34). The schemes in these countries represent a variety of types, such as warning-type schemes (*e.g.,* where a triangle and exclamation point on the FOP call attention to nutrients above a certain threshold in a serving size) and nutrient summary schemes (*e.g.,* where a letter grade is determined and displayed to represent the healthfulness of a food's nutrient profile), among other types of schemes. We examined these various schemes in the literature review we conducted, which informed our consumer research studies. We describe our literature review and consumer research in the sections that follow.

1. Literature Review

To inform our proposed Nutrition Info box, we first conducted a systematic review of the scientific literature on FOP nutrition labels, the most recent version of which we made public in April 2023 (Ref. 20). Results of the scientific literature review showed that FOP nutrition labels have been extensively studied and some large-scale literature reviews on FOP nutrition labels have been conducted. As mentioned elsewhere in this document, the IOM conducted a two-phase literature review on FOP nutrition labels, concluding that such FOP nutrition labeling schemes benefit consumers and that consumers prefer simple, interpretive schemes, which are also rated most helpful to consumers (Refs. 26 and 27). The body of research after the IOM reviews has been consistent with the IOM findings. Specifically, certain overarching themes emerged from our updated literature review, including that an FOP nutrition label can help consumers identify and select healthy foods, consumers generally prefer simple labels, and government endorsement of logos may be related to greater confidence in the label (Ref. 20). Moreover, recent literature on FOP nutrition labeling schemes suggests that familiarity with these schemes will make them even more useful as time passes, and that these schemes are useful across all demographics and levels of nutrition knowledge, can help consumers understand the nutrition quality of food, and can positively impact consumers' intention to purchase healthful foods (id.). The scientific literature on consumers' use of FOP nutrition labels has strongly and consistently found that FOP nutrition labels attract consumer attention, and any FOP nutrition label communicates something more about the product's nutrient content to consumers than no FOP nutrition label (id.). FDA began its most recent round of consumer research exploration of FOP nutrition labeling schemes using the findings from the literature review (id.) and continued to monitor the literature throughout the research process.

2. First Focus Group Testing

In 2022, FDA conducted its first set of focus groups (OMB control number 0910–0497, ''Front-of-Pack Focus Groups'') to test FOP concepts and draft FOP labels, some of which we had included in the 2008 focus group testing (see Refs. 32 and 33; see also *https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202008-0910-021&icID=253321*). We tested variations of four FOP nutrition labeling schemes in these focus groups, which were composed of U.S. adult food shoppers whose race/ethnicity, age, sex, and education reflected U.S. population demographics (Ref. 35). The schemes were based on those currently found in the U.S. and international marketplace: (1) Guideline Daily Amount (GDA); (2) Nutrition Tips; (3) Nutrition Tips—High In; and (4) High In (id.). The GDA scheme listed calories, quantitative amount of nutrients (sometimes including both nutrients to limit (those

that may be associated with adverse health effects and that Americans generally consume too much of—*e.g.,* saturated fat, sodium, added sugars) and nutrients to get enough of (those that Americans generally do not get the recommended amount of—*e.g.,* fiber, calcium)), and the adult proportion recommended for daily consumption represented by a serving of the food in both numerical (*i.e.,* percent DV) and interpretive (*i.e.,* ''Low,'' ''Med,'' and ''High'') form. This scheme resembled the voluntary FUF scheme developed by the U.S. food industry. The Nutrition Tips scheme mimicked the design of the Nutrition Facts label and included low, medium, and high interpretive descriptions about nutrient levels for saturated fat, sodium, and added sugars (and, in certain test schemes, fiber and calcium). The Nutrition Tips—High In scheme also mimicked the Nutrition Facts label design, but it only listed a nutrient, its interpretive description, and corresponding percent DV when a serving of the product was ''high in'' saturated fat, sodium, or added sugars. The High In scheme showed the nutrient(s) (and, in certain test schemes, the percent DV) in the product that, per serving, were considered high. In total, we tested 41 variations of these schemes—14 GDA schemes, 12 Nutrition Tips schemes, 9 Nutrition Tips—High In schemes, and 6 High In schemes (Ref. 36). We used these varied schemes to learn more about consumer reactions to the elements depicted (*e.g.,* use of color, use of interpretive words, use of numbers) and to help us understand which FOP nutrition labeling schemes may be most useful to consumers.

Within the GDA category, we tested schemes that included both nutrients to limit (*i.e.,* saturated fat, sodium, and added sugars) and nutrients to get enough of (*i.e.,* fiber and calcium), schemes that used colors beyond black and white (*i.e.,* red, yellow, and green), schemes that included interpretive descriptions (*i.e.,* low, medium, and high) of nutrient levels, schemes that included quantitative nutrient level information (*e.g.,* how much a nutrient in a single serving of food contributes to your daily diet (*i.e.,* percent DV), quantitative declaration of grams (g) or milligrams (mg) of a nutrient), and schemes that included descriptive terms (*i.e.,* ''avoid too much'' or ''get enough''). In the Nutrition Tips category, we tested schemes that included both nutrients to limit and nutrients to get enough of, schemes that used either black and white colors only or colors beyond black and white (*i.e.,* red, yellow, and green), schemes that included and excluded interpretive descriptions regarding nutrient levels, schemes that included and excluded quantitative nutrient level information (*i.e.,* percent DV), and schemes that included and excluded an ''*FDA.gov*'' statement in the FOP nutrition label. In the Nutrition Tips—High In category, we tested schemes that included only nutrients to limit, different color variations (*i.e.,* black on white compared to white on black), and the use of an abbreviated heading for ''% Daily Value.'' In the High In category, we tested schemes that included only nutrients to limit and schemes that included and excluded quantitative percent DV information.

These focus groups provided FDA with qualitative feedback and insight into the varying ways that consumers react to and comprehend FOP nutrition information and helped us understand which schemes might be most helpful for U.S. consumers to quickly and easily identify how foods can be part of a healthy diet (Ref. 37). Among other things, participants reported they believed that products bearing ''High In'' labels without quantitative percent DV information were not healthy (id.). Participants were also confused by the colors red, yellow, and green when schemes contained both nutrients to limit and nutrients to get enough of (*e.g.,* they had trouble interpreting the scheme when red indicated a high amount of a nutrient to limit *and* a low amount of a nutrient to get enough of) (id.). These focus group participants also preferred differing amounts of information in the FOP schemes we tested and reacted positively to neutrally about the inclusion of ''*FDA.gov*'' in the scheme (id.). For example, when ''*FDA.gov*'' appeared in a scheme, some participants thought it made the scheme more credible or trustworthy and understood it to mean that the information on the FOP nutrition label was not marketing, but rather information provided by a government source, while others reported they would not notice the FDA attribution in a label (id.). We considered this information, as well as the literature review, in identifying FOP scheme types for quantitative testing.

3. Experimental Study

We used our learnings from the focus group testing and the information from the literature reviews to help inform the scheme types we chose to test in the experimental study (OMB Control Number 0910–0920, ''Quantitative Research on Front of Package Labeling on Packaged Foods'') to further explore consumer responses to various FOP nutrition labeling schemes. In the experimental study, we tested a smaller subset of FOP nutrition labeling schemes from the focus group testing, with additional variations informed by, among other things, focus group results. The study was a controlled, randomized experiment, using a 15-minute web-based questionnaire to collect information from 9,200 U.S. adult members of an online consumer panel maintained by a contractor (Ref. 38). The sample reflected U.S. Census data on sex, education, age, and race/ethnicity, in a balanced manner (id.). A measure of nutrition literacy was also used to balance the sample to ensure a variety of nutrition literacy levels for each condition (id.). The ''Quantitative Research on Front of Package Labeling on Packaged Foods, Final Study Report'' has been peer reviewed by independent external experts. Taking into consideration comments from this peer review, we revised the final report, which is available in the docket for this proposed rule (Ref. 38). The findings from the experimental study informed the development of this proposed rule.

We tested three FOP scheme categories with various features (*e.g.,* one scheme category, shown both with and without percent DV), for a total of eight FOP schemes, in our experimental study (id.). Each scheme displayed information about the three nutrients of interest (*i.e.,* saturated fat, sodium, and added sugars) in the three scheme categories: (1) GDA; (2) Nutrition Info (formerly ''Nutrition Tips'' but renamed in the experimental study to better align with the Nutrition Facts label and to underscore that the FOP nutrition label contains fact-based disclosures, including additional nutrient content interpretation); and (3) High In (id.). The ''Low,'' ''Med,'' and ''High'' interpretive descriptions included in the study for the three nutrients were based on our longstanding general approach for interpreting the percent DV of a nutrient (*i.e.,* 5% DV or less for ''Low,'' 20% DV or more for ''High'') (see section V.B.3 of this document for further discussion).

The study guided participants through two independent tasks (id.). In the first task, participants viewed three different nutrient profiles (healthiest, middle, and least healthy, which for study purposes was based on saturated fat, sodium, and added sugars levels) of a single FOP nutrition scheme and were asked to select the most and least healthy nutrient profile, based only on the levels of saturated fat, sodium, and added sugars displayed (id.). If participants wanted additional nutrition information when reviewing the

nutrient profiles, instructions indicated they could click anywhere on the profiles for more detail. By doing so, the corresponding Nutrition Facts label was displayed (we note, however, that our data showed that participants rarely did this (id.)). The nutrient profiles were similarly based on our longstanding general approach for interpreting the percent DV of a nutrient as either ''low'' or ''high'' (88 FR 39257) (see section V.B.3 of this document for further discussion). Each participant viewed a total of three randomly assigned FOP nutrition schemes (Ref. 38). In the second task, participants viewed an FOP nutrition scheme that varied by nutrient profile on one of three mock food product labels (cereal, frozen meal, or canned soup). Participants answered questions about the product and the FOP nutrition scheme, including questions about perceptions of healthfulness and nutrient content, and also answered questions about their attitudes toward the scheme (id.).

a. Nutrition Info. Similar to the ''Nutrition Tips'' design tested in the first focus groups, the Nutrition Info scheme mimicked the design of the Nutrition Facts label and provided interpretive nutrition information by identifying the level of the three nutrients per serving as ''Low,'' ''Med,'' or ''High.'' The nutrient information was displayed vertically, using contrasting colors. We tested versions that:

- Included and excluded quantitative percent DV amounts;
- Used either black and white colors only or used black, white, green, yellow, and red, with the latter three colors representing low, medium, and high, respectively; and
- Included and excluded a magnifying glass icon.

The Nutrition Info schemes performed best overall in helping consumers identify healthier nutrient profiles (id.). Specifically, the Nutrition Info schemes produced more correct answers regarding the healthfulness of the product shown than the other schemes tested, and participants were generally able to correctly identify the level of saturated fat, sodium, and added sugars in products (id.). Participants viewing the Nutrition Info schemes also spent significantly less time evaluating the nutrient profile of a product than those viewing the other schemes tested (*i.e.,* they felt confident enough to answer questions in a shorter amount of time) (id.). In the various Nutrition Info schemes described elsewhere in this document that were tested against each other, none performed better than the others across all measures, but the versions that were black and white with percent DV performed best in most instances (id.).

b. High In. The High In scheme only displayed any of the three nutrients to limit that fell into the ''High'' description according to our longstanding general approach for interpreting a nutrient's percent DV per serving of a product. For example, if a test product was medium in saturated fat, high in sodium, and low in added sugars per the established criteria, the High In scheme for that product would only include ''Sodium,'' and, in some instances, additional information about the sodium content. Specifically, we tested High In schemes both with and without a quantitative percent DV.

While the High In schemes seemed to emphasize to participants higher levels of nutrients to limit, they performed the worst among the schemes tested when participants were asked to identify a product's healthfulness (id.). Participants viewing the High In schemes were significantly less likely to correctly identify the healthiest and least healthy nutrient profiles and were more likely to rank the products as less healthy than those who viewed the GDA and Nutrition Info schemes (id.). Participants viewing the High In schemes also spent significantly more time evaluating the information provided before answering questions about the healthiest and least healthy nutrient profiles (*i.e.,* they were not as confident in providing an answer in the same amount of time as compared to their responses when using other schemes) (id.). Although very few participants overall clicked to see the Nutrition Facts label when responding to the study questions, those viewing the High In schemes were significantly more likely to do so than those viewing either the GDA or the Nutrition Info schemes, suggesting that participants needed or wanted additional nutrition information before providing a response (id.). Most of the ratings on the attitude and perception questions were significantly lower for the High In schemes than they were for the GDA and Nutrition Info schemes (id.).

c. Guideline daily amounts. The GDA scheme we tested was a set of icons placed horizontally that displayed nutrition information per serving. This scheme was quantitative-only and did not include any interpretive descriptions, such as whether nutrient levels were low, medium, or high. Each icon displayed the number of grams or milligrams of a nutrient in its center and the nutrients' corresponding percent DV at the bottom.

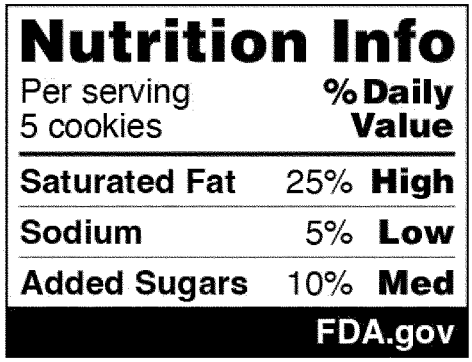
While participants had a positive reaction to and perception of the GDA scheme (*e.g.,* liking its look), it tested lower than the other schemes on several important factors we measured. In contrast to participants' reactions to the Nutrition Info and High In schemes, they were significantly less likely to correctly identify the level of saturated fat, sodium, and added sugars when viewing the GDA scheme (id.). Additionally, participants viewing the GDA scheme spent more time evaluating the information provided before answering questions about the healthiest and least healthy nutrient profile as compared to the Nutrition Info schemes (id.).

4. Second Focus Group Testing

In Fall 2023, we conducted a second set of focus groups (OMB control number 0910–0497, ''Front-of-Package Nutrition Labeling Focus Groups 2'') as a follow-on to the experimental study to gather additional input on our assumption that consumers would react to FOP nutrition labeling on beverage products and non-beverage products in the same way (Ref. 39). Almost all participants reported that they viewed the FOP nutrition information on beverage and non-beverage products similarly (Ref. 21).

5. Summary of FDA's Research and How It Relates to Our Current Proposal

We are proposing the Nutrition Info box, which would be a mandatory, compact, standardized FOP nutrition label that closely aligns with the Nutrition Info scheme tested in our quantitative research. An example Nutrition Info box that reflects all proposed requirements is as follows:



This Nutrition Info box would address our public health goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify, at the point of decision-making, how foods can be part of a healthy diet—including by allowing them to compare nutrition information across foods.

Including interpretive information on the label or labeling of a food is expected to provide a more accessible description of the numerical information contained in the Nutrition Facts label, thereby helping to address the differences in use that we see with the Nutrition Facts label (Refs. 15 to 17). For example, our experimental study, which included a diverse sample of participants that varied by age, sex, geography, race/ethnicity, and education, showed that all groups tested can use interpretive FOP nutrition information equally well (Ref. 38), and the scientific literature indicates that interpretive FOP nutrition information is helpful for all consumers (Ref. 20). Moreover, in our consumer research, participants reported that using interpretive descriptions, such as ''Low,'' ''Med,'' and ''High,'' put the percent 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 (Ref. 21). Additionally, the scientific literature shows that making this information available on the front of food packages, so it is immediately visible at the point of decision-making, captures consumers' attention, which could further help address these differences (Ref. 20). Thus, interpretive FOP nutrition labeling, such as the Nutrition Info box proposed here, would supplement the Nutrition Facts label by providing additional context that consumers could use to help them quickly and easily identify how foods can be part of a healthy diet.

IV. Legal Authority

We are proposing to require FOP nutrition labeling consisting of an informational FOP nutrition label that includes interpretive content regarding the levels of certain nutrients to limit, consistent with our general food labeling and nutrition labeling authorities in the NLEA and the FD&C Act. Specifically, this rule proposes a mandatory label element on the principal display panel that details and interprets—using low, medium, and high descriptions—the percent DV for saturated fat, sodium, and added sugars in a serving of food. This rule also proposes updates to the low sodium and low saturated fat nutrient content claims.

A. Statutory Framework

Congress authorized FDA to require that certain information be included on food labels or labeling and that the information presented assists consumers in maintaining healthy dietary practices. The NLEA added section 403(q) to the FD&C Act, which specifies, in part and with certain exceptions, that food is deemed misbranded unless its label or labeling bears nutrition information regarding certain nutrients. The statute lists certain information that must be included in food labeling and authorizes the Secretary, and by delegation, FDA to specify additional requirements by regulation. Under section 403(q)(1) of the FD&C Act, FDA may issue regulations to require that any required nutrition information be highlighted with larger type, bold type, or contrasting color after determining that such highlighting will help consumers in maintaining healthy dietary practices. Further, sections 403(q)(2)(A) and 403(q)(2)(B) of the FD&C Act provide a process for adding nutrition information to or removing statutorily required nutrition information from the label if FDA determines that such actions would help consumers maintain healthy dietary practices. In addition, section 403(f) of the FD&C Act specifies, in part, that a food is misbranded if any information required under the authority of the FD&C Act is not prominent on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. These provisions demonstrate that Congress intended that nutrition information required to be on the label be presented in a way that helps consumers use that information to maintain healthy dietary practices. To that end, Congress gave FDA authority to determine what information is required and how it is presented to achieve this aim.

Additionally, the NLEA specifically directs FDA to require nutrition information be presented in a way that makes it observable, understandable, and useful to consumers. Under the NLEA, FDA must require the information to be disclosed on the label in a way that enables consumers to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet (NLEA § 2(b)(1)(A), Pub. L. 101–535, 104 Stat. 2353, 2357; 21 U.S.C. 343 note). This provision gives us the authority to require that interpretive information about the relative amount of certain nutrients required to be included in the Nutrition Facts label be displayed in a readily observable and understandable format so that consumers can quickly and easily determine how a food fits into their daily diet, as we are proposing in this rule. Additionally, the NLEA does not specify where on the label the nutrition information must appear to enable the public to readily observe the information, and, for decades, industry has been able to place the required Nutrition Facts labels on different panels (*e.g.,* principal display panel, information panel) and in various locations on different products throughout the food marketplace.

