

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): Guidance for Industry

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**U.S. Department of Health and Human Services
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Table of Contents

1. Introduction

2. Background

3. Definitions

Claims

Establishments

Food types and menu items

Labeling and nutrition information

4. Covered Establishments – General Requirements

5. Nutrition Labeling for Covered Establishments (21 CFR 101.11)

Which establishments and foods are subject to the calorie and other nutrition labeling regulations at 21 CFR 101.11 (21 CFR 101.11(b)(1))?

What labeling is required on a menu or menu board for standard menu items in covered establishments?

- General information
- Menu/Menu Board
- Declaration of calories on the menu or menu board (21 CFR 101.11(b)(2)(i)(A))
- Calorie Disclosures
- Combination Meals
- Succinct statement and statement regarding the availability of additional written nutrition information (21 CFR 101.11(b)(2)(i)(B) and (C))
- Nutrition information that must be available in written form (21 CFR 101.11(b)(2)(ii))
- Information required for standard menu items that are self-service or on display (21 CFR 101.11(b)(2)(iii))
- Other self-service foods (including grab-and-go foods)

6. How to Determine the Nutrient Values for Restaurant-type Foods

General criteria to establish a reasonable basis for determining the nutrient values of standard menu items in covered establishments (21 CFR 101.11(c))

- Nutrient databases
- Published cookbooks that contain nutritional information for the recipes in the cookbook
- Nutrition Information determined by laboratory analyses
- Nutrition information determined by other reasonable means
- Compliance

7. Alcoholic Beverages

8. Voluntary Registration

Appendix A: Rounding Rules for Restaurant-Type Foods

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): Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

1. Introduction

“A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods – Part II” is intended to help restaurants and similar retail food establishments understand nutrition labeling requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations that may apply to them. Broadly, these requirements include the menu labeling provisions of section 403(q)(5)(H) of the (FD&C Act) [21 U.S.C. 343(q)(5)(H)]

¹ This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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and the final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments we published on December 1, 2014 ([79 FR 71156](#)) (menu labeling final rule).

Throughout this guidance the terms “you” and “I” refer to persons or establishments that are subject to these labeling requirements.

Please see “A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods – Part I” for guidance on other nutrition-related information that must be provided to customers of restaurants or similar establishments that are not covered by this guidance but that choose to make certain types of claims about nutrients in the food it serves or about beneficial health effects that can be obtained from the food it serves.

We will continue to update and issue additional editions of guidance as resources permit. We will collect questions from correspondence and other inquiries that we receive and consider including them in future editions of this guidance. Submit your questions concerning the interpretation of the requirements of the food labeling regulations to the Office of Nutrition and Food Labeling (HFS-800), Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

Our guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents 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 FDA guidance documents means that something is suggested or recommended, but not required.

2. Background

In 2010, section 4205 of the Patient Protection and Affordable Care Act amended 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)) to require that 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 items², provide calorie information for standard menu items (including food on display and self-service food) and provide, upon request, additional written nutrition information for standard menu items.

² In this document, we refer to those entities covered under section 403(q)(5)(H) of the FD&C Act as “covered establishments.” We refer to restaurants and other establishments that are not covered by under section 403(q)(5)(H) of the FD&C Act as “non-covered establishments.” Foods may also be exempt from the provisions of section 403(q)(5)(H) of the FD&C Act. We refer to those foods as “exempt foods.” This includes exempt foods sold in covered establishments. These conventions will be used unless there is some reason to distinguish these entities differently.

On December 1, 2014, we published a final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments to implement the menu labeling provisions (79 FR 71156); the menu labeling final rule is codified at Title 21 of the Code of Federal Regulations at § 101.11 (21 CFR § 101.11).

This guidance document describes nutrition labeling that is required for foods sold in covered establishments, how this information (calorie and nutrition labeling) may be presented, and when exempt foods, as defined further below, must provide nutrition labeling. The guidance also describes means (reasonable basis) by which nutrient values may be derived. In addition, this guidance clarifies certain issues, and is intended as a companion to “[A Food Labeling Guide](#).”

3. Definitions

Claims

- 3.1 Health claim:** An expressed or implied claim that characterizes the relationship of any substance to a disease or health related condition (for example, “adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis”). An implied health claim may include a symbol (such as a heart), a vignette, or “third party” endorsement (21 CFR 101.14(a)).
- 3.2 Nutrient content claim:** An expressed or implied claim that characterizes the level of any nutrient of the type required to be in nutrition labeling (for example, “low fat” or “reduced sodium”). An expressed nutrient content claim is a direct statement about the level or range of a nutrient in a food. An implied nutrient content claim is any claim that describes the food, or an ingredient in the food, in a manner that suggests that a nutrient is absent or present in a certain amount, such as “high in oat bran.” An implied nutrient content claim is also any claim that suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient, such as “healthy, contains 3 grams of fat.” (21 CFR 101.13(b)).
- 3.3 Other claims:** Other label statements about nutrients. These may range from general statements about nutrients to “structure/function” claims. Structure/function claims describe the role of a nutrient intended to affect the structure or function of the human body, such as “calcium helps build strong bones,” or characterize the documented mechanism by which a nutrient acts to maintain such structure or function, such as “fiber maintains bowel regularity.”

Establishments

- 3.4 Authorized official of a restaurant or similar retail food establishment:** The owner, operator, agent in charge, or other person authorized by the owner, operator, or agent in charge who has authority to voluntarily register their restaurant or establishment so that

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the establishment is subject to the requirements that apply to section 403(q)(5)(H) of the FD&C Act. (21 CFR 101.11(a))

- 3.5 Covered establishment:** A restaurant or similar retail food establishment, as defined below, that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, such as individual franchises) and offering for sale substantially the same menu items. This term also includes restaurants and similar retail food establishments that have voluntarily registered with us to be subject to the requirements of 21 CFR 101.11 (Nutrition labeling of standard menu items in covered establishments), and would otherwise not be covered by the requirements. (21 CFR 101.11(a))
- 3.6 Doing business under the same name:** Sharing the same name. The term “name” refers to either the name of the establishment presented to the public; or, if there is no name of the establishment presented to the public (for example, an establishment with the generic descriptor such as “concession stand”), the name of the parent entity of 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 of each other, due to things such as the region, location, or size (for example, “New York Ave. Burgers” and “Pennsylvania Ave. Burgers” or “ABC” and “ABC Express”). (21 CFR 101.11(a))
- 3.7 Non-covered establishment:** Any restaurant or establishment that does not meet the criteria for a covered establishment.
- 3.8 Location:** A fixed position or site. (21 CFR 101.11(a))
- 3.9 Restaurant or similar (or other) retail food establishment:** For establishments subject to section 403(q)(5)(H) of the FD&C Act, it means any retail food establishment that offers for sale restaurant-type food (as defined below). It includes bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities and concession stands located within entertainment venues (such as amusement parks, bowling alleys, and movie theatres), food service vendors (such as ice cream shops and mall cookie counters), food takeout or delivery establishments (such as pizza takeout and delivery establishments), grocery stores, retail confectionary stores, superstores, quick service restaurants and table service restaurants. It does not include school lunch or breakfast programs as defined by 7 CFR 210.2 or 220.2. (21 CFR 101.11(a))

Food types and menu items

- 3.10 Combination meal:** A standard menu item that consists of more than one food item, such as 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. For example, the side dish may vary among several options (such as fries, salad, or onion rings) or the drinks may vary (such as soft drinks, milk, or juice) and the customer selects which of these items will be included in the meal. (21 CFR 101.11(a))

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- 3.11 Custom order:** 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, such as a club sandwich made without the bacon if the establishment usually includes bacon on its club sandwich. (21 CFR 101.11(a))
- 3.12 Daily special:** 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))
- 3.13 Exempt food sold in a covered establishment:** Food sold in a covered restaurant or establishment that is not a standard menu item. Such food may include items such as condiments that are for general use, including those placed on the table or on or behind the counter; a custom order; a daily special; a temporary market item; or food that is part of a customary market test. Such food may also include 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)). In general, these foods are exempt from nutrition labeling unless the restaurant or establishment makes a claim about calories or other nutrients or provides other nutrition information. (21 CFR 101.9(j)(2) and 101.10).
- 3.14 Food on display:** A 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))
- 3.15 Food that is part of a customary market test:** 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))
- 3.16 Offering for sale substantially the same menu items:** 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 (for example, "Bay View Crab Cake" and "Ocean View Crab Cake"). "Menu items" refer 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 establishments 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))
- 3.17 Restaurant-type food:** Food that is usually eaten on the premises, while walking away, or soon after arriving at another location. It may either be: (a) served in restaurants or other establishments in which food is served for immediate human consumption (such as food traditionally sold in restaurants), or sold for sale or use in such establishments (such as bulk items used to prepare restaurant foods); or (b) processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in (a) of this paragraph and offered for sale to consumers but not for immediate human

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consumption in that establishment and not offered for sale outside that establishment. (21 CFR 101.11(a))

Examples of these types of foods may include meals served at sit-down restaurants, foods purchased at a drive-through, take-out and delivery foods, hot buffet foods, foods ordered from a menu/menu board at grocery stores and intended for immediate consumption, and foods that are self-serve and intended for immediate consumption.

- 3.18 Self-service food:** A 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))
- 3.19 Standard menu item:** 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))
- 3.20 Temporary menu item:** A food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days may be consecutive or not consecutive or a combination of the two. (21 CFR 101.11(a))
- 3.21 Variable menu item:** A standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item such as sodas. (21 CFR 101.11(a))

Labeling and nutrition information

- 3.22 Calorie labeling:** The written designation of the amount of calories in a standard menu item in a covered establishment. It is placed on the menu or menu board adjacent to the name or the price of the standard menu item, or for self-service foods and foods on display that are not listed on the menu or menu board, in a manner in close proximity and clearly associated with the standard menu item. (21 CFR 101.11(b)(2)(i)(A)(I))
- 3.23 Menu and menu board:** 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 (such as, catering), electronic menus, and menus on the Internet. 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 views the writing. The menus may be in different forms, such as booklets, pamphlets, or single sheets of paper. Menu boards include mounted or freestanding panels inside or outside a covered establishment including those used for counter service or drive-in or drive through service. (21 CFR 101.11(a))

3.24 Additional written nutrition information: Written information for a standard menu item in a covered establishment which provides the amount of total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in that item. It may be provided by counter card, sign, poster, handout, booklet, loose-leaf binder, menu, or electronic device or by other similar means. (21 CFR 101.11(a))

4. Covered Establishments – General Requirements

4.1 Which types of establishments are covered by 21 CFR 101.11?

Answer: The requirements of section 403(q)(5)(H) of the FD&C Act and 21 CFR 101.11 apply to restaurants or similar retail food establishments (see definition section, #3.9) that are part of a chain with 20 or more locations (see also definition section, #3.8) doing business under the same name (see definition section, #3.6) and offering for sale substantially the same menu items (see definition section, #3.16). Restaurants and similar retail food establishments that are 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 covered under these requirements (section 403(q)(5)(H)(ix) of the FD&C Act). This document refers to these types of establishments as “covered establishments.”

Covered establishments may be bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities and concession stands located within entertainment venues (such as amusement parks, bowling alleys, movie theatres, and sports arenas), food service vendors (such as ice cream shops and mall cookie counters), food takeout and delivery establishments (such as pizza takeout), grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants, to the extent such establishments satisfy the criteria for coverage.

Table 1 lists establishments which may be regulated under 21 CFR 101.11.

In general, covered establishments must provide the following nutrition information: (1) the number of calories contained in a standard menu item listed on a menu or menu board; (2) the number of calories contained in a standard menu item that is a self-service food or food on display on a sign adjacent to the corresponding food; and (3) additional written nutrition information upon consumer request (21 CFR 101.11(b)(2)(A)). However, some foods, such as temporary menu items, daily specials, and custom orders are not covered under these requirements. We refer to these items as “exempt foods.”

4.2 What establishments are NOT “covered establishments” and not covered by the requirements of 21 CFR 101.11?

Answer: Establishments that are not covered under 21 CFR 101.11 include establishments that are not restaurants or similar retail food establishments and that are 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. Examples include local or regional coffee shops or chain restaurants with less than

20 locations. In addition, establishments that are not covered include schools as defined by the United States Department of Agriculture (USDA) school lunch program or school breakfast programs (7 CFR 210.2 or 220.2), transportation carriers such as trains or airplanes, and lunch wagons (food trucks and sidewalk carts). Also, not covered are in-patient only food-service facilities located in hospitals because these facilities generally do not present themselves as restaurants or similar retail food establishments, nor do they offer for sale foods in the same way as restaurants or similar retail food establishments.

4.3 I am a covered establishment that offers menu items, for example, a St. Patrick’s Day Low-Fat Shamrock Smoothie, that are not covered by the menu labeling requirements in accordance with 21 CFR 101.11. I understand that if I make a nutrient content claim or health claim for my smoothie, I must provide certain nutrition labeling for the smoothie. What information am I required to provide?

Answer: For food that is not covered by the requirements of 21 CFR 101.11, if you make a nutrient content claim or health claim, you must provide certain nutrition information either by providing: (1) nutrition labeling for such food in accordance with 21 CFR 101.9 upon request; or (2) information on the nutrient amounts that are the basis for the claim, may serve as the functional equivalent of complete nutrition information as described in 21 CFR 101.9 within this context (21 CFR 101.10). In general, if you make a nutrient content claim or health claim for a food offered for sale in your establishment, you must provide information on the particular nutrient amounts that are the basis for the claim (such as, “low fat, this smoothie provides less than 3 grams of fat”) (21 CFR 101.10; see also 21 CFR 101.9(j)(2)). Such information may be provided on a counter card, sign, poster, handout, booklet, loose-leaf binder, menu, or electronic device or by other similar means.

