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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2012-N-1210]

Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is revising certain provisions of the proposed rule, issued in March 2014, that would amend FDA's labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the Nutrition Facts and Supplement Facts labels to assist consumers in maintaining healthy dietary practices ("the NFL/SFL proposed rule"). We are proposing text for the footnotes to be used on the Nutrition Facts label. We are taking this action after completing our consumer research in which we tested various footnote text options for the label. We are also proposing to establish a Daily Reference Value (DRV) of 10 percent of total energy intake from added sugars, proposing to require the declaration of the percent Daily Value (DV) for added sugars on the label, and are providing additional rationale for the declaration of added sugars on the label. We are taking these actions based, in part, on the science underlying a new report released by the 2015 Dietary Guidelines Advisory Committee.

DATES: Submit either electronic or written comments on the supplemental notice of proposed rulemaking by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see the “Paperwork Reduction Act of 1995” section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5360 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2012-N-1210 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional

information on submitting comments, see the “How to Submit Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the supplemental notice of proposed rulemaking: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-5429, email: NutritionProgramStaff@fda.hhs.gov. With regard to the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville, Rd., COLE-14526, Silver Spring, MD 20993-0002, email: PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

FDA is revising certain provisions of the proposed rule that published in the Federal Register on March 3, 2014 (79 FR 11879), that would amend FDA’s labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the NFL/SFL proposed rule.

In the NFL/SFL proposed rule, we proposed to remove the requirement for the footnote listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets and reserved space to provide a proposed footnote. We stated in the preamble of the NFL/SFL proposed rule that we would continue to perform research during this rulemaking process to evaluate how

variations in label format may affect consumer understanding and use of the Nutrition Facts label. We also stated that we would publish the results of our research for public review and comment. We are making results of our research available in this document. We are also proposing text for the footnotes to be used on the Nutrition Facts label. We are taking this action after completing our consumer research in which we tested various footnote text options for the label. We are also providing an exemption from the footnote requirement for certain foods.

In addition, the NFL/SFL proposed rule would require the declaration of added sugars as an indented line item underneath the declaration of “Sugars” on the Nutrition Facts label. We discussed in the NFL/SFL proposed rule that we were considering whether to use the term “Total Sugars” instead of “Sugars” on the label if we finalize a declaration of added sugars.

We stated in the NFL/SFL proposed rule that we were planning to conduct a consumer study that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label in order to help enhance our understanding of how consumers would comprehend and use this new information. We also stated that we would publish the results of the study when they become available.

As we prepared to make the consumer study results for the footnote and added sugars declaration available, new information emerged from the “Scientific Report of the 2015 Dietary Guidelines Advisory Committee” (the 2015 DGAC report) regarding added sugars. The new information on added sugars led us to reconsider our thinking for not establishing a DRV or requiring the declaration of a percent DV for added sugars on the Nutrition Facts and Supplement Facts labels. Specifically, the 2015 DGAC report provided evidence suggesting a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of added sugars and a reduced risk of cardiovascular disease. The evidence also suggested an

applicable reference amount for added sugars, i.e., limiting added sugars intake to no more than 10 percent of total daily caloric intake. As a result of our review of the science underlying the 2015 DGAC report, we are proposing to establish a DRV for added sugars and to require the percent DV declaration of added sugars on the Nutrition Facts and Supplement Facts labels. We are not proposing to establish a DRV for total sugars or to require the mandatory declaration of a percent DV for total sugars because there is no quantitative intake level or other reference amount for which there is sufficient scientific evidence upon which we can base a DRV for total sugars. We are proposing to establish a DRV for added sugars because science underlying the 2015 DGAC report provided a scientific basis for a reference amount for added sugars upon which we can propose a DRV (a recommended maximum of 10 percent of total energy intake). We also received many comments suggesting that, if added sugars are declared on the label, a percent DV declaration would assist consumers in putting the amount of added sugars in a serving of a product into the context of their total daily diet.

A summary of the results of FDA's consumer research on footnote text options and on the added sugars declaration is available in section I.C., and a detailed description of the results is available in the docket.

Summary of the Major Provisions of the Regulatory Action in Question

We are proposing to establish a DRV for added sugars of 50 grams (g) for children 4 years of age and older and adults, and of 25 g for children 1 through 3 years of age. We are also proposing to require the declaration of the percent DV for added sugars on Nutrition and Supplement Facts labels, and have proposed revisions to the NFL/SFL proposed rule codified to reflect these changes. These proposed revisions are outlined in section III. We are also proposing footnote text for the space reserved in §101.9(d)(9) (21 CFR 101.9(d)(9)) of the

NFL/SFL proposed rule. The footnote text would explain that the % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet and that 2,000 calories a day is used for general nutrition advice. The language in this footnote is similar to the wording of one of the options tested in our study (as described in section I.C.), except that the sentences have been reversed. We believe this footnote explains the %DV in the most concise manner by providing a brief description of “% Daily Value,” which is lacking in the current footnote. While the consumer research study did not suggest strong support for a particular footnote, the language in this footnote was perceived by study participants to be more useful than the current footnote. We consider that switching the order of the sentences is important because it allows the first sentence to clearly follow the asterisk in the “%DV” column heading that leads to the footnote. When consumers look down to the footnote to see what additional information is linked to the asterisk that they see after the “%DV” column heading, they may expect to find the sentence that explains percent daily value first, rather than a sentence about calories. This supplemental notice of proposed rulemaking would also allow the footnote proposed in § 101.9(d) to be omitted from products that qualify for a simplified format (§ 101.9(f)), and on small or intermediate packages (§ 101.9(j)(13)(ii)(A)(1); § 101.9(j)(13)(ii)(A)(2)), provided that the following abbreviated statement is used: “%DV = % Daily Value.”

