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# **Guidance for Industry**

## **Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments**

### **Small Entity Compliance Guide**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
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# **Guidance for Industry<sup>1</sup>**

## **Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Small Entity Compliance Guide**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

### **I. Introduction**

On December 1, 2014, FDA (we) published a final rule entitled “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” (“the rule”) in the Federal Register to implement the nutrition labeling provisions in section 4205 of the Patient Protection and Affordable Care Act of 2010 (“section 4205”).<sup>2</sup> The rule is effective on December 1, 2015. Section 4205 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), among other things, to require 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 to provide calorie and other nutrition information for standard menu items, including food on display and self-service food. Under section 4205, restaurants and similar retail food establishments not otherwise covered by the law may elect to become subject to the Federal requirements by registering every other year with FDA. Providing accurate, clear, and consistent nutrition information, including the calorie content of foods, in restaurants and similar retail food establishments will make such nutrition information available to consumers in a direct and accessible manner to enable consumers to make informed and healthful dietary choices.

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the requirements set forth in 21 CFR 101.11 concerning nutrition labeling of standard menu items in establishments covered by the rule. We have organized this guidance in a question/answer format and also identify the relevant regulation in parentheses after each answer. The rule is binding and has the full force and effect of law.

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<sup>1</sup> This guidance has been prepared by the Food Labeling and Standards Staff in the Office of Nutrition, Labeling and Dietary Supplements in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

<sup>2</sup> The rule is codified at 21 CFR 101.11.

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FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

In the remainder of this guidance, "you" and "I" refer to establishments that are subject to the rule.

## **II. Coverage of the Rule**

### **A. Establishments Covered by the Rule**

#### II.A.1. Who is subject to the rule?

You are subject to the rule if you are a "covered establishment." The rule defines "covered establishment" as a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is registered to be covered under the rule. (21 CFR 101.11(a)).

#### II.A.2 Where can I find information about registering voluntarily to be covered by the rule?

See section VI of this document and 21 CFR 101.11(d) for information on how a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the rule.

#### II.A.3. How does the rule define "restaurant or similar retail food establishment"?

The rule defines "restaurant or similar retail food establishment" as a retail establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2. (21 CFR 101.11(a))

#### II.A.4. How does the rule define "restaurant-type food"?

The rule defines "restaurant-type food" as food that is:

- (1) Usually eaten on the premises, while walking away, or soon after arriving at another location; and
- (2) Either:
  - (a) Served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or
  - (b) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in subparagraph (a) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. In other words, restaurant-type food is the subset of

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food previously exempt from Federal nutrition labeling requirements under sections 403(q)(5)(A)(i) and (ii) of the FD&C Act that is usually eaten on the premises of the establishment, while walking away, or soon after arriving at another location. (21 CFR 101.11(a))

II.A.5. What are some examples of foods that general would be considered “restaurant-type food”?

Examples of food that generally would be considered restaurant-type food include: food for immediate consumption at a sit-down or quick service restaurant; food purchased at a drive-through; take-out and delivery pizza, hot pizza at grocery and convenience stores that is ready to eat, and pizza slices from a movie theater; hot buffet food, hot soup at a soup bar, and food from a salad bar; foods ordered from a menu or menu board at a grocery store intended for individual consumption (e.g., soups, sandwiches, and salads); and self-service foods and foods on display that are intended for individual consumption (e.g., sandwiches, wraps, and paninis at a deli counter; and cookies from a mall cookie counter; bagels, donuts, and rolls offered for individual sale).

II.A.6. What foods would not be considered “restaurant-type food”?

Foods that are grocery-type items that may be ready for immediate consumption but that consumers usually store for use at a later time or customarily further prepare would not be considered “restaurant-type food.” Examples of food that generally would not be considered restaurant-type food include: food bought from bulk bins or cases (e.g., dried fruit, nuts) in grocery stores; foods to be 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 sold by weight that are not self-serve and are not intended solely for individual consumption (e.g., deli salads sold by unit of weight such as potato salad or chicken salad), either prepacked or packed upon consumer request; and foods that are usually further prepared before consuming (e.g., deli meats and cheeses).

II.A.7. How does the rule define “location”?

The rule defines “location” as a fixed position or site.  
(21 CFR 101.11(a))

II.A.8. How does the rule define “doing business under the same name”?

The rule defines “doing business under the same name” as sharing the same name. The term “name” refers to the name of the establishment presented to the public. If there is no name of the establishment presented to the public (e.g., an establishment with the generic descriptor “concession stand”), the term “name” refers to the name of the parent entity that operates the establishment. When the term “name” refers to the name of the establishment presented to the public, the term “same” includes names that are slight variations or each other, for example, due to the region, location or size (e.g., “New York Ave. Burgers” and “Pennsylvania Ave. Burgers” or “ABC” and “ABC Express”).  
(21 CFR 101.11(a))



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II.A.9. How does the rule define “offering for sale substantially the same menu items”?

The rule defines “offering for sale substantially the same menu items” as offering for sale 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 the menu item varies, (e.g. “Bay View Crab Cake” and “Ocean View Crab Cake”). “Menu items” in this definition refers to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. Restaurants and similar retail food establishment that are part of a chain can still be offering for sale substantially the same menu items if the availability of some menu items varies within the chain. Having the same name may indicate, but does not necessarily guarantee, that menu items are substantially the same.

(21 CFR 101.11(a))

### **B. Establishments Not Covered by the Rule**

II.B.1. Who is not covered by the rule?

Establishments that do not meet the definition of “restaurant or similar retail food establishment” are not covered by the rule. This means that establishments that do not offer for sale restaurant-type food are not covered. In addition, schools (as that term is defined in 7 CFR 210.2 or 220.2) are excepted from the definition of “restaurant or similar retail food establishment” in the rule and, thus, are not covered by the rule.

(21 CFR 101.11(a))

A restaurant or similar retail food establishment is not covered by the rule if it is not a covered establishment – i.e., it is not:

- Part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items; or
- A restaurant or similar retail food establishment that is registered to be covered under the rule.

