

MEMORANDUM

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Re: FDA Proposes Revisions to Nutrition and Supplement Facts Labels and Serving Sizes

Today the Food and Drug Administration (FDA) proposed sweeping changes to the Nutrition Facts Panel (NFP) more than 20 years after the original requirements were developed. ^{1/} The “refresh,” issued in two proposed rules, would amend the nutrition labeling requirements for conventional foods and dietary supplements, and update the regulations on serving sizes. The current proposed revisions have been in the works since the agency’s 2005 two Advance Notices of Proposed Rulemaking (ANPRs) on the prominence of calories on the food label and on serving sizes, published in response to FDA’s “Calories Count” report. ^{2/}

The proposed rules warrant close study as to the merits of the specific changes contemplated and to appreciate their effect on how companies utilize the food label to convey meaningful nutrition information to consumers. Many of the proposed changes are framed in technical details but would in practice have important consequences that should be carefully assessed by food marketers. Among the most significant proposed changes are the mandatory declaration of added sugar, the revised definition of dietary fiber, and the serving size and dual-column labeling revisions.

In this memorandum, we provide a top-line summary of the proposed changes. Comments are due 90 days after publication of the proposed rules in the *Federal Register*.

Proposed Revisions to Nutrition Labeling

FDA proposes to amend its nutrition labeling regulations for conventional foods and dietary supplements to provide updated nutrition information and improve how the information is presented to consumers, reflecting current scientific data, dietary recommendations, and consumer research. In particular, the proposed rule would make the following changes.

1. Update the list of nutrients that must or may be declared:
 - Declaration of added sugars would be required;
 - FDA states that added sugars refers to “sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are

^{1/} The proposed rules have not yet been published in the *Federal Register* but pre-publication versions are available at <http://tinyurl.com/ljtqvex>.

^{2/} 70 Fed. Reg. 17008 (Apr. 4, 2005); 70 Fed. Reg. 17010 (Apr. 4, 2005).

- isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners.”
- While acknowledging that added sugars are no more likely to contribute to weight gain than any other source of calories, the agency views declaration of added sugars as necessary to provide consumers with information they need to implement the dietary recommendations to reduce the intake of calories from added sugars and construct diets containing nutrient-dense foods.
 - The agency also recognizes that “there are currently no analytical methods that are able to distinguish between naturally occurring sugars and those sugars added to a food” but states that the amount can be verified through maintenance and review of records. As discussed below, recordkeeping requirements would apply to support the declaration of added sugars. Note also that no DRV would be established for added sugars.
- Declaration of potassium and vitamin D would also be mandatory, as FDA proposes that these are “nutrients of public health significance”;
 - Calories from fat would no longer be declared because research shows that the type of fat is more important than the total amount;
 - Declaration of Vitamins A and C would be voluntary unless claims about these vitamins are made on the label or labeling of foods, or when the vitamins are added as a nutrient supplement;
 - FDA proposes to expand the definition of dietary fiber to include not only naturally occurring fiber but also non-digestible carbohydrates that FDA has determined to have a physiological effect that is beneficial to human health, either through an authorized health claim or an agency response to a petition;
 - FDA states the proposed definition would be consistent with the Institute of Medicine (IOM) and Codex Alimentarius definitions for total fiber.
 - “Other carbohydrate” could no longer be declared voluntarily;
 - Fluoride could be declared voluntarily.

With respect to *trans* fat, FDA requests comment on whether mandatory labeling of *trans* fat would still be necessary if the agency’s tentative determination on the generally recognized as safe (GRAS) status of partially hydrogenated oils (PHOs) is finalized. FDA does not propose any changes to the rounding rules, which permit declaration of *trans* fat as zero when the food contains less than 0.5 gram per serving.

2. Update the Reference Daily Intakes (RDI) and Dietary Reference Values (DRVs) based on current dietary recommendations:

- The daily value (DV) for sodium would decrease from 2,400 to 2,300 mg;
- The DRVs for dietary fiber and calcium would increase from 25 to 28 g and from 1,000 to 1,300 mg, respectively;
- The RDI for Vitamin B12 would decrease from 6 to 2.4 µg/day;
- FDA proposes to establish DRVs of 4,700 mg/day for potassium and 2,300 mg/day for chloride; and RDIs of 120 mcg for vitamin K and 550 mg for choline.

The rationale for revising and establishing each of these levels is highlighted in the preamble.

