

Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Much Anticipated Final Rules on Menu and Vending Machine Nutrition Labeling

The U.S. Food and Drug Administration (FDA) recently published the long awaited final rules on menu and vending machine nutrition labeling.¹ The rules implement section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act), which amended section 403(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to establish: (1) requirements for the nutrition labeling of standard menu items at restaurants or similar retail food establishments with 20 or more locations; and (2) calorie disclosure requirements for certain foods that are sold out of vending machines operated by a person engaged in the business of owning or operating 20 or more vending machines.² Establishments and vending machine operators that are not covered by the rules may elect to be subject to the rules by voluntarily registering with FDA. The intent of these rules is to provide clear, accurate, and consistent nutrition information—calorie content in particular—to enable consumers to make informed and healthful decisions.

Although certain requirements of section 4205 of the Affordable Care Act became effective upon enactment, FDA announced in a January 2011 notice that it would exercise enforcement discretion on those requirements until final rules were published and effective.³ The Agency published proposed rules for menu labeling and vending machine labeling in April 2011.⁴ After considering comments to the proposals, FDA issued final rules on December 1, 2014. The final rule for menu labeling will become effective on December 1, 2015, and the vending machine labeling rule will become effective on December 1, 2016.

Several important changes were made in the process of finalizing these two rules. For example, FDA broadened its interpretation of the entities and food items that are subject to the menu labeling rule, and provided greater flexibility on where calorie information could be posted for items in vending machines. The following overview describes the basic scope and requirements of the menu and vending machine labeling rules. Affected entities should closely review the final regulations in their entirety to ensure full compliance with the new requirements.

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Final Rule on the Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

The final menu labeling rule establishes requirements for the disclosure of certain nutrition information for “standard menu items” in restaurants and similar retail food establishments with 20 or more locations. Under the rule, calorie information must be provided clearly and conspicuously next to the listed standard menu item on a menu or menu board, and on signs adjacent to standard menu items when they are on display or available for self-service. In addition to calorie information, each menu or menu board must prominently include a succinct statement concerning suggested caloric intake (*i.e.*, “2,000 calories a day is used for general nutrition advice, but calorie needs vary”),⁵ and a notice stating “Additional nutrition information available upon request.” Upon request, covered establishments must provide information about the total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fiber, sugars, and protein in their standard menu items. The final rule contains detailed requirements for providing calorie and nutrition information, determining nutrient content, and voluntarily registering to be subject to the menu labeling requirements. Provided below is a discussion of some of the more notable elements of the rule.

- **Establishments and Foods Subject to the Rule** - The final rule applies to “covered establishments.” A covered establishment is defined as (1) “a restaurant or similar retail food establishment” that is (2) “part of a chain with 20 or more locations” (3) “doing business under the same name (regardless of the type of ownership, *e.g.*, individual franchises)” and (4) “offering for sale substantially the same menu items.”⁶ Restaurants or similar retail food establishments that would otherwise be excluded from the rule, but that elect to voluntarily register with FDA, are also “covered establishments” subject to the menu labeling requirements.

The regulations define “restaurant or similar retail food establishment” as a “retail establishment that offers for sale restaurant-type food”⁷ As a general matter, “restaurant-type food” is defined as food that “is usually eaten on the premises, while walking away, or soon after arriving at another location,” and that is either served in the establishment or processed and prepared primarily in the establishment.⁸ Examples of “restaurant-type food” provided in the rule include take-out and delivery pizzas, food purchased at a drive-through, foods ordered from a menu/menu board at a grocery store, hot buffet food, and food from a salad bar.⁹ In addition, FDA clarifies that alcoholic beverages that are standard menu items are now also subject to the menu labeling requirements. Accordingly, the rule applies broadly to establishments such as eat-in restaurants, grocery stores, confectionary stores, and certain facilities within facilities (*e.g.*, food stands in amusement parks),¹⁰ as well as bakeries, cafeterias, convenience stores, delicatessens, food service facilities in movie theaters and bowling alleys, food service vendors such as mall cookie counters, take-out and delivery food services, and superstores.¹¹

The final rule further clarifies that “offering for sale substantially the same menu items” means offering for sale menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components. The name of the menu item need not be the same at all locations in order for it to be substantially the same. Additionally, not all menu items need to be the same across locations for the chain to offer for sale substantially the same menu items.¹²

- **Establishments and Foods Excluded From the Rule** - Establishments that are not covered by the rule include elementary, middle, and high schools (as defined and governed by the U.S. Department of Agriculture school breakfast and lunch programs), and transportation venues such as food trucks, airplanes, and trains because they do not have a “location” (*i.e.*, “fixed position or site”) as required by the definition of covered establishment. Food items excluded from the rule include, among other things: (1) foods sold at

deli counters or grocery stores that are intended for consumption over multiple occasions, by multiple people, or stored for later use (*e.g.*, sliced turkey, a whole cake, a loaf of bread, or bulk bin foods) since such foods do not meet the definition of “restaurant-type food”; and (2) alcoholic beverages that are foods on display and are not self-service (*e.g.*, bottles of alcohol displayed behind a bar).¹³ Additionally, non-standard menu items such as condiments for general use, daily specials, temporary menu items (served fewer than 60 days a year), custom orders of a standard item, and food that is part of a customary market test (*i.e.*, offered for fewer than 90 consecutive days to test consumer acceptance) are also excluded.¹⁴