### **C. Food Covered by the Rule**

II.C.1. What foods are covered by the rule?

The rule applies to foods that are standard menu items offered for sale in a covered establishment.

(21 CFR 101.11(b)(1)(i))

II.C.2. How does the rule define “standard menu item”?

The rule defines “standard menu item” as a 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.

(21 CFR 101.11(a))

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### II.C.3. How does the rule define “menu or menu board”?

The rule defines “menu or menu board” as the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch and dinner menus; dessert menus; beverage menus; children’s menus; other specialty menus; electronic menus; and menus on the Internet. The rule specifies that determining whether a writing is or is part of the primary writing of the covered establishment from which a customer makes an order selection depends on a number of factors, including whether the writing lists the name of a standard menu item (or an image depicting the standard menu item) and the price of the standard menu item, and whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing. Menus may be in different forms, e.g., booklets, pamphlets, or single sheets of paper. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments.

(21 CFR 101.11(a))

### II.C.4. How does the rule define “food on display”?

The rule defines “food on display” as 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.

(21 CFR 101.11(a))

### II.C.5. How does the rule define “self-service food”?

The rule defines “self-service food” as restaurant-type food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility and that is served by the customers themselves. Self-service food also includes self-service beverages.

(21 CFR 101.11(a))

### II.C.6. How does the rule define “combination meal”?

The rule defines “combination meal” as a standard menu item that consists of more than one food item, for example a meal that includes a sandwich, a side dish, and a drink. A combination meal may be represented on the menu or menu board in narrative form, numerically, or pictorially. Some combination meals may include a variable menu item or be a variable menu item as defined in this paragraph where the components may vary. For example, the side dish may vary among several options (e.g., fries, salad, or onion rings) or the drinks may vary (e.g., soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal.

(21 CFR 101.11(a))

Examples of combination meals other than those included in the definition include:

- A burger and fries;
- A sandwich and a package of chips;
- Pancakes and eggs;
- Soup and sandwich; and
- Sandwich and salad.

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### II.C.7. How does the rule define “variable menu item”?

The rule defines “variable menu item” as a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.

(21 CFR 101.11(a))

Examples of variable menu items include the following items where such items are listed as single menu items on the menu or menu board:

- Milkshakes, ice cream, soft drinks, and doughnuts that are available in multiple flavors;
- Pizza prepared with a selection of crusts and toppings;
- Chicken that may be grilled or fried; and
- A grilled cheese sandwich that can be made with either Cheddar or Swiss cheese.

## **D. Foods Not Covered by the Rule**

### II.D.1. What foods are not covered by the rule?

The labeling requirements of the rule do not apply to foods that are not standard menu items, including:

- Items such as condiments that are for general use, including those placed on the table or on or behind the counter;
- Daily specials;
- Temporary menu items;
- Custom orders;
- Food that is part of a customary market test; and
- Self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance.

(21 CFR 101.11(b)(1)(ii)(A)(1) and(2))

### II.D.2. Are alcoholic beverages covered by the rule?

Yes. However, alcoholic beverages that are foods on display and are not self-service foods are not subject to the new requirements, established in 21 CFR 101.11(b)(2)(iii), for standard menu items that are self-service or on display.

(21 CFR 101.11(b)(1)(ii)(B))

For example, a bottle of liquor behind a bar used to prepare mixed drinks is not subject to the labeling requirements in 21 CFR 101.11(b)(2)(iii) that otherwise apply to standard menu items that are self-service or on display.

### II.D.3. What terms related to foods not covered by the rule does the rule define?

The rule defines the following terms related to foods not covered by the rule:

- Custom order
- Daily special
- Food that is part of a customary market test
- Temporary menu item

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(21 CFR 101.11(a))

II.D.4. How does the rule define “custom order”?

The rule defines “custom order” as a food order that is prepared in a specific manner based on an individual customer’s request, which requires the covered establishment to deviate from its usual preparation of a standard menu item, e.g., a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich.

(21 CFR 101.11(a))

II.D.5. How does the rule define “daily special”?

The rule defines “daily special” as a menu item that is prepared and offered for sale on a particular day, that is not routinely listed on a menu or menu board or offered by the covered establishment, and that is promoted by the covered establishment as a special menu item for that particular day.

(21 CFR 101.11(a))

II.D.6. How does the rule define “food that is part of a customary market test”?

The rule defines “food that is part of a customary market test” as food that appears on a menu or menu board for less than 90 consecutive days in order to test consumer acceptance of the product.

(21 CFR 101.11(a))

II.D.7. How does the rule define “temporary menu item”?

The rule defines “temporary menu item” as a food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

(21 CFR 101.11(a))

## **III. Compliance Dates**

III.1. If I am subject to the rule, when must I comply with it?

You must comply with the rule by December 1, 2015 if you are subject to the requirements of the rule on or before that date.

## **IV. Labeling Requirements for Nutrition Information**

### **A. Types of Labeling Requirements**

IV.A.1. What Labeling Requirements Does the Rule Establish for Standard Menu Items that are Offered for Sale in a Covered Establishment?

The rule establishes labeling requirements for:

- Information that must be provided on menus and menu boards (21 CFR 101.11(b)(2)(i)). This includes all of the following:
  - Calories (21 CFR 101.11(b)(2)(i)(A));

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- A 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 (21 CFR 101.11(b)(2)(i)(B)); and
- A statement on menus and menu boards about the availability of additional written nutrition information (21 CFR 101.11(b)(2)(i)(C));
- Nutrition information that must be available in written form on the premises of the covered establishment and provided to the customer upon request (21 CFR 101.11(b)(2)(ii)); and
- Standard menu items that are self-service or on display (21 CFR 101.11(b)(2)(iii)).

## **B. General Format Requirements for Declaring Calories on Menus and Menu Boards**

### IV.B.1. How do I list the number of calories on the menu or menu board?

You must declare the number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale.