The proposed statement is shorter than the current statement to allow for more space on the label. In addition, we realize that the standard format in the NFL/SFL proposed rule for the Nutrition Facts label had a placeholder for the footnote and did not explain the “%DV.” It is important for consumers to know what “%DV” on the label means. Consequently, we are proposing a statement that spells out “%DV” for products that qualify for a simplified format and on small or intermediate packages.

This supplemental notice of proposed rulemaking also proposes an exemption to the proposed footnote requirement in section § 101.9(d)(9) for the foods that can use the terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietary insignificant source of calories” on the label or in the labeling of foods as defined in 21 CFR 101.60(b). Such products would have little to no impact on the average daily 2,000 calorie intake, which the footnote addresses. Exempting the footnote for these packages is a practical solution that would assure adequate space is still available for the required nutrient declarations.

We are inviting comment only with respect to the following issues discussed in greater detail later in this document: (1) New information from the 2015 DGAC report and the science upon which that report is based regarding added sugars; (2) the proposal to establish a DRV for added sugars and to require the declaration of the percent DV for added sugars on the Nutrition and Supplement Facts labels; (3) using the term “Total Sugars” instead of “Sugars” on the label (4) the proposed text for the footnotes to be used on the Nutrition Facts label; (5) exemptions from the proposed footnote requirement; (6) whether we should make changes to the footnote used on the Supplement Facts label; and (7) whether there should be a footnote on labels of food represented for infants 7 through 12 months of age or children 1 through 3 years of age, and, if so, what that footnote should say. We will not consider comments outside the scope of these issues.

Costs and Benefits

In the NFL/SFL proposed rule we stated that we have developed one comprehensive Preliminary Regulatory Impact Analysis (PRIA) that presents the benefits and costs of this proposed rule as well as the proposed rule entitled “Food Labeling: Serving Sizes of Foods That

Can Reasonably Be Consumed at One Eating Occasion; Dual Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" (the original PRIA). As stated earlier, we are proposing revisions to the NFL/SFL proposed rule. We are proposing footnote text and an exemption to that text for certain foods, and we are proposing that manufacturers declare the percent DV for added sugars on the Nutrition Facts and Supplement Facts labels. We estimate that just the changes specified in this supplemental notice of proposed rulemaking, if finalized, will generate annualized costs of \$10 million (at 7 percent discount rate) and \$8 million (at 3 percent discount rate), annualized benefits of \$200 million (at 7 percent) and \$300 million (at 3 percent), and annualized net benefits of \$190 million (at 7 percent) and \$292 million (at 3 percent) on top of those estimated in the previous proposed rules. In total, we estimate that these rules, including the changes outlined in this proposal, if finalized, will generate annualized costs of \$200 million (at both 3 and 7 percent), annualized benefits of \$2.1 billion (at 7 percent) and \$2.3 billion (at 3 percent), and annualized net benefits of \$1.9 billion (at 7 percent) and \$2.1 billion (at 3 percent). This represents an annual increase in net benefits from the original PRIA's estimates of approximately \$200 million per year.

We summarize the annualized costs and benefits (over a 20-year period discounted at both 3 percent and 7 percent) of the previous and revised proposed rules in the following table.

Summary of Annualized Costs and Benefits Over 20 Years of Previous and Revised Proposed Rules (in Billions of 2011 Dollars)

	Benefits	Costs	Net Benefits
Previous Proposed Rules			

Annualized @ 3%	\$2.0	\$0.2	\$1.8
Annualized @ 7%	\$1.9	\$0.2	\$1.7
Revised Proposed Rules			
Annualized @ 3%	\$2.3	\$0.2	\$2.1
Annualized @ 7%	\$2.1	\$0.2	\$1.9

Notes: Compliance period is 24 months. Analysis assumes that the proposed rules will be enacted together. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

I. Background

A. NFL/SFL Proposed Rule

In the Federal Register of March 3, 2014 (79 FR 11879), we published a proposed rule entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (the “NFL/SFL proposed rule”). The NFL/SFL proposed rule would amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. In the NFL/SFL proposed rule, we proposed to: (1) Update the list of nutrients that are required or permitted to be declared; (2) provide updated DRVs and Reference Daily Intake values that are based on current dietary recommendations from U.S. consensus reports; (3) amend requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establish nutrient reference values specifically for these population subgroups; and (4) revise the format and appearance of the Nutrition Facts label.

In the NFL/SFL proposed rule, we proposed to remove the requirement for the footnote listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets and reserved space to provide a proposed footnote (proposed § 101.9(d)(9)). We stated in the preamble of the NFL/SFL proposed rule that we would continue to perform research during this rulemaking

process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label. We also stated that we would publish the results of our research for public review and comment (79 FR 11879 at 11882). See section I.C. for a summary of the consumer study results.

In addition, the NFL/SFL proposed rule would require the declaration of added sugars as an indented line item underneath the declaration of “Sugars” on the Nutrition Facts label (proposed § 101.9(c)(6)(iii)). Such a declaration would only be required for the Supplement Facts label if added sugars are present in quantitative amounts that exceed the amount that can be declared as zero in § 101.9(c) (see proposed § 101.36(b)(2)(i)). Given our proposal to require the declaration of added sugars, we also considered establishing a DRV for added sugars. However, based on our review of scientific evidence and recommendations of U.S. consensus reports, we tentatively concluded in the NFL/SFL proposed rule that there was no sound scientific basis for the establishment of a quantitative intake recommendation upon which a DRV could be derived for total sugars (79 FR 11879 at 11902) and added sugars (79 FR 11879 at 11906). Therefore, we did not propose a DRV for added sugars. Accordingly, we proposed to require the declaration of added sugars on the Nutrition Facts label only in absolute amounts (in grams), similar to the declaration of total sugars.

