

May 2018

FDA'S FINAL MENU LABELING RULE

SUMMARY AND COMPLIANCE ASSISTANCE

Overview

On Tuesday, November 25, 2014, the Food and Drug Administration (“FDA”) released its long-awaited final rule establishing “menu labeling” requirements for chain restaurants and “similar retail food establishments.” On April 29, 2016, the FDA issued a final guidance document for industry addressing some of the questions that had been raised about the final rule. That rule was published in the Federal Register on May 5, 2016. Most recently, on May 7, 2018, FDA finalized a supplementary guidance document to help covered entities implement the final rule. That guidance contained information on three particular issues: (1) branded fuel marketers with fewer than 20 locations; (2) marketing materials; and (3) correcting minor violations. The changes are described in greater detail below.

Generally, establishments that are covered by the rule must post calories for standard menu items on menus or menu boards or, for self-service items and foods on display, on signs adjacent to the items. They also will be required to provide additional written nutrition information to consumers upon request. Covered establishments were scheduled to begin complying with the final rule no later than December 1, 2016. However, Congress passed language calling for FDA to delay the compliance date. Final guidance was published on May 5, 2016 and additional draft guidance was published in November 2017. FDA began requiring compliance as of May 7, 2018.

It is important to note that many of the menu labeling rule’s requirements are difficult to navigate – particularly as they apply to convenience stores. This is in part because the law is designed primarily for chain restaurants, and applying it to convenience stores creates many complexities that the final rule does not adequately address. NACS is continuing to work with key members of Congress to pass legislation allowing its members and others to comply with the rule in ways that are more helpful to consumers and more reasonable for businesses of all types to follow.

This document provides a brief summary of the final rule that was released on November 25, 2014 as clarified by subsequent guidance. This document is intended to provide convenience store owners and operators with a general understanding of their obligations under the final rule. But compliance obligations and strategy should be developed on a company-by-company, and often store-by-store basis. If you would like to discuss the rule in further detail, please contact Lyle Beckwith, Senior Vice President for Government Relations at the National Association of Convenience Stores (lbeckwith@convenience.org).

What Establishments are Covered by the Menu Labeling Rule?

The menu labeling rule generally covers any retail establishment with 20 or more locations that sells food that is intended for consumption soon after being purchased (“restaurant-type” food). This includes most hot prepared foods and similar items. It is likely that FDA will take a broad view of what foods are intended to be consumed soon after purchase. It does not matter what type of store is involved – if it sells any food that is meant to be consumed soon after purchase, then it meets that part of the test.¹

The full test for whether the rule applies to a business is whether that business:

- Is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.*, individual franchises);
 - Note that the number of establishments owned and operated by a particular company/individual is not relevant to this criterion. The key is whether there are multiple locations *doing business under the same name*. For example, if an individual owns and operates three 7-Eleven franchises, or three gas stations that are Exxon branded with a Tiger Mart, those establishments would be subject to the menu labeling rule because there are 20 or more 7-Eleven and Tiger Mart locations, respectively.
- The different locations in that chain offer for sale substantially the same menu items.² A business offers “substantially the same menu items” if a significant proportion of its menu items use the same “general recipe” and are prepared in “substantially the same way with substantially the same food components” as items offered at at least 19 other locations within the chain. It is likely that FDA will take a broad view of whether a particular chain offers “substantially the same menu items.”

What type of food is “restaurant-type” food that is covered by the rule?

Food qualifies as “restaurant type food” if it is intended to be consumed soon after purchase. The menu labeling rule states that this means the food is:

- Usually eaten on the premises, while walking away, or soon after arriving at another location; and either
 - served in restaurants or other establishments in which food is served for immediate consumption or which is sold for sale and use in such establishments; or

¹ FDA has stated that the rule is designed to cover not only chain restaurants, but also convenience stores and grocery stores, bakeries, cafeterias, coffee shops, delis, candy stores, and facilities located within entertainment venues (such as movie theaters, bowling alleys, amusement parks, and sports stadiums). The guidance states that food trucks, planes, trains, complimentary hotel breakfasts, prisons, and school lunch programs are not covered by the rule.

² 21 CFR 101.11(a).

- processed and prepared primarily in a retail establishment, ready for immediate human consumption, and which is not offered for sale outside such establishment.³
 - FDA has indicated that the phrase “not offered for sale outside such establishment” means food that is ready-to-eat, and that is portioned on-site, and that there is not a reasonable possibility that the product will be purchased directly by consumers in a setting other than a covered establishment in which it is served for immediate consumption.⁴
 - Notwithstanding this “clarification,” NACS believes that the term “not offered for sale outside such establishment” is ambiguous and will seek clarification as to its definition from federal officials.