4.4 In my covered establishment, I decide to offer my St. Patrick’s Day Low-Fat Shamrock Smoothie as a “low-fat” smoothie routinely available on my menu. Must I provide the nutrition information for my claim in the same manner (as referenced in question 4.3)?

Answer: No. If the low-fat smoothie is now routinely available in your covered establishment, it is considered a standard menu item. For food that is a standard menu item that makes a nutrient content or health claim, the information provided in the additional written nutrition information required by 21 CFR 101.11(b)(2)(ii) will serve to meet the nutrition labeling requirements of 21 CFR 101.10, provided that the written nutrition information includes information on the particular nutrient amounts that are the basis for the claim.

4.5 I am a covered establishment that offers a standard menu item making a nutrient content claim for a vitamin, for example, “Sunburst Punch- High in Vitamin C”. How must I provide the nutrient information required in 21 CFR 101.10 for the vitamin C?

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Answer: If a food that is a standard menu item makes a nutrient content claim, such as “High in Vitamin C,” you must provide this information either by providing: (1) nutrition labeling for such food in accordance with 21 CFR 101.9 upon request; or (2) information on the nutrient amounts that are the basis for the claim, which may serve as the functional equivalent of complete nutrition information as described in 21 CFR 101.9 within this context (21 CFR 101.10). Such information may be provided on a counter card, sign, poster, handout, booklet, loose-leaf binder, menu, or electronic device or by other similar means. For example, “High in Vitamin C, provides 20% of the RDI for vitamin C.”

Table 1. Examples of restaurants or similar retail food establishments that may be subject to the menu labeling regulation in accordance with 21 CFR 101.11. (To be covered, a particular establishment must meet all of the criteria for being a covered establishment, including being part of a chain with 20 or more locations)*

Type of restaurant or similar retail food establishments	Regulated under 21 CFR 101.11
Chain Bakeries	Yes
Chain Cafeterias	Yes
Chain Coffee shops	Yes
Chain convenience stores that sell restaurant-type foods	Yes
Chain delicatessens	Yes
Chain food takeout and delivery establishments (such as pizza takeout and delivery establishments)	Yes
Chain superstores that sell restaurant-type foods	Yes
Community coffee shop with less than 20 locations	No
Dining facilities at colleges and universities that are part of a chain	Yes
Food service facilities and concession stands located in entertainment venues (such as amusement parks, bowling alleys, and movie theaters) and are part of a chain	Yes
Grocery stores that sell restaurant-type foods and are part of a chain	Yes
Ice cream shops and mall cookie counters that are part of a chain	Yes
In-patient only food service facilities located in hospitals)	No
Mobile lunch wagons, food trucks, and sidewalk carts	No
Quick service restaurants, including those that located in other types of establishments, such as airports, shopping malls, and hospitals when they are part of a chain	Yes
Retail confectionary stores that are part of a chain	Yes
Schools serving meals under The National School Lunch or Breakfast Programs as defined in 7 CFR 210.2 or 220.2	No
Single or Regional Bakeries with less than 20 locations	No
Table service restaurants that are part of a chain	Yes
Transportation carriers (trains and airplanes)	No

* We note that 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 covered under the menu labeling requirements of 21 CFR 101.11.

5. Nutrition Labeling for Covered Establishments (21 CFR 101.11)

Under 21 CFR 101.11, covered establishments must provide calorie and other nutrition information for standard menu items and satisfy other applicable requirements. Which establishments (and foods) are subject to these requirements and what information they must provide is covered in this section.

Which establishments and foods are subject to the calorie and other nutrition labeling regulations at 21 CFR 101.11 (21 CFR 101.11(b)(1))?

5.1 What types of foods offered for sale in covered establishments must comply with 21 CFR 101.11, (Nutrition labeling of standard menu items in covered establishments)?

Answer: The requirements to provide calorie and other nutrition information (see questions 5.13-5.97) in 21 CFR 101.11 apply to standard menu items offered for sale in covered establishments, that is, restaurant-type foods that are routinely included on a menu or menu board or routinely offered as self-service food or food on display.

5.2 What types of foods in covered establishments are exempt from the calorie and other nutrition labeling requirements of 21 CFR 101.11?

Answer: Foods in covered establishments that are exempt from the calorie and other nutrition labeling requirements include:

- Condiments that are for general use: These include condiments that are placed on the table or kept elsewhere in the restaurant, such as on or behind a counter, and are for use by the customer.
- Daily specials: These are menu items that are offered for sale on a particular day and 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 (see definition section, #3.12).
- Temporary menu items: These are foods that appear on a menu or menu board for less than 60 days per calendar year (such as Jack O'Lantern cookies or holiday gift tins of popcorn). The days do not need to be consecutive, but must be a total of less than 60 days per calendar year (see definition section, #3.20).
- Custom order: This is an item prepared in a specific way based on a customer's request. It deviates from the covered establishment's usual preparation of a standard menu item (see definition section, #3.11).
- Food that is part of a customary market test: These are menu items that appear on a menu/menu board for fewer than 90 consecutive days and are used to test consumer acceptance of the product (see definition section, #3.15).

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- Self-service food and food on display that is offered for sale less than a total of 60 days per calendar year (such as, Jack O’Lantern cookies or holiday gift tins of popcorn) or fewer than 90 consecutive days to test consumer acceptance.
- Alcoholic beverages that are on display, but are not self-service foods: This includes bottles of alcohol that are on display behind a bar that a bartender uses to prepare drinks. (21 CFR 101.11(b)(1)(ii)) For example, mixed drinks/rail drinks that are prepared by a bartender behind the bar and that are not listed on a menu or menu board are not covered.

5.3 Are items sold from a bulk bin in a supermarket that are meant to be eaten over several eating occasions, such as loaves of bread and bags or boxes of dinner rolls considered restaurant-type food and are they required to have calorie declarations?

Answer: Generally, foods bought from bulk bins or cases in grocery stores that are meant to be eaten over several eating occasions or stored for later use would not be considered restaurant-type food and therefore would not require calorie declarations.

5.4 A covered establishment enters into a contract to sell food to a company. The company offers the food in its executive dining room at no cost to its employees. Does the company have to provide calorie information in the executive dining room?

Answer: In this case, the company’s executive dining room would not appear to be a covered establishment (see definition section, #3.5) because it is not a restaurant or similar retail food establishment that offers for sale standard menu items. Therefore, the executive dining room would not be required to provide calorie information or other nutrition information under the menu labeling final rule. Similarly, other establishments that do not offer for sale standard menu items (see definition section, #3.19), for example, hotels that offer complimentary breakfast and hospitals that provide food at no cost to the consumer, would not be considered covered establishments.

5.5 I am a covered establishment that offers off-site catering for private events. Menu items for these events are typically purchased by one or two persons from my catering menu for a large group to consume at an event at no cost. Does the catered event have to provide calorie declarations to its guests?

Answer: Similar to the executive dining room described in question 5.4, the catered event is likely not a covered establishment because it is not a restaurant or similar retail food establishment that offers for sale standard menu items. Therefore, the catered event would not be required to provide calorie information or other nutrition information under the menu labeling final rule. (For example, customers purchasing items from a catering menu for their catered event would not be required to provide calorie information or other nutrition information to the guests at their catered event.)

However, we note that the menu labeling final rule requires that the number of calories be listed on a menu or menu board for each standard menu item listed on such menu or menu board as it is usually prepared and offered for sale. As discussed in section 5.13, a menu or menu board is the primary writing of a covered establishment from which a customer makes an order selection.

The covered establishment that offers off-site catering must accordingly provide calorie declarations for standard menu items listed on its catering menu to the extent such menu meets the definition of a “menu” in the menu labeling final rule. (For example, the covered establishment would be required to include calorie declarations for standard menu items on the catering menu provided to the customers when making their purchase selections for their catered event.)

5.6 I am a third-party contractor who operates cafeterias in various buildings. Some of my locations are named with a general description of “cafeteria,” and some have a name tied to the specific location (such as, ABC Movie Theater Snack Shack). Would these cafeterias be considered “covered establishments” under the menu labeling final rule?

Answer: Such cafeterias would be covered if they are doing business under the same name and otherwise meet the criteria specified in question 4.1 above. In general, restaurants or similar retail food establishments that are doing business under the same name means that they share the same name, as either presented to the public, or, if there is no name of the establishment presented to the public, the name of the parent entity of the establishment. For the locations that do not present a name of the establishment to the public and only use a generic name, such as “cafeteria,” then the name of the parent entity would be considered as the name under which the establishment is doing business. If there are 20 or more locations of such establishment doing business under the same name and selling substantially the same standard menu items, they are covered and are required to provide calorie and other nutrition information to consumers.

If an establishment presents a name to the public, the term “name” means the name of the establishment that the public “sees,” such as on the front of the establishment or on its menus and menu boards. Within this context, the term “same” includes names that are slight variations of each other, due to things such as location (such as, “ABC Movie Theater Snack Shack” or “XYZ Movie Theater Snack Shack”) or size (such as, “ABC Movie Theater Snack Shack” or “ABC Movie Theater Snack Shack Express”). Accordingly, if a cafeteria is part of a chain with 20 or more locations doing business under the same name presented to the public, even if there are slight variations in the name, and these locations are offering for sale substantially the same menu items, then the cafeteria would be covered.

5.7 I am the owner of a chain of over 20 restaurants. Twelve of my restaurants are full-service restaurants and operate under the name Ed’s Bar & Grill. My other restaurants operate under Super Studio 3, Super Studio Lite and Super Studio Grill. These establishments are generally found in movie theaters or may be stand alone in malls. We offer four variations of expanded menus in each establishment. How would I determine whether my restaurants are covered establishments?

Answer: In general, as described in question 4.1, a covered establishment is a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items. An establishment is not covered unless each criterion for coverage is satisfied. We would consider the establishments described in the question that operate under the names “Super Studio 3,” “Super

Studio Lite” and “Super Studio Grill” to be doing business under the same name, even though there are slight variations in the names (see definition section, #3.6). To the extent these establishments are part of a chain of 20 or more locations doing business under the same name and offering for sale substantially the same menu items, they would meet the criteria for coverage under the menu labeling final rule and be required to provide calorie information and other nutrition information for standard menu items and otherwise comply with the menu labeling final rule.

We would not consider the full-service restaurant, “Ed’s Bar & Grill,” described in the question, to be doing business under the same name as the “Super Studio” restaurants. Accordingly, the number of “Ed’s Bar & Grill” locations would not count in considering whether the “Super Studio” restaurants are part of a chain with 20 or more locations. Further, because “Ed’s Bar & Grill,” as described in the question, only has 12 locations, “Ed’s Bar & Grill” would likely not be a covered establishment.

5.8 Are prisons covered under 21 CFR 101.11?

Answer: Federal prisons are primarily regulated by the Bureau of Prisons, Department of Justice at the federal level and State prisons by respective State and local government authorities. FDA does not consider prisons to be included in the definition of “restaurant or similar retail food establishment” under the menu labeling final rule.

5.9 Within stadiums and arenas, are the mobile vendors that are walking through the stands and selling food and beverages from a tray or bag required to declare calories?

Answer: The menu labeling final rule defines a covered establishment, in part, as a restaurant or similar retail food establishment that is part of a chain with 20 or more locations, with the term location referring to a fixed position or site (21 CFR 101.11(a)). Since mobile vendors walking through the stands generally do not have a fixed location or site, they would not be considered a covered establishment and would not have to meet the requirements of the menu labeling final rule.

5.10 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 food items be covered? For example, if Mary’s Seafood Restaurant only sells “Cajun-style shrimp” in its New Orleans’s location (i.e., not in any other Mary’s Seafood Restaurant across the country), would this dish be covered?

Answer: If the New Orleans location of Mary’s Seafood Restaurant is a covered establishment and the “Cajun-style shrimp” 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.

5.11 If a covered establishment has a menu item that they offer occasionally, for example once or twice a month, is that food considered a standard menu item?

Answer: No. If a covered establishment has a menu item that is not offered routinely and is being offered for less than a total of 60 days per calendar year, such menu item is not covered because it fits the definition of a “temporary menu item.”

5.12 We are a covered grocery store that prepares and offers for sale certain types of prepared foods such as barbecue meat items and pizza. Some of these items are listed on our menu or menu board, or are offered at our hot self-service buffet. We also offer certain barbecue meat items behind our deli counter. We offer these items by weight. Do we have to provide calorie and other nutrition information for these foods?

Answer: In general, our aim is to cover the food most like the food offered for sale in restaurants. If the item, for example, a two-piece barbecue chicken lunch or a slice of pizza, is routinely included on a menu or menu board, or offered at a hot self-service buffet, then that item would be covered and the covered establishment would be required to provide calorie and other nutrition information for such menu item. If, on the other hand, the food involves additional preparation, such as reheating, before consuming and is typically eaten over several eating occasions or stored for later use, such food would generally not be covered (such as, cold, prepared barbecue meat items offered from behind a deli counter sold by weight rather than by piece and that is generally reheated by the consumer before being eaten).

What labeling is required on a menu or menu board for standard menu items in covered establishments?

- General information

5.13 What is a menu or menu board?

Answer: Menus and menu boards are 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; takeout menus; menus mailed or delivered from a restaurant; other specialty menus (such as, catering); electronic menus; and menus on the Internet. The primary writing of a covered establishment can include more than one form of written material; the critical factor is whether the written material is or is part of the primary writing of a covered establishment from which a customer makes an order selection.