We stated in the NFL/SFL proposed rule that we were planning to conduct a consumer study that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label to help enhance our understanding of how consumers would comprehend and use this new information. We stated that we would publish the results of the study when they became available. We also stated that we were interested in receiving, as part of any comment, other available research data and other factual information relevant to these

issues, including the proposed double indented placement of added sugars below total sugars (79 FR 11879 at 11952). See section I.C. for a summary of the consumer study results.

B. Public Outreach

We requested comments on the NFL/SFL proposed rule by June 2, 2014, and comments on information collection issues under the PRA by April 2, 2014 (79 FR 11879). In the Federal Register of May 27, 2014 (79 FR 30055), we extended the comment period until August 1, 2014. In the Federal Register of May 29, 2014 (79 FR 30763), we announced our intent to hold a public meeting to discuss the NFL/SFL proposed rule and a proposed rule on serving sizes. The purpose of the public meeting was to inform the public of the provisions of the proposed rules, to invite oral stakeholder and public comments on the proposed rules, and to respond to questions about the proposed rules.

Nearly 300,000 comments were submitted to the docket on the NFL/SFL proposed rule. We continue to review these comments as part of our development of the NFL/SFL final rule. However, for the reasons discussed in section II., we are issuing revisions to certain provisions in the NFL/SFL proposed rule and requesting comment on the revisions.

C. Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars

We conducted research to examine how a declaration of added sugars and alternative footnote statements may influence consumer use of the Nutrition Facts label in the absence of any consumer education. The study was a controlled, randomized, Web-based experiment completed in 2014. Although the research involved a single data collection effort, this data collection was composed of two separate experiments; one designed to address the effects of added sugars declarations and the other designed to address the effects of modified footnotes. At

the time the research was designed, we were not aware of any previous studies of consumer responses to added sugars information. This research was undertaken to help inform consumer education if added sugars were declared on the Nutrition Facts label. The research design did not include a percent DV for added sugars on the food label or the ingredient listing that will appear on packages, so we do not have data on how those pieces of information would affect consumer responses to an added sugars declaration. The study achieved its intended objectives of providing an initial understanding of potential consumer reactions to added sugars declarations and modified footnote information on Nutrition Facts labels. This information will help inform our future educational efforts related to food labeling. As with other new information, we would expect consumer understanding of an added sugars declaration, if finalized, to improve as the public's exposure to added sugars information increases and educational activities to explain the concept and how to use the new information on the Nutrition Facts label are undertaken.

1. Added Sugars Experiment

In the added sugars experiment, participants viewed Nutrition Facts label images displayed in one of three possible Nutrition Facts formats (see Ref. 1 for label formats):

- The “Added Sugars” Format, where an added sugars declaration was indented below a “Sugars” declaration;
- The “Total Sugars + Added Sugars” Format, where an added sugars declaration was indented below a “Total Sugars” declaration; and
- The Control Format, where participants viewed the current Nutrition Facts label throughout the study.

While viewing these label images, participants were asked a series of questions on their ability to accurately recognize and compare nutrients on the Nutrition Facts label, and their judgments about the foods' overall healthfulness and relative nutrient levels. Participants responded to these questions in the context of a one-product judgment task and a two-product comparison task. Participants were not given the proposed definition of added sugars or provided with the ingredients lists for the products tested, which could have affected their understanding.

The study found that when both total and added sugars declarations appeared on the label, the majority correctly reported the added sugars amount and accurately identified which products had less added sugars. The “Total Sugars + Added Sugars” format appeared to help participants better comprehend the total amount of sugars in a food than the “Added Sugars” format. The effect of the added sugars declarations on product judgments varied depending on the food category and the level of added sugars in the product. When declared, higher amounts of added sugars tended to produce more negative judgments about the product’s healthfulness. Although the majority of the respondents correctly identified the total amount of sugars in a serving of food with each label presented that included an added sugars declaration, the added sugars experiment results show that a number of participants were confused about the distinction between sugars and added sugars, regardless of whether added sugars declarations appeared on the Nutrition Facts label. When participants were viewing Nutrition Facts labels without added sugars declarations, they could not accurately determine the amount of added sugars in the products, with the majority reporting that the total sugars amount was the amount of added sugars. Moreover, many participants who viewed Nutrition Facts labels without added sugars declarations assumed that the more nutritious products in the study had less added sugars.

A full description of the Added Sugars Experiment is in the Docket (Ref. 1).

2. Footnote Experiment

The footnote experiment compared consumer reactions to seven footnote formats, which included five modified footnotes, in addition to the current footnote and no footnote at all, for explaining percent DVs and how to use them. Results indicated that none of the modified footnotes significantly affected product perceptions or judgments of nutrient levels; all five footnote options produced similar perceptions and judgments relative to the current footnote and a no-footnote control. Nevertheless, all five modified footnotes were rated as easier to understand than the current footnote. Footnote 1 was perceived to be more believable than the current footnote. Footnote 1 stated the following: “2,000 calories a day is used for general nutrition advice. *The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet.” We are proposing footnote text from Footnote 1 in this supplemental notice of proposed rulemaking. See section III.B. A full description of the Footnote Experiment is in the Docket (Ref. 2).

II. Decision to Issue Supplemental Notice of Proposed Rulemaking Regarding Limited

Additional Provisions

As we prepared to make the consumer study results discussed in section I.C. available, new information emerged from the 2015 DGAC report (Ref. 3) regarding added sugars. The DGAC reviews the scientific evidence on specific topics and provides their assessment of the scientific evidence and recommendations. The new information on added sugars led us to reconsider our thinking for not establishing a DRV or requiring the declaration of a percent DV for added sugars on the Nutrition Facts and Supplement Facts labels. The 2015 DGAC report also included new important information and analysis related to requiring the declaration of

added sugars on the Nutrition Facts label, which we had proposed in the NFL/SFL proposed rule, specifically evidence related to dietary patterns and risk of disease.