- In the case of multiple-serving standard menu items, this means the calories declared must be for the whole menu item listed on the menu or menu board 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 on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (e.g., “pizza pie: 200 cal/slice, 8 slices”).

(21 CFR 101.11(b)(2)(i)(A))

You must list the number of calories:

- Adjacent to the name or the price of the associated standard menu item;
- In a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller;
- In the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item; and
- With the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.

(21 CFR 101.11(b)(2)(i)(A)(1))

### IV.B.2. How do I declare increments of calories on the menu or menu board?

You must declare calories to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that you may express amounts less than 5 calories as zero.

(21 CFR 101.11(b)(2)(i)(A)(2))

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### IV.B.3. How do I declare the term “Calories” or “Cal” on the menu or menu board?

The term “Calories” or “Cal” must appear as a heading above a column listing the number of calories for each standard menu item or adjacent to the number of calories for each standard menu item.

- If the term “Calories” or “Cal” appears as a heading above a column of calorie declarations, the term must be:
  - In a type size no smaller than the smallest type size of the name or price of any menu item on that menu or menu board;
  - In the same color or a color at least as conspicuous as that used for that name or price; and
  - In the same contrasting background or a background at least as contrasting as that used for that name or price.
- If the term “Calories” or “Cal” appears adjacent to the number of calories for the standard menu item, the term “Calories” or “Cal” must appear:
  - In the same type size as the number of calories; and
  - In the same color and contrasting background as the number of calories.

(21 CFR 101.11(b)(2)(i)(A)(3))

## **C. Additional Format Requirements That Apply When Declaring Calories on Menus and Menu Boards for Variable Menu Items, Combination Meals, and Toppings**

### IV.C.1. What additional requirements apply to individual variable menu items?

- When the menu or menu board lists flavors or varieties of an entire individual variable menu item (such as soft drinks, ice cream, doughnuts, dips, and chicken that can be grilled or fried), you must declare the calories separately for each listed flavor or variety. For example, if the menu or menu board lists vanilla, chocolate, and strawberry flavors of ice cream, you must declare the calories separately for each of those listed flavors. Where flavors or varieties have the same calorie amounts (after rounding in accordance with 21 CFR 101.11(b)(2)(i)(A)(2)), the calorie declaration for such flavors or varieties can be listed as a single calorie declaration adjacent to the flavors or varieties, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amounts for each individual flavor or variety. (21 CFR 101.11(b)(2)(i)(A)(4)(i)).
- When the menu or menu board does not list flavors or varieties for an entire individual variable menu item, and only includes a general description of the variable menu item (e.g. “soft drinks”), you must declare the calories for each option as follows (21 CFR 101.11(b)(2)(i)(A)(4)(ii)):
  - With a slash between the two calorie declarations where only two options are available (e.g., “150/250 calories”); or
  - As a range in accordance with the requirements of 21 CFR 101.11(b)(2)(i)(A)(7) where more than two options are available (e.g., “100 - 250 calories”).
- When the menu or menu board describes flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a grilled cheese sandwich

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(e.g., “Grilled Cheese (Cheddar or Swiss)”), you must declare the calories for each option as follows (21 CFR 101.11(b)(2)(i)(A)(4)(iii)):

- With a slash between the two calorie declarations where only two options are available (e.g., “450/500 calories”); or
- As a range in accordance with the requirements of 21 CFR 101.11(b)(2)(i)(A)(7) where more than two options are available (e.g., “450 - 550 calories”).

IV.C.2. What additional requirements apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board?

When the menu or menu board lists toppings that can be added to a menu item (such as pizza or ice cream):

- You must declare the calories for the basic preparation of the menu item as listed (e.g., “small pizza pie,” “single scoop ice cream”). (21 CFR 101.11(b)(2)(i)(A)(5)(i))
- You must declare the calories separately, for each topping listed on the menu or menu board (e.g., pepperoni, sausage, green peppers, onions on pizza; fudge, almonds, sprinkles on ice cream), specifying that the calories are added to the calories contained in the basic preparation of the menu item.

For example,

Ice Cream Scoop: 300 cal

Topping	Added Cal
Almonds	25
Fudge	50

Where toppings have the same calorie amounts (after rounding in accordance with 21 CFR 101.11(b)(2)(i)(A)(2)), the calorie declaration for such toppings can be listed as a single calorie declaration adjacent to the toppings, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amount for each individual topping. (21 CFR 101.11(b)(2)(i)(A)(5)(ii))

- You must declare the calories for the basic preparation of the menu item for each size of the menu item. The calories for each topping listed on the menu or menu board must be declared for each size of the menu item, or declared using a slash between the two calorie declarations for each topping where only two sizes of the menu item are available (e.g., “adds 150/250 cal”) or as a range for each topping in accordance with the requirements of 21 CFR 101.11(b)(2)(i)(A)(7) where more than two sizes of the menu item are available (e.g., “adds 100-250 cal”). If a slash between two calorie declarations or a range of calorie declarations is used, the menu or menu board must indicate that the variation in calories for each topping arises from the size of the menu item to which the toppings are added. (21 CFR 101.11(b)(2)(i)(A)(5)(iii))

For example,

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Plain pizza pie: Small (12") 500 cal \* Medium (14") 750 cal \* Large (16") 1000 cal

Toppings	Added Cal		
	Small	Med	Large
Pepperoni	200	300	400
Sausage	250	350	450
Green Peppers	15	20	25

or

Plain pizza pie: Small (12") 500 cal \* Medium (14") 750 cal \* Large (16") 1000 cal

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

- If the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings), you must declare the calories for each topping as single values representing the calories for each topping when added to a one-topping menu item, specifying that the calorie declaration is for the topping when added to a one-topping menu item. (21 CFR 101.11(b)(2)(i)(A)(5)(iv))

For example,

Plain pizza pie (14"): 750 cal

Toppings	Added cal (single topping)
Pepperoni	300
Sausage	350
Green peppers	20

Also, recall that if the pizza pie comes in multiple sizes, a range could be used. For example:

Plain pizza pie: Small (12") 500 cal \* Medium (14") 750 cal \* Large (16") 1000 cal

Toppings	Added cal (single topping S/M/L pie)
Pepperoni	200-400
Sausage	250-450
Green peppers	15-25



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### IV.C.3. What additional requirements apply to a combination meal?