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. The menus may be in different forms such as a booklets, pamphlets, or single sheets of paper. Menu boards include mounted or free standing panels inside or outside a covered establishment including those used in counter service or drive-in or drive-through service. (See also definition section, #3.23)

5.14 What nutrition information must be provided on a menu or menu board for standard menu items listed on such menu or menu board in a covered establishment?

Answer: The following nutrition information must be provided on a menu or menu board for standard menu items listed on such menu or menu board in a covered establishment:

- The number of calories in each listed standard menu item as usually prepared and offered for sale (21 CFR 101.11(b)(2)(i)(A)). (See questions 5.19-5.46)
- The following succinct statement designed to enable consumers to understand the significance of the calorie information provided on menus and menu boards in the context of a total daily diet (21 CFR 101.11(b)(2)(i)(B)):

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

(See questions 5.47-5.52)

- A statement regarding the availability of additional written nutrition information, as follows (21 CFR 101.11(b)(2)(i)(2)(C)):

Additional nutrition information available upon request.

(See questions 5.49, 5.53-5.55)

- Menu/Menu Board

5.15 I am a covered establishment that also has a catering menu. On my catering menu I offer some menu items that are offered through my regular establishments and some items that are only offered on my catering menu. Do I have to declare calories for all of the menu items on this catering menu?

Answer: As discussed in section 5.13, the primary writing of a covered establishment can include more than one form of written material, including the catering menu of a covered establishment. To the extent a catering menu meets the definition of a “menu” in the menu labeling final rule, such catering menu must meet the requirements of the menu labeling final rule. All items listed in the catering menu that meet the definition of a standard menu item would require calorie declarations.

5.16 If a combination meal is pictured along with its name on the menu, and then another section of the menu includes the name, description and price of that item, do calories need to be listed in both sections of the menu?

Answer: If the name, price, and calories of the combination meal in accordance with the requirements of 21 CFR 101.11 are listed in another section of the menu then it would likely not be necessary to list calories where the combination meal is pictured.

Contains Nonbinding Recommendations

For example, on the menu/menu board, a plate with eggs, bacon, French toast, and grits is pictured and directly beneath that picture is the name of the combination meal (such as, Aunt Cora's French toast breakfast). If Aunt Cora's French toast breakfast is also listed in a separate section of the menu and includes the calorie declarations for the entire combination meal then the calorie declaration would not be needed next to the picture of the combination meal since the consumer would have the calorie information elsewhere on the menu.

Similarly, a menu/menu board might describe an opportunity for a consumer to combine standard menu items for a special price (such as, "Combine Any Sandwich with Any Soup or Any Salad for \$8.99), using pictures of those items (such as, a picture of a sandwich, a bowl of soup, and a salad). If the calories for each standard menu item available to combine for the special price, including each size option available for the consumer to combine, are declared elsewhere on the menu/menu board, then the calorie declarations are not required next to the pictures of the items that can be combined for the special price listed.

5.17 If a pizza coupon that states "1 large 2 topping pizza \$9.99" is attached to a takeout menu, does the menu item on this coupon require calorie information?

Answer: If a coupon for a standard menu item states "1 large 2-topping pizza \$9.99" and is attached to a takeout menu where the calories for such standard menu item are declared elsewhere on the takeout menu, then a calorie declaration on the coupon would not be needed, as consumers would already have access to the calorie information for the standard menu item elsewhere on the menu. For a stand-alone coupon, if it can be used to place an order (i.e. it contains the name of a standard menu item, its price, and a phone number or website where the customer can place an order), then the calorie declaration would need to be provided in accordance with 21 CFR 101.11(b)(2)(i)(A).

5.18 Is marketing material required to bear calorie information? For example, if a pizza coupon that includes a phone number or web address where the customer can place an order states "1 large pepperoni and sausage pizza \$9.99," does the menu item on this coupon require calorie information?

Answer: The menu labeling final rule requires that covered establishments declare calories for standard menu items listed on menus and menu boards. As defined in the menu labeling final rule, a menu or menu board includes any writing of the covered establishment that is a primary writing from which a consumer can make an order selection. As discussed in question 5.13, determining whether a writing is or is part of the primary writing from which a consumer 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 consumer to make an order selection at the time the consumer is viewing the writing.

Using these factors, advertising or marketing material (including coupons) generally would not be considered menus or menu boards. However, in the example of a pizza coupon that includes a phone number or web address where the customer can place an order and that states "1 large pepperoni and sausage pizza \$9.99," the "coupon" can be used by a consumer to make an order

Contains Nonbinding Recommendations

selection at the time a consumer is viewing the coupon (i.e., the coupon includes the name of the standard menu item, price of the standard menu item and a phone number or web address where an order can be placed). Therefore, in this situation, the coupon would be considered a menu (and not simply a coupon) and would be required to include a calorie declaration for the listed standard menu item. (21 CFR 101.11(a))

If the coupon did not include a web address for placing orders and there is no phone number provided for placing orders, then the coupon would not be considered a menu and a calorie declaration would not be required on the coupon.

- Declaration of calories on the menu or menu board (21 CFR 101.11(b)(2)(i)(A))

5.19 How do I list calorie information for a standard menu item that is offered as a multiple-serving item?

Answer: In this case the calories must be declared for the whole menu item as usually prepared and offered for sale (such as, “pizza pie 1,600 cal” or “bowl of spinach dip 980 cal”) or per discrete serving unit if the unit (such as, individual pre-portioned units such as pizza slices) and total number of units contained in the menu item are declared and the menu item is usually prepared and offered for sale divided into these discrete units (such as, “pizza pie 200 cal/slice, 8 slices”). (21 CFR 101.11(b)(2)(i)(A))

5.20 How do I list calorie information for a multi-serving standard menu item that includes several types of foods (such as, wings, cheese sticks and potato skins on one appetizer plate) or that may be served with sauce?

Answer: For a multi-serving standard menu item that includes several types of foods, you must declare calories for the whole menu item as usually prepared and offered for sale (such as, the entire appetizer plate) or you may, alternatively, decide to declare calories per discrete serving unit, in accordance with 21 CFR 101.11(b)(2)(i)(A). If you declare calories per discrete serving unit, you should declare the calories for each type of discrete serving unit available in the menu item (such as, “appetizer sampler: 80 cal/wing, 5 wings; 170 cal/cheese stick, 5 cheese sticks; 280 cal/loaded potato skin, 5 loaded potato skins).

If the menu item is usually prepared and offered for sale with sauce(s), then calories for the sauce(s) must also be included in the calorie declaration for the multi-serving standard menu item. If the options for the sauces are individually listed on the menu or menu board as part of the multi-serving standard menu item, then the calorie declarations for each sauce would also need to be included in accordance with 21 CFR 101.11(b)(2). However, such calorie declarations for each individually listed sauce would not be necessary if the sauce options and their calorie declarations are already individually declared elsewhere on the menu or menu board.

5.21 I am a covered establishment and offer a catering menu that lists standard menu items that are sold in an array of party platters. These party platters contain one or

more different types of pre-set selections of standard menu items, for example, a platter of deviled eggs or assorted turnovers. How do I declare calories for these party platters?

Answer: For such platters, the calorie declaration must either be for the entire platter listed on the menu, or, if the platter is usually prepared and offered for sale in discrete units (such as, deviled egg, turnover), per discrete serving unit, provided the discrete serving unit and the total number of discrete serving units contained in the menu item are also declared on the menu (such as, “Platter of deviled eggs: 840 calories” or “Platter of deviled eggs: 70cal/deviled egg, 12 deviled eggs” or “Platter of turnovers: 3600 calories” or “Platter of turnovers: 60cal/turnover, 60 turnovers”).

5.22 My catering menu also lists platters that consist of standard menu items that are variable menu items. For example, my menu lists a platter of sandwich selections that include turkey, roast beef, or veggie sandwich options on a choice of bread. How do I declare calories for these platters?

Answer: For such platters, a calorie declaration must be provided for each individual variable menu item, consistent with the requirements of 21 CFR 101.11(b)(2)(i)(A)(4). In general, for multiple-serving standard menu items, such as platters, calories may be declared per discrete serving unit, as long as the discrete serving unit and the total number of discrete serving units contained in the menu item are declared on the menu or menu board. In this case, because the number of calories in each type of discrete serving unit (such as, each type of sandwich) can vary based on the customer’s selection, disclosing the total number of discrete serving units is unlikely to be helpful to consumers. Accordingly, establishments should only disclose calories per discrete serving unit for each variety offered. Below are examples of how calories can be declared for platters listed on a catering menu that consist of sandwiches that are offered with wheat or Italian bread:

Sandwich Selections

<u>Sandwich</u>	<u>Wheat Bread/ Italian Bread</u>
Turkey	110 Cal/120 Cal
Roast Beef	120 Cal/130 Cal
Veggie	80 Cal/90 Cal
Ham & Cheese	150 Cal/160 Cal

Party Pinwheel Sandwiches

<u>Sandwich</u>	
Turkey Avocado with Bacon	200 Cal
Italian	200 Cal
Roast Beef	150 Cal
Veggie	110 Cal
Ham & Cheese	180 Cal

5.23 Where should the calorie information be located on a menu or menu board? Are there additional requirements for calorie declarations on electronic menus or menus on the Internet?

Answer: The number of calories must be listed adjacent to the name or price of the associated standard menu item. (21 CFR 101.11(b)(2)(i)(A)(1))

In general, the calorie declaration requirements for electronic menus and menus on the Internet are the same as the requirements for printed menus. If electronic menus or menus on the Internet meet the definition of a menu in the menu labeling final rule (see definition section, #3.23), then they must meet the requirements of the menu labeling final rule including listing the number of calories adjacent to the name or price of the associated standard menu item. Calories may not be listed on a webpage or screen that is separate from the associated menu item listed on the electronic or Internet menu.

5.24 In what format must I present the required calorie information on menus or menu boards?

Answer: The calories must be in a type size that is no smaller than that used for the name or price of the associated standard menu item, whichever is smaller. The calorie declaration must be in the same color or one that is at least as conspicuous as that used for the name of the associated standard menu item; and the contrasting background of the calorie declaration must be the same or at least as contrasting as that used for the associated standard menu item. (21 CFR 101.11(b)(2)(i)(A)(1))

5.25 Must I round the number of calories?

Answer: Yes. The table below shows how to round the number of calories in accordance with 21 CFR 101.11(b)(2)(i)(A)(2).

Number of calories in standard menu item	Round to
Fewer than 5 calories	0 or 5 calories
5-50 calories	Nearest 5-calorie increment
More than 50 calories	Nearest 10-calorie increment

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

5.26 How do I specify that the calorie declaration is the number of calories contained in the associated standard menu item as opposed to something else such as the price?

Answer: You must identify the calories using the term “Calories” or “Cal.” If the caloric values are listed for each standard menu item in a column, the term “Calories” or “Cal” must appear as

a heading above that column. 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 item on that menu or menu board in the same color or one that is 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 and in the same color and contrasting background as the number of calories. (21 CFR 101.11(b)(2)(i)(A)(3))

5.27 Must I always list the calories in a column?

Answer: No. You could include the term “Calories” or “Cal” adjacent to the number of calories for the associated standard menu item. In that case, the term “Calories” or “Cal” must be in the same type size, and use the same color and contrasting background as the number of calories. (21 CFR 101.11(b)(2)(i)(A)(3))

5.28 How do I declare the calories for standard menu items listed on my menu that have a number of flavors or variety of ways the items may be prepared? For example, I might have a soft drink, ice cream, doughnuts, or dips that come in several flavors or chicken that may be grilled or fried.

Answer: When you offer a number of flavors or varieties for standard menu items (such as soft drinks, ice cream, doughnuts, or dips) or ways that a standard menu item may be prepared (such as baked or fried chicken), you must list the calories separately for each flavor or variety listed on the menu or menu board. (21 CFR 101.11(b)(2)(i)(A)(4)(i)) If your menu or menu board does not list each flavor or variety for an entire individual variable menu item and only includes a general description of the variable menu item (such as, “soft drinks,” “ice cream”), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available, or as a range where more than two options are available. (21 CFR 101.11(b)(2)(i)(A)(4)(ii))

- Calorie Disclosures

5.29 The menu labeling final rule permits the term “calories” or “cal” to appear as a heading above a column listing the number of calories for each standard menu item (instead of adjacent to the number of calories for each standard menu item). Can the term “calories” appear at the beginning of a list of the standard menu options? For example:

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

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

Answer: Yes. Such format can be used, provided that the type size, color, and contrasting background requirements of 21 CFR 101.11(b)(2)(i)(A)(3) are satisfied, as such format would

help ensure that the calorie declaration is clearly associated with a particular standard menu item and the use of the term “Calories” would help inform consumers that the number listed refers to calories.

5.30 If the varieties of a variable standard menu item are listed on my menu and all varieties have the same caloric value, must I list the calories for each variety, or may I give one calorie declaration for the variable menu item?

Answer: Where flavors or varieties of a variable menu item are listed on the menu or menu board and have the same calorie amounts (after rounding in accordance with 21 CFR 101.11(b)(2)(i)(A)(2)), you may give one calorie declaration adjacent to such flavors or varieties, provided it is clear that the calorie declaration represents the calorie amounts for each individual flavor or variety listed. (21 CFR 101.11(b)(2)(i)(A)(4)(i))

5.31 How do I declare the calories if my menu does not list specific flavors or varieties of an individual variable menu item but instead gives only a general description of the variable menu item such as “soft drinks”?