FDA has stated that it considers the following types of food to be “restaurant-type food”:

- food purchased at a drive-through establishment;
- take-out and delivery pizza;
- hot pizza at grocery and convenience stores that is ready to eat;
- pizza slices from a movie theater;
- hot buffet food, hot soup at a soup bar, and food from a salad bar;
- foods ordered from a menu/menu board at a grocery or convenience store intended for individual consumption (e.g., soups, sandwiches, and salads); and
- self-service foods and foods on display that are intended for individual consumption (e.g., sandwiches, wraps, and paninis at a deli counter; salads plated by the consumer at a salad bar; bagels, donuts, and rolls offered for individual sale).⁵

At the same time, FDA has stated that it would not consider foods that may be ready for immediate consumption but that consumers usually store for use at a later time or customarily further prepare to be restaurant-type food. Such foods include:

- foods to be eaten over several eating occasions or stored for later use (e.g., loaves of bread, bags or boxes of dinner rolls, whole cakes, and bags or boxes of candy or cookies);
- food sold by weight that are not self-serve and are not intended solely for individual consumption (e.g., deli salads sold by unit of weight such as potato salad and chicken salad), either prepacked or packed upon consumer request; and
- foods that are usually further prepared before consuming (e.g., deli meats and cheeses).⁶

³ *Id.*

⁴ See 58 Fed. Reg. 2146; see also 79 Fed. Reg. 71170 (cross-referencing 58 Fed. Reg. 2146 for purposes of interpreting the phrase “not offered for sale outside such establishment.”); see also 58 Fed. Reg. 2185.

⁵ 79 Fed. Reg. 71170.

⁶ *Id.*

What is a chain of 20 or more locations?

The rule only applies to businesses that are part of a chain of 20 or more locations, but FDA does not care who owns those locations. That is, the owner of a single franchise business is subject to the rule if that franchise has 20 or more locations “doing business” under the same franchise name. In terms of whether an establishment is “doing business under the same name” for purposes of meeting the 20 location threshold, the term “name” refers to either (a) the name of the establishment presented to the public, or (b) if there is no name of the establishment presented to the public (e.g., “concession stand”), the name of the parent entity of the establishment. One name is considered to be the “same” as another even if there are slight variations between different names. For example, if a chain distinguishes its stores’ names based on the street where the stores are located, e.g., “New York Avenue Burgers” vs. “Pennsylvania Avenue Burgers,” this would qualify as “doing business under the same name.”⁷

As noted above, businesses are subject to the rule even if they have fewer than 20 locations (indeed, if they only have a single location) if they use the same name as at least 19 other locations. This includes franchisees and in some cases, owners/operators of branded motor fuel outlets. The May 2018 guidance, however, means that branded fuel marketers with fewer than 20 locations likely do not have to comply with the rule if they do not sell substantially the same menu items. Specifically, the guidance states, “where...marketing alliances or independent convenience stores that participate in branded fuel contracts do not offer for sale substantially the same menu items, they are not covered by the menu labeling final rule unless they choose to voluntarily register with FDA.”⁸ The guidance made clear for the first time that having the same foods as other branded outlets (for example, if the outlets sold hot dogs and soft drinks) does not mean those outlets sell “substantially the same menu items.” As long as the outlets have different recipes (such as having different brands of hot dogs supplied by different suppliers), then those outlets will not meet the “substantially the same” part of the test and will not be required to comply with the regulations (providing they themselves do not have 20 or more locations meeting the parts of the test).

What counts as selling “substantially the same” menu items?

A chain is considered to offer for sale “substantially the same menu items” if 20 or more of its locations have 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.” The foods can count as substantially the same even if different locations use different names for them.⁹ By the “same general recipe,” FDA means that the establishments share a recipe, even if one establishment substantially tweaks that recipe due to regional tastes or dietary practices. By “prepared in substantially the same way,”

⁷ *Id.*

⁸ Food and Drug Administration, *Guidance for Industry: Menu Labeling Supplemental Guidance*, (May 2018), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM583492.pdf>, pages 37-38. [hereinafter *Guidance*]

⁹ See 79 Fed. Reg. 71170

FDA means to include slight deviations from the recipe because of, for example, food service worker variability. And by “substantially the same food components,” FDA means to include situations where ingredients may vary based on local availability or sourcing.¹⁰

For convenience stores, whether or not two different establishments are offering the “same” menu items is a fact-specific determination. FDA recognized in the explanation of its rule that “depending on the extent to which the menu items vary, a convenience store may or may not meet the criterion of offering for sale substantially the same menu items as defined in the rule.”¹¹

If two establishments operating under the same name offer the same type of food product (*e.g.*, a brownie), they are only considered to be offering for sale the “same” product as one another if the two products are prepared in substantially the same way, with substantially the same food components. If the two establishments share a general recipe, but one of them adds a “secret ingredient,” the two products could still be considered the “same” product, depending on the importance of that ingredient. Even in this circumstance, the two establishments would not be offering for sale “substantially the same” menu items if they offer a number of other menu items and the brownie is the only item the two establishments share.¹² This is because establishments must offer for sale “a significant proportion” of the same menu items. This criterion is qualitative rather than quantitative, and thus it is unclear how many of the same or similar items are “enough” to cross the threshold and subject the establishment – and the items – to the menu labeling rule. The latest guidance helps with this determination by making clear that, for example, different brands of hot dogs (or similar items) would not qualify as sharing the same general recipe.