We have considered the evidence that the DGAC relied upon and have tentatively concluded that the new evidence provided in the 2015 DGAC report related to dietary patterns of intake that are associated with a reduced risk of chronic disease (specifically cardiovascular disease (CVD)) as well as the evidence provided in the report related to excess intake of added sugars in the U.S. supports our proposal to require the mandatory declaration of added sugars on the Nutrition and Supplement Facts labels. The DGAC report also provides evidence to support a reference amount for added sugars upon which we can establish a DRV for use in calculating a percent DV on the label. The percent DV is included to assist consumers in understanding the relative significance of the amount of added sugars in a serving of a product in the context of a total daily diet.

The 2015 DGAC report does not contain federal government recommendations. The independent advisory committee's views will be taken into consideration by the Federal government as the dietary guidelines are updated. In this supplemental notice of proposed rulemaking, we have considered the scientific evidence underpinning the recommendations provided in the advisory committee's report. As a result of our review of the 2015 DGAC report and the evidence that the DGAC relied upon, we are proposing to establish a DRV and to require the percent DV declaration for added sugars on the Nutrition Facts and Supplement Facts labels.

We are also proposing text for the footnotes to be used on the Nutrition Facts label. We are not proposing any revisions to the footnote text used on the Supplement Facts label. As discussed in the NFL/SFL proposed rule, the current footnote statement required for the Supplement Facts label differs from that which is currently required on the Nutrition Facts label.

We stated that based on the results of the consumer study, we will consider whether it is necessary to make corresponding changes to the footnote used on the Supplement Facts label when certain macronutrients are declared. We invited comment on whether we should consider changes to the footnote statement on the Supplement Facts label to be consistent with any changes to the footnote statement in the Nutrition Facts label (79 FR 11879 at 11948). We also noted that “[a] comment to the 2007 ANPRM requested that we permit the use of a footnote statement about not limiting fat intake on foods represented or purported to be specifically for infants and children less than 2 years to enable consumers to make informed choices, should the Agency decide to propose the mandatory declaration of saturated fat for infants and children less than 2 years. The comment noted that saturated fat should not be limited in the diets of children less than 2 years of age. The comment provided no consumer data about such a footnote statement. At this time, we are not proposing to require a footnote stating that total fat and other types of fat should not be limited in infants and children less than 2 years in response to this comment. However, we request comments and information on how consumers would understand and use the amount of saturated fat and cholesterol declared on the Nutrition Facts label, as well as on the need for an explanatory footnote to accompany the declaration of saturated fat and cholesterol, on food represented or purported to specifically for infants 7 through 12 months or children 1 through 3 years” (79 FR 11879 at 11934-11935). We did not receive many comments on these issues in response to the proposed rule. We are inviting comment on whether we should consider requiring, instead of the current footnote for the Supplement Facts label that links the percent DV with a 2,000 calorie level, part of the Nutrition Facts label footnote text we are proposing for the Nutrition Facts label that states “2,000 calories a day is used for general nutrition advice.” We are also inviting further comment on whether we

should consider a footnote for foods, other than infant formula, represented or purported to be specifically for infants 7 through 12 months or children 1 through 3 years of age in the NFL/SFL proposed rule, and if so, what the footnote should say.

This supplemental notice of proposed rulemaking provides the public with the opportunity to provide comment on our tentative conclusions with respect to the footnote, the DRV, the percent DV declaration for added sugars, and the new information from the 2015 DGAC report for the added sugars declaration. As noted, we are not seeking and will not consider comments with respect to other issues.

III. Description of the Supplemental Notice of Proposed Rulemaking

A. Proposing to Establish a DRV and Require the Declaration of the Percent DV for “Added Sugars”

As originally proposed, the NFL/SFL proposed rule would require the declaration of the gram amount of added sugars on the Nutrition Facts and Supplement Facts labels, but would not establish a DRV or require the disclosure of the percent DV for added sugars. The proposed requirement for the declaration of the gram amount of “added sugars” was based, in large part, on data and information in the Dietary Guidelines for Americans, 2010 (2010 DGA)(Ref. 4) related to the intake of excess calories in the U.S. diet from solid fats and added sugars, and the impact that these excess calories may have on the nutrient density of the diet. As discussed in the NFL/SFL proposed rule, no more than 5 to 15 percent of calories from solid fats and added sugars combined can be reasonably accommodated in the U.S. Department of Agriculture (USDA) Food Patterns for most people to avoid excess calorie consumption, yet added sugars alone contributed an average of 16 percent of the total calories in American diets (79 FR 11879 at 11903 through 11904).

In the 2014 NFL/SFL proposed rule we stated that although there is sufficient science to support a relationship between the intake of sugar-sweetened beverages and an increase in adiposity (body fat) in children, “inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease.” (79 FR 11879 at 11904). Thus, we included the evidence that added sugars contribute excess calories to the American diet as part of our rationale for proposing the mandatory declaration of added sugars.

We did not propose to establish a DRV or to require the declaration of a percent DV for added sugars in the NFL/SFL proposed rule because, at the time we issued the NFL/SFL proposed rule, there was “no scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived” (79 FR 11879 at 11906). Following publication of the NFL/SFL proposed rule, the 2015 DGAC, a group of outside experts, submitted its recommendations to the Secretaries of the Department of Health and Human Services (HHS) and USDA, to inform the Dietary Guidelines for Americans, 2015. The Secretaries released the advisory committee’s recommendations report online on February 19, 2015, making it available for public review and comment (see <http://www.health.gov/dietaryguidelines/2015-scientific-report/>).

