

# FDA Menu Labeling: Final Rule

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# Background

- California SB 1420 - July 1, 2009
- Affordable Care Act (ACA) enacted – March 23, 2010
  - Section 4205, Amends FD&C Act 403(q)5(H)
- FDA issued proposed rule in 2011 (received ~ 900 comments)
- California SB 20 – 2011
- Issues final rule on December 1, 2014
  - Menu labeling compliance date – December 1, 2015
- Issued 2<sup>nd</sup> final rule on July 10, 2015
  - Menu labeling compliance date – December 1, 2016
- FDA Compliance Date: May 5, 2017
- **California - December 1, 2016 with 1<sup>st</sup> 6 months training**

# Covered Establishments

**Restaurants or similar retail food establishments (SRFE)** that offer for sale “**restaurant type food**”

1. Part of a chain with 20 or more locations (regardless of the type of ownership)
2. Doing business under the same name
3. Offering for sale substantially the same menu items

**Exempt:** Schools, food trucks, sidewalk carts, trains, airplanes, and in-patient only food service facilities located in hospitals

**Includes:** Restaurants, grocery and convenience stores, cafeterias, superstores, and entertainment venues (e.g. movie theaters, amusement parks)

# Definitions

- ***Restaurant-type foods*** are foods usually eaten on the premises, while walking away, or soon after arriving at another location and either served in the establishment or processed and prepared primarily in the establishment, and not offered for sale outside of that establishment.
- ***Food on display:*** Restaurant or 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 or restaurant-type food that is offered for sale at a salad bar, buffet line, cafeteria line, or similar self-service facility, and self-service beverages.

# 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 narratively, numerically, or pictorially
- **Variable menu items:** Standard menu item that **comes in different flavors, varieties, or combinations**, and is listed as a single menu item
  - Example: List of toppings for pizza or ice cream

# Examples of Restaurant-Type Foods

- Meals served at sit-down or quick service restaurant
- Food purchased at a drive-through
- Take-out and delivery foods (e.g., hot pizza at grocery and convenience stores that is ready to eat; pizza slice from a movie theater)
- Hot buffet food, hot soup at a soup bar, and food from a salad bar
- Foods ordered from a menu/menu board at a grocery store intended for individual consumption (e.g., soups, sandwiches, and salads)
- Self-service foods and foods on display that are intended for individual consumption (e.g., sandwiches, wraps, and paninis at a deli counter; salads plated by the consumer at a salad bar; cookies from a mall cookie counter; bagels, donuts, rolls offered for individual sale)



# Examples of Foods Not Considered Restaurant-Type Foods

- Bulk foods (e.g., dried fruit, nuts)
- Foods eaten over several eating occasions or stored for later use (e.g., loaves of bread, bags or boxes of dinner rolls, whole cakes, and bags or boxes of candy or cookies)
- Foods that are usually further prepared before consuming (e.g., deli meats and cheeses)
- Foods that are not self-service and not intended solely for an individual consumption (e.g., deli salads, items sold by weight)



# Foods that are Exempt

- **Custom orders**, which are prepared in a specific manner at the customer's request
- **Daily specials**, foods that are not routinely listed on the menu and are promoted as a special menu item for that day
- **Temporary menu items**, which appear on a menu or menu board for less than a total of 60 days per calendar year
- **Customary market test items**, that are offered for fewer than 90 consecutive days to test consumer acceptance
- **Condiments** available for general use, including those placed on the table or on or behind the counter
- Foods that are not on a menu or menu board and are not on display or self-service (these foods are not considered "standard menu items")





