

ethnological material representing Greece's Byzantine culture (approximately the 4th century through the 15th century A.D.); and made the necessary determinations to extend the import restrictions for an additional five years. Diplomatic notes have been exchanged, reflecting the extension of those restrictions for an additional five-year period. Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect this extension of the import restrictions.

The Designated List archaeological materials representing Greece's cultural heritage from the Upper Paleolithic (beginning approximately 20,000 B.C.) through the 15th century A.D., and ecclesiastical ethnological material representing Greece's Byzantine culture (approximately the 4th century through the 15th century A.D.) covered by these import restrictions is set forth in CBP Dec. 11–25. The Agreement and Designated List may also be found at the following Internet Web site address: <https://eca.state.gov/cultural-heritage-center/cultural-property-protection/bilateral-agreements/greece>.

The restrictions on the importation of these archaeological and ecclesiastical ethnological materials from Greece are to continue in effect for an additional five years. Importation of such material continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). In addition, CBP has determined that such notice or public procedure would be impracticable and contrary to the public interest because the action being taken is essential to avoid interruption of the application of the existing import restrictions (5 U.S.C. 553(b)(B)). For the same reasons, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action under Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

§ 12.104g [Amended]

■ 2. In § 12.104g, paragraph (a), the table is amended in the entry for Greece (Hellenic Republic) by adding after the phrase “CBP Dec. 11–25” the phrase “extended by CBP Dec. 16–21”.

R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border Protection.

Approved: November 21, 2016.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2016–28355 Filed 11–21–16; 4:15 pm]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

Food Labeling

CFR Correction

■ In Title 21 of the Code of Federal Regulations, Parts 100 to 169, revised as of April 1, 2016, on page 50, § 101.11 is added to read as follows:

§ 101.11 Nutrition Labeling of Standard Menu Items in Covered Establishments

(a) *Definitions.* The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this section. In addition, for purposes of this section:

Authorized official of a restaurant or similar retail food establishment means the owner, operator, agent in charge, or

other person authorized by the owner, operator, or agent in charge to register the restaurant or similar retail food establishment, which is not otherwise subject to section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act, with FDA for the purposes of paragraph (d) of this section.

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

Covered establishment means a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.*, individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is registered to be covered under paragraph (d) of this section.

Custom order means a food order that is prepared in a specific manner based on an individual customer's request, which requires the covered establishment to deviate from its usual preparation of a standard menu item, *e.g.*, a club sandwich without the bacon if the establishment usually includes bacon in its club sandwich.

Daily special means 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.

Doing business under the same name means sharing the same name. The term “name” refers to either:

- (i) The name of the establishment presented to the public; or
- (ii) If there is no name of the establishment presented to the public (*e.g.*, an establishment with the generic descriptor “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 under paragraph (i) of this definition, the term “same” includes names that are slight variations

of each other, for example, due to the region, location, or size (e.g., “New York Ave. Burgers” and “Pennsylvania Ave. Burgers” or “ABC” and “ABC Express”).

Food on display means restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.

Food that is part of a customary market test means food that appears on a menu or menu board for less than 90 consecutive days in order to test consumer acceptance of the product.

Location means a fixed position or site.

Menu or menu board means the primary writing of the covered establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children’s menus; other specialty menus; electronic menus; and menus on the Internet. 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, e.g., booklets, pamphlets, or single sheets of paper. Menu boards include those inside a covered establishment as well as drive-through menu boards at covered establishments.

Offering for sale substantially the same menu items means offering for sale a significant proportion of menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies, (e.g., “Bay View Crab Cake” and “Ocean View Crab Cake”). “Menu items” in this definition refers to food items that are listed on a menu or menu board or that are offered as self-service food or food on display. Restaurants and similar retail food 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.

Restaurant or similar retail food establishment means a retail

establishment that offers for sale restaurant-type food, except if it is a school as defined by 7 CFR 210.2 or 220.2.