Answer: If your menu does not list flavors or varieties for an individual variable menu item and only includes a general description of the variable menu item (such as, “soft drinks”), you must declare the calories for each option with a slash between the two calorie declarations where only two options are available, such as soft drinks 150/250 calories. If more than two options are available, then you must declare the calories for the menu item in a range, such as soft drinks 100-250 calories. (21 CFR 101.11(b)(2)(i)(A)(4)(ii))

5.32 How do I declare the calories if my menu or menu board describes flavors or varieties for only part of an individual variable menu item such as “grilled cheese (cheddar, Swiss, or Colby)”?

Answer: If two options are available, you must declare the calories for each option with a slash between the two calorie declarations, such as 450/500 calories. If more than two options are available, then you must declare the calories as a range, such as 450-550 calories. (21 CFR 101.11(b)(2)(i)(A)(4)(iii))

5.33 Can a food item that is listed on the menu in different sizes be considered a variable menu item?

Answer: No. A standard menu item offered in various sizes is not considered a variable menu item unless it comes in different flavors, varieties, or combinations and is listed as a single menu item. When a standard menu item, including a beverage, is listed on a menu or menu board by name with different sizes, or each size has its own price, each size would constitute a standard menu item rather than a different flavor, variety, or combination, and each standard menu item must include a calorie declaration.

5.34 How should menus or menu boards declare calories for variable menu items that are offered for sale with the option of adding toppings listed on the menu or menu board (such as, pizza, ice cream)?

Answer: The menu or menu board must declare the calories for the basic preparation of the standard menu item as listed (such as, single scoop ice cream). The calories must also be separately declared for each topping listed on the menu or menu board and indicate that the calories for each topping are added to the calories in the basic preparation of the menu item. If the toppings have the same calorie amounts (after rounding), they can be grouped, but the declaration must specify that the calorie amount listed is the calorie amount for each individual topping.

Ice cream scoop: 300 cal

Toppings	Added Cal
Almonds	25
Fudge	50

(21 CFR 101.11(b)(2)(i)(A)(5)(i) and (ii))

5.35 My menu lists pizzas and other menu items in various sizes with the option of adding various toppings. How do I declare the calories for these items?

Answer: The calories for the basic preparation of the menu item must be declared for each size of the menu item. The calories for each topping listed on the menu must be declared for each size of the menu item or, if there are only two sizes of the menu item, declared for each topping using a slash (such as, “adds 150/250 cal”) or if there are more than two sizes, declared as a range (such as, “adds 100-250 cal”). (21 CFR 101.11(b)(2)(i)(A)(5)(iii))

5.36 When a pizza, for example, is ordered with multiple toppings, we provide less of each topping based on the total number of toppings ordered for the menu item. How do we declare calories for such menu items to account for this variation?

Answer: If the amount of the topping included on the basic preparation of a menu item decreases based on the total number of toppings ordered for the menu item, the number of calories for each topping must be declared as single values representing the number of calories for each topping when added to a single topping menu item, specifying that the calorie declaration is for the topping when added to a single topping menu item, such as “pepperoni 200 added calories for a one-topping pizza.” (21 CFR 101.11(b)(2)(i)(A)(5)(iv))

5.37 Can I use a table to declare the amount of calories for each topping listed on my menu or menu board? If so, could you provide examples?

Answer: Yes. See below for tables that provide examples of the calorie declaration requirements for pizza that is offered for sale in different sizes and with the option of adding

Contains Nonbinding Recommendations

toppings listed on the menu or menu board (see questions 5.34-5.35). Note that toppings that have the same number of calories may be grouped together.

Example 1:

Plain pizza pie: Small (12") 500 cal, Medium (14") 750 cal, Large (16") 1,000 cal

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

Example 2:

Plain pizza pie: Small (12") 500 cal, Medium (14") 750 cal, Large (16") 1,000 cal

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

5.38 For menu items that are offered for sale in different sizes, can we use a "+" sign instead of Adds (such as "+ XXX Cal") and "-" sign instead of Subtracts (such as, "- XXX Cal")?

Answer: Symbols could be confusing to consumers because a "-" (minus) symbol could be mistaken for a bullet point, which would not convey the subtraction of calories, or a dash, which is used for declaring calorie ranges. "Add" or "subtract" should be spelled out in letters, but other terms such as "minus" or "less" could be substituted in place of "subtracts."

- Combination Meals

5.39 I offer for sale a combination meal that includes a sandwich and a choice of sides. The menu lists the combination meal as a single menu item, including the options for menu items in the combination meal. How do I provide the calories for that meal?

Answer: If the menu lists a choice of two sides with the combination meal, such as a sandwich with a choice of side salad or chips, you must declare the calories for each option with a slash between the two calorie declarations, such as “350/450 calories.” If you list a menu item with a choice of three or more options, such as a sandwich with a choice of chips, side salad, or fruit, you must declare the calories as a range, such as “350-500 calories.” (21 CFR 101.11(b)(2)(i)(A)(6)(i) and (ii))

5.40 How do I declare the calories in a combination meal listed on the menu or menu board if the meal comes in multiple sizes with multiple choices of sides?

Answer: When the menu or menu board includes an opportunity to increase or decrease the size of a combination meal, you must declare the calorie difference for the increased or decreased combination size using terms such as “adds” or “subtracts” and specify the number of calories added or subtracted based on the size. As in question 5.39 above, when the menu or menu board lists two options for sides in a combination meal, you must declare the calorie difference for the increased or decreased size using a slash between the two calorie declarations, for example, “adds 100/150 calories,” or “subtracts 100/150 calories.” When the menu or menu board lists three or more options for sides in a combination meal, you must declare the calorie difference for the increased or decreased size as a range, for example, “adds 100-250 calories,” or “subtracts 100-250 calories.” (21 CFR 101.11(b)(2)(i)(A)(6)(iii))

Example 1:

Cheeseburger Meal (550/600 calories).....	\$5.99
(comes with medium sized fries or medium sized onion rings)	
Large (adds 60/110 calories).....	\$6.99

In this example, the combination meal only allows the option to upsize either the fries *or* the onion rings. There are only two options and therefore the calorie declaration for the additional calories would be separated with a slash.

Example 2:

Cheeseburger Meal (550-720 calories).....	\$7.99
(comes with medium sized fries or medium sized onion rings and medium drink)	
Small (subtracts 50-100 calories)	

This example assumes that there are several options for the type of drink that can be ordered as part of the standard menu item including a 0 calorie drink. Thus, in this example, the standard menu item is a combination meal that includes a variable menu item, i.e. medium drink. Consequently, the calorie declarations would be listed as a range for both the standard menu item as usually prepared and offered for sale as well as the declarations for changing the size of the sides and the drink.

5.41 My menu offers combinations of standard menus items, such as a soup and sandwich, for a special price. I offer both menu items separately. How do I declare calories for these combinations?

Answer: Where the menu or menu board describes an opportunity for a consumer to combine standard menu items for a special price (such as, “Combine any soup with a sandwich for \$8.99”), and the calories for each standard menu item, including calories for each size option, if applicable, that may be combined, are declared elsewhere on the menu or menu board, you do not need to also declare the calories for the combinations in a range. (21 CFR 101.11(b)(2)(i)(A)(6)(iv))

5.42 What format should I use when declaring calories in a range?

Answer: When declaring calories for an individual variable menu item, combination meal, or toppings as a range, the format “xx-yy” must be used, 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))

5.43 If the food items that make up a combination meal are individually listed on the menu or menu board, can the calories be listed separately for each component, rather than as a total for all items in the combination meal? An example appears below:

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.

Answer: The menu items described constitute combination meals that include variable menu items (i.e., the sides), as defined by the menu labeling final rule. The requirements for declaring calories for such combination meals depends on how such menu items are listed on a menu or menu board and how many options are listed for menu items in the combination meal. If the menu or menu board lists three or more options for the sides in the combination meal, then the calories for the combination meal must be declared as a range. However, for the example described above, you can declare the calories for each food item that makes up a combination meal, as declaring calories in this manner would provide consumers with more specific calorie information for foods that make up a combination meal. Further, in the example above, the placement of the calorie declaration may also follow the description of the associated standard

menu item, because it is likely that a consumer would be able to clearly associate each calorie declaration with its associated standard menu item.

5.44 How should I declare the calories on the menu or menu board for items in my “all-you-can-eat” buffet?

Answer: If such item appears on the menu or menu board, then the menu or menu board must include a statement next to the name or price of the item on the menu board that refers the customer to the self-service station for calorie information, such as “See the buffet for calorie information.” See also questions 5.76-5.92. (21 CFR 101.11(b)(2)(i)(A)(8))

5.45 What are the type size, color, and background requirements for the statement described in question 5.44 that refers customers to the self-service facility for calorie information?

Answer: The size of the type for this statement must be no smaller than the type size for the name or price of the menu item (whichever is smaller). The statement must also be in the same color or a color at least as conspicuous as that used for that name or price and have the same contrasting background or a background at least as conspicuous as that used for that name or price. (21 CFR 101.11(b)(2)(i)(A)(8))

5.46 What calorie requirements apply to beverages that are not self-service?

Answer: When declaring the calories in a beverage that is not self-service, you must state the number of calories in the full volume of the cup as 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 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 the number of calories based on such standard beverage fill or standard ice fill. (21 CFR 101.11(b)(2)(i)(A)(9))

- Succinct statement and statement regarding the availability of additional written nutrition information (21 CFR 101.11(b)(2)(i)(B) and (C))

5.47 What must the succinct statement that is required on menus and menu boards say?

Answer: The following succinct statement must be provided on menus and menu boards:

“2,000 calories a day is used for general nutrition advice, but calorie needs vary.” (21 CFR 101.11(b)(2)(i)(B))

5.48 I have a children’s menu. Is there a different statement that I can use on this menu?

Answer: Yes. For menus and menu boards targeted to children, you may use the following statements 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)) A statement specifically targeted to the calorie needs of children may enable parents and children to make informed dietary choices.

5.49 Some establishments, such as movie theater concession stands, use digital menu boards with a rotating display that may have multiple panels, some of which list standard menu items and some of which do not. How should such digital menu boards incorporate the succinct statement and statement of availability of additional written nutrition information?

Answer: The succinct statement and the statement of availability need only appear on rotating displays of such digital menu boards that list standard menu items. Additionally, if the covered establishment has multiple digital menu boards with rotating displays, then the statements should appear on each rotating display of each digital menu board that lists standard menu items to help ensure that the statements are clear and conspicuous to the consumer and posted prominently. In general, for the purposes of the menu labeling final rule, we consider a multi-paneled menu board to be a single menu board if the entire multi-paneled board is visible to consumers when consumers are placing order selections for the standard menu items listed on such menu board. For menu boards, the succinct statement and the statement of availability must appear on the bottom of the menu board, as required by 21 CFR 101.11(b)(2)(i)(B)(3) and 21 CFR 101.11(b)(2)(i)(C)(3), and must be visible to consumers when consumer are placing order selections for the standard menu items listed on such menu board, and otherwise meet the applicable format requirements in 21 CFR 101.11(b)(2)(i)(B)(1) and 21 CFR 101.11(b)(2)(i)(C)(1).

5.50 What is the purpose of the succinct statement?

Answer: The succinct statement is designed to enable consumers to understand the significance of the calorie information provided on menus and menu boards in the context of a total daily diet.

5.51 Where must I place the succinct statement on menus and menu boards?

Answer: For menus, the succinct statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement “Additional nutrition information available upon request,” as required by 21 CFR 101.11(b)(2)(i)(C), the succinct statement must appear immediately above, below, or beside the statement of availability required by paragraph 21 CFR 101.11(b)(2)(i)(C). For menu boards, the succinct statement must appear at the bottom of the menu board, immediately above, below, or beside the statement of availability required by 21 CFR 101.11(b)(2)(i)(C). (21 CFR 101.11(b)(2)(i)(B)(2) and (3))

5.52 What are the type size, color, and background requirements for the succinct statement?

Answer: The succinct statement must be posted on the menu or menu board prominently and in a clear and conspicuous manner. The type size of the succinct statement must be no smaller than

the smallest type size of any calorie declaration that appears on the same menu or menu board. The succinct statement must be in the same color or in a color at least as conspicuous as that used for the calorie declarations, and must have 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)(I))

5.53 What must the statement regarding the availability of additional written nutrition information say?

Answer: Menus and menu boards must provide the following statement regarding the availability of the additional written nutrition information required in 21 CFR 101.11(b)(2)(ii), “Additional nutrition information available upon request” (statement of availability). (21 CFR 101.11(b)(2)(i)(C))

5.54 What are the type size, color, and background requirements for the statement of availability on menus and menu boards?

Answer: You must post the statement of availability on the menu or menu board prominently and in a clear and conspicuous manner. The type size of the statement of availability must be no smaller than the smallest type size of any calorie declaration that appears on the same menu or menu board. The statement of availability must be in the same color or in a color at least as conspicuous as that used for the calorie declarations, and must have 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)(I))

5.55 Where must I place the statement of availability on menus and menu boards?

Answer: For menus, the statement of availability must appear on the bottom of the first page with menu items. For menu boards, the statement of availability must appear on the bottom of the menu board. For both menus and menu boards, the statement of availability must be placed immediately above, below, or beside the succinct statement required by 21 CFR 101.11(b)(2)(i)(B). (21 CFR 101.11(b)(2)(i)(C)(2) and (3))

- Nutrition information that must be available in written form (21 CFR 101.11(b)(2)(ii))

5.56 What other nutrition information must be available in written form for standard menu items in covered establishments?

Answer: You must make available nutrition information for each standard menu item in a covered establishment. This information must be in written form, must be available on the premises of the covered establishment, and must be provided to customers upon request. (21 CFR 101.11(b)(2)(ii))

5.57 Since I sell many of my standard menu items for home delivery, do I need to provide calorie information for those standard menu items listed on a “delivery” menu?