3. Revise the format of the Nutrition Facts label: ^{3/}

- FDA proposes to increase the prominence of the following information: “Calories,” the numeric value of calories, “Servings per container,” and the numeric value of servings per container;
- The order of the “Serving Size” declaration and “Servings Per Container” would be reversed;
- The quantitative amount declared in the serving size declaration (e.g., “2/3 cup”) would be right justified to create additional white space on the label;
- The “Amount Per Serving” statement would be revised to read, e.g., “Amount per 2/3 cup”; and “Total Carbohydrates” would be revised to read “Total Carbs”;
- The “% DV” declarations would be moved to the left side of the label;
- The footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets would be removed. With respect to the remainder of the footnote, FDA is conducting consumer research to determine a revised statement that would more clearly communicate to consumers the importance of the percent DV;
- Declaration of absolute quantitative amounts (in addition to percent DVs) would be required for mandatory vitamins and minerals, and, when declared, voluntary vitamins and minerals.

FDA is also considering an alternative visual format that would indicate “quick facts” (e.g., amount of total carbohydrate, fat, and protein) about a product’s nutrient content, and would then include separate sections for nutrients to “avoid too much” of as well as nutrients to “get enough” of. FDA seeks comment on this alternative approach of separating nutrients out on the label. An image of the alternate visual format appears at Appendix B to this memorandum.

4. Require recordkeeping to support the declaration of certain nutrients for which there is no reliable analytical procedure:

- FDA proposes that manufacturers must make and keep written records to verify their declarations of the relevant nutrients for products that contain (1) non-digestible carbohydrates that do not meet the proposed definition of dietary fiber, (2) added sugars (where the product also contains naturally occurring sugars), (3) added sugars that undergo fermentation, (4) various forms of Vitamin E, and (5) folate (when a food contains both folate and folic acid).
- Records would be required to be kept for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. FDA also proposes that the records would need to be made available to FDA upon request for review and copying while the product is available for purchase in the marketplace.
- FDA discusses the authority for this proposed provision in the preamble.

FDA proposes to make corresponding changes to the nutrition labeling regulations for dietary supplements. The proposed rule would also amend the 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.

Proposed Revisions to the Serving Size Regulations

FDA is also proposing to amend the serving size regulations to reflect updated consumption data and consumer research. In addition, FDA proposes to make technical amendments to the serving size regulations, not discussed here. The proposed rule would make the following broad changes.

^{3/} See Appendix A to this memorandum for a comparison of the original and proposed NFP formats.

1. Amend the definition of a single-serving container.

FDA proposes that all containers containing less than 200 percent of the RACC be labeled as a single-serving container. FDA would delete the current exemption for products with a RACC of 100 g or 100 mL or larger, under which manufacturers may decide whether a package that contains between 150 and 200 percent of the RACC will be labeled as 1 or 2 servings.

FDA based this decision on NHANES consumption data that shows the current exemption is no longer warranted, as well as on an argument that the revised definition may help consumers to more accurately interpret the nutrient amounts in these products.

2. Require dual-column labeling for certain containers.

Containers that contain between 200 and 400 percent of the RACC would require dual-column labeling for both the serving size and the entire container. This proposed requirement is based in part on results of consumer studies suggesting that dual-column labels resulted in better understanding of the number of calories and nutrients per container and per serving, and a reduction in the amount of food consumed by consumers who are not dieting.

FDA proposes that the label would provide both the quantitative amounts and percent DVs for each column. As an alternative, FDA is considering only requiring the calorie information to be provided on a dual column basis, with the remaining nutrition information provided on a per serving basis only. A second co-proposed option is to provide nutrition information per serving and per container for calories, saturated fat, and sodium, and the remaining information would be listed on a per serving basis in a single column below the dual columns.

To the extent that nutrient content claims or health claims are made for products with a dual-column nutrition label, FDA proposes that the claim would need to clarify that the level of the nutrient that is the subject of the claim is based on the RACC and not the amount in the entire container. Specifically, the claim would need to be followed by a statement that sets forth the basis on which the claim is made (e.g., “good source of calcium” “a serving of __ oz of this product contains 150 mg of calcium”). This requirement does not apply where the product meets the criteria for the claim based on the entire container amount.

Dual-column labeling would not be required for all multi-serving products, such as a family-sized package of lasagna, as products that contain more than 400 percent of the RACC are less likely to be consumed in one eating occasion. Nor would dual-column labeling be required for bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or bulk products traditionally used for multi-purposes (e.g., eggs, butter, margarine), and multipurpose baking mixes, because labeling these products with nutrition information based on the entire container would not be consistent with how these products are typically consumed.

Further, FDA proposes exemptions from the dual-column labeling requirements for products that:

- Qualify for the tabular or linear NFP format; or
- Require further preparation, such as macaroni and cheese kits, pancake mixes, pasta products, and rice products; or
- Are commonly consumed in combination with other foods (e.g., cereal and skim milk).