- **Key Definition: “Menu or Menu Board”** - The final rule defines “menu or menu board” as “the primary writing of the covered establishment from which a customer makes an order selection.”¹⁵ Among the examples listed are breakfast, lunch, and dinner menus, dessert menus, beverage menus, children’s menus, electronic menus and internet menus, and drive-through menu boards. Factors to consider in determining if something falls within the definition are whether the writing lists the name (or includes an image) of a standard menu item and the price of the menu item, and whether the writing can be used by a customer to make a selection at the time the customer is viewing the writing. Calorie information must be included on every menu or menu board available to customers.¹⁶
- **Variable Menu Items** - Generally speaking, the number of calories in each standard menu item must be listed on menus and menu boards. In the case of multiple serving standard menu items, calories must be declared for the whole menu item (*e.g.*, “pizza pie: 1600 cal”), or per discrete serving unit as long as the discrete serving unit and total number of serving units contained in the menu item are declared on the menu or menu board, and the item is usually prepared and offered for sale divided in discrete serving units (*e.g.*, “pizza pie: 200 cal/slice, 8 slices”). The final rule, however, clarifies the requirements for menu items that may have variable calorie contents. These “variable menu items” are defined as “a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item” (*e.g.*, soft drinks, ice cream, doughnuts, dips, certain combination meals, or different meat preparations).¹⁷

When a menu or menu board lists flavors or varieties for an entire individual variable menu item, the calories must typically be declared separately for each listed flavor or variety, or flavors and varieties may be grouped together as a single listing if they have the same calorie content.¹⁸ If the menu or menu board does not list flavors or varieties, 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.*, “150/200 calories”), or as a range where more than two options are available (*e.g.*, “100-250 calories”). The final rule contains additional provisions and requirements applicable to specific types of variable menu items such as beverages, combination meals, and variable menu items that are offered for sale with the addition of toppings that are separately listed on the menu or menu board (*e.g.*, pizza or ice cream). For example, for beverages that are not self-service, the final rule requires that calorie content be determined “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... or standard ice fill.”¹⁹

- **Self-Service Foods and Foods on Display** - For standard menu items that are available for self-service or on display, calorie information must be provided per displayed food item or by serving depending upon the specific scenario. For items such as muffins, bagels, or a slice of pizza, the calorie content should be displayed for the item as a single unit (*e.g.*, “150 calories per muffin”). For food that is not available as a discrete unit, however, calorie information must be declared “by serving,” which should be based on the uniform serving instrument provided (*e.g.*, “150 calories per scoop”), or if no standard serving instrument is provided, by common household measure or weight. For self-service beverages, “per serving” is the total

number of fluid ounces in the cup in which a self-service beverage is served (e.g., “140 calories per 12 fluid ounces (small)”). The calorie information may be provided: (1) on a sign adjacent to, and clearly associated with, the corresponding food; (2) a sign attached to a sneeze guard above each specific food; or (3) on a single sign or placard listing the calorie declaration for several food items so long as it is located where a consumer can view the name, calorie declaration, and serving or unit of a particular item while selecting that item.

- **Determining and Substantiating Nutrient Content** - The final rule provides that a covered establishment must have a “reasonable basis” for its nutrient content declarations.²⁰ Nutrient values may be determined based on information from nutrient databases, cookbooks, laboratory analyses, Nutrition Facts Labels on packaged foods used to produce the menu item, or other reasonable and supported means. Upon request from FDA, covered establishments must provide FDA with information substantiating the nutrient values they claim, as well as the method and data used to derive these values. Covered establishments must certify that the information contained in their analyses is complete and accurate and that the establishment “has taken reasonable steps to ensure that the method of preparation . . . and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values are determined.”²¹

Final Rule on the Calorie Labeling of Articles of Food in Vending Machines

The final vending rule requires persons who own or operate 20 or more vending machines to disclose the number of calories contained in any article of food sold from a vending machine that does not already provide visible nutrition information at the point of purchase. Provided below is a brief summary of some of the key provisions in the final rule.

- **Scope** - The final rule provides that covered vending machines are subject to calorie-labeling requirements. Covered “vending machines” include any “self-service machine that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses servings of food in bulk or packages, or prepared by the machine, without the necessity of replenishing the machine between each vending operation.”²² Food products sold in vending machines that are subject to this rule include any “article of food” that is: (1) sold from a vending machine that does not allow the purchaser to examine the Nutrition Facts label prior to purchase or otherwise provide visible nutrition information; and (2) sold from a vending machine that is owned or operated by a person engaged in the business of owning or operating 20 or more vending machines, or is operated by a person who voluntarily elects to be subject to these requirements.

This rule encompasses those vending machines that sell and dispense sodas, packaged snacks, hot-and-cold cup beverages, refrigerated prepared food, dietary supplements, and handfuls of nuts or candies, to name a few. Game machines that dispense candy or other edible items as a prize or part of the game are not covered by the rule.