The 2015 DGAC reaffirmed recommendations in the 2010 DGA, which included recommending reducing the intake of added sugars. The 2015 DGAC examined the relationship between dietary patterns and health outcomes more extensively than did earlier DGAC reports, through the use of a food modeling approach using the USDA Food Patterns (Ref. 5). The 2015 DGAC reviewed the current science, status and trends in the dietary pattern of intake in the U.S. population compared to a “Healthy U.S.-style Pattern,” a “Healthy Mediterranean-style Pattern,” and a “Healthy Vegetarian Pattern” associated with health benefits. The report found the current

U.S. population intake of solid fats and added sugars is high across all age groups and genders with nearly 90 percent of the general population “exceeding the recommended daily limits” (Ref. 6). Added sugars intake alone remains high at 13.4 percent of total calories per day among the total population ages 1 year and older (Ref. 7). Importantly, the 2015 DGAC found strong and consistent evidence demonstrating that, relative to less healthy patterns, dietary patterns associated with decreased risk of cardiovascular disease (CVD) are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grain, and sugar-sweetened foods and beverages (Ref. 8). The 2015 DGAC suggested the NFL/SFL should include an added sugars declaration and the declaration of a percent DV for added sugars (Ref. 9). The Federal government has not issued a final 2015 Dietary Guidelines for Americans report.

Based on our review of the evidence presented in the 2015 DGAC report (see link to individual studies reviewed by the 2015 DGAC – (<http://www.nel.gov/>) - then click on “Dietary Patterns and Health Outcomes Systematic Review Report.”), we find that the evidence further supports FDA’s proposal to require an added sugars declaration in the Nutrition and Supplement Facts labels. Specifically, there is evidence of a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD. There is also evidence to support a reference amount for added sugars, i.e., limiting added sugars intake to no more than 10 percent of total daily caloric intake.

The 2015 DGAC report also recommended that Americans keep added sugars intake below 10 percent of total energy intake (Ref. 10). The 2015 DGAC based this “less than 10 percent” recommendation on modeling of dietary patterns, current added sugars consumption

data, and a published meta-analysis on sugars intake and body weight. (Ref. 11). Based on the scientific evidence, we tentatively conclude that limiting consumption of added sugars to 10 percent of daily calories is a reasonable goal for consumers to achieve and is consistent with the goals of the Dietary Guidelines for Americans to provide advice for choosing and maintaining a healthful dietary pattern.

In the NFL/SFL proposed rule, we recognized that we did not have a scientifically supported quantitative intake recommendation for added sugars, based on a biomarker of risk of disease or other public health endpoint, on which a DRV for added sugars could be derived. However, we did consider a reference point for added sugars consumption based on the calories from solid fats and added sugars limits at each calorie level in the USDA Food Patterns in the 2010 DGAC report (79 FR 11879 at 11906). Based on that analysis, and without a declaration in the Nutrition Facts label of “calories from solid fats and added sugars,” consumers would have to multiply grams of saturated, trans fats, and added sugars by the number of calories per gram to determine the amount of calories from solid fats and added sugars in a product. The 2015 DGAC report, in its analysis of added sugars as part of a dietary pattern of intake among the U.S. population, found a strong association with that pattern of intake to an increase in CVD risk, in comparison to healthier dietary patterns with lower added sugars intakes. This analysis included publications of clinical trials and prospective cohort studies (<http://www.nel.gov/> - then click on “Dietary Patterns and Health Outcomes Systematic Review Report.”) Therefore, we tentatively conclude that the 2015 DGAC report and the scientific information on which it relies provide a basis for FDA to establish a DRV reference point for the added sugars declaration at 10 percent of calories that is based on a public health endpoint and is necessary to assist consumers to maintain healthy dietary practices.

We are proposing a DRV of 50 g for added sugars from which the percent DV can be calculated. We determine a DRV of 50 g by first multiplying the 2,000 reference calorie intake by 10 percent ($2,000 \times .10 = 200$ calories). The 2,000 reference calorie intake is used for other nutrients to calculate the DRV when the recommendations for the nutrient intake may fluctuate based on calorie intake. The 2,000 calorie value represents a reference intake for adults and children 4 years of age and older, including pregnant and lactating women. Dividing 200 calories by 4 calories/g ($200 \text{ calories} \div 4 \text{ calories/g} = 50 \text{ g}$) provides us with the gram amount (50 g) of added sugars as a reference amount for use as the DRV. A 1,000 calorie reference amount would be used to calculate the DRV for children 1 through 3 years of age at 25 g of added sugars ($1,000 \text{ calories} \times .10 = 100 \text{ calories}$ and $100 \text{ calories} \div 4 \text{ calories/g} = 25 \text{ g}$).

The comments we received on the NFL/SFL proposed rule were generally supportive of a DRV of no more than 10 percent of total energy intake from added sugars. Many of the comments in support of a DRV of no more than 10 percent of total energy intake cited the 2014 World Health Organization (WHO) draft guideline. This WHO guideline, however, is not a U.S consensus report and was not specific to added sugars. There were also some comments that did not support a DRV for added sugars, citing a lack of scientific evidence to set a quantitative intake recommendation. We now have the 2015 DGAC report that supports a proposal to establish a DRV of 10 percent of total energy intake from added sugars and to require the declaration of percent DV for added sugars on the label. Specifying and requiring a percent DV declaration is also supported by comments we received stating that such a declaration will help consumers determine the amount of added sugars on the label in the context of their total daily diet.

If we finalize a declaration of added sugars, we tentatively conclude that a DRV or point of reference for consumers to understand the declaration of added sugars and what that number means in the context of the total daily diet is needed. We are proposing in section III.A. that a percent DV be declared for added sugars on the label.