In sum, entities are subject to the menu labeling rule if they: (1) sell any amount of food for immediate consumption (restaurant-type food); (2) are part of a chain with 20 or more locations doing business under the same name (including franchises or branded motor fuel outlets); and (3) those locations (or, at least 20 of them) offer for sale “substantially the same menu items.” Whether a convenience store is subject to the rule is a fact-specific determination and businesses should consider all of these factors in making their determination as to whether they are subject to the rule.

What if there is a restaurant or other business inside/part of my convenience store?

Many establishments have a chain restaurant located within it (such as a Subway inside a convenience store). In these instances, the chain restaurant must comply with the menu labeling rule, even if it is located within an establishment that is not covered by the rule (for example, a Subway in a convenience store that is not part of a chain). Whether a particular establishment – either the convenience store or the restaurant or other business inside/part of the store – is covered by the rule will be determined based on whether there

¹⁰ See 79 Fed. Reg. 71173.

¹¹ 79 Fed. Reg. 71173-74.

¹² See 79 Fed. Reg. 71175.

are 19 or more other locations doing business under the same name and offering for sale substantially the same menu items as the establishment in question.

The final rule does not say, however, whether the larger facility (convenience store) or the smaller facility (Subway) is ultimately responsible for compliance with the menu labeling rule. The FDA says that the person with “authority and supervisory responsibility” over an establishment can be held responsible for violations, and that enforcement decisions on these matters will be determined on a case-by-case basis.¹³

Based on the above, a convenience store owner/operator should only be held accountable for the compliance obligations of a chain restaurant located within the owner/operator’s store if the owner/operator has authority or supervisory responsibility over the operations of the restaurant. These issues can generally be negotiated contractually and it may be wise to specify up-front in contracts which entity will be responsible for this compliance. As noted above, however, FDA has not set forth a clear “chain of liability” for purposes of enforcing the menu labeling rule.

What if I’m not subject to the rule but want to comply (and not comply with my state/local rules)?

You can do that. Establishments that are not subject to the menu labeling rule may voluntarily register to be subject to the federal menu labeling rules. This provision is designed to enable entities subject to state/local menu labeling requirements to become subject to the federal requirements in lieu of such state/local requirements.¹⁴

What Food Items Are Covered by the Menu Labeling Rule?

Covered establishments must post the calories for “standard menu items” that either (a) appear on “menus or menu boards,” or (b) are “self-service food” or “food on display” (in which case the establishment must post the calories on signs adjacent to such foods).

A “menu item” refers to food items that are either listed on a menu or menu board or that are offered as self-service food or food on display. Thus, even establishments that do not have menus will have obligations under the rule if they have self-service food or food on display. Chains can still be considered to be offering for sale substantially the same menu items even if the availability of some menu items varies within the chain.¹⁵

¹³ 79 Fed. Reg. 71161.

¹⁴ See generally 21 C.F.R. 101.11(d). Registration must be renewed every other year.

¹⁵ *Id.* The term “location” means a fixed position or site. *Id.* Thus, establishments occupying separate fixed positions or sites within the same building (*e.g.*, a mall) are treated as separate establishments. At the same time, facilities that do not have fixed positions or sites, such as trains, airplanes, and food trucks, are not covered by the menu labeling rule. See 79 Fed. Reg. 71171.

What is a standard menu item?

Covered establishments are only required to provide nutrition information for “standard menu items.”¹⁶ A “standard menu item” means a restaurant-type food (see definition above) that is (a) “routinely” included on a menu or menu board and/or (b) “routinely” offered as a self-service food or food on display.¹⁷

Although the term “routinely” is not further defined, as further discussed below FDA has defined “temporary” (*i.e.*, non-routinely offered) menu items as those offered fewer than 60 days per year; therefore, any item offered 60 or more days per year will likely be considered to be “routinely” offered.

It should be noted that a covered establishment must provide nutrition information for a standard menu item even if it is only offered at one location.

What is a menu or menu board?

A “menu or menu board” means the primary writing of the covered establishment from which a customer makes an order selection. While “primary” seems to indicate that there is one menu/menu board, FDA does not view it that way. There may be multiple menus and menu boards in a single establishment that must include the information required by the final rule. Notably, however, the FDA’s May 2018 guidance clarified that marketing materials (e.g., coupons, posters in store windows, or signs on gas pumps), which includes certain materials both inside and outside the covered establishment, generally are not menus and do not need to contain calorie information.¹⁸

Determining whether a writing is, or is part of, the primary writing from which a customer makes a selection depends on a number of factors, including: (1) whether the writing lists the name or includes the image of a standard menu item and the price of the standard menu item, and (2) whether the writing can be used by a customer to make an order selection at the time the customer is viewing the writing.

A menu may be in different forms (booklets, pamphlets, single sheets of paper, etc.), and menu boards include those inside a covered establishment as well as drive-through menu boards.¹⁹ It is important to note that under the rule a single establishment may have multiple “primary” menus or menu boards on which calorie information must be displayed.²⁰ The critical factor is whether a particular piece of written material is likely to be used by a customer in making an order.

¹⁶ 21 C.F.R. 101.11(b)(1)(i).

¹⁷ 21 C.F.R. 101.11(a).

¹⁸ See Guidance, *supra* note 8, at pages 20-24.