Answer: Yes.

5.58 Must I provide the written nutrition information for standard menu items listed on the “take out” menu?

Answer: Yes, written nutrition information is required to be available to the customer upon request for standard menu items on the take-out menu and must be on the premises of the covered establishment. The covered establishment should determine the most feasible way to provide this information to the customer for food that is delivered, as long as the applicable requirements are satisfied. For example, the covered establishment could deliver the written nutrition information with the standard menu item ordered by a consumer if the consumer requests the information. (21 CFR 101.11(b)(2)(ii)) Please note that the “take-out” menu must also include the succinct statement required by 21 CFR 101.11(b)(2)(i)(B) and the statement of availability of the written nutrition information required by 21 CFR 101.11(b)(2)(i)(C).

5.59 What nutrition information must be available in written form on the premises of the covered establishment when a customer requests nutrition information for standard menu items?

Answer: For each menu item, the following nutrients must be listed in the order specified below, using the measurements specified:

Total calories (cal)

Calories from fat (fat cal)

Total fat (g)

Saturated fat (g)

Trans fat (g)

Cholesterol (mg)

Sodium (mg)

Total carbohydrate (g)

Dietary fiber (g)

Sugars (g)

Protein (g)

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

5.60 Must I round the nutrients required in the written nutrition information?

Answer: Rounding of the nutrients is required in the written nutrition information and must be in compliance with 21 CFR 101.9(c). Please see [Appendix A](#) for rounding rules. (21 CFR 101.11(b)(2)(ii))

5.61 How should I present the written nutrition information?

Answer: You must present the written nutrition information in a clear and conspicuous manner. The written nutrition information must use 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. (21 CFR 101.11(b)(2)(ii))

5.62 How should the written nutrition information be provided for a standard menu item that contains insignificant amounts of some of the required nutrients?

Answer: If a standard menu item contains insignificant amounts of six or more of the required nutrients, the written nutrition information may be presented in a simplified format, as specified in 21 CFR 101.11(b)(2)(ii)(B). (See questions 5.64-5.66.) (21 CFR 101.11(b)(2)(ii)(B)) Note that this format is different from the simplified format specified in 21 CFR 101.9(f).

5.63 How should the written nutrition information be provided for a standard menu item that contains insignificant amounts of all of the required nutrients?

Answer: If a standard menu item contains insignificant amounts of all nutrients required to be listed in the written nutrition information (see question 5.64), a covered establishment is not required to provide written nutrition information for such standard menu item. (21 CFR 101.11(b)(2)(ii)(B)) However, if the covered establishment makes a nutrient content claim or health claim, the establishment is required to 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))

5.64 What is considered an insignificant amount of a nutrient?

Answer: An insignificant amount of a nutrient is an amount that can be declared as zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, an insignificant amount is an amount that can be declared as “less than one gram.” ([See Appendix A](#)) (21 CFR 101.11(b)(2)(ii)(B)(I))

5.65 How must the simplified format be presented, and what nutrient information must be provided?

Answer: The simplified format must be presented in a column, list, or table. It must include information for total calories, total fat, total carbohydrates, protein, and sodium. In addition, if calories from fat and any other nutrients identified in 21 CFR 101.11(b)(2)(ii)(A) (i.e., saturated fat, trans fat, cholesterol, dietary fiber, sugars) are present in more than insignificant amounts,

they must also be included in the simplified format of the written nutrition information. (21 CFR 101.11(b)(2)(ii)(B)(2))

5.66 Is any other information required as part of the simplified format?

Answer: Yes. If you use the simplified format, you must include at the bottom of the list of nutrients the statement “Not a significant source of ____.” The blank must be filled in with the names of the nutrients (including calories from fat) that are required to be listed in the written nutrition information (see question 5.59) that are present in insignificant amounts. (21 CFR 101.11(b)(2)(ii)(B)(3))

5.67 How do I provide the written nutrition information for my variable menu items?

Answer: In general, for each size of the variable menu item offered for sale, you must provide the written nutrition information (see question 5.59 for required nutrients) for the basic preparation of the item and separately for each topping, flavor, or variable component. (21 CFR 101.11(b)(2)(ii)(C)(1))

5.68 When there are multiple toppings available for selection on my pizza, I decrease the amount of each topping based on the total number of toppings ordered by the consumer. How should I provide the written nutrition information for this item?

Answer: For each size of such pizza, you must declare the amount of each nutrient for each topping as a single value representing the amount of each nutrient for each topping when added to a single topping pizza. In this case, you must state that the nutrient declarations are for the topping when added to a one topping pizza, such as “pepperoni, total calories: 200 calories, calories from fat: 90 calories, total fat: 10 g, etc., when added to a one-topping pizza.” (21 CFR 101.11(b)(2)(ii)(C)(2))

5.69 I am a covered establishment and I have a kiosk that consumers can use to order made-to-order subs. How do I declare calorie information for such foods?

Answer: Where 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. If there is no basic preparation of the menu item that the customer starts with, and the customer instead selects each item that would make up the made-to-order sub (such as, bread, meat), then the calorie information should be provided for each item that makes up the sub as that item is displayed for selection on the kiosk. For example, “6-inch wheat bread – 210 Cal.” Further, if the software of the kiosk permits, the total calorie content of the sub may also be provided to the customer once the order is complete. (21 CFR 101.11(b)(2)(iii)(A))

If there is a basic preparation of the menu item, for example, a turkey sandwich with provolone cheese on white bread (350 calories), for which the customer would select toppings at the kiosk to add to the basic preparation of the menu item, then the covered establishment should declare calories for each topping in accordance with 21 CFR 101.11(b)(2)(i)(A)(5). For example, if you

add mayonnaise to a sandwich at the kiosk, the kiosk would include a calorie declaration for the mayonnaise option such as “adds 90 calories.”

5.70 How and where should I provide the succinct statement on such kiosk in my covered establishment?

Answer: Where such kiosk constitutes a menu, the succinct statement must be posted 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 and 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)). For menus, the succinct statement must appear on the bottom of each page of the menu. Similarly, in the case of a kiosk that constitutes a menu, the succinct statement should appear on each screen of the kiosk.

5.71 How and where should I provide the statement of availability on such kiosk in my covered establishment?

Answer: Where such kiosk constitutes a menu, the statement of availability must be posted 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 and 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)) For menus, the statement of availability need only appear on the bottom of the first page of the menu with standard menu items. Similarly, in the case of a kiosk that constitutes a menu, the statement of availability need only appear on the first screen with standard menu items.

5.72 For some of my variable menu items that are standard menu items, the nutrient values are the same for different flavors, varieties, or variable components of a combination meal. How should I declare the required nutrient values for the written nutrition information when they are the same for different flavors, varieties, or variable components?

Answer: If the calories and other nutrient values are the same for different flavors, varieties, or variable components of a combination meal, then those items that have the same nutrient values may be listed together with the nutrient values listed only once (for example “honeydew or cantaloupe 50 calories” or “curly fries or regular fries 200 calories.”) Other flavors, varieties, or variable components that do not have all of the same calorie or other nutrient values must be listed separately. (21 CFR 101.11(b)(2)(ii)(C)(3))

5.73 What are the various types of materials that I may use to provide the required written nutrition information?

Answer: You may provide written nutrition information (see question 5.59) for each standard menu item using various materials. Such material may include counter cards, signs, posters,

handouts, booklets, loose leaf binders, electronic devices, menus, or any other form of written material that similarly permits the written declaration of the required nutrient content information for all standard menu items.

If the written nutrition information for the standard menu items 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 to review the written nutrition information upon request. (21 CFR 101.11(b)(2)(ii)(D))

5.74 Can I comply with the requirements to provide written nutrition information to customers upon request by providing only an app or Internet link at my location?

Answer: You can provide the written nutrition information required by 21 CFR 101.11(b)(2)(ii) to consumers at your covered establishment using an app or Internet link, provided access to the written nutrition information is available on the premises of the establishment (such as, at a kiosk or other electronic device available at the establishment) and provided to the consumer upon request without the need for customers to supply their own electronic device. (21 CFR 101.11(b)(2)(ii)(D))

In addition to ensuring that written nutrition information is available on the premises of the establishment, a covered establishment also could provide the written nutrition information on its website or include a link directing the consumer to a website providing the written nutrition information for consumers ordering from an Internet menu on a covered establishment's website. However, website information cannot replace the requirement for written information being available at the covered establishment for consumers without their own electronic device.

5.75 If I voluntarily provide calorie information for my menu items but do not voluntarily register under 21 CFR 101.11(d) to become subject to the menu labeling final rule, am I required to make additional written nutrition information available upon consumer request?

Answer: No. The requirement to provide additional written nutritional information to consumers upon request only applies to covered establishments, including establishments that voluntarily register to be subject to 21 CFR 101.11. However, for establishments that are not covered by the menu labeling final rule and have not voluntarily registered to be subject to the menu labeling final rule, providing calorie information would be considered a nutrient content claim, and the establishment would have to follow the provisions in 21 CFR 101.10.

- Information required for standard menu items that are self-service or on display (21 CFR 101.11(b)(2)(iii))

5.76 Am I required to provide calorie information for my standard menu items that are self-service (such as, buffet) or on display if they are not listed on a menu or menu board?

Answer: Yes. You must specify the calories for standard menu items that are self-service or food on display per displayed food item (for example, per bagel, per slice of pizza, per muffin) or per serving (for example, per scoop, per cup), as well as the serving or discrete unit used to determine the calorie content. (21 CFR 101.11(b)(2)(iii)(A))

5.77 Where must I place the calorie information?

Answer: There are three options for the placement of calorie information for standard menu items that are self-service foods or foods on display. One option is to place the calorie information on a sign adjacent to and clearly associated with the food for which the calories are provided. (21 CFR 101.11(b)(2)(iii)(A))

Another option is to provide the calorie information on a sign attached to the sneeze guard (glass should be positioned above the food at about chest height). (21 CFR 101.11(b)(2)(iii)(A))

The third option is to place the calorie information on 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 menu item while the consumer is selecting that item. (21 CFR 101.11(b)(2)(iii)(A))

5.78 Are there special requirements for posting calorie information on the sneeze guard?

Answer: Yes. If you place the calorie information on the sneeze guard, a sign with the calorie declaration and the serving or unit used to determine the calorie content must be above each specific food so that the consumer can clearly associate the calorie declaration with the food to which it applies. If it is not clear from the placement of the sign to which food the calorie declaration applies, the sign must also include the name of the food, such as “Broccoli and cheese casserole, 200 calories per scoop.” (21 CFR 101.11(b)(2)(iii)(A))

5.79 How should I declare the calories for salad dressing that is self-serve at my salad bar? Can the calorie information be on the bottle?

Answer: Yes. The calorie information for the salad dressing at a self-serve salad bar (calories per serving and the serving used to determine the calorie content) could be declared in three ways: (1) on a sign or placard adjacent to and clearly associated with the salad dressing, including listing the information on the salad dressing bottle; (2) on a sign attached to the sneeze guard with the calorie declaration and the serving used to determine the calorie content above the specific salad dressing so that the consumer can clearly associate the calorie declaration with the salad dressing, except that if it is not clear to which salad dressing the calorie declaration and serving refers, then the sign must also include the name of the salad dressing; or (3) on 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. When the calorie information is provided on the bottle of the salad dressing, we consider it providing calorie information on a sign or placard adjacent to and clearly associated with the salad dressing, as

required by 21 CFR 101.11(b)(2)(iii)(A), provided that the calorie information otherwise complies with applicable requirements of 21 CFR 101.11.

5.80 I have a cafeteria line that lists the self-service foods in the line with prices on a menu board. However, as the customer moves down the line, this board is not visible when selecting the various foods. How must I provide the calorie declaration in this case?

Answer: For self-service foods, if the menu board is not visible to the customers as the customers moves down the line to make their selections, you must provide the calorie declarations through additional signage such as a large posted sign, individual signs by the item or signs over the item on the sneeze guard so that the customers can view the name, calorie declaration, and serving or unit of a particular item while the customers are selecting that item. (21 CFR 101.11(b)(2)(iii)(A))

5.81 How should I declare calories for food on display that is offered for sale in portions, such as a cup of pudding, slice of pie, or piece of cake?

Answer: The calorie declaration must be made for the portioned unit such as “piece of cake 300 calories,” “cup of pudding 250 calories.” (21 CFR 101.11(b)(2)(iii)(A))

5.82 How should I declare the calories for standard menu items in my buffet line?

Answer: You must state the number of calories for each displayed food item, such as a bagel, slice of pizza, or muffin, or if the food is not offered for sale as a discrete unit, such as soup or vegetables, you must state the number of calories per serving such as per scoop or cup. You must also state the serving or discrete unit used to determine the calorie content. (21 CFR 101.11(b)(2)(iii)(A))

5.83 Can I use the utensil that is used to serve the item as the “per serving” unit of measure for my calorie declaration?

Answer: If the serving utensil dispenses a standardized amount of food, yes. You can base the unit of measure for the calories on the serving utensil used to dispense the food offered for sale if the serving utensil, such as a ladle, dispenses a uniform amount of food each time. However, if the utensil, such as salad tongs, does not dispense a uniform amount of food each time, you must specify the amount of calories per each common household measure, such as a cup or tablespoon, or per unit of weight as it is offered for sale, such as “200 calories per cup” or “150 calories per 4 ounces.” (21 CFR 101.11(b)(2)(iii)(A)(2))

5.84 How do I declare the calories for self-service foods that are served in a sauce, such as slices of meatloaf with gravy?