# Menus and Menu Boards

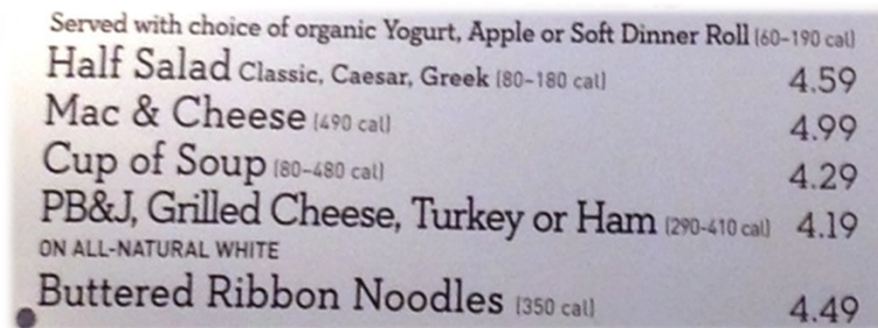
- Defined as the **primary writing** of the restaurant or similar retail food establishment from which a customer makes an order selection
- Includes the name and price of the menu item and can be used to place an order by customer
- Includes specialty menus, e.g., drink menu, dessert menu (even when there is a separate general menu)
- Includes drive-through menu boards and electronic menus and menu boards
- Includes online menus if consumer can order online/phone



# Displaying Calories on Menus and Menu Boards

Calories for each standard menu item listed on a menu or menu board must be displayed adjacent to the name or price of the menu item

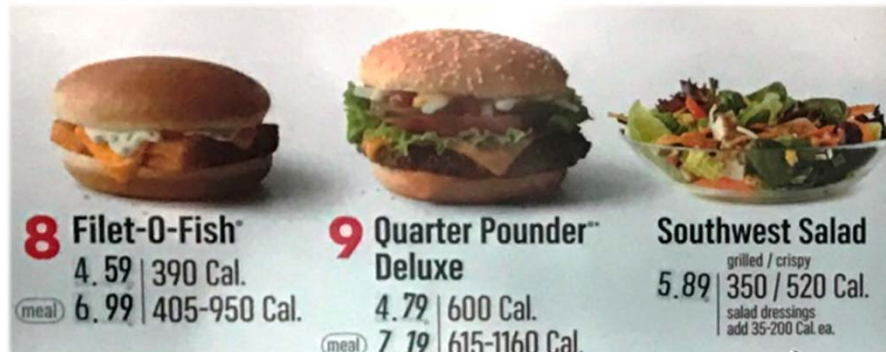
- In a type size **no smaller** than that of the name or price of the menu item, whichever is smaller
- In the same color or in a color **“at least as conspicuous”** as that used for the calorie declarations
- Rounded in accordance with the requirements
- If a column format is used, the term **“Calories”** or **“Cal”** must appear at the top of the column



# Displaying Calories on Menus and Menu Boards

For menu items that come in different flavors or varieties that are listed as a single item, calorie declarations must be presented:

- With a slash when there are only two options (e.g., “120/240 calories”)
- As a range if there are three or more options (e.g., “120-400 calories”)
- These top bullets do not apply, when a customer combines standard menu items for a specific price (e.g., “**Combine Any Sandwich with Any Soup or Any Salad for \$8.99**”) and the calories for each standard menu item are already listed on the menu or menu board.



# Displaying Calories on Menus and Menu Boards

- The number of calories contained in each standard menu item listed, as usually prepared and offered for sale

TAKE HOME ICE CREAM		
FRESH-PACKED		
PINT	90-210 CAL 1/2 CUP SERVING, 4 SERVINGS	5.29
QUART	90-210 CAL 1/2 CUP SERVING, 8 SERVINGS	7.49
PRE-PACKED QUART		5.59
	100-210 CAL 1/2 CUP SERVING, 8 SERVINGS	
2 PRE-PACKED QUARTS		9.99
	100-210 CAL 1/2 CUP SERVING, 8 SERVINGS PER QUART	

- In the case of multiple-serving, the calories declared must be:
  - **For the whole menu item listed**, as usually prepared and offered for sale (e.g. “pizza pie: 1600 cal”)
  - Or
  - **Per discrete serving unit** as long as the discrete serving unit (e.g., pizza slice) and total number of discrete serving units contained in the menu item are declared (e.g., pizza pie: 200 cal/slice, 8 slices)

# Displaying Calories for Beverages that Are Not Self-service

Must state number of calories in full volume of the cup as served without ice UNLESS facility ordinary dispense and offer for sale a standard beverage fill that is less than the volume of the cup or dispense a standard ice fill



# Display Calories for Toppings

- **Calories 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

Toppings (25-60 Cal).....\$0.50

- Individual listed toppings must have specific calorie disclosure, but can be grouped if declaration would be the same

