



FDA New Menu and Menu Board Food Labeling Regulations

Lynn M. Szybist
Team Leader

Labeling Regulations Implementation Team
Division of Food Labeling and Standards
Office of Nutrition and Food Labeling, CFSAN
U.S. Food and Drug Administration



Agenda

- Section 4205 of the Patient Protection and Affordable Care Act of 2010
- Requirements of the Final Rule on Menu Labeling
- Next Steps
- Q&As



Section 4205 of the Patient Protection and Affordable Care Act

- Enacted March 23, 2010
- Amends certain nutrition labeling provisions of the 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
- Issued final rules on December 1, 2014
 - Menu labeling effective date – December 1, 2015
- Issued extension of the Compliance Date on July 10, 2015
 - Menu labeling effective date – December 1, 2016
- 2016 Omnibus Bill established Compliance Date as one year after Final Guidance publishes.



Who is covered by Section 4205?

- Applies to restaurants and similar retail food establishments (SRFEs)
 - 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
- Applies to restaurants and SRFEs that voluntarily register with FDA to be covered



What does section 4205 require for Restaurants and SRFEs?

- 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 a statement that written nutrition information is available upon request



Menu Labeling Final Rule



Key Components of the Menu Labeling Final Rule

- **Definitions**
 - Covered establishments
 - Restaurant-type food
- **Alcohol**
- **Multi-serving Foods**
- Menus/menu boards and displaying calories
- Self-service food and food on display
- Succinct statement concerning the suggested daily caloric intake
- Written nutrition information
- **Determination of nutrition content of food**
- **Compliance Date**



Definitions



Covered Establishments

- Establishments are covered that are:
 - **Restaurants or similar retail food establishments**
 - Retail establishment that offers for sale “restaurant type food”
 - **Part of a chain with 20 or more locations**
 - Fixed locations (**mobile vendors are not covered**)
 - **Doing business under the same name**
 - Name presented to the public or **the name of the parent entity if no name is presented to the public, (e.g., concession stand)**; this includes slight variations of the name, for example, due to location, region, or size.
 - **Offering for sale substantially the same menu items**
 - A significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components even if the name of item varies (e.g. “Bay View Crab Cake” and “Ocean View Crab Cake”)



Restaurant-Type Foods

Restaurant-type foods are foods usually eaten on the premises, while walking away, or soon after arriving at another location; **and**

- Served in restaurants or other establishments in which food is served for immediate consumption or which is sold for sale or use in such establishment; **or**
- Processed and prepared primarily in a retail establishment and offered for sale to be consumed elsewhere and which is not offered for sale outside such establishment.



Restaurant-Type Foods

Examples include:

- Meals served at sit-down restaurants or sold at quick service restaurants (including foods purchased at a drive-through)
- Take out and delivery foods
- Foods sold at concession stands (includes entertainment venues, e.g., amusement parks, stadiums, and movie theaters)
- Foods ordered from menu/menu board at grocery store and intended for immediate consumption
- Foods that are self-serve and intended for immediate consumption
- Foods sold at dining facilities at colleges and universities that are part of a chain.



Examples of Facilities That Are 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, stadium concession stands)**
- Cafeterias
- Coffee shops
- Some managed food service operations, e.g., Sodexo



Foods That Are Covered

- **Standard menu items**
 - Restaurant type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display
- **Combination meals**
 - Standard menu item that consists of more than one food item; may be represented on the menu or menu board in narrative form, numerically, or pictorially
 - May include a variable menu item or be a variable menu item
- **Variable menu items**
 - Standard menu item that comes in different flavors, varieties, or combinations and is listed as a single menu item



Foods That Are Covered

- **Food on display**
 - 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
- **Self-service food**
 - 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; includes self-serve beverages



Alcohol Covered in Final Rule

- Not covered in the proposed rule
- Majority of comments supported covering alcohol
 - Public health rationale
 - FDA has jurisdiction to cover
- Now, covered establishments must disclose calories and other nutrition information for alcoholic beverages that are on menus and menu boards
- Exemption for alcohol that is on display behind the bar (and not on the menu, menu board, or not self service) at covered establishments.
- Establishments that sell only alcohol are covered if they meet the requirements of being a covered establishment.



Foods That Are Exempt

The following foods are exempt from the rule:

- **Custom Order**
 - A food order that is prepared in a specific manner based on an individual customer’s request, which requires a deviation from the usual preparation of a standard menu item
- **Daily Special**
 - Menu item that is prepared and offered for sale on a particular day, is not routinely listed on a menu or menu board, or offered for sale by the establishment and is promoted as a special menu item for that day
- **Food that are part of a customary market test**
 - Food that appears on the menu or menu board for less than 90 consecutive days



Foods That Are Exempt

The following foods are exempt from the rule:

- **Temporary menu item**
 - Foods that appear on a on menu or menu board for less than a total of 60 calendar days per year
- **General use condiments**
 - Condiments that are available for general use, e.g., flasks of pancake syrup on the table.
- **Foods that are not on a menu/menu board and are not on display or self-serve.**
 - These foods are not considered “standard menu items.”