Restaurant-type food means food that is:

(i) Usually eaten on the premises, while walking away, or soon after arriving at another location; and

(ii) Either:

(A) Served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; or

(B) Processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in paragraph (ii)(A) of this definition, and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

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

Standard menu item means 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.

Temporary menu item means a food that appears on a menu or menu board for less than a total of 60 days per calendar year. The 60 days includes the total of consecutive and non-consecutive days the item appears on the menu.

Variable menu item means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.

(b) *Requirements for nutrition labeling for food sold in covered establishments*—(1) *Applicability*. (i)

The labeling requirements in this paragraph (b) apply to standard menu items offered for sale in covered establishments.

(ii)(A) The labeling requirements in this paragraph (b) do not apply to foods that are not standard menu items, including:

(1) Items such as condiments that are for general use, including those placed on the table or on or behind the counter; daily specials; temporary menu items; custom orders; food that is part of a customary market test; and

(2) 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.

(B) The labeling requirements of paragraph (b)(2)(iii) of this section do not apply to alcoholic beverages that are foods on display and are not self-service foods.

(2) *Nutrition information*. (i) Except as provided by paragraph (b)(2)(i)(A)(8) of this section, the following must be provided on menus and menu boards:

(A) The number of calories contained in each standard menu item listed on the menu or menu board, as usually prepared and offered for sale. In the case of multiple-serving standard menu items, this means the calories declared must be for the whole menu item listed on the menu or menu board as usually prepared and offered for sale (e.g., “pizza pie: 1600 cal”); or per discrete serving unit as long as the discrete serving unit (e.g., pizza slice) and total number of discrete serving units contained in the menu item are declared on the menu or menu board, and the menu item is usually prepared and offered for sale divided in discrete serving units (e.g., “pizza pie: 200 cal/slice, 8 slices”). The calories must be declared in the following manner:

(1) The number of calories must be listed adjacent to the name or the price of the associated standard menu item, in a type size no smaller than the type size of the name or the price of the associated standard menu item, whichever is smaller, in the same color, or a color at least as conspicuous as that used for the name of the associated standard menu item, and with the same contrasting background or a background at least as contrasting as that used for the name of the associated standard menu item.

(2) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

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

must appear in the same type size and in the same color and contrasting background as the number of calories.

(4) Additional requirements that apply to each individual variable menu item:

(i) When the menu or menu board lists flavors or varieties of an entire individual variable menu item (such as soft drinks, ice cream, doughnuts, dips, and chicken that can be grilled or fried), the calories must be declared separately for each listed flavor or variety. Where flavors or varieties have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(2) of this section), the calorie declaration for such flavors or varieties can be listed as a single calorie declaration adjacent to the flavors or varieties, provided that the calorie amount listed represents the calorie amounts for each individual flavor or variety.

(ii) When the menu or menu board does not list flavors or varieties for an entire individual variable menu item, and only includes a general description of the variable menu item (e.g., “soft drinks”), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (e.g., “150/250 calories”) or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section where more than two options are available (e.g., “100–250 calories”).

(iii) When the menu or menu board describes flavors or varieties for only part of an individual variable menu item (such as different types of cheese offered in a grilled cheese sandwich (e.g., “Grilled Cheese (Cheddar or Swiss)”), the calories must be declared for each option with a slash between the two calorie declarations where only two options are available (e.g., “450/500 calories”) or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section where more than two options are available (e.g., “450–550 calories”).

(5) Additional requirements that apply to a variable menu item that is offered for sale with the option of adding toppings listed on the menu or menu board. When the menu or menu board lists toppings that can be added to a menu item (such as pizza or ice cream):

(i) The calories must be declared for the basic preparation of the menu item as listed (e.g., “small pizza pie,” “single scoop ice cream”).