Except as provided in 21 CFR 101.11(b)(2)(i)(A)(6)(iv) (see Question IV.C.4):

- When the menu or menu board lists two options for menu items in a combination meal (e.g., a sandwich with a side salad or chips), you must declare the calories for each option with a slash between the two calorie declarations (e.g., “350/450 calories”). (21 CFR 101.11(b)(2)(i)(A)(6)(i))
- When the menu or menu board lists three or more options for menu items in a combination meal (e.g., a sandwich with chips, a side salad, or fruit), you must declare the calories as a range in accordance with the requirements of 21 CFR 101.11(b)(2)(i)(A)(7) (e.g., “350-500 calories”). (21 CFR 101.11(b)(2)(i)(A)(6)(ii))
- When the menu or menu board includes a choice to increase or decrease the size of a combination meal, you must declare the calorie difference for the increased or decreased size:
  - With a slash between two calorie declarations (e.g., “Adds 100/150 calories,” “Subtracts 100/150 calories”) if the menu or menu board lists two options for menu items in the combination meal; or
  - As a range in accordance with the requirements of 21 CFR 101.11(b)(2)(i)(A)(7) (e.g., “Adds 100-250 calories,” “Subtracts 100-250 calories”) if the menu or menu board lists three or more options for menu items in the combination meal. (21 CFR 101.11(b)(2)(i)(A)(5)(iii))

### IV.C.4. What exception applies to the additional requirements for a combination meal?

Where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (e.g., “Combine Any Sandwich with Any Soup or Any Salad for \$8.99”), and the calories for each standard menu item, including each size option as described in 21 CFR 101.11(b)(2)(i)(A)(6)(iii) if applicable, available for the consumer to combine are declared elsewhere on the menu or menu board, the requirements of 21 CFR 101.11(b)(2)(i)(A)(6)(i), (ii), and (iii) do not apply. (21 CFR 101.11(b)(2)(i)(A)(5)(iv))

### IV.C.5. What format requirements apply for declaring calories for an individual variable menu item, a combination meal, and toppings as a range, if applicable?

When you declare calories as a range, you must use the format “xx-yy,” where “xx” is the caloric content of the lowest calorie variety, flavor, or combination, and “yy” is the caloric content of the highest calorie variety, flavor, or combination. (21 CFR 101.11(b)(2)(i)(A)(7))

For examples of declaring calories as a range, see questions IV.C.1, IV.C.2, and IV.C.3.

## **D. Exception from Additional Format Requirements for Variable Menu Items**

IV.D.1. What exception applies to the additional format requirements for variable menu items? If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, e.g., all-you-can-eat buffet, then:

- The menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, e.g., “See buffet for calorie declarations.”
- This statement must appear:
  - In a type size no smaller than the type size of the name or price of the variable menu item, whichever is smaller;
  - In the same color or a color at least as conspicuous as that used for that name or price; and
  - With the same contrasting background or a background at least as contrasting as that used for that name or price.

(21 CFR 101.11(b)(2)(i)(A)(8))

## **E. Additional Requirements that Apply to Beverages That Are Not Self-Service**

IV.E.1. What additional requirements apply to beverages that are not self-service?

For beverages that are not self-service:

- You must declare calories based on the full volume of the cup served without ice, unless you ordinarily dispense and offer for sale a standard beverage fill (i.e., a fixed amount that is less than the full volume of the cup per cup size) or dispense a standard ice fill (i.e., a fixed amount of ice per cup size).
- If you ordinarily dispense and offer for sale a standard beverage fill or dispense a standard ice fill, you must declare calories based on such standard beverage fill or standard ice fill.

(21 CFR 101.11(b)(2)(i)(A)(9))

## **F. Succinct Statement on Menus and Menu Boards to Provide Context About Calories in a Total Daily Diet**

IV.F.1. What must the succinct statement say?

The succinct statement must say “2,000 calories a day is used for general nutrition advice, but calorie needs vary.”

(21 CFR 101.11(b)(2)(i)(B))

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IV.F.2. What options may I use for the succinct statement on menus and menu boards targeted to children?

For menus and menu boards targeted to children, you may use the following options as a substitute for, or in addition to, the succinct statement:

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

(21 CFR 101.11(b)(2)(i)(B))

IV.F.3. What are the format requirements for the succinct statement?

You must post the succinct statement:

- Prominently and in a clear and conspicuous manner;
- In a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board;
- In the same color or in a color at least as conspicuous as that used for the calorie declarations; and
- With the same contrasting background or a background at least as contrasting as that used for the calorie declarations

(21 CFR 101.11(b)(2)(i)(B)(1))

IV.F.4. Where must the succinct statement appear on menus?

The succinct statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement regarding the availability of the additional written nutrition information, the succinct statement must appear immediately above, below, or beside that statement.

(21 CFR 101.11(b)(2)(i)(B)(2))

IV.F.5. Where must the succinct statement appear on menu boards?

The succinct statement must appear on the bottom of the menu board, immediately above, below, or beside the statement regarding the availability of the additional written nutrition information.

(21 CFR 101.11(b)(2)(i)(B)(3))

## **G. Statement on Menus and Menu Boards Regarding the Availability of Additional Written Nutrition Information**

IV.G.1. What must the statement regarding the availability of the additional written nutrition information say?

The statement regarding the availability of the additional written nutrition information (“statement of availability”) must say “Additional nutrition information available upon request.”

(21 CFR 101.11(b)(2)(i)(C))

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See section IV.H of this document for more information about the written nutrition information.