Cheese Pizza: small (12") 400 Cal, Medium (14") 650 Cal, Large (16") 900 Cal

Toppings	Added Cal (S/M/L)
Pepperoni.....	200-400
Sausage.....	250-450
Green Peppers....	15-25
Onions.....	20-30

Ice Cream Scoop: 210 -580 Cal

Toppings	Added Cal
Almonds.....	25
Fudge.....	50
Caramel.....	60
Strawberry Syrup.....	45



# Self-Serve Foods and Food on Display

- **Must have a sign(s) near the food with the number of calories per serving or per item**
  - “550 calories per pastry”
  - “180 calories per scoop of pasta salad”
  - “120 calories per 12 fluid ounces (small)”
- **The final rule provides 3 options for calorie declarations:**
  - On a sign adjacent to and clearly associated with the corresponding food
    - *Including calories directly on the package of “grab and go” items*
  - On a sign attached to the sneeze guard
  - On a single sign or placard listing the calorie declaration for several food items (as long as it’s located where the consumer can view the information while making their selection)

# Calorie Declarations for Foods on Display

**If foods on display are also listed on the menu or menu board they must**

- Meet the requirements for declaration of calories on menus and menu boards AND
- Meet the requirements for foods on display

Section 403(q)(5)(H)(i) of the Act requires that when a self-service food or food on display is listed on a menu or menu board, the food is subject to both 101.11(b)(2)(i) for posting of calories on menu and menu board and to 101.11(b)(2)(iii) for self-service foods or foods on display.

- Ask yourself, “can the customer view posted calories while making their selection?”



# Calorie declaration for All-You-Can-Eat Buffet

- The menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service buffet for calorie information. (*e.g.*, “See buffet for calorie declarations”)
- Establishment must place a sign adjacent to the food with number of calories per item or serving.



On a sign attached to the sneeze guard

Spinach walnut salad  
4 oz. = 80 cal  
Spanish spaghetti salad  
1 cup = 120 cal  
Tomato spaghetti salad  
110 cal per 1 cup

# Calorie Declarations for Deli Salads



- Exempt deli salads were added to a menu board and now are considered “restaurant type foods”
- Display calories on a menu board and on display

# Succinct Statement

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

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

- Optional statements are permitted on children’s menus and menu boards

“1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years, but calorie needs vary.”

“1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years and 1,400 to 2,000 calories a day for children ages 9 to 13 years, but calorie needs vary.”

- Statement must appear **on the bottom of each page** of a multi-page menu and **on the bottom of the menu board**, above, below or besides the statement of availability.
- Statement must be in type size no smaller than smallest type size for any calorie declaration appearing on same menu/menu board

# Written Nutrition Information

## “Additional nutrition information available upon request”

- For menus, statement must be posted on the bottom of the *first page* along with succinct statement
- For menu boards, statement must be posted *besides* succinct statement
- Written nutritional information must include the nutrients that are currently required in the Nutritional Facts label on packaged foods.
- Written nutritional information may be provided on a counter card, sign, poster, handout, binder, booklet or electronic device (computer), or ...

2,000 calories a day is used for general nutrition advice, but calorie needs vary. Additional nutritional information available upon request.

# Written Nutrition Information

- **Must be available** in written form **and provided or readily available** to the customer upon request.
- This nutrition information must be presented in the order listed and using the measurements listed.

<b>(1) Total calories (cal)</b>	<b>(7) Sodium (mg)</b>
<b>(2) Calories from fat (fat cal)</b>	<b>(8) Total carbohydrate (g)</b>
<b>(3) Total fat (g)</b>	<b>(9) Dietary fiber (g)</b>
<b>(4) Saturated fat (g)</b>	<b>(10) Sugars (g)</b>
<b>(5) <i>Trans</i> fat (g)</b>	<b>(11) Protein (g)</b>
<b>(6) Cholesterol (mg)</b>	

- The information must be presented in a **clear and conspicuous** manner likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

# Written Nutrition Information

- **A simplified format** may be presented for standard menu items that contain insignificant amounts of 6 or more of the required nutrients.
- Variable menu items must be declared separately for each topping, flavor, or variable component
- All items that have the **same calorie and nutrient values** could be listed together **only once**.