¹⁹ *Id.*

²⁰ See 79 Fed. Reg. 7177-7179. (“The ‘primary writing’ can include more than one form of written material, such as a paper menu, a delivery menu, and a menu board; 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.”)

An establishment's advertisements, such as a poster on a storefront, a coupon or other promotional material, banners, tray liners, billboards, and stanchions, may be considered a "secondary writing" rather than a menu and thus will not have to include calorie information.²¹ That said, advertisements can be considered menus according to FDA if they list the menu item, its price and can be used to make an order. If, however, additional information would be needed to make an order, the advertisement would not be considered a menu. FDA's guidance uses the example of coupons on a pizza box to illustrate its view. If such a coupon offers a particular size pizza with pepperoni at a particular price and provides a phone number to call to make an order, that is likely a menu because it meets all the requirements of the menu. If that same coupon has all the same information but for a "single-topping" pizza (rather than specifying pepperoni, for example), then that is not a menu because the customer would need additional information from a menu to actually make an order.

What is self-service food?

"Self-service food" means restaurant-type food that is available at a salad bar, hot food 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, such as drinks dispensed from a soda fountain and coffee available on a self-service basis.²²

What is food on display?

"Food on display" means restaurant-type food that is visible to the customer before making a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.²³ For example, deli meats and cheese generally have an expectation of further preparation by the consumer (*e.g.*, combining with bread to make a ham and cheese sandwich), and thus would not be subject to the menu labeling rules; other foods, such as prepared sandwiches or hot dogs,²⁴ freshly cooked pizza, and salad and hot food bars do not have an ordinary expectation of further preparation by the consumer before consumption and thus would be subject to the menu labeling rules.²⁵ Essentially, the food on display question restates the question whether something is intended for consumption soon after being purchased (*i.e.*, whether it is in fact "restaurant-type food" as explained above).

Are there any exceptions?

Yes. Not all of the menu items offered for sale – even if they are listed on a menu or are self-serve or on display – require calorie declarations. The menu labeling rule specifies

²¹ See 79 Fed. Reg. 71181.

²² *Id.*

²³ *Id.*

²⁴ Hot dogs served from a roller are to be distinguished from deli meats because the former – when received by a customer on a bun – are not usually further prepared before consuming (unlike deli meats that are not served as part of a sandwich), and thus fall within the definition of "restaurant-type food." See generally 79 Fed. Reg. 71170. In this regard, they are analogous to prepared sandwiches.

²⁵ See generally 79 Fed. Reg. 71184.

certain types of food that are *not* “standard menu items” (and thus are not subject to menu labeling requirements).²⁶ These include:

- Items such as condiments that are for general use, *i.e.*, available for consumers to put onto food products that they purchase, such as a table with ketchup and mustard dispensers.²⁷ Note that this exemption does not apply to condiments that are *part of* a standard menu item as it is usually prepared and offered for sale. (For example, if a burger is generally prepared with ketchup and mayonnaise, such condiments must be incorporated into the burger’s calorie count.)²⁸
- Temporary menu items,²⁹ defined as those that are offered for fewer than 60 total days per year (this includes the total of consecutive and/or non-consecutive days the item appears on the menu).³⁰
- Food that is part of a customary market test,³¹ *i.e.*, food that is offered for less than 90 consecutive days in order to test consumer acceptance of the product.³² The 90-day threshold applies to each establishment within a chain, so two different establishments in the same chain can each test a product for 85 days and the product would still fall within the customary market test exception.³³ The key component here is that the food must be offered as a means of testing consumer acceptance.
- Daily specials,³⁴ defined as a menu item that is prepared and offered for sale on a particular day, is not routinely offered, and is promoted as a special menu item for that particular day.³⁵ FDA would not consider an item that is offered every week on a particular day to be a “daily special” because it is routinely offered for sale.³⁶ Based on the definition of “temporary menu item,” it would be advisable to treat any special that is offered 60 or more times a year as a “routinely offered” item and thus subject to the menu labeling rules. The rules are not clear on this issue, however.

How Must Calorie Information be Presented For Items Listed on Menus or Menu Boards?

Covered establishments must declare the number of calories contained in each standard menu item listed on the menu. The calorie count listed should be the number of calories

²⁶ See 21 C.F.R. 101.11(b)(1)(ii)(A).

²⁷ 21 C.F.R. 101.11(b)(1)(ii)(A)(1).

²⁸ See 79 Fed. Reg. 71189.

²⁹ 21 C.F.R. 101.11(b)(1)(ii)(A)(1).

³⁰ See 21 C.F.R. 101.11(a) (defining “temporary menu item”); *see also* 21 C.F.R. 101.11(b)(1)(ii)(A)(2) (applying 60 day/year threshold to all self-service food and food on display).

³¹ 21 C.F.R. 101.11(b)(1)(ii)(A)(1).

³² See 21 C.F.R. 101.11(a) (defining “food that is part of a customary market test” and requiring that it appear on a menu or menu board); *see also* 21 C.F.R. 101.11(b)(1)(ii)(A)(1) (exempting such food from menu labeling requirements); *see also* 21 C.F.R. 101.11(b)(1)(ii)(A)(2) (extending exemption to self-service foods and foods on display).