### **IV.G.2. What are the format requirements for the statement of availability?**

You must post the statement of availability:

- Prominently and in a clear and conspicuous manner;
- In a type size no smaller than the smallest type size of any calorie declaration appearing on the same menu or menu board;
- In the same color or in a color at least as conspicuous as that used for the calorie declarations; and
- With the same contrasting background or a background at least as contrasting as that used for the calorie declarations

(21 CFR 101.11(b)(2)(i)(C)(1))

### **IV.G.3. Where must the statement of availability appear on menus?**

The statement of availability must appear on the bottom of the first page with menu items immediately above, below, or beside the succinct statement.

(21 CFR 101.11(b)(2)(i)(C)(2))

### **IV.G.4. Where must the statement of availability appear on menu boards?**

The statement must appear on the bottom of the menu board immediately above, below, or beside the succinct statement.

(21 CFR 101.11(b)(2)(i)(C)(3))

## **H. Nutrition Information That Must be Made Available in Written Form**

### **IV.H.1. What nutrition information for a standard menu item must be available in written form?**

The following nutrition information for a standard menu item must be available in written form:

- Total calories (cal)
- Calories from fat (fat cal)
- Total fat (g)
- Saturated fat (g)
- Trans fat (g)
- Cholesterol (mg)
- Sodium (mg)
- Total carbohydrates (g)
- Dietary fiber (g)
- Sugars (g)
- Protein (g)

(21 CFR 101.11(b)(2)(ii)(A)(1)-(11))

Note that “Cal” means calories, “g” means grams, and “mg” means milligrams.

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### IV.H.2. How do I present the written nutrition information?

The written nutrition information must be:

- Available in written form on the premises of the covered establishment;
- Provided to the customer upon request;
- Presented in the order listed and the measurements listed above (see Question IV.H.1);
- Presented in a clear and conspicuous manner; and
- Presented using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

In addition:

- Rounding of these nutrients must be in compliance with 21 CFR 101.9(c); and
- You may use the abbreviations allowed for Nutrition Facts for certain packaged foods in 21 CFR 101.9(j)(13)(ii)(B).

(21 CFR 101.11(b)(2)(ii))

### IV.H.3. When do the requirements for written nutrition information not apply?

If a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in 21 CFR 101.11(b)(2)(ii)(A)(1)-(11) (see Question IV.H.1), you do not have to include nutrition information regarding the standard menu item in the written form. However, if you make a nutrient content claim or health claim, you must provide nutrition information on the nutrient that is the subject of the claim in accordance with 21 CFR 101.10.

(21 CFR 101.11(b)(2)(ii)(B))

### IV.H.4. How does the rule define “insignificant amount”?

The rule defines an “insignificant amount” as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it must be an amount that allows a declaration of “less than one gram.”

(21 CFR 101.11(b)(2)(ii)(B)(1))

### IV.H.5. When may I use a simplified format for the written nutrition information?

You may use a simplified format for the written nutrition information for standard menu items that contain insignificant amounts of six or more of the required nutrients.

(21 CFR 101.11(b)(2)(ii)(B))

### IV.H.6. What information must the simplified format include?

The simplified format must include information, in a column, list, or table, on the following nutrients:

- Total calories, total fat, total carbohydrates, protein, and sodium; and
- Calories from fat, and any other nutrients identified in 21 CFR 101.11(b)(2)(ii)(A) that are present in more than insignificant amounts.

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(21 CFR 101.11(b)(2)(ii)(B)(2)(i)-(ii))

For example, you may use the simplified format for a medium cola beverage as follows:

- Total calories 200 calories
- Total fat 0 g
- Sodium 5 mg
- Total carbohydrate 56 g
- Sugars 56 g
- Protein 0 g
- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, and dietary fiber.

IV.H.7. What statement must I include when I use the simplified format?

If the simplified format is used, you must include the statement “Not a significant source of \_\_\_\_\_” (with the blank filled in with the names of the nutrients required to be declared in the written nutrition information and calories from fat that are present in insignificant amounts) at the bottom of the list of nutrients.

(21 CFR 101.11(b)(2)(ii)(B)(3))

IV.H.8. How must I declare the written nutrition information for variable menu items?

For variable menu items, you must declare the written nutrition information as follows for each size offered for sale:

- You must declare the written nutrition information for the basic preparation of the item and, separately, for each topping, flavor, or variable component.
- For toppings, see Question IV.H.9. If the calories and other nutrients are the same for different flavors, varieties, and variable components of the combination meal, each variety, flavor and variable component of the combination meal, you do not have to list these separately. You could list all items that have the same nutrient values together with the nutrient values listed only once.

(21 CFR 101.11(b)(2)(ii)(C)(1)-(3))

For example, for a meal that consists of a cheeseburger, side dish (fries or salad with fat-free dressing), and medium cola soft drink (diet or regular), you would provide information for the required nutrients for each component of the meal, i.e., the cheeseburger, the fries, the salad with fat-free dressing, a medium regular cola, and a diet cola. The nutrition information for the meal may appear as follows, which includes the simplified formats for the medium regular cola and diet cola:

Cheeseburger:

- Total calories 470 calories
- Calories from fat 190 calories
- Total fat 21 g
- Saturated fat 8 g
- Trans fat 1 g
- Cholesterol 75 mg

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- Sodium 880 mg
- Total carbohydrate 43 g
- Dietary fiber 2 g
- Sugars 10 g
- Protein 26 g

#### Medium fries:

- Total calories 420 calories
- Calories from fat 180 calories
- Total fat 20 g
- Saturated fat 3.5 g
- Trans fat 0 g
- Cholesterol 0 mg
- Sodium 500 mg
- Total carbohydrate 54 g
- Dietary fiber 6 g
- Sugars 0 g
- Protein 5 g

#### Garden salad with fat-free dressing:

- Total calories 150 calories
- Calories from fat 30 calories
- Total fat: 3 g
- Saturated fat 0 g
- Trans fat 0 g
- Cholesterol 0 mg
- Sodium 340 mg
- Total carbohydrate 27 g
- Dietary fiber 2 g
- Sugars 11 g
- Protein 3 g

#### Medium Regular Cola:

- Total calories 200 calories
- Total fat 0 g
- Sodium 5 mg
- Total carbohydrate 56 g
- Sugars 56 g
- Protein 0 g
- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, and dietary fiber.