In enacting the NLEA, Congress ''expressly delegate[d]'' the authority to the Secretary (subsequently delegated to FDA) ''to prescribe rules to 'fill up the details' of a statutory scheme'' (*Loper Bright Enters.* v. *Raimondo,* 144 S. Ct. 2244, 2263 (2024), throughout section 403(q) of the FD&C Act, and in 21 U.S.C. 343 note). As most relevant here, section 403(q)(1) of the FD&C Act provides that ''if [FDA] determines'' that certain highlighting ''will assist consumers in maintaining healthy dietary practices,'' FDA ''may by regulation require'' the required nutrition information ''to be highlighted'' with ''larger type, bold type, or contrasting color.'' Section 403(q)(2)(A) of the FD&C Act provides that ''if [FDA] determines'' that information about an additional nutrient ''will assist consumers in maintaining healthy dietary practices,'' FDA ''may by regulation require that information relating to such additional nutrient be included'' in the food label. Section 403(q)(2)(B) of the FD&C Act provides that ''if [FDA] determines'' that information about a nutrient is ''not necessary to assist consumers in maintaining healthy dietary practices,'' ''[FDA] may by regulation'' remove the requirement to include such information. In 21 U.S.C. 343 note, Congress directed FDA to issue regulations ''to implement section 403(q)'' of the FD&C Act and specifically to ''require the required 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 a total daily diet.'' Therefore, the best reading of section 403(q) of the FD&C Act is that Congress delegated discretionary authority to FDA to decide, as appropriately informed by its technical expertise and within the limits of its statutory authority, how to fill up the details regarding the presentation of nutrition information to assist consumers in comprehending the information and maintaining healthy dietary practices.

The NLEA's legislative history affirms that Congress contemplated that FDA require labeling information to help consumers understand the nutrient levels in a food in the context of a daily diet. For example, the legislative history explicitly contemplates the use of the terms ''low,'' ''medium,'' and ''high'' to achieve this goal. The House report for the bill states that, in order to present nutrition information in a manner that facilitates the public's understanding, FDA may choose among a variety of options, for example, including information about the recommended daily intake on the label or including the use of descriptive terms such as ''low,'' ''medium,'' and ''high,'' or universal symbols to indicate desirable or undesirable levels of particular nutrients (Ref. 40). According to the report, while the bill would not (and the enacted provision did not) mandate that FDA adopt any particular approach, it would (and does) require FDA to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information (id.). This report language further affirms Congressional intent that FDA must issue regulations implementing the NLEA that would help consumers place the amounts of particular nutrients in a context that would help them build their daily diets (see NLEA § 2(b)(1)(A), Pub. L. 101–535, 104 Stat. 2353, 2357; 21 U.S.C. 343 note).

The NLEA also created section 403(r)(1)(A) of the FD&C Act, which provides specifications for a claim made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food. The statute permits the use of these label and labeling claims that expressly or by implication characterize the level of any nutrient in a food, but only if the claims are made in accordance with FDA's authorizing regulations (section 403(r)(1)(A) and (r)(2)(A) of the FD&C Act).

Additional authorities for this rulemaking can be found in section 701(a) of the FD&C Act regarding efficient enforcement of the FD&C Act, as well as in sections 403(a)(1) and 201(n) of the FD&C Act regarding our general food labeling authority.

B. Current Proposal

Since the Nutrition Facts label was last updated in May 2016, FDA has tentatively determined that additional, interpretive nutrition information on the front of food packages—to provide context for certain nutrient declarations—is necessary to help consumers more easily observe and better understand and use this information when building their diets.

As mentioned elsewhere in this document, nearly 80 percent of U.S. food shoppers use the Nutrition Facts label sometimes or often (Ref. 14), and it is a valuable tool to help consumers maintain healthy dietary practices. However, the information, including scientific literature on nutrition labeling, that FDA has received on the Nutrition Facts label after decades of use has demonstrated that certain consumers do not look at the Nutrition Facts label (Refs. 15 to 17), and some struggle to understand the numerical values used to represent the nutrient content of the food or use the information presented there to make their food selections (Refs. 18 and 19). Additionally, information FDA has collected shows that providing context for the levels of certain nutrients to limit that is interpretive rather than solely numeric—to communicate the relative significance in the context of a total daily diet—and requiring that interpretive information appear on the front of the package helps consumers notice and use the nutrition information presented on food packages (Refs. 20 and 21).

Therefore, based on this data and other information referenced in this document, we have tentatively determined that an interpretive FOP nutrition label is needed to ensure that consumers can readily observe and comprehend information about certain nutritional attributes of a food at the point of decision-making that will assist them in maintaining healthy dietary practices. We similarly relied on our authority in section 2(b)(1)(A) of the NLEA to require the declaration of percent DV of a nutrient in a food in the 1993 Nutrition Facts label final rule establishing the Nutrition Facts label, stating that percent DV is needed to help consumers understand the relative significance of nutrition information presented on the label in the context of the total daily diet (58 FR 2206 at 2213, January 6, 1993). We have additionally determined that we have the authority under the NLEA and FD&C Act, as further explained in section IV.C of this document, to specifically require that certain additional interpretive nutrition information be presented on the principal display panel that can help consumers quickly and easily identify how foods can be part of a healthy diet.

As our research study and the broader literature demonstrate, the use of an FOP scheme with interpretive nutrition information allows consumers to make quick and informed decisions about the foods they choose for themselves and their families by making these additional disclosures readily observable and understandable. In our experimental research study, people of different sexes and ages and of all races, ethnicities, education levels, and nutrition knowledge levels were able to understand the nutrients to limit for products bearing the Nutrition Info box that most closely aligns with this

proposal, which includes low, medium, and high interpretive information (displayed as ''Low,'' ''Med,'' and ''High''), as well as percent DV information, and to use that box to correctly identify products with the healthiest or least healthy nutrition profile based on the displayed nutrients (Ref. 38). Further, this Nutrition Info box performed generally better than other schemes that were tested on both of these measures (id.). Additionally, participants viewing this Nutrition Info box were able to answer questions more quickly about a product's healthfulness compared with the other schemes tested (id.). Participants also reported that the box would help them easily find nutrition information on a food package and easily compare nutrition information across foods (id.).

The proposed Nutrition Info box would consist of factual disclosures about the nutrient content of a food that provide additional context to the information currently required to be declared in the Nutrition Facts label. The three nutrients that would be required in the Nutrition Info box—saturated fat, sodium, and added sugars—are recommended to be limited by current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025,* to achieve a nutrient-dense diet within calorie limits (Ref. 6). Current nutrition science emphasizes the consumption of healthy dietary patterns. While all foods can be incorporated into a healthy dietary pattern to some extent, current nutrition science highlights nutrient-dense foods as playing an important role in building a healthy dietary pattern, and those foods are, in part, characterized by limited amounts of saturated fat, sodium, and added sugars (id.). Findings from the 2019 Food Safety and Nutrition Survey (FSANS) found that 87 percent of U.S. consumers reported looking at the Nutrition Facts label. However, of those, fewer than half usually looked for saturated fat and added sugars, and slightly more than half usually looked for sodium, demonstrating that there is a gap in how consumers are currently noticing or using the declarations for these important nutrients (Ref. 14). As such, current dietary recommendations based on nutrition science and recent survey findings further support a need to provide consumers with additional, interpretive information about these important nutrients that can help them quickly and easily identify how the levels of these nutrients in a particular food fit in the context of a total daily diet. Further, manufacturers are able to make claims and provide truthful and non-misleading information about the beneficial nutritional attributes of food products on food labels and labeling including on the principal display panel. Requiring the Nutrition Info box would provide consumers with standardized and factual context about important nutrients on the front of food packages that can be compared across products. To streamline the amount of information provided in, as well as the space we require manufacturers to use for, the proposed Nutrition Info box, we are focusing on the three nutrients to limit to ensure that consumers have this additional context about these three important nutrients on the front of food packages to help inform their food choices.

The descriptions of the level of the nutrients that would be required in the Nutrition Info box (''Low,'' ''Med,'' and ''High'') are similarly science-based and reflective of FDA's long-established use of the nutrition advice regarding how to interpret percent DV declarations on products—that 5 percent or less of a nutrient in a food product is ''low'' and 20 percent or more of a nutrient is ''high'' (see section V.B.3 of this document for further discussion). They are further generally consistent with the levels in the ''low'' and ''high'' nutrient content claims. See, *e.g.,* §§ 101.62(b)(2) (''low'') and 101.54(b) (''high''), and our discussion of updating the low sodium nutrient content claim to align with current nutrition science in section IV.E of this document. We have tentatively determined that the standardized descriptions of the level of the nutrients that would be required in the Nutrition Info box along with the percent DV would help facilitate consumer understanding of a food's nutrient profile and help consumers in identifying foods that can help them build a healthy diet. See, *e.g.,* 58 FR 2302 at 2334 (January 6, 1993) (1993 nutrient content claim rule) (stating FDA's belief that the selection of a food bearing the term ''low'' should help consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients). This is borne out by our recent research study, which found that, when shown a grouping of three distinct nutrient profiles, the vast majority of study participants were able to correctly identify the healthiest and least healthy nutrient profiles (95 percent and 92 percent, respectively) using the proposed Nutrition Info box, which includes the ''Low,'' ''Med,'' and ''High'' descriptions (Ref. 38).

We also note that previous research we conducted further supports the more recent findings. In 1992, in arriving at the use of the percent DV on the current Nutrition Facts label, we tested a variety of options, including the use of adjective descriptions (*e.g.,* ''low,'' ''medium,'' and ''high'') with percent DV (Ref. 41). In the 1993 Nutrition Facts label final rule first establishing the Nutrition Facts label, we stated that the declaration of nutrient amount as percent DV or the placement of adjectival descriptors such as ''high'' and ''low'' next to the nutrient amount were both effective ways to help consumers understand the significance of product nutrition information in the context of a total daily diet (58 FR 2079 at 2118). Although we reported in 1993 that adjective formats (*i.e.,* those featuring ''low,'' ''medium,'' and ''high'') alone led consumers to miss quantitative differences between products when different nutrient levels were described using the same adjective (see, *e.g.,* 58 FR 2079 at 2117), our current research shows that the use of the interpretive low, medium, and high descriptions together with the percent DV in the proposed Nutrition Info box would better inform consumers about where certain foods fall within the ranges of each term than a strictly quantitative label would (Ref. 38).

Further, with regard to the low sodium nutrient content claim and as discussed later in sections V.B.3 and V.G of this document, the low sodium claim may currently be used on the label or in the labeling of a food other than a meal product or main dish if it contains 140 mg or less sodium per reference amount customarily consumed (RACC) (and per 50 g if the food has a RACC of 30 g or less or 2 tablespoons or less) and on the label or labeling of a food that is a meal product or main dish if it contains 140 mg or less sodium per 100 g (see § 101.61(b)(4) and (5)). Consistent with our authority in section 403(r) of the FD&C Act, we are proposing to update the low sodium nutrient content claim so that it may be used on the label or in the labeling of a food other than a meal product or main dish if it contains 115 mg or less sodium per RACC (115 mg or less per 50 g if the food has a RACC of 30 g or less or 2 tablespoons or less) and on the label or labeling of a food that is a meal product or main dish if it contains 115 mg or less sodium per 100 g. The updated definition for the low sodium nutrient content claim is aligned with the regulation that provides a DRV for sodium of 2,300 mg, which was updated in the 2016 Nutrition Facts label final rule, based on scientific evidence and consensus recommendations (see 81 FR

33742 at 33874 and § 101.9(c)(9)). The proposed updated definition for the low sodium claim (at 115 mg or less sodium per RACC) also generally aligns with the proposed definition for the ''Low'' interpretive description in the Nutrition Info box (at 5% DV or less).

In addition, as outlined in section V.G, to prevent inconsistency on food labeling that could result in consumer confusion, we are relying on our authority in section 403(r) of the FD&C Act to propose to revise the definitions for the low sodium nutrient content claim and low saturated fat nutrient content claim to require that, in order to bear a low sodium nutrient content claim or low saturated fat nutrient content claim, a food must display ''Low'' in accordance with proposed § 101.6 for sodium or saturated fat in the Nutrition Info box, respectively. Note that we are not proposing to update the gram amount for the low saturated fat nutrient content claim, as the gram amount for the low saturated fat nutrient content claim (1 g saturated fat) already aligns with the proposed definition for the ''Low'' interpretive description in the Nutrition Info box (at 5% DV or less) and we have not currently identified another need to update it. See section V.B.3 of this document for a further discussion.

C. Legal Basis for the Proposal

The purpose of the Nutrition Info box and this proposed rule is to implement the congressional mandate set forth by the NLEA that FDA must implement regulations to help consumers readily observe and comprehend the nutrition information pertaining to a particular food in the context of a total daily diet. More specifically, the proposed Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet—which includes the consumption of foods that contain little or no saturated fat, sodium, and added sugars (Ref. 6)—and that allows them to quickly make comparisons of the levels of such nutrients across foods. As contemplated by section 2(b)(1)(A) of the NLEA, the proposed Nutrition Info box, including its interpretive descriptions of certain nutrient levels, would present nutrition information required to be placed on the label or labeling of foods under section 403(q) in a manner that allows consumers to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet (21 U.S.C. 343 note). The presentation of such interpretive information on the principal display panel is designed to draw attention to and highlight information about certain nutrients that play an important role in the building of healthy dietary patterns, thereby assisting consumers in maintaining healthy dietary practices (see 21 U.S.C. 343(q)). Importantly, we note that the Supreme Court has considered and rejected narrow readings of the FD&C Act, instead embracing broad constructions of the FD&C Act based on the Court's understanding of its text, congressional intent, and remedial purpose. See, *e.g., United States* v. *Bacto-Unidisk,* 394 U.S. 784, 798 (1969) (''Congress fully intended that the [FD&C] Act's coverage be as broad as its literal language indicates.''); *United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943) (''The purposes of [the FD&C Act] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.'').

As explained in the sections elsewhere in this document, data and other information referenced that FDA has assembled and assessed supports that the proposed Nutrition Info box would be readily observable and comprehensible to consumers; allow them to understand the required information's relative significance in the context of the total daily diet; and assist them in maintaining healthy dietary practices. As discussed, current nutrition science and Federal dietary guidance, including the *Dietary Guidelines, 2020–2025,* emphasize the role of overall healthy dietary patterns and the consumption of nutrient-dense foods containing little or no saturated fat, sodium, and added sugars. Meanwhile, 2019 FSANS findings demonstrate that, of those who look at the Nutrition Facts label, the majority do not look at saturated fat and added sugars, and slightly more than half look at sodium (Ref. 14). Furthermore, in FDA's experimental study, the proposed Nutrition Info box performed best among all schemes tested in helping consumers identify healthier nutrient profiles and led them to correctly describe the level of such nutrients (Ref. 38). Additionally, participants spent less time correctly responding to questions about the nutrient profile of a food when viewing the proposed FOP nutrition labeling scheme and reported that the scheme would help them easily find nutrition information on a food and easily compare nutrition information between foods (id.). Taken together, this data and other referenced information support the inclusion and interpretation of the levels of saturated fat, sodium, and added sugars in the proposed Nutrition Info box and help demonstrate that the box would allow consumers to readily observe and comprehend the information conveyed and assist them in maintaining healthy dietary practices, in line with section 2(b)(1)(A) of the NLEA and section 403(q) of the FD&C Act.

We are also issuing this rulemaking consistent with our authorities in sections 701(a), 403(a)(1), and 201(n) of the FD&C Act, respectively). Sections 403(a)(1) and 201(n) of the FD&C Act represent our general labeling authority and describe when a product label would be misbranded as misleading for failing to include material facts regarding the food. In the context of nutrition labeling, we have considered the declaration of meaningful sources of nutrients to be a material fact (see 55 FR 29487 at 29491 through 29492, July 19, 1990, and 68 FR 41434 at 41438, July 11, 2003). Similarly, here, FDA finds that the relative amounts of these nutrients to limit in food products is material information that consumers must have as they select foods as part of their daily diet. Absent this mandatory, interpretive labeling on the front of food packages to complement the existing nutrition data on the label or labeling of food, data and other referenced information we have gathered show that consumers face challenges in understanding the relative contribution that individual foods make to their total daily intake of these nutrients to limit. Further, under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act to ''effectuate a congressional objective expressed elsewhere in the [FD&C] Act'' (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Supp. 1179, 1183 (D. Del. 1980))).

D. Inapplicability of Nutrient Content Claim Provisions to Proposed § 101.6

Some of the information that would appear in the Nutrition Info box would be a nutrient content claim if a manufacturer chose to voluntarily include it elsewhere on a food label. But we have determined that the proposed information in the Nutrition Info box, when it appears in the Nutrition Info box, is not a nutrient content claim and would not be subject to the requirements for nutrient content claims in section 403(r) of the FD&C Act and

its implementing regulations. Nutrient content claims are voluntary statements used by manufacturers to describe the level of nutrients in a food product. They are permitted by section 403(r) of the FD&C Act and FDA's nutrient content claim regulations. The 1993 nutrient content claim rule stated that the information about the nutrient content of a food be presented in standardized form, using uniform terms defined by FDA, so that consumers will not be misled (58 FR 2302 at 2394). Section 403(r)(1)(A) of the FD&C Act specifies that claims made in the label or labeling of the food that expressly or by implication characterize the level of any nutrient which is of the type required by section 403(q)(1) or (2) of the FD&C Act to be in the label or labeling of the food are only permitted if they are made in accordance with FDA's authorizing regulations. In brief, pursuant to section 403(r) of the FD&C Act and our nutrient content claim regulations, defined nutrient content claims (*e.g.,* ''lite,'' ''free,'' ''low,'' ''high'') may be voluntarily used only on certain food products that meet the established criteria for such claims, as described at part 101, subpart D. However, section 403(r)(1) of the FD&C Act provides that a statement that appears as part of the nutrition information required or permitted under section 403(q) of the FD&C Act is not a nutrient content claim.

As explained elsewhere in this document, we are proposing this Nutrition Info box in line with our authorities in section 2(b)(1)(A) of the NLEA and section 403(q) of the FD&C Act, and therefore, it is not a nutrient content claim under section 403(r) of the FD&C Act. The proposed Nutrition Info box would include additional contextual information that conveys certain nutrition information required by section 403(q) of the FD&C Act in a manner that the public can readily observe and comprehend. This additional contextual information about the three nutrients to limit would appear on nearly all packaged foods, thereby providing such information to consumers about how they can place these foods into their diets. Similar to the required declaration of percent DV in the Nutrition Facts label, which must appear on nearly all food packages and allows consumers to understand the required nutrition information's relative significance in the context of a total daily diet, the information included in the proposed Nutrition Info box, including the interpretive descriptions ''Low,'' ''Med,'' and ''High,'' would be required to be displayed on all foods subject to the rule. For these reasons, we find that the proposed required information in the Nutrition Info box would not constitute a nutrient content claim and would not be subject to the requirements for nutrient content claims in section 403(r) of the FD&C Act.

Thus, we have proposed amending § 101.13(c) to specify that the information proposed to be required as part of this Nutrition Info box would not be a nutrient content claim. This is consistent with our determination that the information in the Nutrition Facts label, including percent DV, is not a nutrient content claim. As noted in more detail elsewhere in this document, other voluntary statements, such as ''100 calories,'' that do not appear as part of the nutrition information required or permitted by section 403(q) of the FD&C Act are expressly permitted by § 101.13 as nutrient content claims. We note that any claims about the nutrient levels of a food outside of the Nutrition Facts label and proposed Nutrition Info box would be nutrient content claims, which must meet applicable statutory and regulatory requirements (see section 403(r) of the FD&C Act and the relevant nutrient content claim regulations (for example, those in § 101.13)).