³³ See 79 Fed. Reg. 71191.

³⁴ 21 C.F.R. 101.11(b)(1)(ii)(A)(1).

³⁵ 21 C.F.R. 101.11(a).

³⁶ See 79 Fed. Reg. 71190.

that the item has when it is prepared in the “usual manner” by the establishment. For example, if a covered establishment only sells 12-inch sub sandwiches, the calorie declaration for such sandwiches should be for a 12-inch sandwich (even if it expects consumers to only eat half a sandwich at a time). The rule is not particularly clear regarding the term “usual manner,” however. Many establishments do not have a precise formula for preparing food products. For example, some food preparers may include more turkey slices on a turkey sandwich than other preparers. The rule requires establishments to take reasonable steps to ensure that the preparation of the item is consistent with the way that the establishment determined the nutrition information.

The number of calories must be listed adjacent to the name or price of the associated menu item, in a type size no smaller than the type size of the name or price of the item (whichever is smaller).³⁷ The term “Calories” or “Cal” must appear (a) as a heading above a column listing the number of calories for each standard menu item, or (b) adjacent to the calorie listing for each item.³⁸ There are also color requirements designed to require the calorie declaration to be as conspicuous as the name and price of the item.³⁹

Calories must be declared to the nearest 5-calorie increment up to and including 50 calories, and to the nearest 10-calorie increment above 50 calories. Amounts less than 5 calories may be expressed as zero.⁴⁰

How do you list items with multiple servings?

In the case of multiple-serving items that are usually prepared and offered for sale divided in discrete serving units⁴¹ (such as a pizza pie), establishments have the option of declaring the number of calories for the whole menu item (*e.g.*, pizza pie: 1600 cal) or per discrete serving unit *and* total number of units contained in the menu item (*e.g.*, pizza pie: 200 cal/slice, 8 slices).⁴² In the case of items that come in multiple sizes (*e.g.*, 6-inch sandwich and 12-inch sandwich), if both sizes are listed on the menu, they qualify as their own respective “menu item” and thus are each subject to the menu labeling requirements.⁴³ If only one size is listed on the menu, then that is the only one for which the calorie count must appear.

How should I deal with variable menu items and toppings?

The final rule includes requirements for declaring calorie information for standard menu items that come in multiple varieties, such that the potential calorie count would depend upon how a customer orders the item. Although the rule contains a number of detailed requirements for different scenarios, as a general matter if only two options are available for an item (*e.g.*, a sandwich with fries or with fruit), establishments must declare the

³⁷ 21 C.F.R. 101.11(b)(2)(i)(A)(1).

³⁸ 21 C.F.R. 101.11(b)(2)(i)(A)(3)

³⁹ 21 C.F.R. 101.11(b)(2)(i)(A)(1), (3).

⁴⁰ 21 C.F.R. 101.11(b)(2)(i)(A)(2).

⁴¹ See 79 Fed. Reg. 71193.

⁴² 21 C.F.R. 101.11(b)(2)(i)(A).

⁴³ See 79 Fed. Reg. 71193.

calories for both options with a forward slash between them (*e.g.*, 450/350). If three or more options are available, calories must be declared as a “range” specifying the smallest and largest potential number of calories for the item (*e.g.*, 150-400).

- *Variable Menu Items* – A “variable menu item” is a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.⁴⁴
 - When the menu lists flavors or varieties of an entire individual variable menu item (such as different ice cream flavors or doughnut varieties; chicken that can be grilled or fried; or listing all available soft drinks), the calories must be declared separately for each listed flavor or variety (unless different varieties have the same amount of calories).⁴⁵
 - When the menu does not list flavors or varieties for an entire variable menu item, and only includes a general description (*e.g.*, simply listing “ice cream” or “soft drinks” or “chicken” without specifying flavors or cooking method), the calories must be declared either
 - (a) where only two options are available, with a slash between the two calorie declarations,⁴⁶ or
 - (b) where more than two options are available, as a range. Calories declared as a range must be in the format “xx-yy,” where xx is the calorie content of the lowest calorie variety, and “yy” is the calorie content of the highest calorie variety.⁴⁷
 - *Toppings* – There are detailed requirements for variable menu items offered with the option for additional toppings (*e.g.*, pizza and ice cream). As a general matter, calories must be declared for the basic preparation of the menu item as listed, and calories must also be listed for each topping that appears on the menu, specifying that the calories are *added* to the calories contained in the basic preparation of the menu item.⁴⁸ If only the general term “toppings” is used on a menu, but the individual toppings are not listed on the menu, standard format requirements for variable menu items apply, *i.e.*, where only two options are available (topping vs. no topping), calories must be declared for each option with a slash between the two calorie declarations, and if more than two topping options are available, the calories must be declared as a range. (As discussed further below, if the toppings are visible to the consumer, the establishment will have to declare the calories for each topping on a sign(s) near the topping items (even if the calorie counts are already listed on the menu.) If toppings have the same calorie amounts (after rounding), the calorie declaration for such toppings can be listed as a single calorie declaration

⁴⁴ 21 C.F.R. 101.11(a).