#### Medium Diet Cola:

- Total calories 0 calories
- Total fat 0 g
- Sodium 40 mg

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- Total carbohydrate 0 g
- Sugars 0 g
- Protein 0 g
- Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, and dietary fiber

When the nutrient values for different flavors, varieties, or components of combination meals are the same, the nutrient values for such food items could be listed together with the nutrient values listed only once. For example:

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

IV.H.9. What additional format requirements apply to written nutrition information for toppings?

If the amount of the topping included on the basic preparation of the menu item decreases based on the total number of toppings ordered for the menu item (such as is sometimes the case with pizza toppings), the nutrients for such topping must be declared as single values representing the nutrients for each topping when added to a one-topping menu item, specifying that the nutrient declaration is for the topping when added to a one-topping menu item.

(21 CFR 101.11(b)(2)(ii)(C)(2))

IV.H.10. What forms may I use to provide written nutrition information?

You may provide the written nutrition information in the following forms:

- Counter card, sign, poster, handout, booklet, loose leaf binder;
- Electronic device, such as a computer;
- In a menu; or
- In any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items.
- If the written nutrition information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

(21 CFR 101.11(b)(2)(ii)(D))

## **I. Requirements for Food that is Self-Service or On Display**

IV.I.1. What nutrition information must I provide for a standard menu item that is self-service or on display?

You must provide:

- Calories per displayed food item (e.g., a bagel, a slice of pizza, or a muffin); or



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- If the food is not offered for sale in a discrete unit, calories per serving (e.g., scoop, cup), and
- The service or discrete unit used to determine the calorie content (e.g., “per scoop” or “per muffin”)

(21 CFR 101.11(b)(2)(iii)(A))

IV.I.2. Where must I place the nutrition information for a standard menu item that is self-service or on display?

You must place the calories for self-service foods and foods on display on either:

- A sign adjacent to and clearly associated with the corresponding food (e.g., “150 calories per scoop);
- A sign attached to a sneeze guard with the calorie declaration and the serving or unit used to determine the calorie content above each specific food so that the consumer can clearly associate the calorie declaration with the food, except that if it is not clear to which food the calorie declaration and serving or unit refers, then the sign must also include the name of the food, e.g., “Broccoli and cheese casserole – 200 calories per scoop”; or
- A single sign or placard listing the calorie declaration for several food items along with the names of the food items, so long as the sign or placard is located where a consumer can view the name, calorie declaration, and serving or unit of a particular item while selecting that item.

(21 CFR 101.11(b)(2)(iii)(A))

IV.I.3. What does “per displayed food item” mean for the purposes of the labeling requirements that apply to standard menu items that are self-service or on display?

For the purposes of the requirements for providing nutrition information for a standard menu item that is self-service or on display, “per displayed food item” means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, or a muffin.

(21 CFR 101.11(b)(2)(iii)(A)(1))

IV.I.4. What does “per serving” mean for the purposes of the labeling requirements that apply to standard menu items that are self-service or on display?

For the purposes of the requirements for providing nutrition information for a standard menu item that is self-service or on display, “per serving” means, for each food:

- Per serving instrument used to dispense the food offered for sale, provided that the serving instrument dispenses a uniform amount of the food (e.g., a scoop or ladle);
- If a serving instrument that dispenses a uniform amount of food is not used to dispense the food, per each common household measure (e.g., cup or tablespoon) offered for sale or per unit of weight offered for sale, e.g., per quarter pound or per 4 ounces; or
- Per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the description of the cup size (e.g., “140 calories per 12 fluid ounces (small”).

(21 CFR 101.11(b)(2)(iii)(A)(2))

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IV.I.5. How must I declare the calories for a standard menu item that is self-service or on display?

The following applies when you declare the calories for a standard menu item that is self-service or on display:

- You must declare calories to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories except that amounts less than 5 calories may be expressed as zero.
- If you provide the calorie declaration on a sign with the food's name, price, or both, you must declare the calories, accompanied by the term "Calories" or "Cal" and the amount of the serving or displayed food item on which the calories declaration is based:
  - In a type size no smaller than the type size of the name or price of the menu item whichever is smaller;
  - In the same color, or a color that is at least as conspicuous as that used for that name or price
  - Using the same contrasting background or a background at least as contrasting as that used for that name or price.
- If you provide the calorie declaration on a sign that does not include the food's name, price, or both, you must declare the calories, accompanied by the term "Calories" or "Cal" and the amount of the serving or displayed food item on which the calorie declaration is based, in a manner that is clear and conspicuous.
- For self-service beverages, calorie declarations must be accompanied by the term "fluid ounces" and, if applicable, the description of the cup size (e.g., "small," "medium").

(21 CFR 101.11(b)(2)(iii)(A)(3)(i)-(iii))

IV.I.6. Do the requirements for the succinct statement and statement of availability apply to self-service foods and foods on display?

You must provide the succinct statement required by 21 CFR 101.11(b)(2)(i)(B) and the statement of availability required by 21 CFR 101.11(b)(2)(i)(C) for food that is self-service or on display and is identified by an individual sign adjacent to the food itself where such sign meets the definition of a menu or menu board as defined in 21 CFR 101.11(a). The succinct statement required by 21 CFR 101.11(b)(2)(i)(B) and the statement of availability required by 21 CFR 101.11(b)(2)(i)(C) may appear:

- On the sign adjacent to the food itself,
- On a separate, larger sign, in close proximity to the food that can be easily read as the consumer is making order selections, or
- On a larger menu board that can be easily read as the consumer is viewing the food.

(21 CFR 101.11(b)(2)(iii)(B))

IV.I.7. What written nutrition information must I provide for a standard menu item that is self-service or on display?