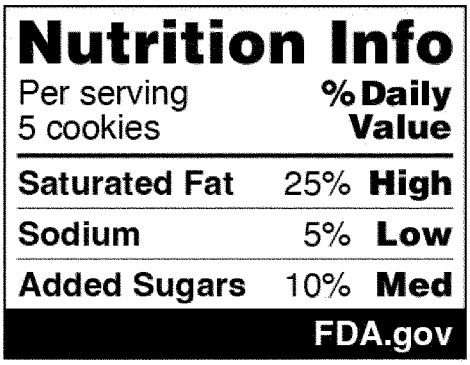
E. Severability

Although we believe that each of the elements of the Nutrition Info box that would be established by this rule, when applied collectively, would best help consumers to identify how foods fit into a healthy diet, each element independently enhances the manner of presentation to increase the likelihood that consumers would be able to readily observe and comprehend the required interpretive nutrition information on the front of food packages. In the event of a stay or invalidation of certain element(s) of the box, the other elements would continue to function sensibly to advance the statutory objectives. See, *e.g., Belmont Mun. Light Dep't* v. *FERC,* 38 F.4th 173, 188 (D.C. Cir. 2022) (finding severability of a portion of an administrative action, applying the principle that severability is appropriate where ''the agency prefers severability to overturning the entire regulation'' and where the remainder of the regulation ''could function sensibly without the stricken provision'') (citations omitted). For example, if the proposed requirement regarding the location of the Nutrition Info box on the upper third of the principal display panel were invalidated, we have tentatively determined that the substantive elements of the box, such as the requirements to include the interpretive descriptions and percent DV of saturated fat, sodium, and added sugars, would still function sensibly and be needed to provide important context to consumers elsewhere on the principal display panel. Likewise, in the absence of the proposed type style requirement, for example, each of the other features of the Nutrition Info box would continue to function and contribute to consumers readily observing and comprehending the nutrition information provided by the box and assist them in maintaining healthy dietary practices. Overall, it is FDA's intent to preserve each of the rule's aspects to the fullest possible extent, to help advance the important interests described in section IV.A.

V. Description of the Proposed Rule

We propose to add new § 101.6 to part 101, ''Food Labeling.'' The proposed rule would require the inclusion of the Nutrition Info box on the principal display panel of most foods that are required to display the Nutrition Facts label. The Nutrition Info box is intended to complement the Nutrition Facts label and would provide consumers with interpretive information on the front of food packages for three nutrients to limit that would allow consumers to compare the levels of these three important nutrients among foods and quickly and easily identify how foods can be part of a healthy diet.

An example Nutrition Info box that reflects all proposed requirements is as follows:



We also propose two overall amendments to certain nutrient content claims: (1) revising § 101.61(b)(4) and (5) to update the limit for the low sodium nutrient content claim to 115 mg per RACC or 100 g, which aligns with current nutrition science; and (2) adding requirements to §§ 101.61 and 101.62 specifying that food subject to this rule must bear ''Low'' in accordance with proposed § 101.6 for sodium and saturated fat, respectively, in the Nutrition Info box for the food's labeling to qualify to bear the related low in nutrient content claim, which would avoid within-label inconsistencies with the proposed FOP scheme.

A. Scope/Applicability (Proposed § 101.6(a)(1))

Proposed § 101.6(a)(1) would require that this rule apply to all food covered under § 101.9 (Nutrition labeling of food) that is marketed for people ages 4 and older unless a specific exemption applies. The congressional record for the NLEA indicates that mandatory nutrition labeling was intended to solve problems with voluntary disclosure—the standard at the time—including that a significant percentage of food was sold without any nutrition information (Ref. 40). Section 403(q) of the FD&C Act therefore specifies, in part and with certain exceptions, that a food is misbranded unless its label or labeling bears nutrition information for certain nutrients, and § 101.9 details these requirements. Most foods we regulate (*i.e.,* all foods not specified in § 101.9(j)) must bear a Nutrition Facts label as described in § 101.9 (see § 101.9(a)).

In addition, we relied on our authority in section 2(b)(1)(A) of the NLEA to require the percent DV declaration in the Nutrition Facts label. In the preamble to one of our first regulations related to the Nutrition Facts label, we noted that the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of a total daily diet, compare the nutritional values of food products, and plan general diets (58 FR 2206 at 2213).

Our research shows that 87 percent of adults living in the United States look at the Nutrition Facts label, and at least 76 percent use the Nutrition Facts label when buying a food for the first time (Ref. 14). However, only 49 percent of adults report looking at the percent DV on the Nutrition Facts label (id.). Data also suggest that up to 40 percent of Americans ages 16 and older do not understand the meaning of percent DV (Ref. 42). Accordingly, and consistent with our statutory direction in section 2(b)(1)(A) of the NLEA to require that certain information be conveyed in a manner that consumers can readily observe and comprehend, we are proposing a mandatory labeling scheme that would complement the Nutrition Facts label by providing additional, easy-to-use, interpretive context in the form of descriptive terms for the percent DV of certain nutrients (discussed later in section V.B.4 of this document) on the principal display panel (*e.g.,* the front of the package) of most foods. We discuss exemptions to this requirement later in section V.F of this document.

We propose that the scope of this rule cover foods marketed for the general population. In the 2016 Nutrition Facts label final rule, we updated the Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs) (the recommended amounts of nutrients to meet or not to exceed each day, which are often referred to collectively as the Daily Values) for adults and children ages 4 years and older to be consistent with the data on the associations between nutrients and chronic diseases, health related conditions, physiological endpoints, and maintaining a healthy dietary pattern (81 FR 33742). We have traditionally used this age category as representative of the general population for nutrition labeling purposes (id.). We note that the DRVs for saturated fat, sodium, and added sugars for pregnant and lactating people are the same as those for the general population (see § 101.9(c)(9)). Therefore, for purposes of this proposed rule, we consider pregnant and lactating people to be part of the general population.

We are not including foods marketed for children under 4 years old within the scope of this proposed rule. We recognize that infants and children ages 1 to 3 years are vulnerable subpopulations and have specific nutritional needs. The 2016 Nutrition Facts label final rule established mandatory labeling requirements to include specific DRVs for children ages 1 through 3 years (81 FR 33742 at 33927–31, codified at § 101.9(c)(9)). FDA has not established DRVs or percent DVs (*i.e.,* how much a nutrient in a single serving of food contributes to the DRV) for saturated fat, sodium, or added sugars for infants through age 12 months.

Our proposed interpretive descriptions for these nutrients are based on percent DVs. Therefore, for food products marketed for infants through age 12 months (*i.e.,* jars of baby food, teething crackers), we tentatively determine that it currently would not be feasible to provide consumers with additional interpretation—the purpose of the proposed Nutrition Info box—about the relative amounts of saturated fat, sodium, or added sugars in the products.

Additionally, since publication of the 2016 Nutrition Facts label final rule, there have been changes to Federal dietary guidance for children ages 1 to 3 years. The *Dietary Guidelines, 2020–2025* established daily nutrition goals for two subpopulations of children: ages 12 to 23 months and 2 to 3 years. This included goals for sodium for children ages 12 to 23 months and goals for saturated fat, sodium, and added sugars for children ages 2 to 3 years (Ref. 6). These categorizations do not align with current FDA regulations that provide DRVs for saturated fat, sodium, and added sugars for the single category of children ages 1 to 3 years (see

§ 101.9(c)(9)). Additionally, in some cases, the *Dietary Guidelines, 2020–2025* calculated daily nutrition goals using a different methodology than FDA used when establishing DRVs. For example, the *Dietary Guidelines, 2020–2025* established recommendations for daily sodium limits based on the Chronic Disease Risk Reduction level established by NASEM (Ref. 6). However, current FDA regulations include a DRV for sodium for children ages 1 to 3 (see § 101.9(c)(9)) that we derived using the upper limit for sodium established by the IOM for this age group (81 FR 33742 at 33929). The *Dietary Guidelines, 2020–2025* indicate that saturated fat should not be restricted in children younger than 2 years (Ref. 6).

Because we continue to evaluate the information on the nutritional needs of these subpopulations, as well as our DRVs for saturated fat, sodium, and added sugars for children ages 1 to 3 years (given the daily nutrition goals included in the *Dietary Guidelines, 2020–2025*), we are not currently proposing to require FOP nutrition labeling on foods marketed for infants and children ages 1 to 3 years. We invite comment, including data and other information, related to: (1) the nutritional needs of these subpopulations; and (2) the need for or value of interpretive nutrition information that can help consumers quickly and easily identify how foods can be part of a healthy diet for these subpopulations. We expect such feedback could help inform any future FOP policy for foods marketed for infants and children ages 1 to 3 years.

We are also proposing to exempt most dietary supplements from bearing a Nutrition Info box. Dietary supplements labeled in accordance with the special nutrition labeling provisions in § 101.36 are exempt from Nutrition Facts labeling under § 101.9(j)(6) and would therefore be exempt from Nutrition Info box labeling under proposed § 101.6(c)(1), discussed elsewhere in this document. Dietary supplements are products intended for ingestion, that, among other requirements, contain at least one dietary ingredient intended to supplement the diet (21 U.S.C. 321(ff)). Dietary ingredients include vitamins and minerals; herbs and other botanicals; amino acids; dietary substances that are part of the food supply, such as enzymes and live microbials (commonly called ''probiotics''); and concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient from the preceding categories (21 U.S.C. 321(ff)(1)). While dietary supplements are considered foods, they serve a different purpose than conventional foods when it comes to building a healthy dietary pattern; they often provide individual nutrients (*e.g.,* Vitamin C) and are intended to supplement, rather than constitute a core part or foundation of, the diet. Given the distinct role of dietary supplements in the overall diet, we propose to exempt such products from this proposed rule. Many dietary supplements do not contain saturated fat, sodium, and added sugars, and they are not required to have these nutrients declared on their nutrition label unless the supplement contains quantitative amounts by weight that exceed the amount that can be declared as zero (see 21 CFR 101.36(b)(2)). However, we are aware that some dietary supplements may contain what this proposed rule would describe as ''High'' levels of saturated fat, sodium, or added sugars per serving. We therefore invite comment on our proposed exemption of dietary supplements from the requirements of this rule.

B. Content (Proposed § 101.6(a)(2))

1. Headings and Subheadings (Proposed § 101.6(a)(2)(i) and (ii))

Proposed § 101.6(a)(2)(i) would require using ''Nutrition Info'' as the heading, or title, for the Nutrition Info box. This title describes what the box would convey and should be familiar in appearance to the ''Nutrition Facts'' title of the Nutrition Facts label (see § 101.9(d)(2)). We are proposing ''Info'' rather than ''Information'' to keep the title shorter and, therefore, the box smaller. This title reflects our intent to provide, in a convenient format, interpretive nutrition information to consumers that can help them quickly and easily identify how foods can be part of a healthy diet. The title would be displayed across the same distance of the box as the ''Nutrition Info'' header to orient the consumer and make it clear that the nutrition information that follows is part of this Nutrition Info box.

For the Nutrition Info box to be useful, consumers need to understand what nutrition information is being conveyed. Proposed § 101.6(a)(2)(ii)(A) would require using the subheading ''Per serving'' to help consumers understand that the Nutrition Info box, like the Nutrition Facts label, provides information about one serving of the food. We also propose including a statement of the serving size, expressed in household measures, alongside the ''Per serving'' subheading (*e.g.,* ''Per serving (whole package)'' or ''Per serving (½ cup)'') to further help consumers understand what one serving is. The inclusion of both ''Per serving'' and the serving size expressed in household measures would be consistent with the information required in the Nutrition Facts label (see § 101.9(b)) and would help consumers understand whether the product is ''Low,'' ''Med,'' or ''High'' in the three nutrients disclosed for a specific amount of the product. Further, listing ''Per serving'' with a statement of the serving size expressed in household measures would help improve awareness that the information presented in the Nutrition Info box does not refer to the contents of the entire package when the package contains multiple servings.

While the Nutrition Facts label includes a statement of the serving's gram amount (see § 101.9(b)(7)), the proposed Nutrition Info box would include only the serving's household measure. Section 403(q)(1)(A)(i) of the FD&C Act specifies that a food is misbranded unless its nutrition labeling bears the serving size, which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food. In our proposed rule to implement this and other labeling requirements, entitled ''Food Labeling; Serving Sizes'' (56 FR 60394, November 27, 1991), we proposed requiring that manufacturers provide the equivalent metric quantity, in parentheses, after the common household measure (*e.g.,* 1 cup (28 g)), on what would become the Nutrition Facts label (id. at 60410). We finalized that requirement in the 1993 Nutrition Facts label final rule and clarified that the gram declaration was for compliance purposes (58 FR 2079 at 2163) (codified at § 101.9(g)(7) (''Compliance will be based on the metric measure specified in the label statement of serving size.'')).

This Nutrition Info box would reflect the serving size, in common household measures, declared in the Nutrition Facts label, and only the Nutrition Facts label would also declare the serving size's metric measure. The inclusion of a metric measure would unnecessarily increase the Nutrition Info box's size, and inclusion of a second statement of serving size measurement could increase the box's complexity. Therefore, we are not proposing to include a second statement of the serving size's metric measure, as its inclusion would not align with our goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet.

Proposed § 101.6(a)(2)(ii)(B) would require including the subheading ''% Daily Value'' in the Nutrition Info box. This heading would appear above the declaration of the quantitative percent DV and the interpretive ''Low,'' ''Med,'' and ''High'' descriptions for the three nutrients included. We propose using the ''%'' symbol instead of the word ''percent'' due to spacing considerations and for consistency with the Nutrition Facts label (see § 101.9(d)(6)).

2. Nutrients to Limit (Proposed § 101.6(a)(2)(iii))

Proposed § 101.6(a)(2)(iii) would require that the Nutrition Info box include information on saturated fat, sodium, and added sugars. We propose that saturated fat, sodium, and added sugars be the only nutrients in the Nutrition Info box, given their significance in building healthy dietary patterns, the scientific research on FOP nutrition labeling, and the current food labeling landscape, in which consumers report being familiar with a wide variety of industry claims (Ref. 14). This Nutrition Info box would be a continuation of our efforts to help consumers by providing information that can help them improve their dietary patterns by providing them with interpretive nutrition information presented on the front of food packages in a consistent, uniform way about the amounts of the three nutrients in covered products so they can quickly and easily understand their relative significance in the context of a total daily diet.

In the 2016 Nutrition Facts label final rule, we noted that nutrition science supports limiting intake of saturated fat, sodium, and added sugars (see 81 FR 33847). Similarly, the *Dietary Guidelines, 2020–2025* includes recommendations to choose nutrient-dense foods across and within food groups while limiting foods (including beverages) higher in saturated fat, sodium, and added sugars as a key strategy in emphasizing healthy overall dietary patterns (Ref. 6). For instance, research shows that people with diets characterized, in part, by lower intake of saturated fat, sodium, and added sugars were at 13 to 27 percent decreased risk for dying from any cause, cancer, or cardiovascular disease (Ref. 43). Still, most Americans exceed the recommended intake limits for saturated fat, sodium, and added sugars (Ref. 6).

FDA has been prioritizing nutrition initiatives that can help improve dietary patterns as part of a broader effort to help reduce the burden of diet-related chronic diseases in the United States and advance health equity, as diet-related chronic diseases are experienced disproportionately by certain racial and ethnic populations and those with lower socioeconomic status. Our initiatives include those that support consumer understanding of nutrients to limit in the diet. For example, on December 27, 2024, FDA published a rule amending the ''healthy'' implied nutrient content claim (89 FR 106064). The framework for the updated ''healthy'' definition includes criteria for nutrients to limit. We state in the rule that these criteria are consistent with current nutrition science and the *Dietary Guidelines, 2020–2025* recommendations to limit intake of saturated fat, sodium, and added sugars, and help ensure that foods bearing the ''healthy'' claim do not contain excess amounts of these nutrients, which can, among other things, increase the risk of chronic disease (id. at 106091, 106093, 106104, and 106110). Additionally, in 2021, FDA published short-term (2.5-year) voluntary sodium reduction targets for the food industry, as part of a gradual, iterative approach to help reduce sodium in the food supply and support reducing sodium intakes over time (see 86 FR 57156, October 14, 2021). We published draft Phase II (3-year) goals in 2024 (see 89 FR 66727, August 16, 2024).

Regarding the scientific research on FOP nutrition labeling, our research found, and the scientific literature we considered confirms, that simpler schemes are easier for consumers to understand and that consumers often have access to information about nutrients to get enough of on the front of food packages. The *Dietary Guidelines, 2020–2025* names five nutrients of public health concern (*i.e.,* nutrients to get enough of) (dietary fiber, vitamin D, calcium, iron, and potassium (Ref. 6)) as well as the three nutrients to limit, and the scientific research and literature on FOP nutrition labeling indicate that the inclusion of nutrients to get enough of with nutrients to limit may not lead to simple schemes that help consumers. For example, we tested FOP nutrition labeling schemes that included fiber and calcium, along with saturated fat, sodium, and added sugars, in our first focus groups (Ref. 36), given that these nutrients to get enough of may be included in certain industry-based, voluntary FOP initiatives in the United States (Ref. 20) and in certain international schemes (Ref. 32). The feedback we collected through our first focus group research indicated that participants were confused by the inclusion of both nutrients to limit and nutrients to get enough of in the same FOP scheme (Ref. 44). This focus group testing helped inform our experimental study, which included schemes with only the three nutrients to limit.

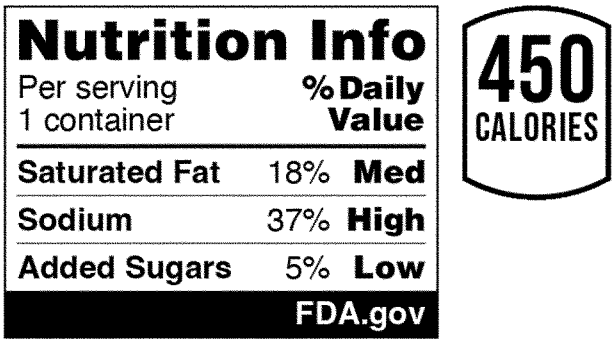
Regarding the current food labeling landscape, we note that manufacturers have many ways to communicate information on the front of a food package about nutrients to get enough of. Use of nutrient content claims can inform consumers interested in intake of specific nutrients. Health claims (*i.e.,* claims that have been reviewed by FDA and are authorized on food products to state that a food or food component may reduce the risk of a disease or a health-related condition) can also highlight the content of specific nutrients in a food and their relation to the risk of various diseases. Other claims can highlight nutrients and provide context to their role in the normal structure or function of the body. In addition to these claims, manufacturers may voluntarily include truthful and non-misleading information about their products on food labels or labeling.