Further, as discussed in the NFL/SFL proposed rule (79 FR 11879 at 11902), we are considering whether to use the term “Total Sugars” instead of “Sugars” on the label if we finalize a declaration of added sugars. The use of “Total Sugars” was supported by many comments. In addition, our added sugars experiment did show that use of the term “Total Sugars” helped improve study participants’ understanding that added sugars are part of the total amount of sugars in the product. Therefore, we intend to consider finalizing the use of the term “Total Sugars” instead of “Sugars” on the label, if we finalize a declaration of added sugars. We are not proposing to establish a DRV for total sugars or to require the mandatory declaration of a percent DV for total sugars because there is no quantitative intake level or other reference amount for which there is sufficient scientific evidence upon which we can base a DRV for total sugars.

Given the discussion in section III.A., this supplemental notice of proposed rulemaking would:

- Amend § 101.9(c)(9) to add “Added sugars” to the list of food components with established DRVs with a unit of measurement of “Grams (g),” and to establish a DRV for adults and children 4 years of age and older, including pregnant and lactating women, of 50 g and a DRV for children 1 through 3 years of age of 25 g.
- Amend § 101.36(b)(2)(iii)(D) to require that the percent DV for added sugars be declared when added sugars are present in a dietary supplement at an amount greater than 1 gram per serving, such that the proposed requirement would say that if the

percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under § 101.9(e)(6) and inside the box, that is followed by the statement “Percent Daily Values are based on a 2,000 calorie diet.”

Proposing to require the declaration of the percent DV for added sugars on the label are not the only revisions to the codified that would be needed if we finalized the added sugars provisions. We proposed additional amendments related to added sugars and they are described in the NFL/SFL proposed rule (79 FR 11879 at 11905-11907).

B. Proposing the Footnote Text that Would be Required on Certain Packages and Proposed Exemptions from the Footnote Requirement

In the NFL/SFL proposed rule, we proposed to remove the requirement for the footnote listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets and reserved space to provide a proposed footnote (proposed §101.9(d)(9)). We consider that a succinct statement about daily calorie intake (2,000 calories) is a necessary part of the footnote because 2,000 calories is consistent with widely used food plans, the percent DV of certain nutrients (e.g., total fat, total carbohydrate, and dietary fiber) is based on 2,000 calories, and 2,000 calories approximates the estimated energy need for adults who are sedentary to moderately active. However, we recognize that a succinct statement about daily calorie intake should not suggest that the percent DV of all nutrients is linked to a 2,000 calorie diet.

We received comments on the footnote and many comments requested that the footnote continue to explain that percent DVs are based on a 2,000 calorie diet but individual calorie needs may be higher or lower. Many comments also emphasized that any revisions to the

footnote should be research-based and that the results of our consumer research studies should be made available for review and comment.

Many comments emphasized that because the NFL/SFL proposed rule does not specify the exact footnote text and the amount of space the new footnote would require, more information is needed in order to comment on the footnote. Some comments emphasized that the footnote should be brief and not take up too much space, and expressed concerns about how the footnote would fit on small packages.

This supplemental notice of proposed rulemaking would add language to the space reserved in proposed § 101.9(d)(9) to explain that the % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet and that 2,000 calories a day is used for general nutrition advice. The language in this footnote is similar to one of the options tested during the consumer research study described in section I.C., except that we have reversed the order of the sentences from the footnote tested. While the consumer research study did not suggest strong support for a particular footnote, the language in this footnote was perceived by study participants to be more useful than the current footnote. We consider that switching the order of the sentences is important because it allows the first sentence to clearly follow the asterisk in the “%DV” column heading that leads to the footnote. When consumers look down to the footnote, to see what additional information is linked to the asterisk that they see after the “% DV” column heading, they may expect to find the sentence that explains percent daily value first, rather than a sentence about calories. We believe that this footnote explains the “% DV” in the most concise manner.

Previously, in the 1993 final rule entitled “Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition” (58 FR 2079 (January 6, 1993))

(1993 final rule), we noted that prior research had shown that although most consumers do not notice footnotes, those who are given the information (and by inference, those who do read the footnote) are able to interpret it appropriately (58 FR 2079 at 2131). Consistent with our rationale in 1993, we continue to expect that the provision of a simple footnote will help those consumers who do read it in understanding the information on the nutrition label. The second sentence of the proposed footnote is the same as the succinct statement that will be required on menus and menu boards under our final rule entitled “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” (79 FR 71156 (December 1, 2014)). It is important to explain calories in the context of the total daily diet and also provide consistency in the wording of this nutritional advice between packaged and restaurant foods.

Some packaged foods do not require the full footnote. The footnote information specified in § 101.9(d)(9)(i) (which includes the footnote table) can be omitted from products that qualify for a simplified format and small or intermediate packages, provided that the following abbreviated footnote statement is used: “Percent Daily Values are based on a 2,000 calorie diet” (§§ 101.9(f)(5) and 101.9(j)(13)). In this supplemental notice of proposed rulemaking, we propose to allow the footnote proposed in § 101.9(d) to be omitted from products that qualify for a simplified format (§ 101.9(f)), and from small or intermediate packages (§ 101.9(j)(13)(ii)(A)(1); § 101.9(j)(13)(ii)(A)(2)), provided that the following abbreviated statement is used: “%DV = % Daily Value.” The proposed statement for these packages shortens it from what is currently required and allows for more space on the label. In addition, we realize that the standard format in the NFL/SFL proposed rule for the Nutrition Facts label had a placeholder for the footnote and did not explain the “%DV.” It is important for consumers

to know what “%DV” on the label means. Consequently, we are proposing a statement for these packages that spells out “%DV.” We recognize that for these packages, additional information in the footnote is not needed. In this supplemental proposed rulemaking, we apply the same rationale we used in the 1993 final rule with regards to exempting small and intermediate packages from some of the footnote language we required for large packages. The 1993 final rule allowed manufacturers flexibility in using the complete footnote on all product labels. We recognized that the benefits of requiring this footnote were not relative to the specific product that carries the information, and that the information would be available to consumers if it appeared on a significant percentage of food labels (58 FR 2079 at 2129).