Raspberry or Peach Flavored Ice tea (14 ounces)	
Total Calories	5 calories
Total Fat	0 g
Sodium	15 mg
Total Carbohydrate	15 mg
Protein	0 g
Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, dietary fiber, and sugars.	

Toppings		Nutritional Facts										
		Calories	Calories from Fat	Total Fat (g)	Saturated Fat (g)	Trans Fat (g)	Cholesterol (mg)	Sodium (mg)	Total Carbohydrate (g)	Dietary Fiber (g)	Sugars (g)	Protein (g)
Almonds	160	130	14	1	0	0	0	6	3	1	6	
Andes Mints®	150	90	10	9	0	0	15	17	1	15	2	
Apples	15	0	0	0	0	0	0	4	1	3	0	
Banana	25	0	0	0	0	0	0	6	1	3	0	
Blackberries	10	0	0	0	0	0	0	3	1	1	0	
Blueberries	15	0	0	0	0	0	0	4	1	3	0	
Brownie Bites	130	50	6	2.5	0	20	160	17	1	10	2	
Butterfinger®	130	45	5	2.5	0	0	65	20	1	15	2	
Cantaloupe	10	0	0	0	0	0	0	2	0	2	0	
Cap'n Crunch®	110	15	1.5	1	0	0	210	24	1	12	1	
Carob Chips	130	50	6	5	0	0	22	2	20	0	0	
Cheesecake Bites	90	60	6	4	0	25	90	10	0	7	2	
Chocolate Covered Peanut Butter Cookies	160	90	10	5	0	105	15	1	9	2	0	
Chocolate Sprinkles	120	20	2.5	2	0	0	35	24	0	10	0	
Coconut Flakes	140	80	9	8	0	0	60	15	3	11	1	
Cookie Dough Minis	120	45	5	2.5	0.5	15	30	18	0	9	1	
Cookies and Cream	130	50	5	2	0	0	130	20	1	11	1	
Frosted Animal Cookies	130	60	6	5	0	0	50	18	0	10	1	
Fruity Pebbles Cereal®	130	10	1	1	0	0	180	25	0	10	1	
Ghirardelli Chocolate Chips®	140	80	8	5	0	0	19	2	15	1	0	
Ghirardelli White Chocolate Chips®	150	80	9	8	0	5	40	16	0	16	3	

# Written Nutrition Information

Nutrition facts	serving size (g)	Calories	Calories from fat	Total fat (g)	Saturated Fat (g)	Trans Fat (g)	Chol (mg)	Sodium (mg)	Total Carb (g)	Dietary Fiber (g)	Total Sugar (g)	Protein (g)
<b>BREAKFAST</b>												
Quaker® Oatmeal Maple Flavor (Artificial maple flavor in Vermont only).	172	170	30	3	1.5	0	5	270	32	3	12	4
Sausage, Egg, Cheese & Hash Brown Burrito	143	370	210	23	8	0	150	930	27	3	2	15
EGG-NORMOUS Burrito™	362	910	490	55	16	0.5	320	2020	73	6	8	33
Supreme Breakfast Sandwich	312	880	530	59	21	1	375	2170	45	2	7	41
BK™ Ultimate Breakfast Platter	464	1190	590	66	15	0.5	320	2460	123	5	32	27
NY Ultimate Platter (Regional menu item)	371	870	400	44	12	0	305	1650	95	4	31	22
Pancake and Sausage platter	217	610	280	31	9	0	80	1010	72	1	30	12
CROISSAN'WICH® Egg & Cheese	114	300	140	15	7	0	130	580	30	1	4	11
CROISSAN'WICH® Sausage, Egg & Cheese	158	470	270	30	12	0	165	890	30	1	4	18
CROISSAN'WICH® Ham, Egg & Cheese	145	330	140	16	7	0	145	1000	31	1	5	16
CROISSAN'WICH® Bacon, Egg & Cheese	121	340	160	18	8	0	140	730	30	1	4	12
Fully Loaded CROISSAN'WICH®	207	570	330	37	15	0.5	195	1650	32	1	5	27
KING CROISSAN'WICH™ w/ Double Sausage	216	700	460	51	20	0.5	210	1410	31	1	5	27
KING CROISSAN'WICH™ w/ Sausage and Bacon	183	580	350	39	16	0.5	190	1370	31	1	5	24

# “Grab-and-Go”

- If a “grab-and-on” item has a Nutritional Facts label **with all required information** then additional written nutritional information and succinct statement, is not required.