You must provide the nutrition information in written form required by 21 CFR 101.11(b)(2)(ii), except for packaged food insofar as it bears nutrition labeling information required by and in accordance with 21 CFR 101.11(b)(2)(ii) and the packaged food, including its label, can be examined by a consumer before purchasing the food.

(21 CFR 101.11(b)(2)(iii)(C))

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An example of a packaged food that bears the required nutrition labeling is a packaged bag of chips that a consumer would purchase as part of a combination meal that includes the packaged chips with a sandwich when the consumer can pick up the packaged chips and read the Nutrition Facts label before purchasing the combination meal.

IV.I.8. Do I need to provide written nutrition information for a packaged food that I offer for sale if the food already has a Nutrition Facts label?

It depends on whether the Nutrition Facts label for the food bears the nutrition information required by and in accordance with 21 CFR 101.11(b)(2)(ii) and the consumer can examine the Nutrition Facts label before purchasing the food. For example, you would not need to provide written nutrition information for a bottled soft drink (that bears the nutrition information required by and in accordance with 21 CFR 101.11(b)(2)(ii)) that a consumer would select from a refrigerated case before paying for the soft drink. However, you would need to provide written nutrition information for a bottled soft drink that you keep behind the counter and hand to the consumer after the consumer has paid for it.

## **V. Determination of Nutrient Content**

### **A. General Requirements**

V.A.1. How may I determine nutrient values for standard menu items?

You must have a reasonable basis for your nutrient declarations. You may determine nutrient values by using any of the following:

- Nutrient databases (with or without computer software programs);
- Cookbooks;
- Laboratory analysis; or
- Other reasonable means, including:
  - Use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.9;
  - FDA nutrients values for raw fruits and vegetables in Appendix C of 21 CFR part 101;
  - FDA nutrient values for cooked fish in Appendix D of 21 CFR part 101

(21 CFR 101.11(c)(1))

For nutrient databases, you may be able to obtain information from sources such as the “USDA National Nutrient Database for Standard Reference” (<http://ndb.nal.usda.gov/>). In general, you should use a database that has a name and version number, as you are required to provide the name and version of the database to FDA, within a reasonable period of time upon request, as part of the information required to substantiate your nutrient values (as discussed further in section V.B. below). In certain cases, the version number might be the date. Databases may be updated to reflect more recent data and information, and different versions of a database may generate different nutrient values. If available, you should consider information on how the database was used including calculations or operations (e.g., worksheets or computer printouts)

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to determine the nutrient values for the standard menu items, as you are required to provide such information to FDA, within a reasonable time period upon request, as part of the information required to substantiate your nutrient values (as discussed further in section V.B. below). Some databases only provide nutrient values for certain food items such as foods typically used as ingredients in standard menu items; while other databases use software to compute nutrient values for a standard menu item prepared with several of the listed foods in varying amounts, taking into consideration the recipe and ingredient amounts used in the preparation. Nutrient databases may be used to determine nutrient values regardless of whether they use computer software programs.

For cookbooks, you should use one that has been published. If available, you should consider information provided by the cookbook or from the author or publisher about how the nutrient information for the recipes was obtained, as you are required to provide such information to FDA, within a reasonable time period upon request, as part of the information required to substantiate your nutrient values (as discussed further in section V.B. below).

For laboratory analyses, consider whether the laboratory provides copies of analytical worksheets, including the analytical method, used to determine and verify the nutrition information, as you are required to provide copies of such analytical worksheets to FDA, within a reasonable period of time upon request, as part of the information required to substantiate your nutrient values (as discussed further in section V.B. below).

V.A.2. How do I determine if the basis I use to determine nutrition information for a standard menu item is reasonable?

You must ensure that nutrient declarations for standard menu items are accurate and consistent with the specific basis used to determine nutrient values. You must take reasonable steps to ensure that the method of preparation (e.g., types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which you determined your nutrient values.

(21 CFR 101.11(c)(2))

For example, if you determine nutrition information for a turkey sandwich based on a recipe along with nutrition information provided in a cookbook for the turkey sandwich, and the recipe specifies using one tablespoon of mayonnaise, you must take reasonable steps to ensure your employees use one tablespoon of mayonnaise when preparing the turkey sandwich--e.g., through appropriate instruction about the importance of the consistent application of one tablespoon of mayonnaise to satisfy the requirements of this rule.

## **B. Information Substantiating Nutrient Values**

V.B.1. What are you required to provide to FDA to substantiate nutrient values?

You must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values.

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V.B.2. If I determine nutrient values using nutrient databases, what specific information must I provide to FDA to substantiate nutrient values?

If you determine nutrient values using nutrient databases, the information must include the following:

- The name and version (including the date of the version) of the database, and, as applicable, the name of the applicable software company and any Web site address for the database. The name and version of a database should include the name and version of the computer software, if applicable;
- The recipe or formula used as a basis for the nutrient declarations;
- Information on:
  - The amount of each nutrient that the specified amount of each ingredient identified in the recipe contributes to the menu item; and
  - How the database was used including calculations or operations (e.g., worksheets or computer printouts) to determine the nutrient values for the standard menu items.
  - If this information is not available, certification attesting that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions;
- A detailed listing (e.g., printout) of the nutrient values determined for each standard menu item;
- Any other information pertinent to the final nutrient values of the standard menu item (e.g., information about what might cause slight variations in the nutrient profile such as moisture variations);
- A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and
- A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (e.g., types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(21 CFR 101.11(c)(3)(i)(A)-(G))

Because your corporate headquarters or parent entity may conduct the nutrient analysis or make arrangements for the nutrient analysis, the responsible individual who certifies that the information contained in the nutrient analysis is complete and accurate can be employed at either your establishment or at your corporate headquarters or parent entity. Whether such individual is employed at your establishment or at your corporate headquarters or parent entity, it is critical that the individual who signs the certification has a factual basis for certifying that the nutrient analysis is complete and correct.