Menus and Menu Boards

- Menus and menu boards are defined as the **primary writing** of the covered establishment from which a customer makes an order selection (includes online menus if consumer can order online/phone)
- Includes specialty menus, e.g., drink menu, dessert menu (even when there is a separate general menu)
- Includes drive-through menu boards and electronic menus and menu boards
- Includes the name and price of the menu item and can be used to place an order by the customer
- Generally will not include coupons unless name, price and method to place order are included on the coupon.



Requirements of Menu Labeling Final Rule



Displaying Calories on Menus and Menu Boards

- Calories for each standard menu item listed on a 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



Displaying Calories on Menus and Menu Boards

- The rule **does not require** a covered establishment to **create a new menu or menu board**.
- *If* a column format is used the term “Calories” or “Cal” must appear at the top of the column in a type size no smaller than the name or price of the menu item, whichever is smaller.
- Standard menu items can also be listed following a general description or grouped if the calorie declaration is the same for all of the standard menu items in the group.



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

Displaying Calories on Menus and Menu Boards

Sandwich	Cal.	Price
1. Chicken sandwich (grilled/fried)	350/550	\$7.99
2. Chicken sandwich (grilled/baked fried)	350-550	\$7.99
3. Soft Drinks	0-130	\$2.79
4. Beverages		\$2.79
– Diet Cola, Diet Lemon-Lime	0	
– Cola	120	
– Fruit Punch	130	
– Lemon-Lime	110	



Displaying Calories on Menus and Menu Boards

Examples:

Variable menu item:

Chicken sandwich (grilled or fried) 350/550 Calories.....\$7.99

Chicken sandwich (grilled/baked/fried) 350-550 Cal.....\$7.99

Combination meal:

Cheeseburger with choice of side salad, or chips.....\$4.79

450/550 Calories

Cheeseburger with choice of side salad, fruit, or chips.....\$4.79

450 – 550 Calories



Displaying Calories on Menus and Menu Boards

The following formats are also acceptable:

BURGER & SANDWICHES

With your choice of French fries (Cal: 520), fresh fruit salad served with mango sorbet (Cal: 130), vine-ripened tomato salad (Cal. 260), a cup of soup (Cal: 150-230) or yellow rice with black beans (Cal: 280).

Grilled Burger Cal: 650 \$xx.xx.

Served with Bibb lettuce, vine-ripened tomatoes, shaved red onions, crisp pickle slices, on a toasted brioche bun.

Applewood Bacon & Cheddar Burger Cal: 1070 \$xx.xx.

Applewood smoked bacon, melted cheddar cheese, crisp pickle slices, vine-ripened tomatoes, shaved red onions, Bibb lettuce, toasted brioche bun.



Displaying Calories on Menus and Menu Boards

Burgers and Sandwiches

With your choice of French fries (Cal. 520); Fresh fruit salad served with mango sorbet (Cal. 130); a cup of soup (Cal. 150-230); or yellow rice with black beans (Cal. 280)

- 1. Cheeseburger (Cal. 420)\$5.50
- 2. Bacon Cheeseburger (Cal. 550).....\$6.49
- 3. Club Sandwich (Cal. 530).....\$7.00

Entrees

Grilled Burger - Bibb lettuce, vine-ripened tomatoes, shaved red onions, crisp pickle slices, on a toasted brioche bun. \$xx.xx. Cal: 650



Displaying Calories on Menus and Menu Boards

MOCK SANGRIA – A blend of sparkling apple cider, fresh fruit and fruit juices. \$5.99

Calories: Berry 190, White Peach 230, Black Raspberry 80

Wines by the Glass

Red Wine120

Cal.....\$8.95

Pinot Noir (Description)

Merlot (Description)

Cabernet Sauvignon (Description)

In this example, all of the wines have the same calorie declaration.



Displaying Calories on Menus and Menu Boards

- Example where individual varieties of beer **are not** listed on the menu/menu board

Beer (70-120 calories).....\$x.xx

- Example where individual varieties of beer **are** listed on the menu/menu board

Mary's beer (70 calories).....\$x.xx

Pete's beer (90 calories)\$x.xx

Frank's beer (120 calories)\$x.xx



Displaying Calories for Toppings and Multi-serving Foods

- Calorie disclosures for toppings will depend on how the toppings are listed on the menu. “Toppings” without listing individual toppings can be declared using a range. Individually listed toppings must have specific calorie disclosure, but can be grouped if declaration would be the same.
- Calories for multi-serving foods can either:
 - Be listed for the entire standard menu item or
 - Be listed per individual unit (e.g. slice of pizza) provided the total number of units is included and the menu item is normally prepared and served in discrete units (e.g. whole pizza cut into slices)