Answer: For self-service foods that are offered for sale in a discrete unit, such as slices of meatloaf with gravy, calories must be declared per displayed food item. For example, the meatloaf with gravy might be declared as “250 calories per slice of meatloaf with gravy.”

5.85 How must I display the calorie information for self-service beverages sold from a beverage dispenser or fountain?

Answer: For self-service beverages sold from a beverage dispenser or fountain, you must declare the total number of fluid ounces in the cup in which the self-service beverage is offered. When there are different sized cups, you must also describe the size of the cup, such as “140 calories per 12 fluid ounces (small).” (21 CFR 101.11(b)(2)(iii)(A)(2)(iii))

5.86 The menu labeling final rule allows covered establishments to consider ice fill when determining calorie declarations for beverages that are not self-service. Are covered establishments also permitted to consider ice fill for determining calorie declarations for self-serve drinks?

Answer: No. Calorie and other nutrition information for self-serve drinks are based on the total number of fluid ounces that the cup can hold.

5.87 Can I provide calorie declarations electronically for beverage dispensers that have over 150 varieties to choose from?

Answer: Yes, provided the electronic display provides calorie declarations for each variety available at the dispenser and the consumer can view the corresponding calorie declaration while selecting the beverage. To the extent the self-service beverages are also listed on the menu or menu board, the covered establishment would be required to declare calories on such menus and menu boards for such beverages using the same methods applicable to other variable menu items, including ranges, depending on how the beverages are listed.

5.88 How must I display the calorie information for standard menu items that are self-service beverages served from a cooler or a display case?

Answer: For beverages in a cooler or a display case, the calorie information must be displayed consistent with other food items on display. (21 CFR 101.11(b)(2)(iii)) As discussed in question 5.92, in some situations the beverage may be a packaged food that bears a Nutrition Facts label in accordance with 21 CFR 101.9; if the consumer can examine the packaged food, including its label, before purchasing the food, additional calorie information would not need to be displayed.

5.89 How must the calorie declaration appear for self-service food or food on display?

Answer: The calorie declaration must include the term “Calories” or “Cal” and the amount of the serving or the identity of the displayed food item on which the calorie declaration is based, such as, “chocolate pudding 150 calories per bowl,” or “broccoli cheddar soup 200 calories per ladle.” (21 CFR 101.11(b)(2)(iii)(A)(3)(ii))

5.90 What are the type size, color, and background requirements?

Answer: If the calorie declaration is provided on a sign with the food’s name, price, or both, the calorie declaration must be in a type size no smaller than the type size of the name or price of the

menu item, whichever is smaller. It must also be in the same color or a color that is at least as conspicuous as that used for the name or price, and must have the same contrasting background or a background at least as conspicuous as that used for the name or price. (21 CFR 101.11(b)(2)(iii)(A)(3)(ii)) If the calorie declaration is provided on a sign that does not include the food's name, price, or both, the calorie declaration must be clear, conspicuous and must be easily associated with the menu item to which it refers.

5.91 What are the requirements for the succinct statement and statement of availability for self-service foods and foods on display?

Answer: The succinct statement (see question 5.47) and the statement of availability (see question 5.53) must be provided on individual signs adjacent to food that is self-service or on display where such signs meet the definition of a menu or menu board. They may be on the individual sign adjacent to the food itself, on a separate, larger sign in close proximity to the food that the customer can easily read as they are making their order selections, or these statements may be on a large menu board that the consumer can easily read as they are ordering the food. See questions 5.47-5.55 for other information about these required statements. (21 CFR 101.11(b)(2)(iii)(B))

5.92 Do I need to provide written nutrition information for my standard menu items that are self-service or on display and are there any exceptions to this requirement?

Answer: Written nutrition information that is described in 21 CFR 101.11(b)(2)(ii) and discussed in questions 5.56-5.75 is required for standard menu items that are self-service or on display. If the product is a packaged food that bears all of the nutrition information required for standard menu items by 21 CFR 101.11(b)(2)(ii) (see question 5.59 for the specific nutrient information required), and the consumer can examine this information before purchasing the food, then other forms of nutrition information such as a pamphlet or poster, are not required. For example, if a packaged food such as a bottled soda or package of potato chips bears a Nutrition Facts label, including the nutrition information required by 21 CFR 101.11(b)(2)(ii), a covered establishment would not be required to provide written nutrition information for such food as required by 21 CFR 101.11(b)(2)(ii), provided that the packaged food, including its label, can be examined by a consumer before purchasing the food. (21 CFR 101.11(b)(2)(iii)(C))

- Other self-service foods (including grab-and-go foods)

5.93 For “grab and go” items sold in grocery stores that are covered by the menu labeling final rule, but are exempt from nutrition labeling under the Nutrition Labeling and Education Act of 1990 (NLEA), such as a packaged sandwich or a package of sushi prepared at the retail establishment, could calories be provided on the package itself rather than on a separate sign to comply with the menu labeling requirements? If so, would the calorie declaration be based on the entire contents of the package or on the reference amount customarily consumed (RACC) and would the exemption from nutrition labeling under 21 CFR 101.9(j)(3) still apply?

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Answer: As discussed in question 5.77, the menu labeling final rule provides three options for declaring calories for self-service foods and foods on display. One option is to declare the calories on a sign adjacent to and clearly associated with the corresponding food (see 21 CFR 101.11(b)(2)(iii)(A)). We would consider calories provided directly on the package of a “grab and go” food that is a standard menu item at a covered establishment to be a way of declaring calories on a sign adjacent to and clearly associated with the corresponding food, as required by 21 CFR 101.11(b)(2)(iii)(A). If calories are declared directly on the package of a “grab and go” food, calories should be declared for the entire package as the menu labeling final rule requires that calories be declared for standard menu items as they are usually prepared and offered for sale. Declaring calories directly on the package of the “grab and go” food would allow the consumer to clearly associate the calorie declaration with the corresponding food and help ensure that the consumer sees such declaration when making his or her selections.

As a part of the menu labeling final rule, FDA made conforming amendments to 21 CFR 101.9(j)(3) in order to clarify that complying with the requirements of 21 CFR 101.11 does not affect the exemptions from nutrition labeling under 21 CFR 101.9(j)(3). In other words, if a food that was previously exempt from nutrition labeling under 21 CFR 101.9(j)(3) is now covered under the menu labeling requirements, declaring the calories for such food, including declaring calories on the package of a “grab and go” food, to comply with the requirements for nutrition labeling in 21 CFR 101.11, would not cause such food to fall out of the exemption in 21 CFR 101.9(j)(3).

Please note however, that additional written nutrition information in accordance with 21 CFR 101.11 must be provided to consumers upon request for all standard menu items at covered establishments. Consistent with the calorie information, the additional written nutrition information must be for the entire standard menu item as usually prepared and offered for sale and not based on reference amounts customarily consumed (RACCs).

5.94 If a covered establishment generates a label for a “grab and go” item that is a standard menu item, (for example yogurt parfaits or prepared sandwiches) would the statement of availability of additional written nutrition information and succinct statement be required on the label as well or could they be on a sign adjacent or near the grab and go items? Such “grab and go” items would not be on a menu or menu board.

Answer: The succinct statement and the statement of availability may be placed on the label of the “grab and “go” item, on a sign in close proximity to the grab and go item that can be easily read at the time the customer is selecting their grab and go item, or on a large menu board that can be easily read as the customer is ordering the food, as specified in 21 CFR 101.11(b)(2)(iii)(B).

5.95 If the written nutrition information is on a label for “grab and go” items, would there still need to be the statement of availability that additional written nutrition information is available upon request?

Answer: If a “grab and go” standard menu item provides the additional written nutrition information required by 21 CFR 101.11(b)(2)(ii) on the label, the statement of availability that additional written nutrition information is available upon request would likely not be useful to consumers, as consumers would be able to examine the nutrition information directly on the label prior to purchase. However, if a “grab and go” standard menu item does not have the additional written nutrition information required by 21 CFR 101.11(b)(2)(ii) on the label, the statement of availability would be required for this “grab and go” item.

5.96 If I choose to add a Nutrition Facts label to a “grab and go” food, would that meet the requirements under 21 CFR 101.11 for calorie and the additional written nutrition information?

Answer: If an establishment voluntarily chooses to use a Nutrition Facts label that meets the requirements under 21 CFR 101.9, the Nutrition Facts label would meet the menu labeling requirements for calorie declaration and additional written nutrition information.

5.97 The preamble to the menu labeling rule explains that certain foods, such as sliced meats and cheeses that are on display behind a deli counter in a grocery store, would not be considered “restaurant-type food” in part because there is an expectation that consumers will further prepare the food before consumption. Can FDA clarify that other types of foods sold from behind a deli counter (such as, cold prepared foods which require the consumer to take an additional step, such as heating, before the food is ready for consumption) are not considered “restaurant-type food” and therefore not covered by the menu labeling final rule?

Answer: Cold prepared foods that: (1) are sold from behind a deli counter; (2) do not appear on a menu or menu board; and (3) require further preparation by the consumer before consumption would not be considered a “restaurant-type food” and therefore, would not be subject to the nutrition labeling requirements in 21 CFR 101.11.

6. How to Determine the Nutrient Values for Restaurant-type Foods

General criteria to establish a reasonable basis for determining the nutrient values of standard menu items in covered establishments (21 CFR 101.11(c))

6.1 How do I determine the calories and other nutrient values for my standard menu items?

Answer: You must have a reasonable basis for determining the values for calorie and other nutrient information that you provide for your standard menu items. (21 CFR 101.11(c)(1)) You may use any one of a number of means to arrive at these values. They include:

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- Calculations based on nutrient databases such as the USDA National Nutrient Database for Standard Reference (<http://ndb.nal.usda.gov/ndb/foods>) (with or without computer software programs).
- Values listed in a cookbook
- Laboratory analysis of your menu items
- Other reasonable means such as:
 - Use of Nutrition Facts on the labels of packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the FD&C Act and 21 CFR 101.9;
 - FDA's nutrient values for raw fruits and vegetables (Appendix C of 21 CFR part 101; or
 - FDA's nutrient values for cooked fish (Appendix D of 21 CFR part 101).

Further details about using these methods are discussed in questions 6.6-6.20. (21 CFR 101.11(c)(1))

6.2 How closely must individual portions of my standard menu items match the nutrient values that I have determined for them?

Answer: The calorie and nutrient declarations for your standard menu items must be accurate and consistent with the nutrient values you determined using a reasonable basis. You must take reasonable steps to ensure that how you prepare your product (that is, the types and amounts of ingredients you use, the cooking process, temperatures, etc.) and how you serve your product (that is, the amounts of that item that are offered for sale in a typical serving) are the same as those used to determine the calorie and nutrient declarations. (21 CFR 101.11(c)(2))

6.3 How do I determine the calories for meats whose portion sizes may vary (such as, pieces of fish or slices of beef)?

Answer: You must have a reasonable basis for your calorie and other nutrient content declarations (21 CFR 101.11(c)). Where variations in portion size may occur, such variations can be taken into consideration when determining the calorie content for the menu item, for example, by basing the nutrient declarations on the average size of a piece of fish or beef.

6.4 Is there anything that I must do to substantiate my nutrient values?

Answer: You should keep records of how you arrive at your nutrient values for standard menu items being offered for sale at your covered establishment. FDA recommends that any such records should be maintained either at the covered establishment or the corporate headquarters for the duration of the time that the standard menu items are offered for sale at the covered establishment. Upon request and within a reasonable period of time, you must supply to FDA, information used to substantiate the required calorie and nutrient values that you use for your standard menu items listed on your menus, menu boards or on display, and for your written nutrition information. This information must include both the data and the method you used to derive these nutrient values, as specified in 21 CFR 101.11(c)(3). FDA considers a reasonable period of time to be about 4-6 weeks after the request is made.

FDA also recognizes that it is not necessary to maintain information on nutrient values for foods that are no longer standard menu items and are no longer offered for sale at a covered establishment as this information is no longer beneficial for consumers if they cannot purchase those items.

6.5 Additionally, for covered establishments that choose to keep records to verify that a menu item meets the definition of a temporary menu item or a food that is part of a customary market test, FDA recommends that information on the date that the item was first offered for sale in the covered establishment and the last date the item was offered for sale should be included as a part of any such record. What if I want to change my recipe or method of preparation?

Answer: All data must reflect current and accurate calorie and nutrient values for each standard menu item. If you wish to modify a recipe, method of preparation, or way of serving the menu item (such as changes in portion size), you should complete a new determination of the calories and nutrient information for that item. You must also ensure that calorie declarations for your standard menu items provided in your facility are current and accurate, whether on the menu, menu board, or for foods on display and in the written nutrition information and are changed at the time any alterations to the recipes are made. (21 CFR 101.11(c)) Information supporting a new determination of the calories and nutrient information for an item should be available to FDA upon request.

A covered establishment should consider the time necessary to update the nutrient information available to consumers when planning to use a new recipe or method of preparation for a standard menu item. If a restaurant is unable to change the menu, menu board, and/or any other written nutrition information prior to the recipe change, you may request further guidance from us at: Food Labeling and Standards Staff, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-820, CFSAN, FDA), Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740 or to CalorieLabeling@fda.hhs.gov.

- Nutrient databases

6.6 I am using a nutrient database to determine the nutrient values for my standard menu items. What information must I provide to FDA to accurately identify the nutrient database that I am using?

Answer: Upon request, you must provide the name and version (including the date of the version) of the database that you use. If you use a software application along with that database, you must include the following:

- The name and version of the computer software used;
- The name of the software company that is responsible for the database, if applicable; and
- Any website address for the database.