With respect to the second and third categories, FDA reasons that most of these products voluntarily provide dual column nutrition labeling on an “as purchased” and “as prepared” basis, and that requiring a third or fourth column representing servings per container would not be useful to consumers. The agency requests comments on whether any other products that voluntarily include

an additional column of nutrition information should be exempt from the proposed dual-column labeling requirements.

3. Update, modify, or establish new reference amounts customarily consumed (RACCs).

FDA is proposing to update or modify several RACCs, based on 2003-2008 National Health and Nutrition Examination Surveys (NHANES) consumption data, as well as comments received on the 2005 ANPR, newer food products in the market place, and several written requests and citizen petitions. In general, if the NHANES data demonstrated an increase or decrease in consumption by at least 25 percent compared to the RACCs established in 1993, FDA is proposing to modify an existing RACC. FDA is also proposing to establish new RACC categories or add to existing RACC categories for a number of foods, such as crepes and cocoa powder.

FDA states that the amounts of food customarily consumed by Americans have changed significantly since the original RACCs were established based on data collected through, due in part to increasing package sizes for many foods. FDA clarifies that the reference amounts customarily consumed are not recommended portion sizes based on what people “should” eat, but rather represent what people usually eat. FDA plans to conduct consumer education efforts to improve consumer understanding of the term serving size.

Examples of changes to existing RACCs include:

- Doubling the RACC for “Bagels” from 55 to 110 grams;
- Increasing the RACC for “Beverages: Carbonated and noncarbonated beverages, wine coolers, water”; and “Beverages: Coffee or tea, flavored and sweetened” from 240 mL to 360 mL;
- Decreasing the RACC for “All other candies” from 40 g to 30 g;
- Decreasing the RACC for “Yogurt” from 225 g to 170 g; and
- Revising the RACC for “Ice Cream” from ½ cup to 1 cup.

In some cases the corresponding label declaration of the serving size would also change based on the changes to the RACC. For example, for the beverage categories listed above, the label statements would change from 8 fl oz (240 mL) to 12 fl oz (360 mL).

FDA also recognizes that foods that currently meet the requirements for nutrient content or health claims on the basis of the existing RACC may no longer be eligible for these claims under the proposed revised RACCs. Similarly, disclosure statements for nutrient content claims and disqualifying levels for health claims are based on RACCs, so the revision of RACCs could change whether a product meets a disclosure or disqualifying level.

* * *

Each rule would become effective 60 days after the date of the final rule’s publication in the *Federal Register* with a compliance date 2 years after the effective date. The agency seeks comment on the proposed compliance timeline.

The two proposed rules contemplate significant changes to the Nutrition Facts panel and the regulations governing serving sizes. Food marketers will be well-served to consider the practical implications of the proposed rules and appropriate areas for comment. Should you have any questions, or wish to discuss these issues further, please contact us.

Appendix A, Label Formats

Original vs. Proposed

[What's the Difference Info-graphic](#) (PDF: 509KB)

Nutrition Facts		Nutrition Facts	
Serving Size 2/3 cup (55g) Servings Per Container About 8		8 servings per container Serving size 2/3 cup (55g)	
Amount Per Serving		Amount per 2/3 cup	
Calories 230	Calories from Fat 40	Calories	230
% Daily Value*		% DV*	
Total Fat 8g	12%	12%	Total Fat 8g
Saturated Fat 1g	5%	5%	Saturated Fat 1g
<i>Trans</i> Fat 0g			<i>Trans</i> Fat 0g
Cholesterol 0mg	0%	0%	Cholesterol 0mg
Sodium 160mg	7%	7%	Sodium 160mg
Total Carbohydrate 37g	12%	12%	Total Carbs 37g
Dietary Fiber 4g	16%	14%	Dietary Fiber 4g
Sugars 1g			Sugars 1g
Protein 3g			Added Sugars 0g
Vitamin A	10%		Protein 3g
Vitamin C	8%		
Calcium	20%	10%	Vitamin D 2mcg
Iron	45%	20%	Calcium 260 mg
		45%	Iron 8 mg
		5%	Potassium 235 mg
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.		* Footnote on Daily Values (DV) and calories reference to be inserted here.	
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Appendix B, Alternate Format

Alternate Format

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per 2/3 cup	
Calories	230
% Daily Value*	
QUICK FACTS:	
12%	Total Fat 8g
12%	Total Carbs 37g
	Sugars 1g
	Protein 3g
AVOID TOO MUCH:	
5%	Saturated Fat 1g
	<i>Trans</i> Fat 0g
0%	Cholesterol 0mg
7%	Sodium 160mg
	Added Sugars 0g
GET ENOUGH:	
14%	Fiber 4g
10%	Vitamin D 2mcg
20%	Calcium 260mg
45%	Iron 8mg
5%	Potassium 235mg
* Footnote on Daily Values (DV) and calorie reference to be inserted here.	