(ii) The calories must be separately declared for each topping listed on the menu or menu board (e.g., pepperoni, sausage, green peppers, onions on pizza;

fudge, almonds, sprinkles on ice cream), specifying that the calories are added to the calories contained in the basic preparation of the menu item. Where toppings have the same calorie amounts (after rounding in accordance with paragraph (b)(2)(i)(A)(2) of this section), the calorie declaration for such toppings can be listed as a single calorie declaration adjacent to the toppings, provided that the calorie declaration specifies that the calorie amount listed represents the calorie amount for each individual topping.

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

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

(6) Additional requirements that apply to a combination meal. Except as provided in paragraph (b)(2)(i)(A)(6)(iv) of this section:

(i) When the menu or menu board lists two options for menu items in a combination meal (e.g., a sandwich with a side salad or chips), the calories must be declared for each option with a slash between the two calorie declarations (e.g., “350/450 calories”).

(ii) When the menu or menu board lists three or more options for menu items in a combination meal (e.g., a sandwich with chips, a side salad, or fruit), the calories must be declared as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section (e.g., “350–500 calories”).

(iii) When the menu or menu board includes a choice to increase or decrease the size of a combination meal, the calorie difference must be declared for the increased or decreased size with a slash between two calorie declarations (e.g., “Adds 100/150 calories,” “Subtracts 100/150 calories”) if the menu or menu board lists two options for menu items in the combination meal, or as a range in accordance with the requirements of paragraph (b)(2)(i)(A)(7) of this section (e.g., “Adds 100–250 calories,” “Subtracts 100–250 calories”) if the menu or menu board lists three or more options for menu items in the combination meal.

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

(7) Additional format requirements for declaring calories for an individual variable menu item, a combination meal, and toppings as a range, if applicable. Calories declared as a range must be in the format “xx–yy,” where “xx” is the caloric content of the lowest calorie variety, flavor, or combination, and “yy” is the caloric content of the highest calorie variety, flavor, or combination.

(8) Exception for a variable menu item that has no clearly identifiable upper bound to the range of calories: If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range, e.g., all-you-can-eat buffet, then the menu or menu board must include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, e.g., “See buffet for calorie declarations.” This statement must appear in a type size no smaller than the type size of the name or price of the variable menu item, whichever is smaller, and in the same color or a color at least as conspicuous as that used for that name or price, with the same contrasting background or a background at least as contrasting as that used for that name or price.

(9) Additional requirements that apply to beverages that are not self-service. For beverages that are not self-service, calories must be declared based

on the full volume of the cup served without ice, unless the covered establishment ordinarily dispenses and offers for sale a standard beverage fill (*i.e.*, a fixed amount that is less than the full volume of the cup per cup size) or dispenses a standard ice fill (*i.e.*, a fixed amount of ice per cup size). If the covered establishment ordinarily dispenses and offers for sale a standard beverage fill or dispenses a standard ice fill, the covered establishment must declare calories based on such standard beverage fill or standard ice fill.

(B) The following statement designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards: "2,000 calories a day is used for general nutrition advice, but calorie needs vary." For menus and menu boards targeted to children, the following options may be used 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 to 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 to 8 years and 1,400 to 2,000 calories a day for children ages 9 to 13 years, but calorie needs vary."

(1) This 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 or menu board 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.

(2) For menus, this statement must appear on the bottom of each page of the menu. On menu pages that also bear the statement required by paragraph (b)(2)(i)(C) of this section, this statement must appear immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(3) For menu boards, this statement must appear on the bottom of the menu board, immediately above, below, or beside the statement required by paragraph (b)(2)(i)(C) of this section.

(C) The following statement regarding the availability of the additional written nutrition information required in paragraph (b)(2)(ii) of this section must be on all forms of the menu or menu board: "Additional nutrition information available upon request."

(1) This 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 or menu board and in the same color or in a color at least as conspicuous as that used for the caloric declarations, and with the same contrasting background or a background at least as contrasting as that used for the caloric declarations.

(2) For menus, the statement must appear on the bottom of the first page with menu items immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(3) For menu boards, the statement must appear on the bottom of the menu board immediately above, below, or beside the succinct statement required by paragraph (b)(2)(i)(B) of this section.