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

⁴⁶ 21 C.F.R. 101.11(b)(2)(i)(A)(4)(ii).

⁴⁷ 21 C.F.R. 101.11(b)(2)(i)(A)(4)(ii), 21 C.F.R. 101.11(b)(2)(i)(A)(7) (specifying requirements for declaring ranges).

⁴⁸ 21 C.F.R. 101.11(b)(2)(i)(A)(5).

adjacent to the toppings, provided it is clear that the calorie amount listed represents the calorie amount for each individual topping.⁴⁹

Do I need to list calories for custom orders?

No. Custom orders are food orders that are 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, or a cheeseburger without the bun).⁵⁰ Custom orders are not subject to the menu labeling requirements.⁵¹ Establishments simply need to comply with the requirements for the underlying standard menu item.

How do I account for combination meals?

A combination meal is a standard menu item that consists of more than one food item (*e.g.*, a meal that includes a sandwich, a side dish, and a drink). Combination meals present complexities because they may vary among several options (*e.g.*, the side dish may be either a salad or potato chips), and/or they may include a variable menu item (such as a sandwich with different meat and topping options). There are detailed requirements for combination meals. Generally:

- When the menu lists two options for combination meals (*e.g.*, a sandwich with either chips or a salad), the calories must be declared with a slash between the two calorie declarations.⁵²
- When the menu includes a choice of three or more options, the calories must be declared as a range.⁵³
- When the menu permits customers to choose between different sizes of combination meals, the calorie count must be declared for each size with a slash between two calorie declarations or, where more than two sizes are available, as a range.⁵⁴

How do I list calories for beverages?

Providing non-self-service beverages presents complexities because the quantity of ice used in a cup can alter the calorie count of a particular beverage product. The final menu labeling rule requires that calories must be declared for such beverages based on the full volume of the cup served without ice, unless the establishment ordinarily dispenses and offers for sale a standard beverage fill (*e.g.*, a fixed amount that is less than the full volume of the cup per cup size).⁵⁵ If the establishment has a standard beverage fill or standard ice fill by which its servers abide (*e.g.*, by using equipment programmed to

⁴⁹ 21 C.F.R. 101.11(b)(2)(i)(A)(5)(ii).

⁵⁰ 21 C.F.R. 101.11(a).

⁵¹ 21 C.F.R. 101.11(b)(1)(ii)(A)(1).

⁵² 21 C.F.R. 101.11(b)(2)(i)(A)(6)(i).

⁵³ 21 C.F.R. 101.11(b)(2)(i)(A)(6)(ii).

⁵⁴ 21 C.F.R. 101.11(b)(2)(i)(A)(6)(iii).

⁵⁵ 21 C.F.R. 101.11(b)(2)(i)(A)(9).

dispense a specific quantity, by using cups that have markings that enable employees to manually add a specific quantity, etc.), the calories must be declared based on that standard.

Do I need to list calories for coffee?

Yes. Coffee is treated like any other beverage and calories must be declared based on the full volume of the cup. For iced coffee, calories must also be declared for the full volume of the cup unless there is a standard beverage fill or standard ice fill.

What Additional Information Must Appear on Menus or Menu Boards?

The following statement must be posted on all menus in a specified clear and conspicuous manner: “2,000 calories a day is used for general nutrition advice, but calorie needs vary.”⁵⁶ Menus targeted at children may, but are not required to, include a different statement addressing children’s recommended caloric intake, either: (i) “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 (ii) “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.”⁵⁷) The statement must appear at the bottom of every page of a multi-page menu, but only once at the bottom of menu boards.⁵⁸

In addition, the final rule requires a clear and conspicuous statement noting the availability of additional nutrition information upon request (see below for more on this additional nutrition information).⁵⁹ Specifically, the statement must read: “Additional nutrition information available upon request.” This statement must be above, below, or beside the aforementioned statement regarding recommended daily caloric intake.⁶⁰ This statement is only required to appear at the bottom of the first page of a multi-page menu, and is similarly required to appear on the bottom of menu boards.⁶¹

Both statements 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.⁶²

How Must Calorie Information be Presented for Self-Service Items and Food on Display?

The final menu labeling rule requires that for standard menu items that are self-service or on display, calories must be declared for each food item (*e.g.*, a doughnut, a slice of

⁵⁶ 21 C.F.R. 101.11(b)(2)(i)(B).

⁵⁷ *Id.*

⁵⁸ 21 C.F.R. 101.11(b)(2)(i)(B)(2), (3).

⁵⁹ 21 C.F.R. 101.11(b)(2)(i)(C).

⁶⁰ See 21 C.F.R. 101.11(b)(2)(i)(B)(2) and (3).

⁶¹ 21 C.F.R. 101.11(b)(2)(i)(C)(2) and (3).