Required nutritional Information

Succinct statement

<b>Nutrition Facts</b>	
Serving Size 172 g	
Amount Per Serving	
<b>Calories</b> 200	Calories from Fat 8
<b>% Daily Value*</b>	
<b>Total Fat</b> 1g	1%
Saturated Fat 0g	1%
Trans Fat	
<b>Cholesterol</b> 0mg	0%
<b>Sodium</b> 7mg	0%
<b>Total Carbohydrate</b> 36g	12%
Dietary Fiber 11g	45%
Sugars 6g	
<b>Protein</b> 13g	
Vitamin A 1%	Vitamin C 1%
Calcium 4%	Iron 24%
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.	
NutritionData.com	



# Alcohol

- **Covered establishments must disclose calories and other nutritional information for alcoholic beverages that are on menus and menu boards**
- **Exemption:** alcohol that is on display behind the bar (and not on the menu, menu board, or not self-service)
- FDA consider that beers on Keg taps to be alcoholic beverages that are foods on display (exempt)

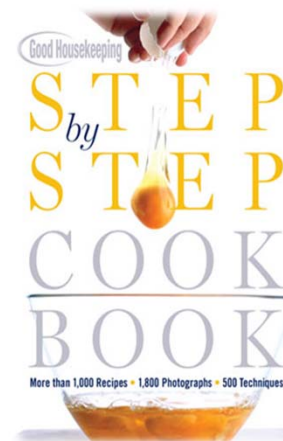


# Determining Nutritional Content

- Covered establishments must have reasonable basis for its nutrient content declarations

- Nutrient values can be determined by:

- Cookbooks
- Laboratory analyses
- Nutrient databases
- Nutritional Facts Label
- Other reasonable means



Nutrition Facts	
Serving Size 2/3 cup (55g)	
Servings Per Container About 8	
Amount Per Serving	
<b>Calories</b> 230	Calories from Fat 72
<b>% Daily Value*</b>	
<b>Total Fat</b> 8g	<b>12%</b>
Saturated Fat 1g	5%
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 37g	<b>12%</b>
Dietary Fiber 4g	16%
Sugars 1g	
<b>Protein</b> 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

- Upon FDA request, covered establishments must provide information substantiating their nutrient values. Two signed/dated statements are needed to:

- Certify that nutrient analysis is accurate and complete, and
- Certify that the facility 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.

# Questions and Answers

- **Q:** The menu labeling final rule only applies to items that are standard menu items at covered establishments. **If there is a restaurant chain that sells some specific dishes in less than 20 of its locations, would those specific foods items be covered?** For example, if Slim-Deli Restaurant only sells “shrimp sandwich” in its New Orleans’s location (i.e., not in any other Slim-Deli Restaurant across the country), **would this dish be covered?**

**A – Yes**

**B – No**

- If the New Orleans location of Slim-Deli Restaurant *is a covered establishment* and the “shrimp sandwich” *is sold as a standard menu item* at such establishment, this dish would be covered under 21 CFR 101.11 even though it is only sold at the one location.

# Questions and Answers

- **Q: If facility lists standard menu items on a menu or menu board and does not list prices, does facility still need to post calories for those standard menu items listed on the menu or menu board?**
  - A. Yes**
  - B. No
  - C. It depends
- It's the **primary writing** of the covered establishment from which a customer makes an order selection.
- When in doubt, ask yourself, "can the customer use this writing to make an order selection at the time they are viewing the writing?"

# Questions and Answers

- **Q: Are items such as bagels, muffins, cookies, and donuts, where the consumer can purchase one or several, covered under the menu labeling final rule?**

A – Yes

B – No

**C – It depends**

- This would depend on how the bagels, muffins, cookies, and donuts are offered for sale
- For example, if these items are offered as individual items, then they are covered

# Resources

- The final rule is available online at FDA.gov at:  
<https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf>
- Issued April 2016 - Guidance for Industry:  
<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM461963.pdf>
- Issued March 2015 - Compliance Guide:  
<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM437566.pdf>

# Questions?