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

Displaying Calories for Toppings

PLAIN PIZZA PIE: SMALL (12") 500 CAL

* MEDIUM (14") 750 CAL * LARGE

(16") 1000 CAL

<u>Toppings</u>	<u>Added cal</u>		
	Small	Med	Large
Pepperoni ...	200	300	400
Sausage	250	350	450
Green Peppers, Red Peppers, or Onions...	15	20	25

ICE CREAM SCOOP: 300 CAL

<u>Toppings</u>	<u>Added cal</u>
Almonds	25
Fudge	50



Displaying Calories on Menus and Menu Boards

Party Platters

- **Platter of Deviled Eggs: 840 Calories**
- **Platter of Deviled Eggs: 70 cal/deviled egg, 12 deviled eggs**
- **Mixed Cookie Platter: 3600 calories**
- **Mixed Cookie Platter: 60cal/cookie, 60 cookies**
- **25 Piece Sandwich Platter (select up to 3 sandwich selections)**

Sandwich

Wheat Bread/Italian Bread

Turkey	110Cal/120Cal
Roast Beef	120Cal/130Cal
Veggie	80Cal/90Cal
Ham & Cheese	150Cal/160Cal



Displaying Calories on Kiosks

- If a covered establishment has a kiosk that consumers can use to order made-to-order subs, we would consider the kiosk to constitute a menu.
- Calorie information should be provided for each item that makes up the sub as that item is displayed for selection on the kiosk
 - E.g., “6-inch wheat bread – 210 Cal”
- Total calorie content may also be provided to the consumer once their order is complete



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, including self-serve beverages 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”
 - “140 calories per 12 fluid ounces (small)”



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”

- Must appear on the bottom of each page of a multi-page menu and the bottom of a menu board, above, below or beside the Statement of Availability.
- Optional statements are permitted on children’s menus and menu boards



Written Nutrition Information

- The statement “Additional nutrition information available upon request” is required on menus and menu boards
- For menus it is required on the first page of the menu with menu items listed either above, below or beside the Succinct Statement
- For menu boards it must appear on the bottom of the menu board either above, below, or beside the Succinct Statement
- Written nutrition information must include the macronutrients that are currently required in the Nutrition Facts label on packaged foods



Written Nutrition Information

Written Nutrition Information can be in the form of:

- Posters
- Tray liners
- Counter cards
- Signs
- Handouts
- Booklets
- Computer/kiosk



Written Nutrition Information

- For a variable menu item or combination meal, the nutrition information must be listed separately for each component in the variable menu item.
- Where the number of variations is large, e.g., pizza, the nutrition information must be declared for the basic preparation and separately for each topping or other variable component.



Written Nutrition Information

When the nutrition information for different flavors, varieties, or components of combinations are the same, the nutrition information for these food items would only need to be listed once, with the food items grouped together.

Raspberry or Peach Flavored Iced tea (14 ounces)

- Total calories 5 calories
- Total fat 0 g
- Sodium 15 mg
- Total Carbohydrate 1 g
- Sugars 0 g
- Protein 0 g
- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol and dietary fiber



Determination of the Nutrition Content of Food

- Covered establishment must have reasonable basis for its nutrient content declarations
 - Not using “80/120 rule standard” from 21 CFR 101.9(g) used for packaged food
- Nutrient values can be determined by:

<ul style="list-style-type: none"> – Nutrient databases – Laboratory analysis – Nutrition Facts label 	<ul style="list-style-type: none"> -Cookbooks -other reasonable means, (e.g. a combination of various bases)
--	--



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

Determination of the Nutrition Content of Food

- Upon request from FDA covered establishments must provide information substantiating their nutrient values.
- A signed/dated statement is needed to certify that the information contained in the nutrient analysis is accurate and complete
- A signed/dated stated is also needed to certify that the covered establishment has taken reasonable steps to ensure the method of preparation and amount of the standard menu items adhere to the factors on which its nutrient values were determined.



Other Issues



Extension of Compliance Date for Menu Labeling

- Industry, trade, and other associations, including the grocery industry, asked for an additional year to comply with the menu labeling final rule
- FDA agreed to additional time to allow the agency to provide further clarifying guidance to help facilitate efficient compliance across all covered establishments to come into compliance with the rule
- On July 9, 2015, FDA extended the compliance date for menu labeling to December 1, 2016
- December 2015, the 2016 Omnibus Bill extended the compliance date to one year following the publication of final guidance



Enforcement Considerations

- FDA investigators
- Partnerships with States and Locals
- States and Locals may adopt identical requirements and choose to enforce them
- Training and education
- Consumer complaints



Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)

- On FDA.gov at:
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm461934.htm>
- Issued September 11, 2015
- 45 day comment period closed on November 2, 2015



Next Steps

- Issuance of final guidance for the industry
- Completion of enforcement strategy
- Continued stakeholder outreach



Contact Information

Mailbox to submit questions on menu labeling

CalorieLabeling@fda.hhs.gov



Questions?