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

Additional information substantiating nutrient values must also be provided for nutrient databases upon request, as required by 21 CFR 101.11(c)(3)(i) and discussed further below.

6.7 What factors should I consider in choosing a nutrient database to determine nutrient values?

Answer: You should consider whether the database is valid, contains an appropriate variety of foods, including ingredients, for which nutrient values are available in order to determine nutrient values for your establishment's standard menu items. You should also consider whether the database is able to easily determine nutrient values for an appropriate range of quantities of a particular food, and provides nutrient values for all of the nutrients that must be quantified under 21 CFR 101.11. For further information on nutrient databases see section V of the *Guidance for Industry: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Small Entity Compliance Guide*.

6.8 Do I need to provide FDA with the recipe or formula for the standard menu item?

Answer: If requested, yes. You must provide us the recipe or formula that you used as a basis for the nutrient declarations. (21 CFR 101.11(c)(3)(i)(B))

6.9 Is there specific information that I must supply about the ingredients in a standard menu item?

Answer: If requested, yes. You must provide the following:

- The amount of each nutrient contributed by the specified amount of each ingredient identified in the recipe; and
- Information on how the database was used, including calculations or operations performed to determine the nutrient values for each standard menu item. This information may be in the form of worksheets, computer printouts, or similar materials. (21 CFR 101.11(c)(3)(i)(C)(I))

6.10 The computer program I use to determine my nutrition information only requires me to enter the amount of my ingredient by brand name and does not provide the nutrient information for each ingredient. What information must I submit in this case?

Answer: If the computer program that you use does not provide the amount of each nutrient that the specific amount of each individual ingredient identified in your recipe contributes to the menu item, and assuming that you are the responsible individual at the covered establishment, you must provide certification that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions. (21 CFR 101.11(c)(3)(i)(C)(2))

6.11 Who provides this certification?

Answer: This certification is provided by the responsible person (as determined by the entity) 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. (21 CFR 101.11(c)(3)(iii)(F))

6.12 Must I provide any information about the nutrient values of my standard menu items?

Answer: If requested, yes. You must provide us a detailed listing such as a printout of the nutrient values determined for each standard menu item. (21 CFR 101.11(c)(3)(i)(D))

6.13 Is anything else required about the nutrient values of my standard menu item?

Answer: Yes. Upon request, you must provide us any other information pertinent to the determination of the nutrient values for your standard menu items. For example, you might have to include information about moisture loss or any other processing or preparation situation or condition that may cause slight variations in the nutrient profile. (21 CFR 101.11(c)(3)(i)(E))

6.14 Must I provide any additional signatures or certifications?

Answer: If asked, yes. You must provide us the following:

- A statement that is signed and dated by a responsible individual who is employed at the covered establishment, its corporate headquarters, or parent entity who can verify that the information in the nutrient analysis is complete and accurate. (21 CFR 101.11(c)(3)(i)(F))
- A statement that is signed and dated by a responsible individual employed at the covered establishment (such as, the manager of the establishment or someone designated by the establishment manager or owner that is also employed at the specific covered establishment) certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (such as the types and amounts of ingredients used, the recipe, and the cooking times and temperatures) and the amount of the standard menu item offered for sale are the same as that on which the nutrient values were determined. (21 CFR 101.11(c)(3)(i)(G)). For example, such a statement could read “I, (name of the responsible individual), certify that (name of the covered establishment) has taken reasonable steps to ensure that the recipe for (name(s) of standard menu item) that was used to determine the calorie declaration and other nutrient values was followed to prepare (name(s) of standard menu item). The ingredients were properly measured, the specified cook times and temperatures were followed, and the specified portion sizes were served to the customer.” Any other statement or format that includes the required information in 21 CFR 101.11(c)(3)(i)(G) would also be acceptable.

The certification described in the first bullet (21 CFR 101.11(c)(3)(i)(F)) may cover multiple establishments. The certification described in the second bullet (21 CFR 101.11(c)(3)(i)(G)) must cover each individual establishment and be signed and dated by a responsible employee of that particular establishment.

- Published cookbooks that contain nutritional information for the recipes in the cookbook

6.15 I am using a cookbook that contains nutritional information to determine the nutrient values for my standard menu items. What information must I provide to FDA about the nutrient information that I am using?

Answer: You must provide the following upon request:

- The name, author, and publisher of the cookbook used (21 CFR 101.11(c)(3)(ii)(A));
- If available, information provided by the cookbook, author, or publisher about how the nutrition information for the recipes was obtained (21 CFR 101.11(c)(3)(ii)(B));
- A copy of the recipe used to prepare the standard menu item and a copy of the cookbook's nutrition information for that item (21 CFR 101.11(c)(3)(ii)(C)); and
- A statement signed and dated by a responsible individual employed at the covered establishment certifying that that the covered establishment has taken reasonable steps to ensure that the method of preparation (such as, 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)(ii)(D)).

6.16 What factors should I consider in choosing a cookbook?

Answer: You should consider whether the cookbook has recipes that provide a precise list of ingredients with precise ingredient measurements, and whether the cookbook is from a reputable publisher. You should also consider whether the cookbook provides nutrient values for all of the nutrients that must be quantified under 21 CFR 101.11. Finally, you should also consider whether the cookbook or the author/publisher provides information as to how the nutrient values were determined.

6.17 Do I have to use the recipe's portion size exactly as specified in the cookbook in order to rely on the nutrition information provided by the cookbook?

Answer: No. You may divide (or multiply) the recipes as necessary to accommodate differences in the portion size derived from the recipe and that are served as the standard menu item, but you may not change ingredients or otherwise make any changes to the proportion of the ingredients used. If you change the proportions of the ingredients used, you can no longer rely on the cookbook as a reasonable basis for your nutrition information. (21 CFR 101.11(c)(3)(ii)(D))

- Nutrition Information determined by laboratory analyses

6.18 I have decided to determine nutrient values for my establishment's standard menu items through laboratory analysis. What information must I provide to FDA?

Answer: You must provide the following upon request:

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- A copy of the recipe for the standard menu item used for the nutrient analysis (21 CFR 101.11(c)(3)(iii)(A));
- The name and address of the laboratory performing the analysis (21 CFR 101.11(c)(3)(iii)(B));
- Copies of analytical worksheets, including the analytical method, used to determine and verify nutrition information (21 CFR 101.11(c)(3)(iii)(C));
- 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 (21 CFR 101.11(c)(3)(iii)(D)); 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 (such as, 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)(iii)(E)).

- Nutrition information determined by other reasonable means

6.19 Are there any other ways that I can determine the nutrition information for my standard menu items?

Answer: You may determine the nutrition information for your standard menu items by any other reasonable means. This may include using the nutrition information that may be provided for some or all of your ingredients together with values from an appropriate database to calculate the nutrient values for the menu item. (21 CFR 101.11(c)(3)(iv))

6.20 What must I provide to FDA to substantiate these other reasonable bases?

Answer: You must provide us the following upon request:

- A detailed description of the means used to determine the nutrition information for the standard menu item (21 CFR 101.11(c)(3)(iv)(A));
- A recipe or formula used as a basis for determining the nutrition information (21 CFR 101.11(c)(3)(iv)(B));
- Any data that you derive in determining the nutrient values for the standard menu item such as nutrition information about the individual ingredients used along with the source of this information (21 CFR 101.11(c)(3)(iv)(C));
- A statement that is signed and dated by a responsible individual who is employed at the covered establishment or its corporate headquarters or parent entity, who can verify that the information in the nutrient analysis is complete and accurate (21 CFR 101.11(c)(3)(iv)(D)); and
- A statement that is signed and dated by a responsible individual employed at the covered establishment that certifies that the covered establishment has taken reasonable steps to ensure that the method of preparation (such as the types and amounts of ingredients used, the recipe, and the cooking times and temperatures) and the amount of the standard menu

item offered for sale are the same as that on which the nutrient values were determined. (21 CFR 101.11(c)(3)(iv)(E)).

- Compliance

6.21 Does the “80/120 rule” apply to calorie and other nutrition labeling for standard menu items? What amount of error or variance is allowed?

Answer: No. It does not apply to standard menu items subject to the requirements of 21 CFR 101.11. Calorie and other nutrition labeling for standard menu items must be based on a reasonable basis, as specified in 21 CFR 101.11(c), and comply with FDA’s rounding rules (21 CFR 101.11(b)(2)(i)(A)(2)). (21 CFR 101.11(c)(1)-(3)) The “80/120” rule only applies to packaged food subject to the requirements of 21 CFR 101.9.

6.22 When a covered establishment makes changes in their standard menu items, either by adding new standard menu items or changing the recipe for a particular standard menu item, how long will the establishment have to change the calorie and other nutrition labeling?

Answer: The purpose of the menu labeling final rule is to provide consumers with timely, accurate information. As part of normal business practices, we expect that establishments will know about new menu items added to their standard offerings well in advance and will generally have ample time to make changes to their menu or menu board associated with the introduction of the new/revised menu items, as appropriate. Keep in mind that the menu labeling final rule does not require information for temporary menu items (appears on a menu or menu board for less than 60-days per calendar year, such as Jack O’Lantern cookies or holiday gift tins of popcorn) or food that is part of a customary market test (appears on a menu or menu board for less than 90 consecutive days in order to test consumer acceptance of the product). Printing the information for these temporary items on a menu insert or using a sticker to correct nutrient information is acceptable. However, we recognize that there may be rare circumstances when the availability of the updated menu does not coordinate with the introduction of the new standard menu item. In such infrequent cases, we suggest that the covered establishment contact us at: Food Labeling and Standards Staff, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, or CalorieLabeling@fda.hhs.gov for information on submitting requests for using old menu or menu boards. We will consider such requests on a case-by-case basis.

6.23 What are the penalties for not providing accurate nutrient information?

Answer: If the calorie and other nutrition information is not accurate, the foods would be considered misbranded and subject to the same penalties that misbranded packaged foods are subject to under the FD&C Act.

6.24 What entities will enforce the menu labeling requirements?

Answer: In general, FDA is delegated with enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C). However, under section 310(b) of the FD&C Act, a state could enforce certain provisions of the FD&C Act, including the menu labeling requirements of section 403(q)(5)(H), under certain circumstances. Alternatively, states or localities could establish menu labeling requirements that are identical to the federal requirements and enforce their identical requirements. FDA intends to work with state and local authorities, as appropriate, to ensure that implementation and enforcement of the menu labeling requirements are uniformly applied.

6.25 Will FDA pre-approve menus, menu boards and the written nutrition information of covered establishments?

Answer: FDA will not pre-approve menu board mock-ups, similar to how we do not pre-approve packaged food labels.

6.26 Can a state or locality require nutrition labeling for foods sold in restaurants and similar retail food establishments not subject to the federal nutrition labeling requirements of 21 CFR 101.11?

Answer: Yes. A state or locality may impose nutrition labeling requirements for foods sold in restaurants and similar food establishments that are **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, unless such establishment has voluntarily registered to be covered by the federal requirements, as specified by 21 CFR 101.11(d) (see 21 U.S.C. 343-1(a)(4)). Establishments that voluntarily register with FDA would be required to follow the federal requirements in 21 CFR 101.11.

7. Alcoholic Beverages

7.1 Can a covered establishment use nutrition information for types of wine, beer or distilled spirits listed in the USDA National Nutrient Database to determine nutrient content for alcoholic beverages offered for sale in such establishment?

Answer: There are several reasonable bases that can be used to determine calorie and other nutrient content of standard menu items, including alcoholic beverages. Nutrition labeling, including calorie labeling, for alcoholic beverages must be accurate and consistent with the specific basis used to determine nutrient values (21 CFR 101.11(c)(2)). If the specific type of wine, beer or distilled spirit offered for sale in your establishment matches the description of the types of beverages that were used to determine the caloric or other nutrient content in the USDA database, then the nutrition information from the USDA database can be used. However, if it is not reasonable to conclude that the specific type of wine, beer or distilled spirit matches the description of the types of beverages that were used to determine the caloric or other nutrient content in the USDA database, then one of the other reasonable bases would have to be relied on to accurately calculate nutrient content. It is also permissible to combine reasonable bases/use multiple sources to determine this information – such as using the USDA nutrient database and other private databases available. Cookbooks, recipes, information provided by the

manufacturer, Nutrition Facts labels, Serving Facts labels (or a combination of these options) can also be used to determine nutrition information. Nutrient laboratory analysis is also an option.

7.2 Can the declaration of calories for alcoholic beverages that are variable menu items be provided in a single calorie declaration?

Answer: It depends on how the alcoholic beverages are listed on the menu or menu board.

As with all variable menu items, including alcoholic beverages, that have the same calorie declaration, they can be grouped with a single calorie declaration, provided that the declaration specifies that the calorie amount listed represents the calorie amounts for each individual flavor or variety. See 21 CFR 101.11(b)(2)(i)(A). For example:

Wines by the Glass

Red Wine (Pinot Noir, Merlot, or Cabernet Sauvignon)	120 Cal	\$8.95
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7.3 Can I use the format in the example below to declare calorie information for varieties of an alcoholic beverage, even though the varieties are listed separately on a menu?

Wines by the Glass

Red Wine	120 Cal.....	\$8.95
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Pinot Noir (Description)

Merlot (Description)

Cabernet Sauvignon (Description)

Answer: If the varieties and their descriptions are listed separately but grouped in a single section of the menu and all of the varieties have the same calorie declaration, then a single calorie declaration could be used provided that the declaration specifies that the calorie amount listed represents the calorie amounts for each individual flavor or variety. See 21 CFR 101.11(b)(2)(i)(A). Otherwise, the calorie declaration must accompany each variety. See 21 CFR 101.11(b)(2)(i)(A)(4).