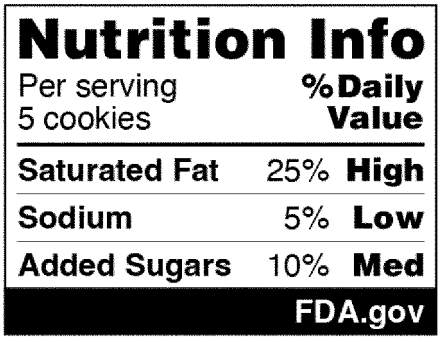
As discussed elsewhere in this document, the proposal would provide consumers with a quick- and easy-to-use scheme immediately visible on the label or labeling that would state relative amounts of the three disclosed nutrients. We tentatively conclude that a scheme that focuses only on certain nutrients to limit would provide consumers with important information to help them build and maintain healthy dietary practices without including additional information that could lessen the effectiveness of a nutrition label designed for quick, easy use. This would also make the scheme simpler, which research shows consumers prefer (Refs. 20 and 27).

We also considered whether to include or allow a calorie disclosure in the proposed Nutrition Info box. We are aware that some interested parties would prefer the inclusion of a quantitative calorie statement in the Nutrition Info box. However, a quantitative calorie statement would not provide consumers with new, interpretive information. Regarding an interpretive description of calories, our regulations, at § 101.9(c)(9), specify the DRVs for, among other things, saturated fat, sodium, and added sugars. While these DRVs are based on the reference caloric intake of 2,000 calories, which we use for general nutrition advice, we note that there is no DRV, and therefore no percent DV, for calories. In the 2014 proposed rule to update the Nutrition Facts label, we explained that setting a DRV for calories would necessitate determining a quantitative intake recommendation for calories, but also

noted that there is no appropriate quantitative intake recommendation for calories and that we were not aware of any other data or information on which a DRV for calories could be determined (79 FR 11880 at 11892–93). We maintained this position in the 2016 Nutrition Facts label final rule. We noted that quantitative intake recommendations for calories are called estimated energy requirements (EERs), and they are based on healthy individuals of defined age, sex, weight, height, and level of physical activity (81 FR 33742 at 33782). We explained that it would be difficult to combine the EERs into a single reference calorie level applicable to the general population because calorie needs vary based on many factors (id.). Therefore, we did not establish a DV for calories and have continued to use the reference caloric intake of 2,000 calories for general nutrition advice (id.). We are aware of no new data or other information published after the 2016 Nutrition Facts label final rule that changes our determination. Therefore, we tentatively conclude that it would not be appropriate to provide consumers with an interpretation of the quantitative calorie information currently required on the Nutrition Facts label.

We acknowledge that some food manufacturers are voluntarily providing calorie information on the front of food labels, including to help vending machine operators comply with FDA's calorie labeling requirements for articles of food sold from certain vending machines (see § 101.8(c)(2)(ii)), and have an interest in continuing this practice. Our existing regulations allow manufacturers to voluntarily include such a statement on the principal display panel (see § 101.13(i)(3)). Our proposal would not change that. Examples of what such labeling might look like are as follows:





We invite comment on the inclusion of a mandatory or voluntary quantitative statement of calories in the Nutrition Info box. We also invite comment on any ways we could consider inclusion of an interpretation of quantitative calorie information in the Nutrition Info box, including any new data or other information on which to base such an interpretation.

3. ''Low,'' ''Medium,'' and ''High'' Interpretive Descriptions (Proposed § 101.6(a)(2)(iv))

Proposed § 101.6(a)(2)(iv) would require low, medium, and high (''Low,'' ''Med,'' and ''High'') descriptions for each nutrient to limit in the Nutrition Info box. These descriptions would interpret the percent DV of saturated fat, sodium, and added sugars per product serving. We propose a range of 5% DV or less for ''Low''; 6% to 19% DV for ''Med''; and 20% DV or more for ''High.'' Because the percent DV declarations will have already been calculated and appropriately rounded for the Nutrition Facts label according to § 101.9(c)(9) and (d)(7)(ii), we do not address calculation or rounding considerations in this proposed rule.

In proposing ranges for the low, medium, and high interpretive descriptions, we considered the regulatory history related to establishment of the percent DV and such descriptions; our longstanding consumer education activities designed to help consumers understand the percent DV in the context of the total daily diet; the nutrition education initiatives of other groups; and our existing regulatory definitions for nutrient content claims, including definitions established for ''low'' and ''high'' claims. The ranges we propose for determining interpretive descriptions for saturated fat, sodium, and added sugars—in particular, the designation of 5% DV or less to be ''Low'' and 20% DV or more to be ''High''—align with our longstanding general approach for interpreting the percent DV.

First, percent DV declarations use a common numeric reference standard (*i.e.,* 0 through 100), and interpretive descriptions help to put those numeric values into the context of a total daily diet using easily understood terms (*e.g.,* ''Low,'' ''Med,'' ''High''). As discussed elsewhere in this document, the NLEA's legislative history explicitly mentions using the terms ''low,'' ''medium,'' and ''high'' to help consumers place the nutrient levels in a food into the context of a daily diet (Ref. 40). As early as 1993, we considered the addition of interpretive descriptions to the Nutrition Facts label next to the percent DV to help consumers understand a food's nutrient profile and identify foods that could fit into healthy dietary patterns (see, *e.g.,* 58 FR 2079 at 2118). While we concluded in the 1993 Nutrition Facts label final rule that both percent DV and interpretive descriptions next to the nutrient amount information were effective in helping consumers understand the significance of nutrition information in the context of a total daily diet, we ultimately finalized contextualizing nutrient amount information as percent DV (58 FR 2079 at 2118 and 2125), stating our belief that consumers would be able to use percent DV declarations more effectively than any other format we tested. However, recent data show that up to 40 percent of American consumers misinterpret or do not understand the meaning of percent DV (Ref. 42). Additionally, our recent research found that, when shown a grouping of three distinct nutrient profiles, the vast majority of participants were able to correctly identify the healthiest and least healthy nutrient profiles (95 percent and 92 percent, respectively) using the Nutrition Info scheme, which included low, medium, and high descriptions and percent DVs (Ref. 38).

Second, for many decades, FDA has publicized a general framework designed to help consumers interpret nutrient levels in a product. This framework (5/20 principle) has informed consumers that 5% DV or less of a nutrient per serving is considered low and 20% DV or more of a nutrient per serving is considered high (Refs. 45 and 46). In 2011, as part of a ''Food Label and You'' campaign, we released several videos to promote consumer awareness and understanding of the 5/20 principle for interpreting percent DV on a food label (Ref. 47). We continued publicizing this general framework on our website as a component of our consumer education campaign, ''The New Nutrition Facts Label: What's in it for You,'' after the 2016 Nutrition Facts label final rule published (id.).

Third, diverse groups, including health agencies, academic institutions, medical and public health groups, and media outlets, have also relied on the 5/20 principle for decades. For example, the American Heart Association, American Diabetes Association, Mayo Clinic, Johns Hopkins University, The Ohio State University, National Institute on Aging, International Food Information Council, Public Broadcasting Service, New York Times, and Business Insider provide this advice in education initiatives designed to help consumers understand and interpret information on food labels (id.). Food retailers and industry groups have also adopted this general approach in public-facing materials when discussing nutrition information on the food label (id.). As such, the designation of 5% DV or less to be ''Low'' and 20% DV or more to be ''High'' for the nutrients required to be listed in the Nutrition Info box aligns with widely adopted and used definitions for low and high in nutrition-related consumer education initiatives.

Fourth, the NLEA and FD&C Act permit claims on a food label that are authorized by FDA regulations and characterize the level of a nutrient in a food (*i.e.,* nutrient content claims). Nutrient content claims can be voluntarily used by manufacturers to describe the level of a nutrient in a food using terms such as ''low'' and ''high,'' and most are applicable only to nutrients that have an established DV. When we first established the regulatory definitions for nutrient content claims, we stated that our objectives included consistency among definitions, claims that aligned with public health goals, and claims that consumers could use to maintain healthy dietary practices (58 FR 2302 at 2319).

FDA has nutrient content claims regulations for low saturated fat (§ 101.62(c)(2) and (3)) and low sodium (§ 101.61(b)(4) and (5)). These regulations provide criteria for ''low'' and its specified equivalent terms. Our regulatory definitions for ''low'' claims provide absolute amounts (*i.e.,* grams, milligrams); however, we have long applied the general principle that 5% DV or less is considered ''low'' in consumer education (Refs. 45 to 47), and the relevant gram amounts are generally consistent with that principle, as discussed further here.

In 1993, we established a DRV of 20 g for saturated fat, which was based on the 1990 Dietary Guidelines recommendation that consumption of saturated fat should be less than 10 percent of calories (58 FR 2206 at 2217). In the 1993 nutrient content claim final rule, we noted that using an average level of 1 g in 16 to 20 servings of food per day would supply 16 to 20 g of saturated fat daily, which is within the DRV of 20 g (58 FR 2302 at 2338 through 2340). In addition to this 1 g or less per RACC criterion, we also established a second criterion for low saturated fat of 15 percent or less of calories from saturated fat for individual foods and 10 percent or less of calories from saturated fat for meals and main dishes. This second criterion was established to limit ''low'' claims on foods with small serving sizes because these foods do not contain especially low levels of saturated fat (58 FR 2338 at 2339). Our analysis highlighted that saturated fat was present in more than half of 18 United States Department of Agriculture-defined food categories (58 FR 2302 at 2338). We also noted that very little saturated fat was found in most fruit, vegetables, and grains. In the 2016 Nutrition Facts label final rule, we retained the DRV of 20 g for saturated fat because consensus reports continued to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of cardiovascular disease (81 FR 33786). The low saturated fat claim of 1 g or less per RACC is 5% DV or less.

We established the nutrient content claim for low sodium in a final rule entitled ''Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content'' (49 FR 15510, April 18, 1984) (1984 final rule). In the proposed rule entitled ''Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content'' (47 FR 26580, June 18, 1982), we estimated that the consumption of 20 low-sodium foods would contribute about 2,800 mg of sodium per day (using 20 servings per day as a reasonable average number of servings for adults and 140 mg of sodium per serving—considered to be low in sodium), which at the time fell into the National Academy of Sciences (now NASEM) and National Research Council's range for a mildly restricted sodium diet (id. at 26581 through 26585) (we proposed using the term ''moderately low sodium'' for this nutrient content claim but finalized the term ''low sodium'' to characterize nutrient content claims for foods containing 140 mg or less of sodium per serving—see 49 FR 15510 at 15519). Assuming 20 servings per day, 140 mg sodium per serving equaled 5 percent of 2,800 mg sodium per day for a mildly

restricted sodium diet. In the 1984 final rule, we concluded that a significant proportion of the food supply would be eligible to bear the low sodium claim (49 FR 15510). We noted that foods that could be labeled ''low sodium'' included some hot and cold cereals, many cuts of fresh meat and poultry, some fish, frozen vegetables, and some desserts and snacks such as cookies, cakes, and candy (id.).

In the 1993 Nutrition Facts label final rule, we established a DRV for sodium of 2,400 mg per day (58 FR 2206 at 2217). However, in the 1993 nutrient content claim final rule, we retained the definition for the low sodium claim as 140 mg or less sodium, highlighting that comments related to the rulemaking and at public hearings did not indicate a need for change and supported the existing criteria (58 FR 2302 at 2335 through 2336). We also established weight-based criteria for low claims for products with small serving sizes—RACCs of 30 g or less or 2 tablespoons or less—stating that this would prevent misleading claims on certain nutrient-dense foods (we stated in the proposed rule entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms'' (56 FR 60421, November 27, 1991) (one of two proposed rules underlying the 1993 nutrient content claim final rule) that (1) without the weight-based criterion, low claims would be allowed on certain foods that are nutrient dense on a weight basis yet still qualify for a low claim because of their small serving size, and (2) that nutrient-dense foods with small serving sizes could be consumed frequently throughout the day and ultimately make substantial contributions to the diet despite their low claims (id. at 60430)). We also established a weight-based criterion for meal products and main dishes in the 1993 nutrient content claim final rule, stating that providing for the level of a nutrient per 100 g of food is generally sufficient to prevent misleading claims on meal-type products (58 FR 2302 at 2315 through 2320 and 2379 through 2381).

In the 2016 Nutrition Facts label final rule, we updated the DRV for sodium from 2,400 mg to 2,300 mg based on consensus recommendations to reduce sodium intake because there is a direct relationship between sodium intake and increased blood pressure (81 FR 33742 at 33875 through 33880). With these updates, the low sodium threshold of 140 mg or less per serving equals 6% DV or less for low sodium nutrient content claims.

Given the updated 2,300 mg DRV for sodium in the 2016 Nutrition Facts label final rule, and in line with FDA's ongoing efforts to support reducing sodium intake in the United States (*https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction,* accessed June 13, 2024), we propose to update the low sodium nutrient content claim limit to 115 mg sodium (20 servings at 115 mg equals 2,300 mg). With this update, the low sodium nutrient content claim could be used on the label or in the labeling of a food other than a meal product or main dish if it contains 115 mg or less sodium per RACC (115 mg or less per 50 g if the food has a RACC of 30 g or less or 2 tablespoons or less) and on the label or labeling of a food that is a meal product or main dish if it contains 115 mg or less sodium per 100 g. This updated definition for the low sodium nutrient content claim would generally align with the 5% DV or less range that we are proposing for ''Low'' for sodium in the proposed Nutrition Info box. Additionally, the revised definition would apply to foods that are not subject to the proposed requirement to display a Nutrition Info box.

We are aware of limited exceptions to this alignment. For example, foods with RACCs greater than 30 g that have 116 mg to 125 mg sodium per serving (*e.g.,* certain reduced sodium canned vegetables) would fall under the ''Low'' categorization for sodium in the proposed Nutrition Info box but would not qualify to bear a low sodium nutrient content claim. Additionally, meal products or main dishes that contain 115 mg or less sodium per 100 g might fall into the ''Med'' categorization for sodium in the proposed Nutrition Info box and therefore would not be able to bear a low sodium nutrient content claim. However, in most cases, the updated definition for the low sodium nutrient content claim (115 mg sodium or less) would align with the 5% DV or less that we are proposing for ''Low'' for sodium in the proposed Nutrition Info box. We also note that, in all cases in which the Nutrition Info box would be required, labeling would be consistent, as we are proposing an update to the low sodium nutrient content claim that would require consistency between the Nutrition Info box and use of a low sodium nutrient content claim (see section V.G of this document).

While FDA has nutrient content claim regulations for low sodium and low saturated fat, we do not have a nutrient content claim regulation for low added sugars. However, the *Dietary Guidelines for Americans, 2020–2025* recommends limiting intake of added sugars to less than 10 percent of calories per day, or 50 g for a 2,000 calorie per day diet (which we use for general nutrition advice) (Ref. 6). In the 2016 Nutrition Facts label final rule, we established a DRV for added sugars of 50 g (see 81 FR 33742 at 33982, codified at § 101.9(c)(9)). As we stated in that final rule, small amounts of added sugars found in many different foods and ingredients can add up throughout the day and can contribute empty calories in the diet at levels that exceed what would otherwise be reasonable within recommended calorie limits (id. at 33813). With this information in mind, and consistent with our longstanding advice regarding how to interpret the percent DV, we propose using 5% DV or less as the range for ''Low'' for added sugars to provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, which includes limiting their overall intake of added sugars.

Applying a range of 20% DV or more for ''High'' is consistent with our nutrient content claim regulations (§ 101.54(b)(1)) for nutrients having either an RDI established in § 101.9(c)(8)(iv) or a DRV established in § 101.9(c)(9). While we are not aware that industry uses the claim for nutrients to limit, a ''high'' nutrient content claim for saturated fat, sodium, and added sugars is permitted under our existing regulations (see § 101.54). Moreover, under our general requirements for health claims, we use 20% DV to derive disqualifying levels (*i.e.,* the levels of these nutrients above which the label or labeling of a food may not bear a related health claim) for saturated fat and sodium (§ 101.14(a)(4)) (58 FR 2478 at 2494). Twenty percent DV is also used to establish the disclosure levels for, among other nutrients, saturated fat and sodium when a food bears a nutrient content claim about one of the other enumerated nutrients under § 101.13(h)(1) (58 FR 2302 at 2308). For example, if a food displays a low sodium nutrient content claim and also has 4 g saturated fat (*i.e.,* 20% DV saturated fat), the food would be required to display a disclosure such as ''See nutrition information for saturated fat content.''

FDA does not have a regulation for a nutrient content claim of ''medium'' for any nutrient. However, we are proposing a range of 6% to 19% DV for ''Med'' for purposes of the Nutrition Info box. This range falls between the proposed low and high ranges for saturated fat, sodium, and added sugars and provides a categorization for such nutrients that are too high to fall into ''Low'' but too low to fall into ''High.''

The adjective ''medium'' is defined as, for example, ''being in the middle between an upper and lower amount, size, degree, or value'' (Ref. 48) and ''intermediate in quantity, quality, position, size, or degree'' (Ref. 49). The common meaning of the adjective ''medium,'' then, aligns with the meaning of the interpretive description ''Med'' we are proposing. Additionally, many participants in our experimental study recognized that 15% DV of a nutrient fell somewhere in between ''High'' and ''Low'' (Ref. 38), and we provided no form of consumer education before they responded.

We recognize that some other countries use more than one value to establish their categorizations and provide different categorizations based on product type. For example, foods with smaller serving sizes, such as peanut butter, might fall under the ''High'' categorization at a lower percent DV than most other foods, while foods with larger serving sizes, such as prepackaged main dishes, might fall under the ''High'' categorization at a higher percent DV. We have established a similar tiered approach for certain nutrient content claims that would meet a ''low'' criterion for amount per serving but still, on a weight basis, contain a substantial amount of the nutrient. For example, to use the ''low fat'' claim, we require foods with small RACCs of less than 30 g or 2 tablespoons or less to be calculated at a 50 g basis (§ 101.62(b)(2)(i)(B)). Without this weight-based criterion, a dessert topping that contains 2 g fat per serving would meet the definition of ''low fat'' but contain as much as 25 g fat per 100 g of food. We invite comment on this serving size issue and welcome data and other information on possible different approaches.

Additionally, we request data and other information on any alternative criteria for the proposed interpretive ''Low,'' ''Med,'' and ''High'' descriptions that could support our goals of providing consumers with interpretive information for the levels of the three nutrients to limit in the Nutrition Info box that can help them quickly and easily identify how foods can be part of a healthy diet. We also invite comment on use of the ''Low'' categorization for products that declare 0% DV for any of these three nutrients, rather than a fourth categorization, such as ''Zero'' or ''Free,'' to indicate that the product is not simply ''Low'' for that nutrient but contributes zero percent to the DV.

In FDA's experimental study, we tested variations of the Nutrition Info box that included the colors green, yellow, and red to help communicate to consumers that a product was low, medium, or high, respectively, in the listed nutrients to limit. While there is some information in our literature review suggesting that color coding with text can lead to improved understanding of nutrition information, our experimental study found that colors neither significantly increased the utility of the Nutrition Info box for U.S. consumers nor increased understanding of the interpretive information provided in a statistically significant way (Ref. 38). Additionally, we have heard concerns from interested parties about potential difficulty with using color coding for consumers with red-green color blindness (which is the most common form (Ref. 50)) and that mandating colors would substantially increase the cost of complying with the rule. Given these factors, the importance of maintaining consistency for consumers, and to facilitate comparisons between products, our proposal would not require or allow such colors.

