

An Update from FDA on the Revised Nutrition Facts Panel

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Presenter:

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Director, Office of Nutrition and Food Labeling
FDA

Moderator:

James M. Rippe, MD – Leading cardiologist, Founder and Director,
Rippe Lifestyle Institute

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Today's Faculty

- ▶ Douglas Balentine, PhD

Director, Office of Nutrition and Food Labeling
FDA

- ▶ Moderator:

James M. Rippe, MD – Leading cardiologist,
Founder and Director, Rippe Lifestyle Institute



Learning Objectives

- ▶ Gain awareness of objectives of NLEA and the current nutrition label reform
- ▶ Inform clients about the rationale for and the specific changes that will be appearing on the Nutrition Facts Panel as a result of federal nutrition label reform
- ▶ Help their clients apply the labeling changes to more effectively meet individual dietary goals



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Final Rules to Update the Nutrition Facts Label

**Dr. Douglas Balentine, Director
Office of Nutrition and Food Labeling**

Food and Drug Administration

Nutrition Labeling and Education Act of 1990 (NLEA)

- Gives explicit authority for nutrition labeling
- Requires disclosure of certain nutrients
- Provides some discretion to add or remove nutrients required to be declared on the label
- Requires that information be provided in context of total daily diet

Why Update the Nutrition Facts Label?

- Scientific information on diet and health has improved, including link between diet composition and risk of chronic diseases and public health.
- Amount of foods consumed changed and FDA's reference amounts customarily consumed, used to set serving sizes, needed adjustment.
- Priorities for dietary guidance changed, with focus shifting to calories and serving sizes as two important elements in making healthier food choices.

Regulatory Process

- Two proposed rules issued in March 2014
- Supplemental proposed rule issued in July 2015
- Two final rules published on May 27, 2016
 - Revision of the Nutrition and Supplement Facts Labels
 - Revision of Serving Size Requirements

Populations

- General population 4 years of age and older, including those at risk of chronic disease
 - At risk includes those overweight and obese (>2/3 of adults)
 - Label not meant to treat individuals with chronic disease
- Pregnant and lactating women
 - Different Daily Values
- Young children (1-3 years)
- Infants (through 12 months of age)

Key Information Considered

- Scientific evidence, including consensus reports
- Public comments
- Citizen petitions (e.g., manufacturers, advocacy groups, individuals)
- Data from National Health and Nutrition Examination Survey (NHANES)
- Findings from consumer studies

Key Changes

- Mandated declaration of added sugars with % DV
- Modernized the format to highlight calories and serving size information; updated footnote
- Updated the Daily Values
- Updated nutrients of public health significance
- *Trans* fat and dietary fiber
- Included records requirements

Key Changes (cont.)

- Changed some reference amounts used to calculate serving sizes
- Required dual-column labeling with nutrition information listed per serving and per package or unit for certain products
- Changed the criteria for single serving packages
- Compliance date

NEW LABEL / WHAT'S DIFFERENT

Servings:
larger,
bolder type

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
<i>Trans Fat</i> 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) 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.

Serving sizes
updated

Calories:
larger type

Updated
daily
values

New:
added sugars

Change
in nutrients
required

Actual
amounts
declared

New
footnote

Added Sugars Mandatory

- Based on evidence that:
 - High intake of added sugars decreases intake of nutrient dense foods and increases overall caloric intake
 - Dietary patterns lower in sugar-sweetened foods and beverages are associated with a reduced risk of cardiovascular disease
- Daily Value:
 - Meeting nutrient needs while staying within calorie limits is difficult with more than 10 percent of total daily calories from added sugar

Added Sugars Mandatory

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- Added “includes” to help clarify that “added sugars” is subcomponent of “total sugars”
- Changed “Sugars” to “Total Sugars”
- Removed part of the hairline between “total sugars” and “added sugars”

Added Sugars Definition

Includes sugars that are either added during processing of foods, or are packaged as such, and includes:

- | | |
|------------------------------|-------------------------------|
| -syrups | -honey |
| -brown sugar | -molasses |
| -high fructose
corn syrup | -sucrose |
| -invert sugar | -lactose |
| -maltose | -maltose sugar |
| -trehalose | -concentrated
fruit juice* |

*Sugars from concentrated fruit or vegetable juices in excess of what would be expected from 100 percent fruit or vegetable juice. Excludes fruit or vegetable juice concentrated from 100 percent fruit juice that is sold to consumers (e.g., frozen concentrated orange juice).