⁶² See 21 C.F.R. 101.11(b)(2)(i)(B) and (C)

pizza, etc.), or if the food is not offered for sale in a discrete unit, calories per serving (e.g., scoop, cup, etc.). The calorie information must also state the serving or discrete unit relevant to the calorie content (e.g., calories “per doughnut” or “per scoop”).⁶³

Calories can be declared on:

- 1) a sign adjacent to and clearly associated with the corresponding food;
- 2) 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 the consumer can clearly associate the calorie declaration with the food.⁶⁴ If it is not clear to which food the calorie declaration and serving unit refers, the sign must include the name of the food (e.g., “potato salad—200 calories per scoop”);⁶⁵ or
- 3) a single sign or placard listing the calorie declaration for several food items along with the names of the items, so long as the sign or placard is located where a consumer can view it while selecting the item.⁶⁶

The May 2018 guidance also notes that “if calories are declared using [front-of-pack] labeling on “grab and go” foods, the calories must 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 (21 CFR 101.11(b)(2)(i)(A)).”⁶⁷ Furthermore, if calorie declarations are made on the package of grab-and-go items, the succinct statement and statement of availability do not have to be on every individual package and can instead be on a “separate sign in close proximity to the food.”⁶⁸

The same general rules for presentation and conspicuousness of calorie declarations apply to self-service foods and foods on display as apply to foods that are listed on a menu: Calories must be declared to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increments above 50 calories except that amounts less than 5 calories may be expressed as zero.⁶⁹ Calories may be declared as “calories” or “cal” and must be clear and conspicuous.⁷⁰

Can self-service foods and foods on display be variable menu items as well?

Yes. Foods on display and self-serve foods may qualify as “variable menu items” if they are offered for sale in different flavors, varieties, or combinations and listed as a single item (e.g., “doughnuts” with several varieties). When this is the case, the requirements for variable menu items (see above discussion) would apply to calories declared for the food on display or self-serve food. If the items are also listed on a menu, then those foods would need the relevant calorie information on both the menu (or menu board) and where the food is displayed.⁷¹

⁶³ 21 C.F.R. 101.11(b)(2)(iii).

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ See Guidance, *supra* note 8, at page 16.

⁶⁸ See Guidance, *supra* note 8, at page 19.

⁶⁹ 21 C.F.R. 101.11(b)(2)(iii)(A)(3)(i).

⁷⁰ 21 C.F.R. 101.11(b)(2)(iii)(A)(3)(ii).

⁷¹ See 79 Fed. Reg. 71222.

For example, suppose a convenience store offers five varieties of doughnuts in a display case that customers can see. It also has a menu board behind the counter listing all of the different restaurant-type food offerings available for purchase. The menu board simply says “doughnuts” and does not specify each type of doughnut available. In this case, the menu labeling law requires the number of calories to be declared on the *menu board* presented as a range from amount of calories in the lowest-calorie doughnut to the amount of calories in the highest-calorie doughnut (pursuant to the variable menu item rules); it *further* requires the specific number of calories for *each type of doughnut* to be declared near the display case in accordance with one of the three permissible approaches outlined above (pursuant to the food on display rules).

What other information is required for self-service foods and foods on display?

The final rule provides establishments flexibility regarding the “additional statements” regarding suggested daily caloric intake and the availability of additional nutrition information (see above) as this requirement applies to self-service foods and foods on display. As a general matter, if an establishment identifies self-service food or food on display via an individual sign adjacent to the food itself, such sign could meet the definition of a “menu” or “menu board” and thus would have to contain the same statements as menus (“2,000 calories a day is used for general nutrition advice, but calorie needs vary”; “Additional nutrition information available upon request”). The rules, however, permit establishments to post these statements either on the adjacent sign itself, or on a separate, larger sign in close proximity to a number of such foods that can be easily read while the consumer is making an order selection, or on a large menu board that can be easily read as the consumer is viewing the food.⁷²

The final rule does not say whether these statements are required in the case of establishments that only identify foods via individual signs adjacent to each item. It appears, however, to require such establishments to create an additional sign on which the “additional statements” would appear.⁷³

What are the rules for self-service beverages?

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.*, “140 calories per 12 fluid ounces (small)”).⁷⁴

At the point of service, for example near the soda fountain, calories must be declared for each specific flavor or type of beverage available at the machine rather than as a range, in

⁷² 21 C.F.R. 101.11(b)(2)(iii)(B).

⁷³ See generally 79 Fed. Reg. 71227. In these cases, each individual item would be viewed collectively as the primary writing from which consumers choose among items in making order selections, and thus the additional statements would be permitted to be posted on separate signs pursuant to 21 C.F.R.

101.11(b)(2)(iii)(B).

⁷⁴ 21 C.F.R. 101.11(b)(2)(iii)(A)(3)(ii)

accordance with the rules applicable to self-service foods.⁷⁵ (Similar to the above example regarding doughnuts.)

If the self-service beverages are also listed on a menu or menu board, then the requirements for those menus (and boards) must also be met.

Can self-service beverages also be variable menu items?

Yes. Self-service beverages may qualify as “variable menu items” to the extent they are offered for sale in different flavors or varieties and listed as a single menu item on menus or menu boards (*e.g.*, “soft drinks”). In these instances, a covered establishment would be able to declare calories on such menus or menu boards using the same methods applicable to other variable menu items, including ranges. Then, the requirements for including calorie information at or near the self-service display would also need to be met.