This supplemental notice of proposed rulemaking proposes an exemption to the proposed footnote requirement in § 101.9(d)(9) for the foods that can use the terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietary insignificant source of calories” on the label or in the labeling of foods as defined in § 101.60(b). Such products would have little to no impact on the average daily 2,000 calorie intake, which the footnote addresses. Exempting the footnote for these packages is a practical solution that would assure adequate space is still available for the required nutrient declarations.

We believe that consumer education programs regarding using and understanding the Nutrition Facts and Supplement Facts labels (including the footnote) are important, and plan to work with our federal partners to develop such programs after publication of the final rule.

Given the discussion in section III.B., this supplemental notice of proposed rulemaking would:

a. Amend § 101.9(d)(9) to replace the reserved space. Specifically, after the language in § 101.9(d)(8) explaining that when listed horizontally in two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line--the proposed requirement would replace “[Reserved]” with text stating that a footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and be separated from the list by a hairline, except that the footnote may be omitted from foods that can use the terms “calorie free,” “free of calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietary insignificant source of calories” on the label or in the labeling of foods as defined in § 101.60(b). The footnote text would explain that the %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet and that 2,000 calories a day is used for general nutrition advice.

b. Amend § 101.9(j)(13)(ii)(C) to revise the footnote text. Specifically, after “Sugar alcohol–Sugar alc,” the proposed requirement would provide for omitting the footnote statement and placing another asterisk at the bottom of the label followed by the statement ‘%DV=%Daily Value’.”

C. Other Related Provisions-Future Revisions to the Sample Labels

The revisions to the NFL/SFL proposed rule described in this section would require revisions to the labels illustrated in §§ 101.9(d)(11)(iii), 101.9(d)(12), 101.9(d)(13)(ii), 101.9(e)(5), 101.9(e)(6)(i), 101.9(e)(6)(ii), 101.9(f)(4), 101.9(j)(13)(ii)(A)(1), and 101.9(j)(13)(ii)(A)(2) of the NFL/SFL proposed rule. As stated in section VII. we provided a sample label in proposed § 101.9(j)(5)(i) for foods, other than infant formula, represented or purported to be specifically for infants 7 through 12 months or children 1 through 3 years of age in the NFL/SFL proposed rule, however, we invite further input on whether such a footnote is

needed and, if so, what it should say. If the NFL/SFL is finalized as proposed in this supplemental notice, we will make the changes needed to the labels in the codified in the NFL/SFL final rule.

IV. Preliminary Regulatory Economic Analysis of Impacts

As explained in the NFL/SFL proposed rule, we performed the necessary analyses to examine the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and the PRA (44 U.S.C. 3501-3520). We provided a PRIA of the proposed rule (see Ref. 187 of the NFL/SFL proposed rule) for public input (79 FR 11879 at 11959).

We performed additional analysis to examine the impacts of the revised proposed provisions described in the Federal Register document under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act of 1995, and the PRA. We present our additional analyses, including the total estimated costs and benefits of this supplement to the NFL/SFL proposed rule, in our supplemental PRIA for this proposed rule (Ref. 12), which will be made available at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/>. We invite comment on our additional analyses.

V. Paperwork Reduction Act of 1995

This supplemental notice of proposed rulemaking contains information collection provisions that are subject to review by OMB under the PRA. As explained in the NFL/SFL proposed rule, we performed the necessary analyses to examine the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act of 1995, and the PRA. We provided a PRIA of the NFL/SFL

proposed rule (see Ref. 187 of the NFL/SFL proposed rule) for public input (79 FR 11879 at 11959). A description of the information collection provisions of the NFL/SFL proposed rule was given in the PRIA of the NFL/SFL proposed rule with an estimate of the annual third-party disclosure burden. A description of the information collection provisions of the supplemental notice of proposed rulemaking is given in the Description section 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.

We invite comments on these topics:(1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion

Description: This supplemental notice of proposed rulemaking proposes two changes to the third-party disclosure requirements discussed in the analysis of the NFL/SFL proposed rule: a percent DV labeling requirement as well as footnote requirements.

Description of Respondents: The likely respondents to this information collection are manufacturers of retail food products marketed in the United States whose products contain (1) a

mixture of naturally occurring and added sugars or (2) a mixture of non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber. The likely respondents to this information collection also include manufacturers of retail food products marketed in the United States whose products contain (1) mixtures of different forms of vitamin E or (2) both folate and folic acid.

We estimate the burden of the information collection provisions of the supplemental notice of proposed rulemaking as follows. After careful review of the burden estimate analysis provided in the PRIA for the NFL/SFL proposed rule, we tentatively conclude that our previous estimate of the burden hours has not changed meaningfully as a result of this supplemental notice of proposed rulemaking. Thus, we have calculated no additional burden related to the proposed percent DV labeling requirement for added sugars described in this supplemental notice of proposed rulemaking.

With regard to the proposed footnote labeling requirements in this supplemental notice of proposed rulemaking, we note that the text of the footnote statements would be supplied by FDA in the final regulation. We tentatively conclude that the proposed footnote provisions in this supplemental notice of proposed rulemaking are “public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, we have calculated no additional burden related to the proposed footnote labeling requirements in this supplemental notice of proposed rulemaking.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All

comments should be identified with the title, “Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion.”