7.4 Can calorie declarations for varieties of beer or wine be disclosed in a range at the top of the list of such beverages on a menu or menu board?

Answer: It depends on how the alcoholic beverages are listed on the menu or menu board. If just a generic term is used and there are 3 or more varieties available, then a range can be used, for example:

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

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However, if each variety or flavor is separately listed then the calorie declaration has to be for each one listed. (See 21 CFR 101.11(b)(2)(i)(A)(4)) For example:

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

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

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

As with other variable menu items, if multiple beers have the same calorie amounts, then a single calorie declaration could be used, provided that the declaration specifies that the calorie amount listed represents the calorie amounts for each individual beer variety.

Light beers (60 calories)

Pete's light.....\$x.xx

Frank's light.....\$x.xx

7.5 Do the labeling requirements of the menu labeling final rule in § 101.11(b)(2)(iii) that apply to standard menu items that are self-service food and food on display apply to beers on tap?

Answer: In general, the menu labeling final rule covers alcoholic beverages that are standard menu items that are listed on a menu or menu board. The menu labeling final rule specifies requirements for standard menu items that are self-service food and food on display in § 101.11(b)(2)(iii). We consider beers on tap to be alcoholic beverages that are foods on display, however. As specified in § 101.11(b)(1)(ii)(B), the labeling requirements of § 101.11(b)(2)(iii) do not apply to alcoholic beverages that are foods on display and are not self-service foods. Therefore, to the extent that beers on tap are not self-serve, they are exempt from the labeling requirements specified in § 101.11(b)(2)(iii) for standard menu items that are food on display. Specifically, as discussed in the menu labeling final rule, at many covered establishments that serve alcoholic beverages, alcoholic beverages that are not on menus or menu boards, including beers on tap, are ordered by customers sitting at tables from which the bar could be completely out of sight.

7.6 If there is a menu or menu board that lists beer on tap (that is not self-serve and is available upon request behind the bar) along with corresponding calorie declarations that can be viewed at the same time that the beer is selected by consumers, do calories also have to be listed on the top of the nozzle or on a sign adjacent to the nozzle?

Answer: No. As discussed in question 7.5, beer on tap is considered a food on display and alcoholic beverages that are foods on display and are not self-serve are exempt from the labeling requirements for standard menu items that are foods on display (21 CFR 101.11(b)(1)(ii)(B)).

However, if a menu or menu board lists beers on tap as standard menu items, then the calories for such beers on tap must be provided on that menu or menu board.

7.7 Can calories for wines be presented by the ounce, or should the calories be representative of the serving size being provided to the customer?

Answer: The calorie declaration must represent how the product is prepared and offered for sale to the customer. If the wine is sold by the glass, then the calorie information must be for the glass of wine. If the wine is sold by the bottle, but served by the glass, then the restaurant has the option of providing the calorie declaration for the entire bottle or per glass provided the number of glasses in the bottle is also included, such as “120 cal/glass, 6 glasses per bottle.” (See 21 CFR 101.11(b)(2)(i)(A))

7.8 If a bottle of wine is on the menu list, should the calories be provided by the bottle or by serving size? For example, a 750 ml bottle of red wine contains 5 servings (5 fluid ounces per serving) with a calorie count of 123 calories per serving according to the USDA National Nutrient Database. Can the calorie declaration for that bottle be provided as 5 servings/123 calories per serving?

Answer: As noted in the previous question, the calorie declaration must reflect how the covered establishment prepares and offers for sale the standard menu item. If the covered establishment serves the bottle of wine with glasses, then the calorie declaration could be based on the calorie content per glass, provided the number of glasses in the bottle is also included. Accordingly, if the bottle of wine is served in glasses whose capacity is 5 fluid ounces, then after applying the appropriate rounding rules, the calories could be disclosed as follows: 120 calories per glass; 5 glasses per bottle.

7.9 If nutrition information on certain alcoholic beverages, such as flavored liqueurs, cordials, ports, or champagne categories, are not available in USDA’s National Nutrient Database or other nutritional databases, how do I get nutrition information for these alcoholic beverages when TTB does not require nutrition labeling for products bearing no nutrition claims? If other databases are not available, is a covered establishment expected to undertake analytical testing?

Answer: As provided in the menu labeling final rule, there are several reasonable bases that can be used to determine calorie and other nutrient content of standard menu items. (See 21 CFR 101.11(c)) Determining calorie and other nutrient contents may require the use of more than one reasonable basis or a combination of two or more reasonable bases or other reasonable means. It is up to the covered establishment to determine the appropriate basis that it uses to determine nutrient values and that the basis is valid for the item and is complete and accurate.

7.10 Alcohol and Tobacco Tax and Trade Bureau’s (TTB’s) Rulings 2004-1 and 2013-2 allows the use of voluntary Statements of Average Analysis and voluntary Serving Facts statements, including calorie information, on labels for alcoholic beverages regulated by TTB. Can covered establishments rely on the calorie information on

alcoholic beverage labels consistent with TTB’s ruling as a reasonable basis for their calorie declarations and additional written nutrition information?

Answer: Calorie information on alcoholic beverage labels consistent with TTB’s ruling could be a reasonable basis for a covered establishment’s corresponding calorie declarations on menus and menu boards. In general, a covered establishment must declare calorie declarations on menus/menu boards to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories. (21 CFR 101.11(b)(2)(i)(A)(2)) In some situations, the calorie information on alcoholic beverage labels consistent with TTB’s rulings may not be in 5-calorie or 10-calorie increments. This could create a situation where a consumer is presented with different caloric values for the same menu item at a covered establishment because the standard menu item is served to the consumer in a bottle or can that has the voluntary Statement of Average Analysis or voluntary Serving Facts Statement on the label and the caloric value provided on such statement is not in a 5- calorie or 10-calorie increment (such as, for a bottle of beer, “64 calories” on the label of the bottle of beer and “60 calories” on the menu or menu board). In order to avoid such situations, covered establishments may use the caloric value provided on a voluntary Statement of Average Analysis or voluntary Serving Facts Statement consistent with TTB’s rulings on the label of an alcoholic beverage standard menu item served to the consumer in a bottle or can for the corresponding calorie declaration on a menu or menu board, even if the calorie value is not in 5-calorie or 10-calorie increments, provided that the calorie declaration on the menu or menu board is for the standard menu item as usually prepared and offered for sale, is truthful and not misleading, and otherwise complies with the requirements of 21 CFR 101.11.

However, if an alcoholic beverage standard menu item is not served to the consumer in a bottle or can, there would be no cause for confusion as discussed above. Therefore, for alcoholic beverages that are standard menu items and are not usually offered for sale by the covered establishment in a bottle or can that contains a Statement of Average Analysis or a voluntary Serving Facts Statement, the covered establishment must round the calories listed on the menu or menu board according to 21 CFR 101.11(b)(2)(i)(A)(2). TTB’s calculation methods for determining nutrient content of alcoholic beverages would be considered a reasonable basis for calorie declarations and nutrition information for these standard menu items.

Similarly, nutrition information on alcoholic beverage labels consistent with TTB’s rulings could be used as a reasonable basis for a covered establishment’s additional written nutrition information. Additionally, for standard menu items including alcoholic beverages that contain insignificant amounts of six or more of the required nutrients, the declaration of nutrition information required by 101.11(b)(2)(ii)(A) may be presented in a simplified format as described in 21 CFR 101.11(b)(2)(ii)(B).

7.11 We are a covered establishment that does not offer for sale alcohol beverages as standard menu items, but we include suggested alcohol pairings with our menu items (such as, “goes great with red wine”). Do we need to include calorie information for the suggested alcohol pairings?

Answer: If the alcoholic beverage is not offered for sale as a standard menu item, as defined in the menu labeling final rule, then a calorie declaration is not required.

7.12 Are establishments that only sell beer, such as concession stands within a stadium, covered by the menu labeling requirements?

Answer: If an establishment meets all of the criteria of a covered establishment (see definition section 3.5) and only sells beer, and that beer is a standard menu item then the covered establishment must provide calorie and other nutrition information for such beer in accordance with the menu labeling requirements. Establishments are not excluded from coverage under the menu labeling final rule because they offer for sale only one type of standard menu item.

8. Voluntary Registration

8.1 I am the owner of a restaurant that is not part of a chain with 20 or more locations. Can I voluntarily provide nutrition information as required by 21 CFR 101.11? What if food sold in my restaurant is subject to state or local nutrition labeling requirements? Must I follow the state or local requirements, or can I follow the federal requirements?

Answer: As an owner of a restaurant that is part of a chain with fewer than 20 locations or otherwise not subject to the requirements of 21 CFR 101.11, you may voluntarily register to be subject to the requirements of 21 CFR 101.11, as specified in 21 CFR 101.11(d). An establishment registered in accordance with 21 CFR 101.11(d), cannot be subject to state or local nutrition labeling requirements that are not identical to the federal requirements found in 21 CFR 101.11 (21 U.S.C. 343-1(a)(4)).

8.2 Who may register?

Answer: An authorized official (see definition section, #3.4) of a restaurant or similar retail food establishment (see definition section, #3.9) may register with us to be subject to the requirements of 21 CFR 101.11, as long as such establishment is not already covered by the requirements (see definition section, # 3.5).

8.3 May an individual restaurant or similar retail food establishment that is part of a chain of fewer than 20 locations register or must an official for the entire chain register all establishments?

An authorized official of an individual restaurant or similar retail food establishment or of a chain of restaurants or similar retail food establishments can determine whether to register a single establishment or several establishments within the chain.

8.4 What registration information am I required to submit in order to register?

Answer: Authorized officials of restaurants and similar retail food establishments must provide us the following information using Form FDA 3757, Menu Labeling Registration Form, at

<http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm239947.pdf> (21 CFR 101.11(d)(3)):

- Contact information (including name, address, phone number, and email address) for the authorized official;
- Contact information (including name, street address, phone number, and email address) for each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official, such as the owner or manager, who will be available onsite for each specific restaurant or similar retail food establishment;
- All trade names the restaurant or similar retail food establishment uses;
- The preferred mailing address (if different from the location address for each establishment) for purposes of receiving correspondence; and
- Certification that the information submitted is true and accurate; that the person submitting the information 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 FD&C Act and 21 CFR 101.11, as discussed in sections V and VI of this document.

8.5 Must I use Form FDA 3757 to voluntarily register my establishments?

Answer: Yes. There is a fillable Form FDA 3757 at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm239947.pdf>. You must use this form to ensure that complete information is submitted.

8.6 How do I submit the completed form?

Answer: After saving your completed form, you should email the form to menulawregistration@fda.hhs.gov. If email is not available, you can either fill in the form and print it out or print out a blank form and fill in the information by hand or typewriter; you can print out and fax the completed Form FDA 3757 to 301-436-2804 or mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, room 0209, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

8.7 Do I have to renew this registration and if so, when?

Answer: The registration period covers two years and becomes active from the date of submission. To keep the registration active, an authorized official of the registered establishment must submit a new registration within 60 days before the expiration of the restaurant's current registration. (21 CFR 101.11(d)(5)) If we do not receive this re-registration, the original registration will automatically expire.

8.8 Will FDA send reminders that it is time to re-register?

Answer: No. We will not send reminders.

8.9 Do the requirements for electronic signatures in 21 CFR part 11 apply to the signature required for voluntary registration?

Answer: No. Simply filling out Form 3757, entering the name of the person certifying the registration and (when submitting the form electronically) checking the box to signify that the printed names serves as the signature, will be sufficient.

8.10 Once I register and am covered by the requirements of 21 CFR 101.11, what if I do not follow the requirements of 21 CFR 101.11?

Answer: If you register to be a covered establishment, your establishment and standard menu items offered for sale in your establishment are subject to 21 CFR 101.11. A standard menu item offered for sale in a covered establishment is deemed misbranded under sections 201(n), 403(a), 403(f), and 403(q) of the FD&C Act if its label or labeling is not in conformity with 21 CFR 101.11(b) or (c) (21 CFR 101.11(f)) and thus subject to the same penalties that misbranded packaged foods are subject to under the FD&C Act.

Appendix A: Rounding Rules for Restaurant-Type Foods

The following table provides rounding rules for declaring nutrients for restaurant-type foods

Nutrient	Increment Rounding	Insignificant Amount
Calories (1) Calories from Fat (1)(ii)	< 5 cal - express as 0 ≤ 50 cal - express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment	< 5 cal
Total Fat (2) Saturated Fat (2)(i) Trans Fat (2)(ii)	< .5 grams (g) - express as 0 < 5 g - express to nearest .5g increment ≥ 5 g - express to nearest 1 g increment	< .5 g
Cholesterol (3)	< 2 milligrams (mg) - express as 0 2 - 5 mg - express as "less than 5 mg" > 5 mg - express to nearest 5 mg increment	< 2 mg
Sodium (4)	< 5 mg - express as 0 5 - 140 mg - express to nearest 5 mg increment > 140 mg - express to nearest 10 mg increment	< 5 mg
Total Carbohydrate (6) Dietary Fiber (6)(i) Sugars (6)(ii)	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" ≥ 1 g - express to nearest 1 g increment	< 1 g
Protein (7)	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" or to 1 g if .5 g to < 1 g ≥ 1 g - express to nearest 1 g increment	< 1 g

To express nutrient values to the nearest 1 g increment, for amounts falling exactly halfway between two whole numbers or higher (such as, 2.5 to 2.99 g), round up (such as, 3 g). For amounts less than halfway between two whole numbers (such as, 2.01 g to 2.49 g), round down (such as, 2 g).