4. Inclusion of Percent Daily Value (Proposed § 101.6(a)(2)(v))

Proposed § 101.6(a)(2)(v) would require that the Nutrition Info box include the corresponding quantitative percent DV for people ages 4 and older for each nutrient listed, which will have already been calculated for the Nutrition Facts label according to § 101.9(c)(9) and (d)(7)(ii). We propose that these values be placed in a column underneath the ''% Daily Value'' subheading and to the left of the interpretive descriptions (see section V.B.3 of this document). As we stated in the 2016 Nutrition Facts label final rule, a percent DV declaration helps consumers understand the nutrient information on the product label in the context of the total diet (81 FR 33742 at 33748). Including the quantitative percent DV in the Nutrition Info box for each nutrient would therefore allow consumers to quickly compare the nutrient levels between products, particularly if the products have the same interpretive description (*e.g.,* comparing two products that are ''High'' in added sugars, where one contains 30% DV and the other contains 60% DV). As noted elsewhere in this document, we reported in 1993 that adjective formats (*i.e.,* those featuring ''low,'' ''medium,'' and ''high'') alone led consumers to miss quantitative differences between products when different nutrient levels were described using the same adjective (see, *e.g.,* 58 FR 2079 at 2117). However, our current research shows that quantitative percent DV together with interpretive descriptions in the Nutrition Info box may help consumers better understand why a serving of food has the interpretive description it does and would better inform consumers about where certain foods fall within the ranges of each term than a strictly interpretive label would (Ref. 38). In addition, we believe that including percent DV along with the interpretive descriptions in the Nutrition Info box could result in additional consumers understanding the meaning of percent DV when it is displayed on food labels, including in the Nutrition Facts label.

Moreover, including the quantitative percent DV in addition to the ''Low,'' ''Med,'' and ''High'' descriptions may help consumers better understand why a serving of a food has the interpretive descriptions it does. In our second set of focus groups, many participants said they liked seeing the percent DV next to the interpretive description because it provided some context for the interpretation (Ref. 33). In addition, of the Nutrition Info schemes we tested in our experimental study, those that included percent DV declarations performed better in measures assessing ease of use and understanding (Ref. 38). Therefore, we are proposing to require both percent DV and interpretive descriptions for the nutrients to limit in the Nutrition Info box to help consumers quickly and easily identify how foods can be part of a healthy diet.

5. Inclusion of an Attribution Banner (Proposed § 101.6(a)(2)(vi))

Proposed § 101.6(a)(2)(vi) would require the inclusion of a banner at the bottom of the Nutrition Info box that includes an ''*FDA.gov*'' attribution statement. Several studies on FOP nutrition labeling found that inclusion of an attribution for the FOP nutrition label increases consumers' trust in and the credibility of the information. For example, in their experimental study to test variations of a ''High In'' FOP nutrition label, Canadian researchers found that the presence of a Health Canada attribution resulted in higher trust in and credibility of the FOP nutrition symbol (Ref. 51). Almost all participants who saw the FOP nutrition symbol with the Health Canada attribution found it helpful to include because it engendered trust in the FOP nutrition symbol, drew their attention to the FOP nutrition symbol, and made the FOP nutrition symbol look more official (id.). Other studies found that government attribution or endorsement by health organizations increased the believability and credibility of the label (Refs. 52 to 54). In our first set of focus groups, participants expressed mixed

reactions to the inclusion of an attribution statement (Ref. 37). However, most participants viewed ''*FDA.gov*'' as making the scheme credible and trustworthy (Ref. 44). Informed by the literature findings, as well as this feedback, we propose to include the attribution statement ''*FDA.gov*'' in the Nutrition Info box to indicate that the proposed Nutrition Info box appears as required by FDA and to signal to consumers where they can find additional information regarding the Nutrition Info box, nutrition information, and our nutrition labeling requirements.

C. Format (Proposed § 101.6(a)(3))

Proposed § 101.6(a)(3) would require nutrition information to be presented on food labels or labeling in a specific format for the standard Nutrition Info box (we discuss our proposal to allow an alternative intermediate-package Nutrition Info box in section V.E.7 of this document). The proposed Nutrition Info box's format elements include type style (*i.e.,* a single font); size (*i.e.,* point); color; justification (*i.e.,* left, right, or centered); and use of boldface and hairlines.

We considered many factors when designing the proposed Nutrition Info box's format, including findings from consumer research and literature reviews (Refs. 20, 21, 26, 27, 37, 38, and 44); places where we expect people would use the Nutrition Info box (*i.e.,* at the point of decision-making); and the diversity of the intended audience (*e.g.,* level of nutrition knowledge, time available to make a purchase or consumption decision). Studies consistently confirm that simple formats are easier to comprehend and require less consumer effort than complex formats (Refs. 28 and 55). In our view, a simple format is one that minimizes clutter and enables the public to readily observe and comprehend the required nutrition information (21 U.S.C. 343 note). Use of a simple format aligns with our goal for FOP nutrition labeling, which is to provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. Thus, our proposed Nutrition Info box is designed to serve as a visual cue to the reader that the information it contains is quickly and easily understandable interpretive nutrition information about the three nutrients to limit.

Additionally, while we are committed to the flexible application of graphic techniques to make the required nutrition information easy to read and comprehend, we want to ensure that all Nutrition Info boxes, regardless of the products they reflect, look similar so that consumers will immediately recognize them and understand what they are. To accomplish this, our proposed rule would set requirements for certain key graphic elements of the Nutrition Info box. In the interest of uniformity of presentation, FDA strongly recommends that the Nutrition Info box mirrors the examples found throughout proposed § 101.6.

During FDA's experimental study, we tested variations of the Nutrition Info box that included a magnifying glass icon (see Ref. 34). This icon is used in some international High In FOP schemes (*e.g.,* those in Canada and Brazil), and we tested the icon to help us determine whether a graphic image could increase consumer attention to and understanding of the information in the scheme. We are aware that current FOP nutrition schemes in U.S. and international markets use a variety of shapes and symbols to help draw attention to information included in the FOP nutrition label (Ref. 32). We are not proposing to require a graphic image in the Nutrition Info box because our experimental study did not find that the inclusion of a graphic (*i.e.,* the magnifying glass icon) in this particular scheme yielded statistically significant results (Ref. 38). Because the addition of a graphic image did not meaningfully affect U.S. consumers' attention to or use of the Nutrition Info box, we tentatively conclude that including a graphic image, such as a magnifying glass icon, could add unnecessary complexity and clutter to the Nutrition Info box, and therefore our proposal would not require or allow the inclusion of a graphic image.

1. Location (Proposed § 101.6(a)(3)(i))

Our existing regulations include various label and labeling requirements regarding placement of information, such as the declaration of net quantity of contents, which generally must appear on the lower 30 percent of the principal display panel (see § 101.7(f)). Proposed § 101.6(a)(3)(i) would require the Nutrition Info box to appear on the upper third of the principal display panel. We reviewed four consumer research studies on FOP nutrition label placement that tested placement on the upper left, upper right, bottom left, and bottom right of the principal display panel (Refs. 51 and 56 to 58). Each study showed that FOP nutrition labels are most effective when placed in the upper left or right of the principal display panel. While study results were mixed on the best orientation (*i.e.,* left or right placement), the studies found that consumers had improved attention, reaction time, and label understanding when the FOP nutrition label was in the upper left or right of the principal display panel compared to the lower left or right (id.).

However, we are aware that foods' principal display panels often contain other informational and graphic design elements in addition to the information we require and that certain foods come in packages of different shapes. We want to balance our goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet with maintaining flexibility for industry in the design of their principal display panels. Therefore, we propose to require placement of the Nutrition Info box somewhere in the top third of the principal display panel, without specifying the exact location (*e.g.,* upper right corner, 'x' inches from any side or design element).

We invite comment, including studies or other research, on the location and specifically on whether to take a flexible approach rather than designating the proposed Nutrition Info box's exact location.

2. Type Style (Proposed § 101.6(a)(3)(ii))

Proposed § 101.6(a)(3)(ii) would require use of a single, easy-to-read type style in the Nutrition Info box. Information required under the FD&C Act must be prominent, conspicuous, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see section 403(f) of the FD&C Act). We tentatively conclude that a single, easy-to-read type style would be easier for consumers to read and understand, while not proposing to require a specific type style would maintain flexibility for industry. The proposed type style requirement aligns with the Nutrition Facts label's type style requirements (see § 101.9(d)(1)(ii)(A)). Similarly, we use Helvetica in our example proposed Nutrition Info box (see proposed § 101.6(a)(5))—the same type style we use in our example Nutrition Facts label (Ref. 59)—which is recognized as a very readable type style (Ref. 60).

3. Type Size (Proposed § 101.6(a)(3)(iii))

Proposed § 101.6(a)(3)(iii) would require the use of a minimum type size (at least 8 point) in the Nutrition Info box that is no smaller than the size of the required net quantity of contents declaration specified in § 101.7(h) and

(i). Our existing food labeling regulations for packaged foods, at § 101.7(i), require, among other things, that the declaration of net quantity be in letters and numerals in a type size that is established in relation to the area of the principal display panel of the package. The regulation prescribes the following size specifications for net quantity declarations:

- Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less;
- Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches;
- Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches; and
- Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than ½ inch in height if the area is more than 400 square inches.

If the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, then the lettering sizes are to be increased by one-sixteenth of an inch (§ 101.7(i)).

In our proposed rule entitled ''Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size'' (83 FR 32221, July 12, 2018) (vending FOP proposed rule), we discussed industry comments noting the existence of several voluntary FOP nutrition labeling programs where nutrition information—in that case, calories—is presented in an FOP type size that ranges from 100 to 150 percent of the size of the net quantity of contents statement on the principal display panel (id. at 32223). We considered those comments when proposing the revised requirement that calorie disclosures on the principal display panel of foods sold from certain vending machines must be at least 150 percent of the size of the net quantity of contents declaration on the front of the package. We also sought comment on an alternative approach of requiring the calorie disclosure to be at least 100 percent of the size of the net quantity of contents statement.

We ultimately finalized our 150 percent proposal (see 84 FR 57603, October 28, 2019) (vending FOP final rule). In the vending FOP final rule, we noted that the area of the principal display panel (calculated in square inches or square centimeters) determines the minimum type size permitted for the net quantity declaration (as described elsewhere in this section). As such, both the 150 percent requirement we were finalizing and the 100 percent requirement we asked for comment on would be based on the size of the principal display panel (id. at 57606). In other words, the size of both the net quantity of contents declaration and the vending FOP disclosure scale proportionately to the size of the principal display panel. We are proposing the same scaling, based on the net quantity of contents type size, for the minimum type size in the Nutrition Info box. We tentatively conclude that such scaling would help ensure that the Nutrition Info box will be prominent on the label or labeling and its contents readable, while not mandating a size that would occupy an unnecessarily large part of the principal display panel.

In the vending FOP final rule, we also explained that, when a vending machine food is in a vending machine, a prospective purchaser cannot handle the product to make it easier for the purchaser to read the nutrition information. Therefore, visible nutrition information on the front of a package must be large enough, and prominent enough, for prospective purchasers to see and use the information (id. (internal citation omitted)). We stated that the 150 percent type size requirement for FOP calorie disclosures on foods sold from glass-front vending machines, rather than the 100 percent type size alternative approach, will ensure that the declarations are visible, clear, and conspicuous and able to be easily read by a prospective purchaser (id.).

Unlike in the vending machine context, consumers would usually be able to pick up, walk up to, or otherwise closely inspect a food's Nutrition Info box at a comfortable reading distance. Therefore, we tentatively conclude that mandating a type size no smaller than that which is used in the net quantity of contents declaration—essentially, the alternative we requested comment on in the vending FOP proposed rule—would generally allow consumers to easily read and comprehend the information in the Nutrition Info box.

We are also proposing an absolute minimum type size of 8 point, regardless of the size of the net quantity of contents statement. It is our tentative view that this is the minimum type size necessary to allow for quick and easy readability of the Nutrition Info box and for the Nutrition Info box's information to be read and understood by the ordinary individual under customary conditions of purchase and use (see section 403(f) of the FD&C Act). Eight point is the same minimum type size allowed for the information in the Nutrition Facts label (see § 101.9(d)(1)(iii)). We established this minimum type size requirement in the 1993 Nutrition Facts label final rule, noting that we were committed to the flexible application of graphic techniques to achieve an acceptable level of readability for the required nutrition information. However, we noted that minimum standards, including a minimum 8-point type, would ensure that the nutrition information was conveyed so that the public could readily observe and comprehend the information (58 FR 2079 at 2136). We maintained the minimum 8-point type size in the 2016 Nutrition Facts label final rule. Therefore, we propose a minimum 8-point type size for the Nutrition Info box to help ensure readability and to be consistent with the type size requirements in the Nutrition Facts label.

4. Type and Hairline Color (Proposed § 101.6(a)(3)(iv)), Background Color (Proposed § 101.6(a)(3)(v)), and Attribution Banner Color (Proposed § 101.6(a)(3)(xv))

Proposed § 101.6(a)(3)(iv) would require the use of one color (*e.g.,* black) for all type and hairlines in the Nutrition Info box, and proposed § 101.6(a)(3)(v) would require the use of a neutral contrasting background color (*e.g.,* white) to the print in the box. Contrast levels between text and background that exceed 70 percent, which we would expect from the use of a single type color and a neutral contrasting background color, and dark text on light backgrounds provide for optimal legibility (Ref. 61).

For the attribution banner, proposed § 101.6(a)(3)(xv) would require that the background be the same color as used for the rest of the box's type and hairlines and that the ''*FDA.gov*'' statement be the same color as used for the rest of the box's background. We tentatively conclude that the use of an opposite color scheme to the rest of the box would help visually differentiate the attribution banner from the food's nutrition information. The attribution banner would appear effectively the same on every Nutrition Info box—it would be at the bottom of the box, in an opposite color scheme, and would always contain ''*FDA.gov*'' right-justified in the banner. That would provide consistency among all Nutrition Info boxes and signal that the Nutrition Info box is an FDA requirement, while

not drawing attention away from the nutrition information above it.

The proposal would allow flexibility for industry to choose background and type colors that meet the requirements in our regulations. However, we believe that some contrasting color combinations might render the proposed Nutrition Info box's text difficult to read. We would consider difficult-to-read type to be unclear, and therefore violative of proposed § 101.6(a)(3)(ii)'s requirement that type be clear and easy to read, which could potentially cause the product to be misbranded under section 403(f) of the FD&C Act. If a particular color combination makes the type unclear, there are other graphic techniques, such as increased type size, bolding, and tracking (the small space between letters) that could be used to overcome this concern.

5. Hairlines (Proposed § 101.6(a)(3)(vi), (vii), and (viii))

Consistent with the Nutrition Facts label design, proposed § 101.6(a)(3)(vi) would require the use of hairlines to delineate the outer box, and proposed paragraphs (vii) and (viii) would require the use of hairlines to distinguish information within the Nutrition Info box. We first introduced the use of hairlines to set the Nutrition Facts label off in a box in the 1993 Nutrition Facts label final rule to preserve a readily identifiable look for the label (see 58 FR 2079 at 2136). Horizontal lines are used throughout the Nutrition Facts label as a key graphic element to divide space, direct the eye, and similarly give the label a unique and identifiable look (id.).

We propose using hairlines in the same way for the Nutrition Info box. Proposed § 101.6(a)(3)(vii) would require the use of a thick, horizontal hairline, centered within the box, and of the same length across the box as the ''Nutrition Info'' heading to distinguish the heading and subheadings (''Nutrition Info,'' ''Per serving,'' and ''% Daily Value'') from the nutrient information that follows them. This horizontal line would divide space and give the box an identifiable look similar to that of the Nutrition Facts label. It would also direct the reader's eye to the nutrition information that follows and help break the information into small chunks, thus making it easier to process and remember the information (Ref. 62). Proposed § 101.6(a)(3)(viii) would require the use of a horizontal hairline, centered within the box, and of the same length across the box as the ''Nutrition Info'' heading to distinguish each row of nutrient information. The repeated use of horizontal lines within the box would help with the organization of the Nutrition Info box and consistency with the Nutrition Facts label (Refs. 60 and 61).

6. Bold or Extra Bold Type (Proposed § 101.6(a)(3)(ix), (xi), (xii), and (xiii))

Proposed § 101.6(a)(3)(ix), (xi), and (xiii) would require the use of extra-bold type print and proposed § 101.6(a)(3)(xii) would require the use of bold type print to highlight certain text. In our proposed rule entitled ''Food Labeling: Format for Nutrition Label'' (57 FR 32058, July 20, 1992), we noted that the graphic presentation of the label had the potential to improve effective communication. We stated that graphic techniques, which included bold typeface to call attention to certain information on the label, go directly to the requirements in section 2(b)(1)(A) of the NLEA that the required nutrition information be presented in a way that enables consumers to readily observe the information (id.). In the 1993 Nutrition Facts final rule, we finalized certain bolding requirements for the Nutrition Facts label, noting that graphic elements such as bolding would, among other things, benefit consumers who have difficulty reading nutrition information on food packages and might otherwise be effectively denied access to that information (58 FR 2079 at 2136). We again used bolding in the 2016 Nutrition Facts label final rule to emphasize the importance of, and draw attention to, certain information (see, *e.g.,* 81 FR 33742 at 33942).

Bold or extra bold type print for certain Nutrition Info box elements would help consumers notice and locate the box and use the information the box contains, according to design principles of highlighting information in bold type (Ref. 62). We propose the use of bold or extra-bold type print for all type in the box other than the ''Per serving'' subheading, the household measurement declaration, and the quantitative percent DV. An extra-bold ''Nutrition Info'' heading would call attention to the box itself (see proposed § 101.6(a)(3)(ix)), and an extra-bold ''% Daily Value'' subheading and the interpretive descriptions underneath the subheading would call attention to the nutrition information the Nutrition Info box would provide (see proposed § 101.6(a)(3)(xi) and (xiii), respectively). Additionally, bold nutrient names would call attention to each nutrient separately (see proposed § 101.6(a)(3)(xii)). In line with our prior rulemakings, we tentatively conclude that the bolding of these elements in the Nutrition Info box would help consumers readily observe the required nutrition information and assist them in maintaining healthy dietary practices. We note that, in our example proposed Nutrition Info box (see § 101.6(a)(5)), we use both standard bolding (for the nutrient names and ''*FDA.gov*'') and the type style Helvetica Black (for the ''Nutrition Info'' heading, the ''% Daily Value'' subheading, and the interpretive descriptions), which is an extra-bold version of Helvetica.