(ii) The following nutrition information for a standard menu item must be available in written form on the premises of the covered establishment and provided to the customer upon request. This nutrition information must be presented in the order listed and using the measurements listed, except as provided in paragraph (b)(2)(ii)(B) of this section. Rounding of these nutrients must be in compliance with § 101.9(c). The information must be presented in a clear and conspicuous manner, including using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Covered establishments may use the abbreviations allowed for Nutrition Facts for certain packaged foods in § 101.9(j)(13)(ii)(B):

- (A)(1) Total calories (cal);
- (2) Calories from fat (fat cal);
- (3) Total fat (g);
- (4) Saturated fat (g);
- (5) *Trans* fat (g);
- (6) Cholesterol (mg);
- (7) Sodium (mg);
- (8) Total carbohydrate (g);
- (9) Dietary fiber (g);
- (10) Sugars (g); and
- (11) Protein (g).

(B) If a standard menu item contains insignificant amounts of all the nutrients required to be disclosed in paragraph (b)(2)(ii)(A) of this section, the establishment is not required to include nutrition information regarding the standard menu item in the written form. 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 § 101.10. For standard menu items that contain insignificant amounts of six or more of the required nutrients, the declaration of nutrition information

required by paragraph (b)(2)(ii)(A) of this section may be presented in a simplified format.

(1) An insignificant amount is defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrates, dietary fiber, and protein, it must be an amount that allows a declaration of "less than one gram."

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

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

(3) If the simplified format is used, the statement "Not a significant source of ____" (with the blank filled in with the names of the nutrients required to be declared in the written nutrient information and calories from fat that are present in insignificant amounts) must be included at the bottom of the list of nutrients.

(C) For variable menu items, the nutrition information listed in paragraph (b)(2)(ii)(A) of this section must be declared as follows for each size offered for sale:

(1) The nutrition information required in paragraph (b)(2)(ii)(A) of this section must be declared for the basic preparation of the item and, separately, for each topping, flavor, or variable component.

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

(3) If the calories and other nutrients are the same for different flavors, varieties, and variable components of the combination meal, each variety, flavor, and variable component of the combination meal is not required to be listed separately. All items that have the same nutrient values could be listed together with the nutrient values listed only once.

(D) The written nutrition information required in paragraph (b)(2)(ii)(A) of this section may be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device

such as a computer, or in a menu, or in any other form that similarly permits the written declaration of the required nutrient content information for all standard menu items. If the written nutrition information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer/consumer to review the written nutrition information upon request.

(iii) The following must be provided for a standard menu item that is self-service or on display.

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

(1) For purposes of paragraph (b)(2)(iii)(A) of this section, “per displayed food item”; means per each discrete unit offered for sale, for example, a bagel, a slice of pizza, or a muffin.

(2) For purposes of paragraph (b)(2)(iii)(A) of this section, “per serving” means, for each food:

(i) Per serving instrument used to dispense the food offered for sale, provided that the serving instrument dispenses a uniform amount of the food (e.g., a scoop or ladle);

(ii) If a serving instrument that dispenses a uniform amount of food is not used to dispense the food, per each common household measure (e.g., cup or tablespoon) offered for sale or per unit of weight offered for sale, e.g., per quarter pound or per 4 ounces; or

(iii) Per total number of fluid ounces in the cup in which a self-service beverage is served and, if applicable, the

description of the cup size (e.g., “140 calories per 12 fluid ounces (small”).

(3) The calories must be declared in the following manner:

(i) To the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories except that amounts less than 5 calories may be expressed as zero.

(ii) If the calorie declaration is provided on a sign with the food’s name, price, or both, the calorie declaration, accompanied by the term “Calories” or “Cal” and the amount of the serving or displayed food item on which the calories declaration is based must be in a type size no smaller than the type size of the name or price of the menu item whichever is smaller, in the same color, or a color that is at least as conspicuous as that used for that name or price, using the same contrasting background or a background at least as contrasting as that used for that name or price. If the calorie declaration is provided on a sign that does not include the food’s name, price, or both, the calorie declaration, accompanied by the term “Calories” or “Cal” and the amount of the serving or displayed food item on which the calorie declaration is based must be clear and conspicuous.

