

August 25, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-1210—Supplemental Proposed Rule: Revision of the
Nutrition and Supplement Facts Labels

To Whom It May Concern:

On behalf of our 158,000 members, we are pleased to comment on the Food and Drug Administration (FDA) supplemental proposed rule to revise the nutrition information required on Nutrition Facts labels for packaged foods. We offer these comments in response to your Federal Register notice of July 27, 2015 (80 FR 44302).

Eating patterns and food choices play an important role in maintaining good oral health. From a dental perspective, a steady diet of foods containing natural and added sugars, processed starches, and low pH-level acids can damage teeth. Diets resulting in micronutrient deficiency also increase the risk of infections and inflamed tissues in the oral cavity.

The FDA is proposing to revise the Nutrition Facts label for packaged foods by:

- Requiring a declaration of added sugars content (in grams) as a separate indented line item underneath the declaration of “Sugars”.
- Requiring a daily reference value (DRV) declaration for added sugars—50 grams for children 4 years of age and older and for adults, and 25 grams for children ages 1 through 3 years of age.
- Requiring a percent Daily Value (DV) declaration for added sugars—not more than 10 percent of total daily caloric intake.

Our detailed comments, which are enclosed, may be summarized as follows:

- The ADA supports the proposal to require a declaration of added sugars content (in grams) as a separate line item on the Nutrition Facts label. We encourage FDA to consider how added sugars content can be declared in more relatable terms (e.g., teaspoons, etc.).
- The proposal to require DRV and percent DV declarations for added sugars seems like a reasonable public health goal for reducing cardiovascular disease. Continued

August 25, 2015

Page 2

research is needed to understand whether and how the nuanced DRV and percent DV recommendations will impact dental caries rates.

- We recommend consulting the Academy of Nutrition and Dietetics about the scientific support for endorsing DRV and percent DV declarations for added sugars without a corresponding DRV and percent DV declarations for total sugars.

The ADA has long encouraged consumers to monitor—and minimize—their intake of natural and added sugars, processed starches, and low pH-level acids. Your proposal will help consumers monitor their intake levels simply by reading a nutrition label.

If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org. Information is also available at ADA.org/advocacy.

Sincerely,

/s/

Maxine Feinberg, D.D.S.
President

MF:KTO:rjb

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

Technical Comments

Food and Drug Administration Supplemental Proposed Rule: Revision of Nutrition and Supplement Facts Labels

August 25, 2015

On behalf of our 158,000 members, we are pleased to offer our technical comments on the Food and Drug Administration (FDA) supplemental proposed rule to revise the nutrition information required on Nutrition Facts and Supplement Facts labels for conventional foods and dietary supplements. We offer these comments in response to your Federal Register notice of July 27, 2015 (80 FR 44302).

The FDA is proposing to revise the Nutrition Facts label for packaged foods by:

- Requiring a declaration of added sugars content (in grams) as a separate indented line item underneath the declaration of “Sugars”.
- Requiring a daily reference value (DRV) declaration for added sugars—50 grams for children 4 years of age and older and for adults, and 25 grams for children ages 1 through 3 years of age.
- Requiring a percent Daily Value (DV) declaration for added sugars—not more than 10 percent of total daily caloric intake.

A. Line Item Declaration

The ADA supports the proposal to require a declaration of added sugars content (in grams) as a separate line item underneath the declaration of “Sugars” on the Nutrition Facts label.

The ADA has long encouraged consumers to monitor—and minimize—their intake of natural and added sugars, processed starches, and low pH-level acids. Your proposal will help consumers monitor their intake levels simply by reading a nutrition label.

We encourage FDA to consider how added sugars content can be declared in more relatable terms (e.g., teaspoons, etc.) on Nutrition Facts labels.

Original vs. Proposed

Nutrition Facts	
Serving Size 2/3 cup (55g) Servings Per Container About 8	
Amount Per Serving	
Calories 230	Calories from Fat 72
% Daily Value*	
Total Fat 8g	12%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	12%
Dietary Fiber 4g	16%
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.	
	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

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

B. Daily Reference Value and Percent Daily Value Declarations

The FDA is proposing to revise the Nutrition Facts label by requiring a daily reference value (DRV) declaration for added sugars—50 grams for children 4 years of age and older and for adults, and 25 grams for children ages 1 through 3 years of age. The FDA is also proposing to require a percent Daily Value (DV) declaration for added sugars—not more than 10 percent of total daily caloric intake.

According to the Federal Register notice of July 27, the proposal to require DRV and percent DV declarations for added sugars is based on new information contained in the Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC). As described by the FDA, the new information suggests “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 proposal to require DRV and percent DV declarations for added sugars seems like a reasonable public health goal for reducing cardiovascular disease. Continued research is needed to understand whether and how the nuanced DRV and percent DV recommendations will impact dental caries rates.

As background, the DGAC concluded there is strong consistent evidence correlating a dietary pattern of added sugars intake with cardiovascular disease and type 2 diabetes. By contrast, the DGAC found there is moderate consistent evidence indicating dental caries would be lower when free-sugars consumption is less than 10 percent of energy intake, and a low degree of consistent evidence when the energy intake cutoff is 5 percent.¹

The ADA agrees with the DGAC assessment on dental caries, which is largely based on the systematic review commissioned by the World Health Organization (WHO) for its 2015 guideline on sugars intake for adults and children.² The WHO evidence review is perhaps the most thorough and reliable evidence review on the subject to date.

Again, the proposal to require DRV and percent DV declarations for added sugars seems like a reasonable public health goal for reducing cardiovascular disease. Continued research is needed to understand whether and how the nuanced DRV and percent DV recommendations will impact dental caries rates.

C. Additional Comments

The Federal Register notice states the FDA is “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 recommend consulting the Academy of Nutrition and Dietetics about the scientific support for endorsing DRV and percent DV declarations for added sugars without a corresponding DRV and percent DV declaration for total sugars.

August 25, 2015

Page 3

¹ Scientific Report of the 2015 Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, to the Secretary of Agriculture and the Secretary of Health and Human Services. Washington, D.C.: U.S. Department of Agriculture, Agricultural Research Service; 2015.

² Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015.