7. Text Justification (Proposed § 101.6(a)(3)(ix) through (xv))

Proposed § 101.6(a)(3)(ix) through (xv) would require the use of left, right, and center text justification as a design technique to help consumers read the Nutrition Info box. Proposed § 101.6(a)(3)(x) and (xii) would require left justification for the ''Per serving'' subheading and the nutrient names, respectively. Proposed § 101.6(a)(3)(xi) and (xiii) would require right justification for the ''% Daily Value'' subheading and the interpretive descriptions, respectively, and proposed § 101.6(a)(3)(xv) would require right justification for ''FDA.gov'' in the bottom banner. Proposed § 101.6(a)(3)(vi) would require center justification for the ''Nutrition Info'' heading. Proposed § 101.6(a)(3)(xiv) would require that the quantitative percent DVs be right-justified with each other, in a column to the left of the interpretive descriptions. This design would create white spaces in the box, which would help isolate elements of the Nutrition Info box and provide information pacing for the reader (Ref. 63). Left-justifying the ''Per serving'' subheading and right-justifying the ''% Daily Value'' subheading would create white space that would result in a less cluttered appearance, heightened focus and emphasis, and improved readability (id.). Similarly, left-justifying the nutrient names, right-justifying the interpretive descriptions, and right-justifying the quantitative percent DVs in each of their respective columns in their own, unbroken row would provide a logical flow of information and create a sense of unity and cohesion, which contributes to overall aesthetic and perceived stability (Ref. 62). Right-justifying ''FDA.gov'' in the banner at the bottom of the Nutrition Info box would similarly provide unity and cohesion (id.).

8. Other Considerations

We considered whether to set off the Nutrition Info box, *e.g.,* by requiring blank space around it. Such a formatting technique could help ensure that the information in the box would be

prominent and conspicuous to consumers. However, we are not proposing to require such a set-off in an effort to provide flexibility for design considerations. Additionally, section 403(f) of the FD&C Act already requires prominence, conspicuousness, readability, and understandability for any information, such as the proposed Nutrition Info box, required under the authority of the FD&C Act. We similarly considered proposing leading, kerning, font weight, tracking, and other typographical requirements, and are not proposing to require any, for the same reasons. While any of these elements might help meet the prominence, conspicuousness, readability, and understandability requirements of section 403(f) of the FD&C Act, we have tentatively concluded that setting specific requirements is not necessary. Throughout this document, we provide examples of Nutrition Info boxes that would comply with the proposed requirements of this rule and also satisfy the requirements of section 403(f) of the FD&C Act. We invite comment on this approach.

D. No Other Information Allowed in the Nutrition Info Box (Proposed § 101.6(a)(4))

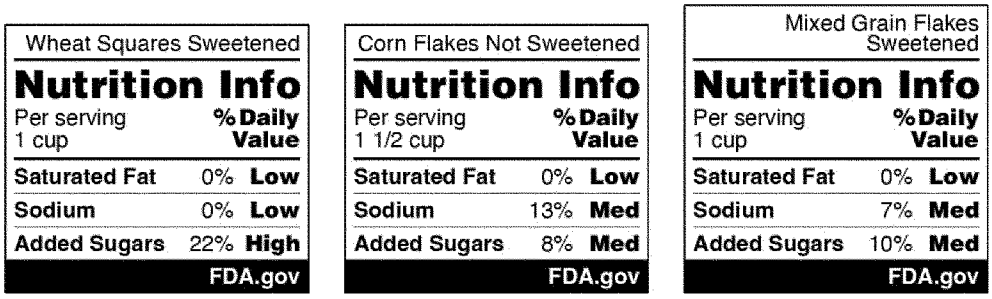
Proposed § 101.6(a)(4) would prohibit any information in the Nutrition Info box other than what proposed § 101.6 would require. As we discuss elsewhere in this document, our research has found that too much information can be confusing to consumers. Additionally, our focus with the Nutrition Info box is to provide consumers with standardized, interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet and allow them to compare nutrition information across foods. See section V.B.2 of this document for a discussion about why we would only require—and only allow—information about saturated fat, sodium, and added sugars in the Nutrition Info box.

E. Special Labeling Provisions (Proposed § 101.6(b))

Proposed § 101.6(b) would describe ways to modify or alternatively display the Nutrition Info box for certain labels and labeling. This section of the preamble also describes additional products for which we considered proposing to establish special labeling provisions but have tentatively concluded must display the Nutrition Info box as required in § 101.6(a)(2) through (4).

1. Packaged Foods That May Use an Aggregate Display in Accordance With § 101.9(d)(13)(i) (Proposed § 101.6(b)(1))

Our regulations, at § 101.9(d)(13)(i) and (h)(2)(ii), allow the use of an aggregate display for the Nutrition Facts label on the outer label of packages of products that contain two or more separately packaged foods that are intended to be eaten individually (*e.g.,* variety packs of cereals or snack foods) or of packages that are used interchangeably for the same type of food (*e.g.,* round ice cream containers). Proposed § 101.6(b)(1) would require packages that may use this aggregate display to display a Nutrition Info box for each different product the package contains or could contain. An example of what such labeling might look like is as follows (see also proposed § 101.6(b)(1)(iii)):



For Nutrition Facts labels, the aggregate display can use less label space than multiple individual Nutrition Facts labels because the ''Nutrition Facts'' heading, most serving size information, and all declared nutrient, vitamin, and mineral names appear only once. While we are aware that the required display of multiple individual Nutrition Info boxes may occupy more space than an aggregate display, we reiterate that our public health goal with the Nutrition Info box is to provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information, at the point of decision-making, that can help them quickly and easily identify how foods can be part of a healthy diet. Separate, rather than aggregate, Nutrition Info boxes would better help consumers to quickly view this information since consumers would not need to refer back to nutrient names, among other information, to understand the interpretive information in the box. We are also concerned that an aggregate Nutrition Info box would appear cluttered and unclear, because we designed the proposed box to occupy as little space on the label as possible while still giving consumers information, including the interpretive high, medium, and low categorizations that can help them quickly and easily identify how foods can be part of a healthy diet.

Proposed § 101.6(b)(1)(i) would require the Nutrition Info boxes to appear together in either horizontal or vertical lines. This would mean that all Nutrition Info boxes on packages that may use an aggregate display for the Nutrition Facts label would appear on the label in an unbroken line or set of lines that run either vertically or horizontally. Grouping the boxes consistently and together on the package, rather than allowing them to appear in different locations on a label or labeling, would help consumers more easily find the boxes and reduce the likelihood that they might not see one of the boxes because it appeared in a different location. While we are proposing to require placement of all boxes in the upper third of the principal display panel, in accordance with and for the same reasons as proposed § 101.6(a)(3)(i), we are not proposing to require any specific location within that upper third to allow flexibility for industry in the design of their labels.

Proposed § 101.6(b)(1)(ii) would require each individual food's name to appear right-justified at the top of the food's Nutrition Info box, separated from the ''Nutrition Info'' header by a horizontal, centered hairline rule.

Inclusion of each individual food's name at the top of its Nutrition Info box would clarify which individual food's nutrition information is represented by which Nutrition Info box. Consistent placement of each individual food's name at the top of its Nutrition Info box on a given package would best help consumers quickly and easily identify the interpretive nutrition information for foods at the point of decision-making because consumers would not need to search for that information. Right-justification of each individual food's name would provide an alignment cue and create a sense of unity and cohesion, contributing to the box's overall aesthetic and perceived stability (Ref. 62). Use of a horizontal hairline to separate the individual food's name from the ''Nutrition Info'' header would divide space and give the box an identifiable look similar to that of the Nutrition Facts label.

We invite comment, particularly data and other information, on this approach.

2. Packaged Foods That Present Nutrition Facts Labeling for Two or More Population Groups Consistent With § 101.9(e) (Proposed § 101.6(b)(2))

Our regulations, at § 101.9(e), allow the display of multiple sets of nutrition information for multiple groups for which RDIs are established (*e.g.,* both ''infants'' and ''people ages 4 and older''). We call this type of labeling ''dual-column labeling'' and provide an example at § 101.9(e)(5).

Proposed § 101.6(b)(2) would require the Nutrition Info box for products that present a dual-column Nutrition Facts label for multiple age groups to reflect only the nutrition information for people ages 4 and older. As we described when discussing the scope of this rule (see section V.A of this document), we propose that this rule apply only to the foods covered under § 101.9 that are marketed for the general population. Therefore, the Nutrition Info box would only represent nutrition information for this population.

3. Packaged Foods That Present Nutrition Facts Labeling for Both ''Per Serving'' and ''Per Individual Unit'' Consistent With § 101.9(b)(2)(i)(D) (Proposed § 101.6(b)(3))

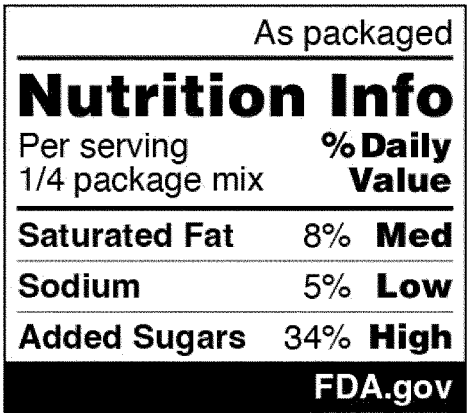
Our regulations, at § 101.9(b)(2)(i)(D), require the display of a dual-column Nutrition Facts label when products are packaged and sold individually and contain at least 200 percent and up to and including 300 percent of the applicable RACC. The first column is required to list the quantitative amounts and percent DVs for a serving of the food, and the second column is required to list the quantitative amounts and percent DVs for the entire package (see § 101.9(b)(2)(i)(D)). This is another example of dual-column labeling (see § 101.9(e)(5)).

Proposed § 101.6(b)(3) would require the Nutrition Info box for products that present a dual-column Nutrition Facts label for ''per serving'' and ''per individual unit'' nutrition information to reflect only the nutrition information ''per serving.'' This is consistent with how the standard Nutrition Info box reflects nutrition information ''per serving'' when the individual unit contains more than one serving. Inclusion of the required ''Per serving'' subheading with a statement of the serving size expressed in household measure would inform consumers that the package contains more than a single serving.

4. Packaged Foods That Present Nutrition Facts Labeling for Both ''As Packaged'' and ''As Prepared'' Forms of the Food Consistent With § 101.9(e) (Proposed § 101.6(b)(4))

Our regulations, at § 101.9(e), allow the display of multiple sets of nutrition information for, among other things, multiple forms of the same food (*e.g.,* both ''as packaged'' and ''as prepared'' for packaged cake mixes) and for common combinations of food as provided for in § 101.9(h)(4) (*e.g.,* both ''as packaged'' and ''with ½ cup of reduced-fat milk'' for cereal). This is also an example of dual-column labeling (see § 101.9(e)(5)).

Proposed § 101.6(b)(4) would require that the Nutrition Info box for products that present a dual-column Nutrition Facts label for multiple forms of the same food and for common combinations of food reflect the food ''as packaged.'' We also propose that a statement clarifying that the box represents ''as packaged'' nutrition information appear right-justified at the top of the Nutrition Info box and separated from the ''Nutrition Info'' header by a horizontal, centered hairline rule, similar to aggregate display information as described in section V.E.1 of this document. This would help ensure that consumers know the Nutrition Info box always represents the food as it is at the point of decision-making, without any additional ingredients that would change the percent DV or interpretive descriptions. As with the information for boxes that may use an aggregate display for the Nutrition Facts label, as described in section V.E.1 of this document, right-justification of ''as packaged'' at the top of the box would provide a sense of unity and cohesion, contributing to the box's overall aesthetic and perceived stability (Ref. 62). Use of a horizontal hairline to separate ''as packaged'' from the ''Nutrition Info'' header would divide space and give the box an identifiable look similar to that of the Nutrition Facts label. An example of what such labeling might look like is as follows (see also proposed § 101.6(b)(4)):

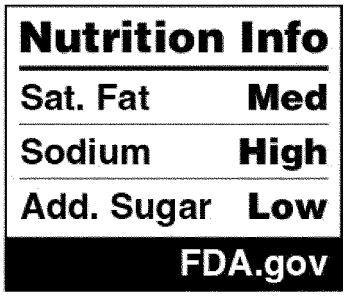


Because the proposed Nutrition Info box would appear on the label of most foods—for instance, on both cereal boxes and cartons of milk, or on dry cake mixes and egg cartons—consumers would have the box's information readily available on the principal display panel of each food that may be combined in whatever way they prefer. Additionally, each Nutrition Info box would reflect unique information (*i.e.,* there would be no overlap or duplication of information), which would help ensure that the Nutrition Info box can help consumers quickly and easily identify how individual foods can be part of a healthy diet.

5. Foods in Packages That Have a Total Surface Area Available To Bear Labeling of 40 or Fewer Square Inches (Proposed § 101.6(b)(5))

Our regulations, at § 101.9(j)(13)(ii)(A), provide that foods in packages that have a total surface area available to bear labeling of 40 or fewer square inches may present the required Nutrition Facts label in a tabular fashion (see § 101.9(j)(13)(ii)(A)(*1*)) or, if the product's package shape or size cannot accommodate a standard or tabular display, in a linear fashion (see § 101.9(j)(13)(ii)(A)(*2*)). We established this upper limit of 40 square inches of surface area available to bear labeling to define an intermediate-sized package in the 1993 Nutrition Facts label final rule. We noted there that we reviewed comment suggestions, examined the space requirements of the Nutrition Facts label, reviewed data on available label area for a sample of packaged foods, and considered what would make the label readily observable and easily comprehensible to arrive at 40 square inches (58 FR 2079 at 2155). In the 2016 Nutrition Facts label final rule, we declined to increase that number, stating that the promulgation of other space-saving requirements would preclude the necessity of doing so (81 FR 33742 at 33957). We propose to allow similar flexibility for such intermediate packages for the purposes of this rule.

Recognizing the increased need for flexibility for packages with 40 or fewer square inches available to bear labeling, and to help ensure the Nutrition Info box is readily observable and easily comprehensible, proposed § 101.6(b)(5) would allow foods in packages with a total surface area available to bear labeling of 40 or fewer square inches to use an alternative Nutrition Info box (intermediate-package Nutrition Info box). This box would be smaller than our proposed Nutrition Info box and is designed to balance our public health goal of providing consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet with the reduced amount of space available to bear labels on intermediate-sized packages relative to larger packages. Consumers have decades of experience with alternate Nutrition Facts label formatting for products that have 40 or fewer square inches of surface area available to bear labeling. Providing flexibility for these intermediate-sized packages to display a modified Nutrition Info box would be consistent with our Nutrition Facts label regulations. An example of an intermediate-package Nutrition Info box is as follows:



We considered whether to propose allowing the use of the intermediate-package Nutrition Info box only when a package uses the tabular or linear Nutrition Facts label format as specified in § 101.9(j)(13)(ii)(A). In other words, we considered proposing to require the display of a standard Nutrition Info box if an intermediate package did not use the flexibilities provided in § 101.9(j)(13)(ii)(A) and chose instead to display the standard Nutrition Facts label. However, given the labeling space constraints with packages of this size, we think it would be appropriate to extend this flexibility to all products with 40 or fewer square inches available to bear labeling that would be subject to this rule.

Proposed § 101.6(b)(5)(i) would establish the intermediate-package Nutrition Info box, which would omit the ''Per serving'' and ''% Daily Value'' subheadings and the quantitative percent DV declarations. The ''Per serving'' subheading, including the statement of the serving size expressed in household measures, would be omitted because doing so would reduce the amount of space needed for the intermediate-package Nutrition Info box. Given the smaller package size, our intent is to help ensure the readability of the interpretive information provided in the Nutrition Info box.

We propose that the intermediate-package Nutrition Info box would also not include the quantitative percent DV declarations for the same space and readability considerations as with the ''Per Serving'' subheading. Without the quantitative percent DV declarations, the ''% Daily Value'' subheading would be unnecessary, and we therefore also propose to exclude it from the intermediate-package Nutrition Info box. However, as discussed in section V.B.4 of this document, we recognize that consumers could use the percent DV declarations to, among other things, quickly compare products that have the same interpretive description for a given nutrient. For example, two products may both have ''high'' added sugars interpretive descriptions, but one may contain 30% DV added sugars, while the other contains 60% DV added sugars. We also recognize that the quantitative percent DV, in addition to the interpretive descriptions, may help consumers better understand why a serving of a food has the interpretive description it does. We invite comment on the exclusion of the quantitative percent DV and on other design factors or choices we could make to balance our public health mission and FOP nutrition labeling goals with the space constraints on intermediate-sized packages.

While we propose certain modifications for the intermediate-package Nutrition Info box, we are

keeping the remaining design elements the same as in the standard Nutrition Info box. This would create consistency between the box types, as well as with the Nutrition Facts label, the design of which underlays our proposed Nutrition Info box formats.

Proposed § 101.6(b)(5)(ii) would require the use of abbreviations for saturated fat (''Sat. Fat'') and added sugars (''Add. Sugar'') to help with potential overcrowding issues in the intermediate-package Nutrition Info box and to help ensure readability. The proposed abbreviation for saturated fat would be consistent with our Nutrition Facts label regulations (see § 101.9(j)(13)(ii)(B)). An abbreviation for added sugars would also help sizing considerations for the intermediate-sized packages, while still providing the information to consumers.

6. Foods Sold From Bulk Containers (Proposed § 101.6(b)(6))

Our existing regulations allow the Nutrition Facts label for foods sold from bulk containers, which do not have a principal display panel, to appear on the labeling of the bulk container plainly in view (§ 101.9(j)(16)), clearly at the point of purchase (§ 101.9(a)(2)), or available in another format consistent with § 101.9(a)(2) (such as in a booklet at the point of purchase). Proposed § 101.6(b)(6) would require that the labeling of foods sold to consumers from bulk containers display the Nutrition Info box plainly in view of the consumer at the point of purchase. This presentation is the best way to ensure that consumers would have immediate access to that information at the point of decision-making—the same way they would have that information on the principal display panel of most packaged foods (see proposed § 101.6(a)(3)(i)). While the Nutrition Facts label may be displayed elsewhere, such as in a booklet, for bulk foods, we tentatively conclude that any such display for the Nutrition Info box would not be consistent with placement on the principal display panel and would not provide consumers with interpretive nutrition information that can help them *quickly and easily* identify how foods can be part of a healthy diet. We invite comment on this approach.

7. Game Meats (Proposed § 101.6(b)(7))

Our regulations, at § 101.9(j)(11), allow the Nutrition Facts label for packaged single-ingredient products that consist of game meat (*i.e.,* animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) to present nutrition information either as packaged or as prepared (unless such products make claims that are based on values as packaged and therefore must provide nutrition information on an as packaged basis). Proposed § 101.6(b)(7)(i) would require game meats to display a Nutrition Info box that reflects how the nutrition information is presented under § 101.9. If the Nutrition Facts label for a game meat presents nutrition information as packaged as required under § 101.9(b)(7), then the Nutrition Info box would reflect the nutrition information as packaged. However, if the Nutrition Facts label presents nutrition information as prepared, following the special labeling provision at § 101.9(j)(11), then the Nutrition Info box also would reflect the nutrition information as prepared. We are proposing this because the percent DVs used to determine the interpretive descriptions for each nutrient in the Nutrition Info box are based on a serving's amount, in grams, of each nutrient. The values may differ between the nutrition information presented as packaged versus as prepared. We tentatively conclude that this approach would ensure that the Nutrition Facts label and the Nutrition Info box provide consistent information.