Calories and Serving Sizes

Nutrition Facts	
8 servings per container	
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Amount per serving	
Calories	230
	% Daily Value*
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
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Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
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- Focus attention on information that is important for addressing current public health problems like obesity
- Increase type size of “Calories,” “servings per container,” and “Serving size” declaration
- Reverse order of “Serving size” and “servings per container”
- Bold “Calories” and “Serving size” declaration

Updated Footnote

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
<i>Trans</i> Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
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- Updated footnote better explains the % Daily Value and helps put calories in context of the daily diet

Updating Daily Values

Nutrition Facts	
8 servings per container	
Serving size 2/3 cup (55g)	
Amount per serving	
Calories	230
	% Daily Value*
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 180mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
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- Using most recent science
- Continuing to use the population-coverage approach for vitamins and minerals
 - Total Fat: 65 to 78 g
 - Total Carbohydrate: 300 to 275 g
 - Dietary Fiber: 25 to 28 g
 - Sodium: 2,400 to 2,300 mg
 - Potassium: 3,500 to 4,700 mg
 - Calcium: 1,000 to 1,300 mg
 - Vitamin D: 400 IUs (10 µg) to 20 µg

Nutrients of Public Health Significance



Nutrition Facts	
8 servings per container	
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- Vitamin D and potassium now mandatory
- Calcium and Iron will remain
- Vitamins A and C are no longer mandatory but can be declared voluntarily
- Including absolute amounts for nutrients of public health significance in addition to % Daily Value

Trans Fat

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
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- Remaining on label since ruminant sources can contribute to intake
- May also have small amounts of industrial produced *trans* fats if food additive petitions approved

Dietary Fiber

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
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Calcium 260mg	20%
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- Final rule: Updated definition to reflect fiber that has physiological effects that are beneficial to human health
- 11/23/16, published
 - Draft guidance: Describes information we'll rely on
 - Request for scientific information: Provides science review on 26 fibers and various physiological endpoints

Records Requirement

- Requires manufacturers, in certain circumstances, to make and keep records to verify mandatory declaration of added sugars as well as for certain fibers, vitamin E and folic acid and folate for which analytical methods not available
- First time records are needed to verify declaration of mandatory nutrients (added sugars and dietary fiber, if certain fibers are added)

Serving Size Changes

What's considered a single serving has changed in the decades since the original nutrition label was created. So now serving sizes will be more realistic to reflect how much people typically eat at one time.

CURRENT SERVING SIZE



NEW SERVING SIZE



Serving Sizes

- Per Nutrition Labeling and Education Act, serving sizes are calculated based on the reference amounts customarily consumed (RACCs) and are required on the Nutrition Facts label
- Approximately 30 out of 158 RACCs changed, e.g.,
 - Bulk ice cream from 1/2 cup to 2/3 cup
 - Carbonated beverages from 8 ounces to 12 ounces
 - Yogurt from 8 ounce to 6 ounces
- Approximately 25 new RACCs
 - Petitions and new foods

Labeling Single-Serving Packages



Calories and other nutrients must be declared for the entire package rather than per serving because people typically consume the package in one sitting.

Dual Column Labeling

Nutrition Facts				
2 servings per container				
Serving size		1 cup (255g)		
Calories	Per serving		Per container	
	220	440		
	% DV*		% DV*	
Total Fat	5g	6%	10g	13%
Saturated Fat	2g	10%	4g	20%
Trans Fat	0g		0g	
Cholesterol	15mg	5%	30mg	10%
Sodium	240mg	10%	480mg	21%
Total Carb.	35g	13%	70g	25%
Dietary Fiber	6g	21%	12g	43%
Total Sugars	7g		14g	
Incl. Added Sugars	4g	8%	8g	16%
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

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- Required on packages that can be consumed in one or multiple sittings
- Nutrition information presented per serving and per package
- For packages that contain 200% and up to and including 300% of the RACC
 - A 3oz (90g) bag of chips would be labeled per serving [1oz (30 g)] and per package [90 g]

Compliance Date

- Original proposal: 2 years for all manufacturers to comply
- Final Rule: 2 years for all manufacturers except:
 - Businesses with less than <\$10M in revenue have 3 years to come into compliance
- The additional year balances need for consumers to have this information and small businesses' need for additional time to comply

Follow-up Actions

Topic	Action	Date Published, Docket
Fiber	Request for scientific information	11/23/16, FDA-2016-N-3389
Fiber	Draft guidance	11/23/16, FDA-2016-D-3401
Q&A on NFL and SFL <ul style="list-style-type: none"> • Compliance date • Added Sugars • Declaration of quantitative amounts of vitamins and minerals 	Draft guidance	1/5/17, FDA-2016-D-4414
RACC List of Products for Each Product Category	Draft guidance	1/5/17, FDA-2016-D-4098

“Healthy” Claim

- Request for information and comments and guidance on enforcement discretion (9/28/16)
- Public meeting (3/9/17)
- Comments due 4/26/17
- FDA-2016-D-2335

Questions

- See <http://go.usa.gov/xkHru>
- Call 888-723-3366 (Mon-Fri, 10 a.m.-4 p.m., eastern time; closed Thursday 12:30-1:30)
- Submit inquiry form
<http://cfsan.force.com/InquiryPage>



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Questions?



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