- **Exempt Articles of Food** - Vending machine operators do not have to provide calorie information for certain articles of food that meet one of the following requirements:
 - The prospective purchaser can view the calories, serving size, and servings per container listed in the Nutrition Facts label on the vending machine food without any obstruction. This label must comply with 21 C.F.R. § 101.9(c) and (d), and be of a size that permits the prospective purchaser to easily read the nutrition information;
 - The calories, serving size, and servings per container are listed in a reproduction of the Nutrition Facts label on the vending machine food, provided that this reproduction is a reproduction of an actual

Nutrition Facts label that complies with 21 C.F.R. § 101.9, and is presented in a size that can be easily read. In addition, the prospective purchaser must be able to view this information prior to purchasing the vending machine food; or

- The prospective purchaser can view “visible nutrition information, including, at a minimum the total number of calories for the article of food as sold at the point of purchase.”²³ This information must appear on the food label itself, and must be visible, clear, and easy to read from the vantage point of the prospective purchaser. Furthermore, FDA mandates that the type size must be at least 50% of the size of the largest printed matter on the label and meet additional color and contrasting background requirements.
- **Calorie Declaration Requirements** - For those articles of food that do not meet one of the exceptions listed above, vending machine operators must display calorie declarations for each vending machine food. In doing so, operators must: (1) label foods to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories, except that foods with amounts less than 5 calories may be labeled as zero; (2) place the term “Calories” or “Cal” adjacent to the caloric content value for each food; (3) include in the calorie declaration, the total calories present in the packaged food, regardless of whether the food item contains a single serving or multiple servings; and (4) if the vending machine enables the purchaser to select options to produce a final vended product (*i.e.*, coffee), calories must be declared “per option or for the final vended products.”

Vending machine operators must display calorie information in a clear and conspicuous manner and the calorie information must be tailored to articles of food that are currently or typically sold in that specific vending machine. This information may be placed prominently on a sign in close proximity to the article of food or selection button (*i.e.*, in, on, or adjacent to the vending machine). FDA does not require, however, that the operator attach the sign to the vending machine, as long as the purchaser can see both the calorie information and the food, name, price, selection button, or selection number at the same time. Operators must also comply with certain font size, color, and display restrictions, as described in the rule.

FDA permits the use of electronic or digital display vending machines. Operators must still supply the calorie information prior to the customer making the purchase, but are not required to present the calorie information simultaneously for all articles of food.

- **Disclosure** - Vending machine operators subject to the rule must provide their contact information on the vending machine. If state law also requires operators to do so, FDA does not expect operators to duplicate these efforts. FDA intends to use this information to contact operators regarding enforcement action, because failure to comply with the final rule would deem the food misbranded under the FFDCA.
- **Determining Calorie Content** - In the preamble to the final rule, FDA indicates that vending machine operators may use a number of different methods to determine the calorie content for covered foods, such as using the manufacturer’s or supplier’s nutrition information, the nutrition information provided on the food packaging, nutrient databases, cookbooks, or laboratory analyses. FDA expects that operators will prepare and maintain records as to how they determine the calorie content for covered foods. FDA could request such information during an inspection.

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King & Spalding will continue to monitor FDA's implementation of these final rules. Please let us know if you have questions or would like assistance in developing programs to comply with the new requirements.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

¹ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Final Rule, 79 Fed. Reg. 71156 (Dec. 1, 2014) (to be codified at 21 C.F.R. part 101); Food Labeling; Calorie Labeling of Articles of Food in Vending Machines, Final Rule, 79 Fed. Reg. 71259 (Dec. 1, 2014) (to be codified at 21 C.F.R. part 101).

² Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 573 (§ 4205 codified at 21 U.S.C. § 343(q)).

³ Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance, 76 Fed. Reg. 4360 (Jan. 25, 2011).

⁴ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Proposed Rule, 76 Fed. Reg. 19192 (Apr. 6, 2011); Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Proposed Rule, 76 Fed. Reg. 19237 (Apr. 6, 2011).

⁵ Certain other options are available for menus and menu boards targeted to children.

⁶ 21 C.F.R. § 101.11(a).

⁷ *Id.*

⁸ *Id.*

⁹ 79 Fed. Reg. at 71157-58.

¹⁰ 79 Fed. Reg. at 71166 - 69.

¹¹ *Id.*

¹² 79 Fed. Reg. at 71172.

¹³ 79 Fed. Reg. at 71188.

¹⁴ 21 C.F.R. § 101.11(b)(ii).

¹⁵ 21 C.F.R. § 101.11(a).

¹⁶ 79 Fed. Reg. at 71177.

¹⁷ 21 C.F.R. § 101.11(a).

¹⁸ 21 C.F.R. § 101.11 (b)(2)(i)(A)(4).

¹⁹ 21 C.F.R. § 101.11(b)(2)(i)(A)(9).

²⁰ 21 C.F.R. § 101.11(c).

²¹ *Id.*

²² 21 C.F.R. § 101.8(a).

²³ 21 C.F.R. § 101.8(b)(2).