Our existing regulations, at § 101.9(j)(12), also allow the Nutrition Facts label for game meats not in packages to appear clearly at the point of purchase (§ 101.9(a)(2)) or available in another format consistent with § 101.9(a)(2) (such as in a booklet at the point of purchase) if it does not appear on the label. Proposed § 101.6(b)(7)(ii) would require these game meats to display the Nutrition Info box plainly in view of the consumer at the point of purchase. Similar to our proposed exemption for bulk foods, providing such information clearly in view of the consumer on the labeling of game meat not in packages is the best way to ensure that consumers would have immediate access to that information at the point of decision-making—the same way they would have that information on the principal display panel of most packaged foods (see proposed § 101.6(a)(3)(i)). While the Nutrition Facts label may be displayed elsewhere, such as in a booklet, for game meats not in packages, we tentatively conclude that any such display for the Nutrition Info box would not be consistent with placement on the principal display panel and would not provide consumers with interpretive nutrition information that can help them *quickly and easily* identify how foods can be part of a healthy diet.

8. Other Products Considered for Special Labeling Provisions

While we are proposing special labeling provisions for some products, we also considered but rejected such proposed provisions for other products. For example, our regulations, at § 101.9(h)(1), allow for foods to display a Nutrition Facts label per serving for each component or as a composite value when separately packaged ingredients (*e.g.,* a salad kit) or assortments of the same type of food (*e.g.,* a package of mixed nuts) are intended to be eaten at the same time (see § 101.9(h)(1)). We considered establishing a special labeling provision for such foods to display either a Nutrition Info box per component or composite value, consistent with the flexibility provided in § 101.9(h)(1). However, such a provision might result in the inconsistent display of Nutrition Info boxes for these products, which would not be consistent with the goal of this proposed rule. For example, consumers would not be able to easily compare a composite Nutrition Info box on one food to multiple Nutrition Info boxes for individual components on another food. Additionally, we tentatively conclude that allowing component Nutrition Info boxes instead of a single, composite box would prevent consumers from quickly and easily identifying how the food can be part of a healthy diet (*e.g.,* the salad kit as a whole). We therefore are not proposing any special labeling provisions for these foods.

F. Exemptions (Proposed § 101.6(c))

Proposed § 101.6(c) would exempt certain foods from the requirement to display a Nutrition Info box. This section of the document also describes additional products we considered proposing to exempt but have tentatively concluded would be subject to the requirements of this rule.

1. Foods Exempt From § 101.9 Under § 101.9(j), Unless Otherwise Stated in This Section (Proposed § 101.6(c)(1))

Our regulations, at § 101.9(j), exempt certain foods, such as raw fruits and vegetables, from bearing a Nutrition Facts label. Proposed § 101.6(c)(1) would similarly exempt those foods from bearing a Nutrition Info box. We are proposing to base the interpretive descriptions of the relative amount of each declared nutrient per serving on the quantitative percent DV, which foods exempt under § 101.9(j) do not have to bear (which, in turn, means that industry would not need to calculate the

percent DVs). Any proposal to change the exemptions in § 101.9(j) would be outside the scope of this rulemaking. Even if it were not, we are not aware of data indicating that we should propose changes to the exemptions.

We note that § 101.9(j) also includes foods subject to special labeling requirements. We propose that only foods *exempt* under § 101.9(j) would be exempt from bearing a Nutrition Info box, unless otherwise specified in this section.

2. Foods in Small Packages That Have a Total Surface Area Available To Bear Labeling of Less Than 12 Square Inches (Proposed § 101.6(c)(2))

Our regulations, at § 101.9(j)(13)(i), provide that foods in small packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from Nutrition Facts labeling, unless nutrition information, such as a claim, is presented on the label. We first proposed this exemption in 1991 (see 56 FR 60366). At that time, we noted our belief that relatively few food packages would qualify as ''small'' under the proposed exemption, namely candy rolls, breath sweeteners, and a few very small individual-serving size canned foods (id. at 60377). We finalized this exemption in the 1993 Nutrition Facts label final rule (58 FR 2079) and kept this exemption in the 2016 Nutrition Facts label final rule (81 FR 33742).

Proposed § 101.6(c)(2) would exempt foods in small packages that have a total surface area available to bear labeling of less than 12 square inches from the requirement to display the Nutrition Info box. While such a small package must bear the appropriately sized Nutrition Facts label if its label includes any other nutrition information, we tentatively conclude that there would not also be enough room to fit a Nutrition Info box on its label that would be legible to consumers without occupying much of the available space to bear labeling. We invite comment, and particularly data and other information, on this approach.

3. Packages Marketed as Gifts That Contain a Variety or Assortment of Foods (Proposed § 101.6(c)(3))

Our regulations, at § 101.9(h)(3), provide special labeling requirements for a package that contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift (gift package). For example, the Nutrition Facts label for foods in such a package may be presented on the label of the outer package or in labeling within or attached to the outer package (§ 101.9(h)(3)(i)). We defined ''outer package'' in the 1993 Nutrition Facts final rule to mean the container directly within which component items are packed (58 FR 2079 at 2159), and we maintain that definition here.

Proposed § 101.6(c)(3) would exempt the outer packaging of gift packages from the requirement to display Nutrition Info boxes. Our purpose in proposing the Nutrition Info box is to provide consumers with interpretive nutrition information at the point of decision-making that can help them quickly and easily identify how foods can be part of a healthy diet. We tentatively conclude that the point of decision-making for gift packages is generally after the package is opened, when a consumer is considering which food from the gift package to eat. While we propose that the outer wrapping be exempt, we note that the inner food products would be subject to the requirements in this rule, unless otherwise exempted.

4. Unit Containers in a Multiunit Retail Food Package (Proposed § 101.6(c)(4))

Our regulations, at § 101.9(j)(15), provide that the unit containers in a multiunit retail food package are exempt from Nutrition Facts labeling so long as certain requirements are met (*i.e.,* the multiunit retail food package labeling contains all nutrition information in accordance with § 101.9; the unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and each unit container is labeled with the statement ''This Unit Not Labeled For Retail Sale'' as described in § 101.9(j)(15)(iii)). We first proposed this exemption in the 1990 Nutrition Facts label proposed rule after receiving a comment requesting such an exemption and agreeing that it would be reasonable to exempt unit containers from Nutrition Facts labeling requirements, provided they meet certain requirements (55 FR 29487 at 29505). In the 1993 Nutrition Facts label final rule, we finalized this exemption. We did not discuss or change this exemption when updating the Nutrition Facts label regulations in 2016.

Proposed § 101.6(c)(4) would similarly exempt the unit containers in a multiunit retail food package from FOP nutrition labeling, so long as the unit containers fall under the exemption for Nutrition Facts labeling in accordance with § 101.9(j)(15); and the multiunit retail food package bears the Nutrition Info box in accordance with § 101.6. If those conditions are met, we tentatively conclude that it is unnecessary for the unit containers to also bear the Nutrition Info box. This is consistent with our similar exemption for the Nutrition Facts label, and it is the Nutrition Info box on the outside of a multiunit retail food package that consumers would use to quickly and easily identify how foods can be part of a healthy diet.

5. Other Products Considered for Exemption

We considered whether to exempt foods that contain insignificant amounts of saturated fat, sodium, and added sugars and use the simplified format of the Nutrition Facts label from the requirement to display the Nutrition Info box. Our regulations, at § 101.9(f), allow for the use of a simplified format for the Nutrition Facts label when a food contains insignificant amounts of, among other things, saturated fat, sodium, and added sugars. We define ''insignificant amount'' in this context as the amount that allows a declaration of zero in nutrition labeling (§ 101.9(f)(1)). If a food contains insignificant amounts of saturated fat, sodium, and added sugars and uses the simplified Nutrition Facts label format, sodium is the only nutrient that would be required to be declared in the Nutrition Facts label—saturated fat and added sugars would not be declared (see § 101.9(f)(2)). However, a proposed exemption from the requirements of this rule would not be consistent with our goal to provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. An exemption would also make quick comparisons between products more difficult. We tentatively conclude that requiring these foods to bear a Nutrition Info box would provide consumers with interpretive information about the amounts of the three nutrients so they could quickly and easily identify how foods can be part of a healthy diet. Therefore, we are not proposing to exempt foods that use the simplified format of the Nutrition Facts label and that contain insignificant amounts of saturated fat, sodium, and added sugars from the requirement to display the Nutrition Info box.

We also considered whether to exempt products such as electrolyte drinks, glucose products, and nutrition shakes that are required to bear Nutrition Facts labels from the requirement to display a Nutrition Info box. These products are often conventional foods and are marketed and used for a variety of purposes, such as rehydration during or after exercise, providing energy, or general meal

replacement. When these products are conventional foods and are required to bear Nutrition Facts labels, they are often used by healthy individuals and the general population; accordingly, we are not proposing to exempt such products from bearing a Nutrition Info box.

G. Low Sodium and Low Saturated Fat Nutrient Content Claims (Revised §§ 101.61(b)(4) and (5) and 101.62(c)(2) and (3))

We are proposing to revise § 101.61(b)(4)(i)(A) and (b)(4)(i)(B) so that a food other than a meal product or main dish product may bear a low sodium nutrient content claim if a serving of the food contains 115 mg or less sodium per RACC rather than 140 mg or less sodium per RACC; and § 101.61(b)(5)(i) so that meal products and main dish products may bear a low sodium nutrient content claim if a serving of the food contains 115 mg or less sodium per 100 g rather than 140 mg or less sodium per 100 g. This revision is consistent with the updated DRV for sodium in the 2016 Nutrition Facts label final rule and with FDA's ongoing sodium reduction efforts (see section V.B.3 of this document). It also generally aligns with the 5% DV or less range that we are proposing for ''Low'' for sodium in the proposed Nutrition Info box.

We are also proposing to amend §§ 101.61(b)(4) and (5) and 101.62(c)(2) and (3) to specify that a food subject to this rule must display ''Low'' in accordance with § 101.6 for sodium or saturated fat in the Nutrition Info box to qualify for a low sodium or low saturated fat nutrient content claim, respectively. A food bearing a low sodium or low saturated fat nutrient content claim but falling into the ''Med'' or ''High'' categorization for that nutrient in the Nutrition Info box would lead to inconsistency in the labeling of such food and could result in consumer confusion (see Ref. 64). Therefore, we tentatively conclude that a food subject to this rule must display ''Low'' in accordance with § 101.6 for the respective nutrient in the Nutrition Info box to qualify for a low sodium or low saturated fat nutrient content claim. In addition to updating the claim to reflect current nutrition science and helping to avoid consumer confusion by aligning with the Nutrition Info box's ''Low'' description, this amendment would also address products that are not subject to the proposed requirement to display a Nutrition Info box.

We are not proposing to amend the definitions of the low sodium and low saturated fat nutrient content claims to be ''5% DV or less'' because our regulations define other ''low'' nutrient content claims based on g or mg amounts of a nutrient and RACC and weight-based criteria. Proposing to change the units for the amount of sodium and saturated fat from mg or g amounts to a percent DV and proposing to change the additional criteria for nutrient content claims that are based on a per RACC (per 50 g of food if the RACC is small) or a weight-based criteria (*e.g.,* per 100 g of food for meals and main dishes) to a per labeled serving basis for the low sodium and low saturated fat nutrient content claims in this proposed rule would make their definitions inconsistent with the definitions for other ''low'' nutrient content claims. We invite comment on this approach.

H. Authority Citation

The proposed rule would add the statutory authority 21 U.S.C. 343 note as a regulatory authority for part 101. Specifically, 21 U.S.C. 343 note gives FDA authority to issue regulations that require certain nutrition information to be conveyed in a manner that allows the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.

I. Conforming Amendments

The proposed rule would necessitate several conforming changes to our food labeling regulations found in part 101. Because we would establish new requirements for an FOP Nutrition Info box in proposed § 101.6, we are proposing updates to the following sections to cross-reference the new nutrition labeling requirement:

- *Section 101.2:* Information panel of package form food (proposing to add § 101.6 to the list of sections the information in which must appear either on a food's principal display panel or on the information panel, unless otherwise specified by regulation) (see also section V.J of this document, where we propose a technical amendment to the title of this section).
- *Section 101.13:* Nutrient content claims—general principles (proposing that the information required by § 101.6 would not be a nutrient content claim). We recognize that our regulations, at § 101.13(c), provide that information required or permitted in the Nutrition Facts label is not a nutrient content claim and is not subject to the requirements regarding nutrient content claims. However, § 101.13(c) further states that if the information in the Nutrition Facts label appears elsewhere on the label, it is a nutrient content claim, and any package bearing such a claim must comply with our nutrient content claim requirements. We propose amending § 101.13(c) to specify that the information in the proposed Nutrition Info box would not be a nutrient content claim, like the information in the Nutrition Facts label is not a nutrient content claim. However, we would still consider all other quantitative calorie or nutrient declarations outside of those in proposed amended § 101.13(c) to be nutrient content claims, unless an exception applies under § 101.13. For example, under § 101.13, the label or labeling of a product may contain a statement about the amount of a nutrient without any disclaimer if the statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (*e.g.,* ''150 calories'') (see § 101.13(i)(3)).
- *Section 101.15:* Food; prominence of required statements (proposing to exempt the proposed Nutrition Info box from foreign language declarations due to space considerations).
- *Section 101.61:* Nutrient content claims for the sodium content of foods (proposing to add § 101.6 to § 101.61(a)(3) so that a claim about the level of sodium or salt in a food may only be made on the label or in the labeling of the food if the food is labeled in accordance with, among other things, § 101.6).
- Section 101.62: Nutrient content claims for fat, fatty acid, and cholesterol content of foods (proposing to add § 101.6 to § 101.62(a)(3) so that a claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label or in the labeling of the food if the food is labeled in accordance with, among other things, § 101.6).
- Section 101.65: Implied nutrient content claims and related label statements (proposing to add § 101.6 to § 101.65(a)(3) so that an implied nutrient content claim may only be made on the label or in the labeling of the food if the food is labeled in accordance with, among other things, § 101.6).

J. Technical Amendments

We propose certain technical amendments in §§ 101.12, 101.13, and 101.15 to make non-substantive edits for purposes of plain language. The Plain Writing Act of 2010 requires that Federal agencies use clear communication that the public can understand and use. Section 1 of Executive Order 13563, ''Improving Regulation and Regulatory Review'' (76 FR 3821, January 21, 2011)), sets forth

''General principles of regulation,'' which include ensuring that regulations are ''accessible, consistent, written in plain language, and easy to understand.'' To make the requirements of part 101 easier to understand, we are proposing to make editorial changes that do not change the meaning or intent of the language in § 101.2(b), (c)(1)(ii)(B)(*1*), and (f); § 101.13(n); and § 101.15(c)(2). Specifically, the proposed rule would:

- Revise the title of § 101.2 and paragraph (b) of that section to read ''packaged food,'' instead of ''package form food'' or ''package of food,'' respectively. We propose these changes for consistency with how we refer to these products throughout our nutrition labeling regulations.
- Replace ''shall'' with ''must'' in § 101.2(b), (c)(1)(ii)(B)(*1*), and (f); § 101.13(n); and § 101.15(c)(2). We propose this change to align with the Federal Plain Language Guidelines, which state that Federal Agencies should use ''must'' and not ''shall'' to impose requirements, as ''shall'' is ambiguous and rarely occurs in everyday conversation (Ref. 65).

VI. Proposed Effective/Compliance Dates

We intend that any final rule resulting from this rulemaking become effective 60 days after the date of the final rule's publication in the **Federal Register**. We propose staggered compliance dates:

- 3 years after the final rule's effective date for businesses with $10 million or more in annual food sales; and
- 4 years after the final rule's effective date for businesses with less than $10 million in annual food sales.

We recognize that it may take industry time to design and print new labels. A 3-year compliance date for businesses with $10 million or more in annual food sales and a 4-year compliance date for businesses with less than $10 million in annual food sales are intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to timely have the proposed information in the Nutrition Info box. We invite comment on these proposed compliance dates.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that the annual economic impact of this proposed rule is less than 3 percent of annual revenue, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would require certain nutrition information to appear in a compact informational box on the front, or principal display panel, of most foods bearing a Nutrition Facts label. The Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. The proposed rule would also amend low sodium and low saturated fat nutrient content claim regulations to align with current nutrition science and avoid within-label inconsistencies. The proposed rule, if finalized, may result in some industry reformulating some products based on the interpretive label information or to maintain nutrient content claims, if some manufacturers choose to do so.

We quantify costs to packaged food manufacturers from updating labeling to meet the proposed requirements. Although it is not a requirement or goal of the proposed rule, we also quantify the costs of reformulation as the rule could result in some food manufacturers reformulating some food products. Over 10 years, the total undiscounted cost is $3.2 billion. Updating labeling to meet the proposed requirements accounts for 32 percent of total costs ($1 billion) while voluntary reformulation accounts for the other 68 percent of total costs over 10 years ($2.2 billion). The present value of costs over 10 years would range from $1.7 billion to $4.9 billion at a 2 percent discount rate, with a primary estimate of $3.1 billion. Annualized costs over 10 years would range from $191 to $530 million at a 2 percent discount rate, with a primary estimate of $333 million.

The proposed Nutrition Info box would give consumers additional standardized context about certain nutrients that appear in the Nutrition Facts label and allow them to compare this nutrition information across foods. Benefits of this proposed rule would come from the value consumers receive from the information provided by the FOP label. If some packaged food manufacturers chose to reformulate products to maintain current nutrient content claims or move into a ''Low'' or ''Med'' interpretive description, consumers whose nutritional intake changes accordingly would also benefit from a healthier food supply. The proposed rule, if finalized, would provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health. We undertake a break-even calculation to describe the magnitude of non-quantified benefits for the benefits to equal or exceed the costs of the regulation.

This is only a summary of our preliminary analysis of the proposed rule. We have developed a Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 66) and at *https://www.fda.gov/about-fda/*

economics-staff/regulatory-impact-analyses-ria.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section below with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food Labeling: Front-of-Package Nutrition Information

Description: This information collection would support statutory and regulatory requirements that govern food labeling. FDA authorities include the NLEA (21 U.S.C. 343 note (1990)) and sections 403(f) and 403(q) of the FD&C Act. This information collection also would support sections 701(a), 403(a)(1), and 201(n) of the FD&C Act.

The proposed rule, if finalized, would add § 101.6 to require the food industry to disclose certain nutrition information in a compact informational box on the principal display panel of most foods bearing a Nutrition Facts label. The Nutrition Info box would give consumers additional context on the front of most food packages about certain nutrients that appear on the Nutrition Facts label. The Nutrition Info box would provide consumers with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet, thereby promoting public health.

Description of Respondents: The respondents to this information collection are manufacturers, packers, and distributors of food products subject to statutory and regulatory food labeling requirements.

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent [2]	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [3]
Front of Package Labeling; 101.6	30,413	11	322,378	4	1,289,512	$143,220,186

[1] There are no operating and maintenance costs associated with this collection of information.
[2] For purposes of this table, we have rounded up to use whole numbers when calculating the number of disclosures per respondent. All other figures are consistent with the Preliminary Regulatory Impact Analysis.
[3] One-time capital cost to relabel.