(iii) For self-service beverages, calorie declarations must be accompanied by the term “fluid ounces” and, if applicable, the description of the cup size (e.g., “small,” “medium”).

(B) For food that is self-service or on display and is identified by an individual sign adjacent to the food itself where such sign meets the definition of a menu or menu board under paragraph (a) of this section, the statement required by paragraph (b)(2)(i)(B) of this section and the statement required by paragraph (b)(2)(i)(C) of this section. These two statements may appear on the sign adjacent to the food itself; on a separate, larger sign, in close proximity to the food that can be easily read as the consumer is making order selections; or on a large menu board that can be easily read as the consumer is viewing the food.

(C) The nutrition information in written form required by paragraph (b)(2)(ii) of this section, except for packaged food insofar as it bears nutrition labeling information required by and in accordance with paragraph (b)(2)(ii) of this section and the packaged food, including its label, can be examined by a consumer before purchasing the food.

(c) *Determination of nutrient content.*

(1) A covered establishment must have a reasonable basis for its nutrient

declarations. Nutrient values may be determined by using nutrient databases (with or without computer software programs), cookbooks, laboratory analyses, or other reasonable means, including the use of Nutrition Facts on labels on packaged foods that comply with the nutrition labeling requirements of section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act and § 101.9, FDA nutrient values for raw fruits and vegetables in Appendix C of this part, or FDA nutrient values for cooked fish in Appendix D of this part.

(2) Nutrient declarations for standard menu items must be accurate and consistent with the specific basis used to determine nutrient values. A covered establishment must take reasonable steps to ensure that the method of preparation (e.g., types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(3) A covered establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient values. This information must include the following:

(i) For nutrient databases:

(A) The name and version (including the date of the version) of the database, and, as applicable, the name of the applicable software company and any Web site address for the database. The name and version of a database would include the name and version of the computer software, if applicable;

(B) The recipe or formula used as a basis for the nutrient declarations;

(C)(1) Information on:

(i) The amount of each nutrient that the specified amount of each ingredient identified in the recipe contributes to the menu item; and

(ii) How the database was used including calculations or operations (e.g., worksheets or computer printouts) to determine the nutrient values for the standard menu items;

(2) If the information in paragraph (c)(3)(i)(C)(1) of this section is not available, certification attesting that the database will provide accurate results when used appropriately and that the database was used in accordance with its instructions;

(D) A detailed listing (e.g., printout) of the nutrient values determined for each standard menu item.

(E) Any other information pertinent to the final nutrient values of the standard menu item (e.g., information about what might cause slight variations in the

nutrient profile such as moisture variations);

(F) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(G) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(ii) For published cookbooks that contain nutritional information for recipes in the cookbook:

(A) The name, author, and publisher of the cookbook used;

(B) If available, information provided by the cookbook or from the author or publisher about how the nutrition information for the recipes was obtained;

(C) A copy of the recipe used to prepare the standard menu item and a copy of the nutrition information for that standard menu item as provided by the cookbook; and

(D) 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 (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the standard menu item but no changes may be made to the proportion of ingredients used.)

(iii) For laboratory analyses:

(A) A copy of the recipe for the standard menu item used for the nutrient analysis;

(B) The name and address of the laboratory performing the analysis;

(C) Copies of analytical worksheets, including the analytical method, used to determine and verify nutrition information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(iv) For nutrition information provided by other reasonable means:

(A) A detailed description of the means used to determine the nutrition information;

(B) A recipe or formula used as a basis for the nutrient determination;

(C) Any data derived in determining the nutrient values for the standard menu item, *e.g.*, nutrition information about the ingredients used with the source of the nutrient information;

(D) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity, who can certify that the information contained in the nutrient analysis is complete and accurate; and

(E) A statement signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the method of preparation (*e.g.*, types and amounts of ingredients in the recipe, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

(d) *Voluntary registration to be subject to the menu labeling requirements—(1) Applicability.* A restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements established in this section. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(2) *Who may register?* The authorized official of a restaurant or similar retail food establishment as defined in paragraph (a) of this section, which is not otherwise subject to paragraph (b) of this section, may register with FDA.

