Update on Nutrition Initiatives

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Food and Drug Administration
Outline

• Introduction
• Menu Labeling
• Updates to the Nutrition Facts label
  • Changes
  • Updating Serving Sizes and Labeling of Certain Sized Packages
• Voluntary Sodium Reduction Initiative
• Relevant Dates
FDA Nutrition Responsibilities

• FDA regulates safety & labeling of 80% of all food consumed in the United States

• Goal: Optimize health through nutrition
  • Improve the way consumers make dietary choices for themselves and ultimately enhance public and health

• Close collaboration with CDC, NIH, USDA and other federal partners
FDA’s Nutrition Objectives and Major Nutrition Initiatives

• Ensure that consumers are provided with accurate and useful information in food labeling
  • Menu and Vending Machine labeling
  • Updating the Nutrition Facts label
• Encourage food product reformulation to create healthier products
  • Voluntary Sodium Reduction Initiative
  • Removing the Generally Recognized as Safe (GRAS) status of Partially Hydrogenated Oil (PHOs – artificial trans fats)
Food Safety, Nutrition, and Health
Menu Labeling
Section 4205 of the Patient Protection and Affordable Care Act (ACA)

- Enacted March 23, 2010
- Amends certain nutrition labeling provisions of Federal Food, Drug, and Cosmetic Act
  - Covers menu and vending machine labeling
- Issued proposed rules on April 6, 2011
  - Received ~900 comments for menu labeling
  - Received ~250 comments for vending machine labeling
- Issued final rules on December 1, 2014
- Issued final guidance from menu labeling on May 5, 2016
Who is covered by Section 4205?

- Applies to restaurants and similar retail food establishments that are part of a chain with 20 or more locations
- Doing business under the same name and
- Offering for sale substantially the same menu items
- Or that voluntarily register with FDA to be covered
- Applies to a person who is engaged in the business of owning or operating 20 or more vending machines or who voluntarily registers with FDA
What Does Section 4205 Require for Restaurants and Similar Retail Food Environments?

• Disclose calorie information on menus and menu boards for standard menu items
• Post a succinct statement concerning suggested daily caloric intake on menus and menu boards
• Disclose calorie information on signs adjacent to foods on display and self-service foods that are standard menu items
• Provide written nutrition information upon consumer request
• Post on menus and menu boards statement that written nutrition information is available upon request
Examples of Facilities that may be Covered

- Restaurants, quick service, and sit-down
- Grocery and convenience stores
- Food take-out facilities and pizza delivery services
- Entertainment venues (e.g., movie theaters, amusement parks)
- Cafeterias
- Coffee shops
- Superstores
Menus and Menu Boards and Displaying Calories

• Menus and menu boards are defined as the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection (includes online menus if consumer can order online/phone)

• Calories for each standard menu item listed on menu/menu board must be displayed adjacent to the name or price of the menu item in a type size no smaller than that of the name or price of the menu item whichever is smaller, with certain color and contrast requirements

• For menu items that come in different flavors or varieties that are listed as a single item, calorie declarations where there are only two options available must be presented with a slash between the two calorie declarations (e.g., "150/250 calories") or as a range (e.g., “150-300 calories”) if there are three or more options
Self-Serve Foods and Foods on Display

• Self-service food means restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by customers themselves.

• Foods on display means restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption (e.g., ice cream, bagels, donuts on display behind a glass counter).

• Must have a sign(s) near the food with the number of calories per serving or per item:
  • “300 calories per muffin”
  • “200 calories per scoop of potato salad”

• Type size no smaller than the name or price of the item.
Succinct Statement

• To enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards

“2,000 calories a day is used for general nutrition advice, but calorie needs vary”

• Optional statements for use on children’s menus and menu boards

• Type size no smaller than the smallest calorie declaration appearing on the same menu or menu board, with certain color and contrast requirements
Nutrition Facts Label
Regulatory Process for Updating the Nutrition Facts Label

- 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 Label
  - Revision of Serving Size Requirements
New Label

NEW LABEL / WHAT’S DIFFERENT

- Serving sizes updated
- Calories: larger type
- Updated daily values
- Actual amounts declared
- New footnote

Servings: larger, bolder type
New: added sugars
Change in nutrients required

Nutrition Facts
8 servings per container
Serving size 2/3 cup (55g)

Amount per serving
Calories 230

- Total Fat 8g
- Saturated Fat 1g
- Trans Fat 0g
- Cholesterol 0mg
- Sodium 160mg
- Total Carbohydrate 37g
- Dietary Fiber 4g
- Total Sugars 12g
- Includes 10g Added Sugars
- Protein 3g

Vitamin D 2mcg
Calcium 260mg
Iron 8mg
Potassium 220mg

*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.