The estimates in table 2 are consistent with the estimates found in the Preliminary Regulatory Impact Analysis (PRIA) (Ref. 66). In table 21 of the PRIA, we estimate that approximately 30,413 manufacturers will need to add the informational Nutrition Info box to the principal display panel of their food product package. In table 4 of the PRIA, we estimate that approximately 322,326 products will need to be relabeled. For the purpose of this analysis, we used the estimates for the number of manufacturers and disclosures to calculate that each manufacturer will need to relabel about 11 products (322,378 disclosures ÷ 30,413 manufacturers = 10.6). In the existing information collection for Food Labeling Requirements approved under OMB control number 0910–0381, we estimated that an establishment would spend 4 hours per label for labeling requirements for disclosure of nutrition information (21 CFR 101.9). We use the 4-hour estimate for the purpose of this analysis. Each disclosure will take an estimated 4 hours to complete for an annual third-party disclosure burden of 1,289,512 hours (322,378 disclosures × 4 hours). Based on table 6 of the PRIA, we estimate each product that will be relabeled will cost $1,333 assuming a 3-year compliance period. That calculates to an annual capital cost of $143,220,186 ($1,333 × 107,442 products) over 3 years associated with relabeling with the total capital cost being $429,660,558. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time capital cost.

To ensure that comments on this information collection are received, OMB recommends that written comments be submitted through reginfo.gov (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(3) of the FD&C Act provides that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) of the FD&C Act.

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local

requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the NLEA). If this proposed rule is finalized, the rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act to the extent that these provisions are consistent with section 403(q) of the FD&C Act.

Further, uniformity in FOP nutrition labeling is critical to achieving the goal of this proposed regulation so that consumers are provided with interpretive nutrition information that can help them quickly and easily identify how foods can be part of a healthy diet. If States were able to establish their own FOP nutrition labeling systems with different requirements, consumers would not be able to rely on a single standardized box to compare products and may be confused by conflicting or different information on a separate state FOP nutrition label. Different State or local requirements for FOP nutrition labeling would not be consistent with the NLEA, which directs FDA to require nutrition information be presented in a way that makes it observable, understandable, and useful to consumers and which established section 403A of the FD&C Act with regard to ''National Uniform Nutrition Labeling.''

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the minimum level necessary to achieve the objectives of the statute that provided the authority to issue the regulations. The proposed rule, if finalized, would meet the preceding requirement because it would preempt State law narrowly, only to the extent required to achieve uniform national labeling with respect to the requirements related to the contents and design of the FOP Nutrition Info box.

Section 4(d) of Executive Order 13132 states that when an agency foresees the possibility of a conflict between State law and federally protected interests within the agency's area of regulatory responsibility, the agency must consult with appropriate State and local officials, as practicable, in an effort to avoid such a conflict. Section 4(e) of Executive Order 13132 provides that when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency must provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings. FDA's Office of Partnerships will invite the States' participation in this rulemaking by providing notice via email to State health commissioners, State agriculture commissioners, and State food program directors as well as FDA field personnel of the publication of the proposed rule. The notice will give the States further opportunity for input on the proposed rule, advise the States of FDA's possible action, and invite State and local governments to provide any comments.

Consequently, we have included § 101.6(d) in the proposed regulatory text stating that a State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this rule. Preemption may also arise regarding other FOP nutrition labeling if a State requirement is found to obstruct the federal purpose articulated in this rule.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, or the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FDA invites comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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List of Subjects in 21 CFR Part 101

Food labeling, nutrition, reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, FDA proposes to amend part 101 as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 343 note, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Amend § 101.2 by:
■ a. Revising paragraph (b);
■ b. Revising paragraph (c)(1)(ii)(B)(*1*);
■ c. Adding paragraph (d)(2)(iv); and
■ d. Revising paragraph (f).

The revisions and addition read as follows:

§ 101.2 Information panel of packaged food.

* * * * *

(b) All information required to appear on the label of any packaged food under §§ 101.4, 101.5, 101.6, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of this part, and part 105 of this chapter must appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(B) * * *

(*1*) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained must bear nutrition labeling if required by § 101.9 and the Nutrition Info box if required by § 101.6; and any vending machine in which it is contained must bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.

* * * * *

(d) * * *
(2) * * *
(iv) The Nutrition Info box required by § 101.6 is not required on the lid if this information appears on the container body in accordance with this section.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.6, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of this part, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, *e.g.,* a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, must be submitted under part 10 of this chapter.

■ 3. Add § 101.6 to read as follows:

§ 101.6 Front-of-package Nutrition Info box.

(a) *General provisions*—(1) *Scope.* All food covered under § 101.9 that is marketed for people ages 4 and older must bear the Nutrition Info box described in paragraphs (a)(2) through (4) of this section on its label, unless the product is subject to special labeling provisions under paragraph (b) of this section or exempt under paragraph (c) of this section.

(2) *Content.* The Nutrition Info box must:

(i) Contain the heading ''Nutrition Info,'' which must be across the top of the Nutrition Info box and in a larger type than all other words in the Nutrition Info box;

(ii) Include two column subheadings under ''Nutrition Info'':

(A) ''Per serving,'' which must be accompanied by a statement of the serving size expressed in household measures as described in § 101.9(b)(5) (*e.g.,* ''Per serving (whole package)'' or ''Per serving (½ cup)''); and

(B) ''% Daily Value'';

(iii) Vertically list ''Saturated Fat,'' ''Sodium,'' and ''Added sugars,'' in that order, under the ''Per serving'' subheading as described in paragraph (a)(2)(ii)(A) of this section;

(iv) Specify, under the ''% Daily Value'' subheading as described in paragraph (a)(2)(ii)(B) of this section and to the right of the quantitative percent Daily Value (% DV) declaration as described in paragraph (a)(2)(v) of this section, whether the amount of the nutrient per serving, expressed as % DV as established in § 101.9(c)(9) and (d)(7)(ii), is ''Low,'' ''Med,'' or ''High.'' The ranges corresponding to ''Low,'' ''Med,'' and ''High'' are as follows:

(A) Low: 5% DV or less.

(B) Med: 6% to 19% DV.

(C) High: 20% DV or more.

(v) Declare the quantitative % DV for people ages 4 and older, as established in § 101.9(c)(9) and (d)(7)(ii), in its own column immediately under the ''% Daily Value'' subheading as described in paragraph (a)(2)(ii)(B) of this section and to the left of the ''Low,'' ''Med,'' and ''High'' categorization as described in paragraph (a)(2)(iv) of this section; and

(vi) Include a banner at the bottom with an ''*FDA.gov*'' attribution.

(3) *Formatting.* The Nutrition Info box must:

(i) Appear on the upper third of the principal display panel, as defined in § 101.1;

(ii) Use a single, easy-to-read type style;

(iii) Use a minimum type size (at least 8 point) that is no smaller than the size of the required net quantity of contents declaration, as specified in § 101.7(h) and (i);

(iv) Use all black or one color type for text and hairlines;

(v) Use a white or other neutral contrasting background to the print in the box;

(vi) Use hairlines to create the outer box;

(vii) Use a thick, horizontal, centered, hairline rule the same distance across the box as the ''Nutrition Info'' heading as described in paragraph (a)(2)(i) of this section to distinguish the heading and subheadings as described in paragraphs (a)(2)(i) and (ii) of this section from the information underneath them;

(viii) Use a horizontal, centered hairline rule the same distance across the box as the ''Nutrition Info'' heading as described in paragraph (a)(2)(i) of this section to distinguish each row of nutrient information as described in paragraph (a)(2)(iii) of this section;

(ix) Use extra-bold type and center-justify the ''Nutrition Info'' heading as described in paragraph (a)(2)(i) of this section;

(x) Left-justify the ''Per serving'' subheading as described in paragraph (a)(2)(ii)(A) of this section;

(xi) Use extra-bold type and right-justify the ''% Daily Value'' subheading as described in paragraph (a)(2)(ii)(B) of this section;

(xii) Use bold type and left-justify the nutrient names as described in paragraph (a)(2)(iii) of this section;

(xiii) Use extra-bold type and right-justify the ''Low,'' ''Med,'' and ''High'' categorizations as described in paragraph (a)(2)(iv) of this section;

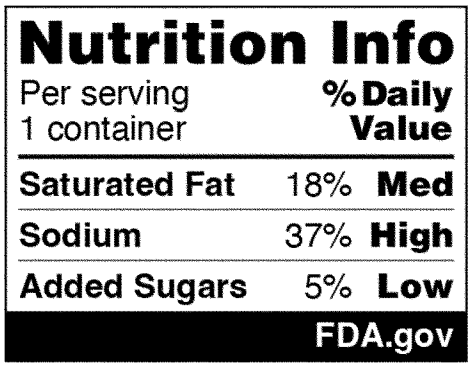
(xiv) Right-justify, within its own column to the left of the ''Low,'' ''Med,'' and ''High'' categorizations as described in paragraph (a)(2)(iv) of this section, the quantitative percent DV declarations as described in paragraph (a)(2)(v) of this section; and

(xv) Use the same color as used for the text and hairlines as specified under paragraph (a)(3)(iv) of this section for the banner background, with ''FDA.gov'' right-justified, in bold or extra-bold type, and in the same color as used for the rest of the box's background as described in paragraph (a)(3)(v) of this section.

(4) *No other information allowed in the Nutrition Info box.* No other information may be included in the Nutrition Info box.

(5) *Example.* The following example label illustrates the provisions of paragraphs (a)(2) through (a)(4) of this section.

Figure 1 to Paragraph (a)(5)—Example Standard Nutrition Info Box



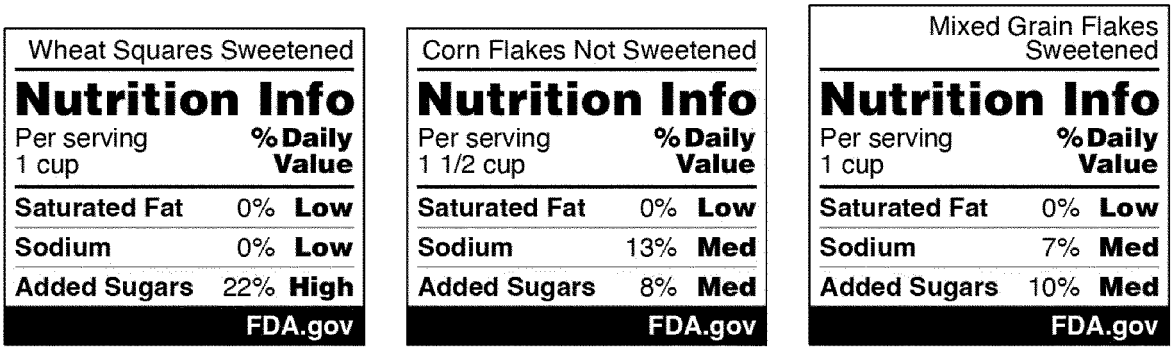
(b) *Special labeling provisions.* (1) Packaged foods that may use an aggregate display under § 101.9(d)(13)(i) and (h)(2)(ii) must display a Nutrition Info box as described in paragraph (a) of this section for each different product the package contains or could contain.

(i) The Nutrition Info boxes must appear together in either horizontal or vertical lines and must appear in the upper third of the principal display panel in accordance with § 101.6(a)(3)(i).

(ii) The package must specify the name of each food right-justified at the top of each food's Nutrition Info box, separated from the ''Nutrition Info'' header by a horizontal, centered hairline rule.

(iii) The following example label illustrates these requirements:

Figure 2 to Paragraph (b)(1)(iii)—Example Nutrition Info Box Modified for Aggregate Display

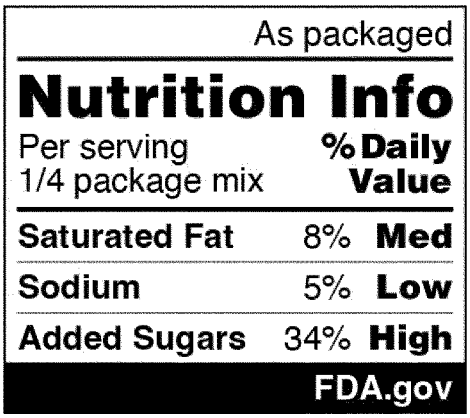


(2) Packaged foods that present Nutrition Facts labeling for two or more population groups must display a Nutrition Info box as described in paragraph (a) of this section, or Nutrition Info boxes as described in this paragraph (b)(2), that only reflect(s) the information for people ages 4 and older.

(3) Packaged foods that present Nutrition Facts labeling for both ''per serving'' and ''per individual unit'' in accordance with § 101.9(b)(2)(i)(D) must display a Nutrition Info box as described in paragraph (a) of this section that reflects the nutrition information ''per serving.''

(4) Packaged foods that present Nutrition Facts labeling for both ''as packaged'' and ''as prepared'' forms of the food consistent with § 101.9(e) must display a Nutrition Info box as described in paragraph (a) of this section that reflects the nutrition information for the ''as packaged'' form and must include a statement right-justified at the top of the box and separated from the ''Nutrition Info'' header by a horizontal, centered hairline rule to clarify that the box represents ''as packaged'' nutrition information (*e.g.,* ''Represents product ''as packaged'' '' or ''See Nutrition Facts for ''As Prepared'' information'').

Figure 3 to Paragraph (b)(4)—Example Nutrition Info Box Modified for ''As Packaged''



(5) Foods in packages that have a total surface area available to bear labeling of 40 or fewer square inches may display an alternative (intermediate-package) Nutrition Info box as described in this paragraph.

(i) The intermediate-package Nutrition Info box omits the following content from the Nutrition Info box described in paragraphs (a)(2) through (4) of this section:

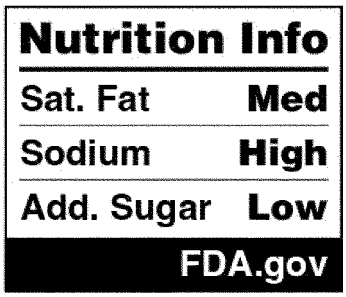
(A) The ''Per serving'' and ''% Daily Value'' subheadings; and

(B) The quantitative percent DV declarations.

(ii) The intermediate-package Nutrition Info box uses the abbreviations ''Sat. Fat'' for ''Saturated Fat'' and ''Add. Sugar'' for ''Added Sugars.''

(iii) The following example label illustrates the provisions of paragraphs (b)(6)(i) and (ii) of this section.

Figure 4 to Paragraph (b)(5)(iii)—Example Intermediate-Package Nutrition Info Box



(6) Foods sold from bulk containers must display a Nutrition Info box as described in paragraph (a) of this section plainly visible to consumers on the bulk container's labeling at the point of purchase.

(7) Game meats (*i.e.,* animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) must display a Nutrition Info box as described in paragraph (a) of this section:

(i) That reflects how the nutrition information is shown under § 101.9; and

(ii) Is plainly visible to consumers at the point of purchase if the food is unpackaged.

(c) *Exemptions.* The following foods are exempt from the requirements in this section:

(1) Any food exempt from § 101.9 under § 101.9(j), unless otherwise stated in this section;

(2) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches;

(3) Packages marketed as gifts that contain a variety or assortment of foods; and

(4) The unit containers in a multiunit retail food package where:

(i) The unit containers are exempt from Nutrition Facts labeling in accordance with § 101.9(j)(15); and

(ii) The multiunit retail food package label bears the Nutrition Info box in accordance with this section.

(d) *Preemption.* A State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this section for the Nutrition Info box.

■ 4. Amend § 101.13 by revising paragraphs (c), (i) introductory text, and (n) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(c) Information that is required or permitted by § 101.9 or § 101.36 as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, or that is required by § 101.6, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

* * * * *

(i) Except as provided in § 101.6, § 101.9, or § 101.36, as applicable, or in

paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

* * * * *

(n) Nutrition labeling in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable, must be provided for any food for which a nutrient content claim is made.

* * * * *

■ 5. Amend § 101.15 by revising paragraph (c)(2) to read as follows:

§ 101.15 Food; prominence of required statements.

* * * * *

(c) * * *

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label must appear thereon in the foreign language, except for labeling in accordance with § 101.6: *Provided, however,* That individual serving-size packages of foods containing no more than 1½ avoirdupois ounces or no more than 1½ fluid ounces served with meals in restaurants, institutions, and passenger carriers and not intended for sale at retail are exempt from the requirements of this paragraph (c)(2), if the only representation in the foreign language(s) is the name of the food.

* * * * *

■ 6. Amend § 101.61 by:
■ a. Revising paragraphs (a)(3) and (b)(4)(i);
■ b. Redesignating paragraph (b)(4)(ii) as (b)(4)(iii) and revising it;
■ c. Adding new paragraph (b)(4)(ii);
■ d. Revising paragraph (b)(5)(i);
■ e. Redesignating paragraph (b)(5)(ii) as (b)(5)(iii) and revising it; and
■ f. Adding new paragraph (b)(5)(ii).

The revisions and additions read as follows:

§ 101.61 Nutrient content claims for the sodium content of foods.

(a) * * *

(3) The food for which the claim is made is labeled in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable.

(b) * * *

(4) * * *

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 115 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 115 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the ''as prepared'' form);

(ii) The food must display ''Low'' in accordance with § 101.6 for sodium in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (*e.g.,* ''fresh spinach, a low sodium food'').

(5) * * *

(i) The product contains 115 mg or less sodium per 100 g;

(ii) The product must display ''Low'' in accordance with § 101.6 for sodium in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

* * * * *

■ 7. Amend § 101.62 by:
■ a. Revising paragraphs (a)(3) and (c)(2)(i);
■ b. Redesignating paragraph (c)(2)(ii) as paragraph (c)(2)(iii) and revising it;
■ c. Adding new paragraph (c)(2)(ii);
■ d. Revising paragraph (c)(3)(i);
■ e. Redesignating paragraph (c)(3)(ii) as paragraph (c)(3)(iii); and
■ f. Adding new paragraph (c)(3)(ii).

The revisions and additions read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) * * *

(3) The food for which the claim is made is labeled in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable; and

* * * * *

(c) * * *

(2) * * *

(i) The food contains 1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids;

(ii) The food must display ''Low'' in accordance with § 101.6 for saturated fat in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (*e.g.,* ''raspberries, a low saturated fat food'').

(3) * * *

(i) The product contains 1 g or less of saturated fatty acids per 100 g and less than 10 percent of calories from saturated fat;

(ii) The product must display ''Low'' in accordance with § 101.6 for saturated fat in the front-of-package Nutrition Info box, if the food label or labeling must comply with the requirements in § 101.6; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

* * * * *

■ 8. Amend § 101.65 by revising paragraph (a)(3) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

(a) * * *

(3) The food or which the claim is made is labeled in accordance with § 101.6, § 101.9, § 101.10, or § 101.36, as applicable.

* * * * *

Dated: January 10, 2025.

Robert M. Califf,

Commissioner of Food and Drugs.

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