In compliance with the PRA, we have submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the Federal Register.

VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. This action revises certain provisions of the NFL/SFL proposed rule. For the NFL/SFL proposed rule, we concluded that the action would not have a significant impact on the human environment, and that an environmental impact statement was not required. Our finding of no significant impact and the evidence supporting that finding may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

We have not received any new information or comments that would affect our previous determination. Furthermore, we have reviewed the revisions to the NFL/SFL proposed rule as described herein, and have determined the revisions do not impact our previous determination. Therefore, our finding of no significant impact remains unchanged.

VII. Request for Comments

We are seeking comment only with respect to the following issues: (1) The new information from the 2015 DGAC report regarding added sugars; (2) the proposal to establish a DRV for added sugars and to require the declaration of the percent DV for added sugars on the Nutrition and Supplement Facts labels; (3) using the term “Total Sugars” instead of “Sugars” on

the label; (4) the proposed text for the footnotes to be used on the Nutrition Facts label; (5) the exemptions from the proposed footnote requirement; (6) whether we should make changes to the footnote used on the Supplement Facts label; and (7) whether we should propose a footnote for foods other than infant formula, represented or purported to be specifically for infants 7 through 12 months or children 1 through 3 years of age. We acknowledge that in the NFL/SFL proposed rule, we provided in proposed § 101.9(j)(5)(i) a sample label for these foods that included a placeholder for a footnote. However, we would appreciate further input on whether such a footnote is needed and, if so, what it should say. We will not consider comments outside the scope of these issues.

Comments previously submitted to the Division of Dockets Management do not need to be resubmitted, because all comments submitted to the docket number, found in brackets in the heading of this document, will be considered in development of the final rule.

VIII. How To Submit Comments

Interested persons may submit either electronic or written comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. These references are also available electronically at

<http://www.regulations.gov>. We have verified the Web site addresses in this section, but we are not responsible for subsequent changes to the Web sites after this document published in the Federal Register.

1. FDA Memorandum to the File -- “Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars” (OMB Control Number 0910-0764), 2015.
2. FDA Memorandum to the File -- “Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats” (OMB Control Number 0910-0764), 2015.
3. USDA and HHS, Scientific Report of Dietary Guidelines for Americans, 2015, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.
4. USDA and HHS, Dietary Guidelines for Americans, 2010., 7th Ed., Washington DC:U.S. Government Printing Office (2010). Retrieved from <http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm>.
5. USDA and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. “Chapter 1: Food and Nutrient Intakes, and Health: Current Status and Trends,” pg. 3, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.
6. USDA and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. “Chapter 1: Food and Nutrient Intakes, and Health: Current Status and Trends,” pg. 35, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.

7. USDA and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. “Chapter 5: Food Sustainability and Safety,” pg. 18, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.
8. USDA and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. “Chapter 2: Dietary Patterns, Foods and Nutrients, and Health Outcomes,” pg. 8, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.
9. USDA and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. “Chapter 6: Cross-Cutting Topics of Public Health Importance,” pg. 27, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.
10. USDA and HHS, Scientific Report of the 2015 Dietary Guidelines Advisory Committee, 2015, Part D. “Chapter 6: Cross-Cutting Topics of Public Health Importance,” pgs. 20-21, available at <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.
11. Te Morenga, L., S. Mallard, J. Mann, “Dietary Sugars and Body Weight: Systematic Review and Meta-Analysis of Randomised Controlled Trials and Cohort Studies,” BMJ 2013;346:e7492.
12. FDA, Supplemental Preliminary Regulatory Impact Analysis for Proposed Rules On “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (Docket No. FDA-2012-N-1210) and “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed;

Serving Size for Breath Mints; and Technical Amendments" (Docket No. FDA-2004-N-0258), 2015.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101, as proposed to be amended on March 3, 2014 (79 FR 11879), be further amended as follows:

PART 101--FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

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

2. In § 101.9, revise paragraphs (c)(9), (d)(9), and (j)(13)(ii)(C) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

Food component	Unit of measurement	DRV			
		Adults and Children ≥ 4 years	Infants 7 through 12 months	Children 1 through 3 years	Pregnant and lactating women
Fat	Grams (g)	65 ¹	30	39 ²	65 ¹
Saturated fatty acids	Grams (g)	20 ¹	N/A	10 ²	20 ¹
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	300 ¹	95	150 ²	300 ¹
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300

Food component	Unit of measurement	DRV			
		Adults and Children \geq 4 years	Infants 7 through 12 months	Children 1 through 3 years	Pregnant and lactating women
Dietary fiber	Grams (g)	28 ¹	N/A	14 ²	28 ¹
Protein	Grams (g)	50 ¹	N/A	13 ²	N/A
Added Sugars	Grams (g)	50 ¹	N/A	25 ²	50 ¹

¹Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant and lactating women

²Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(d)* * *

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from the list by a hairline, except that the footnote may be omitted from foods that can use the terms “calorie free,” “free of calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietary insignificant source of calories” on the label or in the labeling of foods as defined in § 101.60(b). The footnote shall state: *The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

* * * * *

(j)* * *

(13)* * *

(ii)* * *

(C) Omitting the footnote statement required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement “%DV=%Daily Value.”

* * * * *

3. In § 101.36, revise paragraph (b)(2)(iii)(D) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(b) * * *

(2) * * *

(iii) * * *

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement “Percent Daily Values are based on a 2,000 calorie diet.” If the product is represented or purported to be for use by children 1 through 3 years of age, and if the percent of Daily Value is declared for total fat, total carbohydrate, dietary fiber, protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement “Percent Daily Values are based on a 1,000 calorie diet.”

* * * * *

Dated: July 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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