FDA
Added Sugars Mandatory

- FDA adding “includes” to help clarify that “added sugars” is a subcomponent of “total sugars”
- Changed “Sugars” to “Total Sugars”
- Also removed part of the hairline between “total sugars” and “added sugars”
Calories and Serving

- Focus attention on information that is important for addressing current public health problems like obesity

- Increase the type size of “Calories,” “servings per container,” and the “Serving size” declaration

- Reverse the order of “Serving size” and “servings per container”

- Bold the “Calories” and the “Serving size” declaration
Updated Footnote

• Updated footnote better explains the % Daily Value and helps put calories in context of the daily diet
Updated Daily Values

- Using most recent science
- Continue to use the population-coverage approach for Vitamins and Minerals
- Total Fat: 65 >> 78 g
- Total Carbohydrate: 300 >> 275 g
- Dietary Fiber: 25 >> 28 g
- Sodium: 2,400 >> 2,300 mg
- Potassium: 3,500 >> 4,700 mg
- Calcium: 1,000 >> 1,300 mg
- Vitamin D: 400 IU (10 μg) >> 20 μg
Nutrients of Public Health Significance

- Vitamin D and Potassium are now mandatory on the label

- Calcium and Iron will remain on the label

- Vitamins A and C are no longer mandatory on the label but can be declared voluntarily

- Including absolute amounts for nutrients of public health significance in addition to % Daily Value
Dietary Fiber

• Updating the definition to reflect fiber that has physiological effects that are beneficial to human health

• Intend to publish a separate notice to provide a review of the research for about 25 fibers
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**

- 4 SERVINGS
- 200 CALORIES
- 1 PINT

**NEW SERVING SIZE**

- 3 SERVINGS
- 270 CALORIES
- 1 PINT
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

• 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]
Voluntary Sodium Reduction Targets
Overview of FDA Announcement

• Draft, voluntary guidance on sodium reduction targets
  • Gradual approach:
    • Short-term targets (2 years, goal=3,000 mg/day)
    • Long-term targets (10 years, goal=2,300 mg/day)
  • Targets for 150 categories of food that are sales weighted to focus on dominant sellers in each category
  • Applies to food manufacturers, restaurants, and food service operations
• Draft targets serve as a basis for continued dialogue
  • Additional data and information will help refine
Why are Targets Needed?

- Most sodium comes from salt added to processed and restaurant foods
- It is difficult to meet recommended sodium intake with current food supply
- Overall sodium content of food supply remains high, despite industry efforts
- Variability in sodium across similar foods in food supply shows that reductions are possible

Mattes and Donnelly, 1991
3-Step Process to Set Targets

1. Developed ~150 food categories

2. Determined baseline sodium concentrations (mg/100g)

3. Set quantitative goals
   - Target mean levels: apply to average sodium levels of foods in a *category*, not individual products
   - Recommended upper bounds: apply to all *individual products* and discourage products with excessive sodium
Salt/Sodium

- Food Safety
- Texture Development
- Fermentation
- Sodium/Salt
- Color Development
- Flavor
Sample Category: Precooking Sausage

- Top selling products on market
- Shows how sodium concentrations compare (mg/100g)
- Baseline, FDA short- and long-term targets overlaid
- Many products already meeting short- and long-term targets

Number of Products

Sodium Concentration (mg Na/100g)

n = 254 products; 65 brands
How excess salt is killing us, and the FDA guidance that can change it
June 01, 2016
By Former Sens. Bill Frist (R-Tenn.) and Tom Harkin (D-Iowa)

“Imagine saving 100,000 lives a year—preventing a plane crash each day—just by removing a half teaspoon of salt a day from the foods we eat. That is the magnitude of the opportunity before us. Today the Food and Drug Administration (FDA) issued a draft guidance to the processed food, restaurant and food service industries, calling for reduced sodium in our food usually consumed as salt.”

Additional Information

• For more information: [www.fda.gov/SodiumReduction](http://www.fda.gov/SodiumReduction)
  • At-a-Glance fact sheet
  • Web Q&A
  • FDA Voice blog
  • Draft Guidance (includes FDA technical memos)
  • Notice of Availability (includes issues for comment)
  • Sodium reduction targets (available in excel or word format)
  • Histograms for each category
Relevant Dates

• Sodium
  • Comment period deadline for long-term targets: Dec 2, 2016

• Menu labeling
  • Dec 1, 2016 (vending machines)
  • May 5, 2017 (restaurants and similar retail food establishments)

• Nutrition Facts label
  • July 26, 2018 for all manufacturers (July 26 2019 for businesses with less than <$10M in revenue)
Related Education Materials

Link to Changes to the Nutrition Facts label: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

Link to FDA Nutrition Programs and Materials: https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm20026097.htm

Link to Food Safety and Nutrition Resources for Healthcare Professionals, including CME Video on the Nutrition Facts label created in partnership with the American Medical Association: https://www.fda.gov/Food/ResourcesForYou/HealthCareProfessionals/default.htm
Questions?