21 CFR 101.11(c)(3)(i)(F)

In contrast, the responsible individual who certifies that you have taken reasonable steps to ensure that the method of preparation and amount of a standard menu item offered for sale adhere to the factors on which your nutrient values were determined must be employed by your

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establishment, because an individual employed at your corporate headquarters or parent entity likely would not have a factual basis for certifying the actions of your specific establishment because such individual would not be present where the standard items are prepared, and, thus, likely could not certify the actions your establishment takes to comply with the rule.

21 CFR 101.11(c)(3)(i)(G)

V.B.3. If I determine nutrient values using published cookbooks that contain nutritional information for recipes in the cookbook, what specific information must I provide to FDA to substantiate nutrient values?

If you determine nutrient values using published cookbooks that contain nutritional information for recipes in the cookbook, the information must include the following:

- The name, author, and publisher of the cookbook used;
- If available, information provided by the cookbook or from the author or publisher about how the nutrition information for the recipes was obtained;
- A copy of the recipe used to prepare the standard menu item and a copy of the nutrition information for that standard menu item as provided by the cookbook; and
- A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (e.g., types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the standard menu item but no changes may be made to the proportion of ingredients used.)

(21 CFR 101.11(c)(3)(ii))

V.B.4. If I determine nutrient values using laboratory analyses, what specific information must I provide to FDA to substantiate nutrient values?

If you determine nutrient values using laboratory analyses, the information must include the following:

- A copy of the recipe for the standard menu item used for the nutrient analysis;
- The name and address of the laboratory performing the analysis;
- Copies of the analytical worksheets, including the analytical method, used to determine and verify nutrition information;
- A statement signed and dated by the responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and
- A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (e.g., types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

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(21 CFR 101.11(c)(3)(iii))

V.B.5. For nutrition information provided by other reasonable means, what specific information must I provide to FDA to substantiate nutrient values?

If you determine nutrient values using other reasonable means, the information must include the following:

- A detailed description of the means used to determine the nutrition information;
- A recipe or formula used as a basis for the nutrient determination;
- Any data derived in determining the nutrient values for the standard menu item e.g., nutrition information about the ingredients used with the source of the nutrient information;
- A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and
- A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (e.g., types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(21 CFR 101.11(c)(3)(iv))

## **VI. Voluntary Registration to be Subject to the Federal Requirements**

### **A. Applicability**

VI.A.1. What establishments may voluntarily register to be subject to the requirements of the rule?

A restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements of the rule.

(21 CFR 101.11(d)(1))

VI.A.2. If I voluntarily register to be subject to the requirements of the rule, do I remain subject to non-identical State or local nutrition labeling requirements?

No. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(21 CFR 101.11(d)(1))

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### VI.A.3. Who may register my establishment?

The authorized official of a restaurant or similar retail food establishment as defined in the rule, which is not otherwise subject to 21 CFR 101.11(b), may register with FDA. (We discuss who the “authorized official” can be in the next question.)

(21 CFR 101.11(d)(2))

### VI.A.4. How does the rule define “authorized official of a restaurant or similar retail food establishment”?

The rule defines “authorized official of a restaurant or similar retail food establishment” as the owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act, with FDA for the purposes of 21 CFR 101.11(d).

(21 CFR 101.11(a))

## **B. General Requirements for Voluntary Registration**

### VI.B.1. What form do I use for voluntary registration?

You must use Form FDA 3757. You can find this form at [www.fda.gov/menulabeling](http://www.fda.gov/menulabeling).

(21 CFR 101.11(d)(3) and (d)(4))

### VI.B.2. What registration information must an authorized official provide on Form FDA 3757?

Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757:

- The contact information (including name, address, phone number, and e-mail address) for the authorized official;
- The contact information (including name, address, phone number, and e-mail address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;
- All trade names the restaurant or similar retail food establishment uses;
- Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and
- Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.11.

(21 CFR 101.11(d)(3))

### VI.B.3. How does an authorized official register?

Authorized officials of restaurants and similar retail food establishments who elect to be subject to the requirements of the rule can register by visiting [www.fda.gov/menulabeling](http://www.fda.gov/menulabeling). We have created a form (Form 3757) that contains fields requesting the information in 21 CFR



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101.11(d)(3) and made the form available at this web site. Registrants must use this form to ensure that complete information is submitted.

- Information should be submitted by e-mail by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by e-mail to [menulawregistration@fda.hhs](mailto:menulawregistration@fda.hhs).
- If e-mail is not available or cannot be used, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301-436-2804 or mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(21 CFR 101.11(d)(4)(i)-(ii))

VI.B.4. How often must an authorized official renew a voluntary registration to keep it active? To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(21 CFR 101.11(d)(5))

VI.B.5. Is there a cost for voluntary registration?

No.

VI.B.6. Are signatures obtained in the voluntary registration subject to 21 CFR part 11?

No. Signatures obtained under 21 CFR 101.11(d) that meet the definition of electronic signatures in 21 CFR 11.3(b)(7) are exempt from the requirements of 21 CFR part 11.

(21 CFR 101.11(e))

## **VII. Misbranding**

VII.1. What are the consequences of failing to label a standard menu item offered for sale in a covered establishment in accordance with 21 CFR 101.11(b) or (c)?

A standard menu item offered for sale in a covered establishment is deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with 21 CFR 101.11(b) or (c).

(21 CFR 101.11(f))

Penalties for misbranding food are established in the Federal Food, Drug, and Cosmetic Act, and violations of 21 CFR 101.11 may result in enforcement action consistent with those penalties. For example, introducing, delivering for introduction, or receiving a misbranded food in interstate commerce, or misbranding a food while it is in interstate commerce or being held for sale after shipment in interstate commerce, are prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331), carrying criminal penalties under section 303 of the FD&C Act (21 U.S.C. 333). In addition, under section 302 of the FD&C Act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited action. Under section 304(a)(1) of the FD&C Act (21 U.S.C. 334(a)(1)), a food that is misbranded when

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introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce may be seized by order of a Federal court.