(3) *What information is required?* Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757:

(i) The contact information (including name, address, phone number, and

email address) for the authorized official;

(ii) The contact information (including name, address, phone number, and email address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official onsite, such as the owner or manager, for each specific restaurant or similar retail food establishment;

(iii) All trade names the restaurant or similar retail food establishment uses;

(iv) Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

(v) Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act and this section.

(4) *How to register.* Authorized officials of restaurants and similar retail food establishments who elect to be subject to requirements in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act can register by visiting <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm>. FDA has created a form (Form 3757) that contains fields requesting the information in paragraph (d)(3) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(i) Information should be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to menulawregistration@fda.hhs.gov.

(ii) *If email is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301-436-2804 or mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.*

(5) *When to renew the registration.* To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Signatures.* Signatures obtained under paragraph (d) of this section that

meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

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

[79 FR 71253, Dec. 1, 2014]

[FR Doc. 2016–28367 Filed 11–22–16; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

Food Labeling

CFR Correction

■ In Title 21 of the Code of Federal Regulations, parts 100 to 169, revised as of April 1, 2016, on pages 43 and 44, in § 101.9, paragraphs (j)(1)(i), (2) introductory text, (3) introductory text, and the first sentence of (j)(4) are revised to read as follows. And, on page 50, the effective date note at the end of § 101.9 is removed.

§ 101.9 Nutrition labeling of food.

* * * * *

(j) * * *

(1)(i) Food offered for sale by a person who makes direct sales to consumers (e.g., a retailer) who has annual gross sales made or business done in sales to consumers that is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers of not more than \$50,000, *Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section, § 101.10, or § 101.11, as applicable.

* * * * *

(2) Except as provided in § 101.11, food products that are:

* * * * *

(3) Except as provided in § 101.11, food products that are:

* * * * *

(4) Except as provided in § 101.11, foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section,

Provided, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. * * *

* * * * *

[FR Doc. 2016–28363 Filed 11–22–16; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

Food Labeling

CFR Correction

■ In Title 21 of the Code of Federal Regulations, parts 100 to 169, revised as of April 1, 2016, on page 50, § 101.10 is revised to read as follows:.

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., “low fat, this meal provides less than 10 grams of fat”) may serve as the functional equivalent of complete nutrition information as described in § 101.9. For the purposes of this section, restaurant food includes two categories of food. It includes food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. It also includes food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in the previous sentence, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment. For standard menu items that are offered for sale in covered establishments (as defined in § 101.11(a)), the information in the written nutrition information required by § 101.11(b)(2)(ii)(A) will serve to meet the requirements of this section. Nutrient levels may be determined by nutrient databases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient

requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

[79 FR 71253, Dec. 1, 2014]

[FR Doc. 2016–28364 Filed 11–22–16; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. FDA–2016–N–0543]

RIN 0910–AH30

Food and Drug Administration Review and Action on Over-the-Counter Time and Extent Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its nonprescription (over-the-counter or OTC) drug regulations. This final rule supplements the time and extent application (TEA) process for OTC drugs by establishing timelines and performance metrics for FDA’s review of non-sunscreen TEAs, as required by the Sunscreen Innovation Act (SIA). It also amends the existing TEA process to include filing determination and withdrawal provisions to make the TEA process more efficient.

DATES: This rule is effective December 23, 2016.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this final rule, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4246, Kristen.Hardin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose and Coverage of the Final Rule
 - B. Summary of the Major Provisions of the Final Rule