If the menu or menu board lists each beverage available for self-service, the calories for each type beverage would have to be declared both on the menu or menu board, *as well as* near the area where they are dispensed. (Note that if the menu board is located in close proximity to the fountain where beverages are dispensed, there may not be a need for multiple calorie declarations.)

What “Additional Nutrition Information” Do Covered Establishments Need to Make Available Upon Request?

The final menu labeling rules require additional nutrition information for standard menu items to be available in written form on the premises of a covered establishment and provided to customers upon request. Such information must include:

- Total calories
- Calories from fat
- Saturated fat
- *Trans* fat
- Cholesterol
- Sodium
- Total carbohydrate
- Dietary fiber
- Sugars and
- Protein

The final rule contains exceptions for items that contain insignificant amounts of all of the above nutrients. It also contains detailed requirements for how such information must be presented for variable menu items and items with toppings. The information must be provided in a “clear and conspicuous manner,” and may be provided on a counter card,

⁷⁵ See generally 79 Fed. Reg. 71225.

sign, poster, handout, booklet, loose-leaf binder, an electronic device such as a computer, or in any other similar form.⁷⁶

By “clear and conspicuous manner,” the rules mean that the material must be presented using a color, type size, and contrasting background that render the information likely to be read and understood by the ordinary individual under customary conditions.⁷⁷

In the May 2018 guidance, however, FDA said it would use enforcement discretion surrounding the declaring of “calories from fat.”⁷⁸ As long as covered businesses have the additional nutrition information other than “calories from fat,” FDA will not enforce penalties against those business for failure to have information on “calories from fat.” The guidance states that this lenience will only be for a specific time period – but does not indicate what that time period is. NACS is seeking additional guidance on that question.

How May Covered Establishments Determine Calorie and Nutrition Information?

A covered establishment must have a “reasonable basis” for its nutrient declarations (both for (a) calorie declarations on menus, menu boards and for self-service foods and foods on display, and (b) the supplemental nutrition information that is available upon request).⁷⁹ This includes:

- use of nutrient databases (with or without computer software programs);
- cookbooks;
- laboratory analyses;
- Nutrition Facts on labels on packaged foods; or
- other reasonable means.⁸⁰

The final rule contains a number of detailed requirements applicable to different methods of acquiring nutrient information.⁸¹ In general, if FDA or its enforcement agent requests substantiation of nutrient values for food offered at the establishment, the establishment must within a reasonable amount of time demonstrate that it has complied with the applicable requirements. This includes furnishing a signed statement from a responsible individual employed at the covered establishment (or its parent entity) certifying that the nutrient information is complete and accurate, and another statement signed by a responsible individual employed at the covered establishment stating that the establishment has taken reasonable steps to ensure that the method of preparation and the amount of a standard menu item offered for sale adheres to the factors on which its nutrient values were determined. Businesses may want to create and maintain these statements ahead of time so that they are prepared in the event of a request from the FDA.

⁷⁶ See 21 C.F.R. 101.11(b)(2)(ii).

⁷⁷ *Id.*

⁷⁸ See Guidance, *supra* note 8, at page 4.

⁷⁹ 21 C.F.R. 21 C.F.R. 101.11(c)(1).

⁸⁰ *Id.*

⁸¹ See generally 21 C.F.R. 101.11(c)(3).

How Soon Must the Information at the Establishment Change if the Calorie or Nutrition Information Changes?

If the calorie or nutrition information of an item changes such as by changing a recipe or supplier of a food, the new and accurate information must be provided as soon as the food changes. That is, FDA expects the establishment to change menus and other signage to reflect changes in the information for standard menu items prior to (or at the same time as) the new standard menu item is offered. There is no allowance for the establishment to begin to offer the new item and change nutrition information later (unless, of course, the item is a temporary or test item rather than a standard menu item).

How Will FDA Enforce the Menu Labeling Rule?

The final rule may be enforced in a variety of ways. First, a state or local government may establish menu labeling requirements that are *identical* to the federal menu labeling rule. In this case, the state or local government would act on its own behalf to enforce “its own” requirements (albeit requirements that are identical to the federal requirements).

Second, the FDA could conduct examinations through an applicable state or local official, *i.e.*, the state/local official would act on FDA’s behalf to enforce the federal requirements.

Third, states are permitted in certain circumstances to bring – in their own name and within their jurisdiction – proceedings for the civil enforcement of certain laws under FDA’s jurisdiction, including the menu labeling laws.

FDA has partnered with States to conduct examinations and inspections in other contexts – including inspections of food processing facilities and retail tobacco sales restrictions – and FDA expects to continue such cooperation as part of its menu labeling enforcement efforts.⁸²

For the first year that compliance is required, FDA intends to engage in “educational enforcement.” FDA’s intention is to focus on helping covered businesses properly comply with the rules during this time period rather than enforcing penalties. That said, FDA is not barred from seeking penalties.

In addition, FDA’s May 2018 guidance indicates that in enforcing the rule (even after the first year of compliance), the agency intends to give businesses an opportunity to correct minor violations before they are penalized. Specifically, FDA states that, “Our goal is to seek compliance and to work flexibly with establishments to achieve compliance with menu labeling requirements. Thus, we would allow establishments a reasonable opportunity to make corrections for minor violations.”⁸³

⁸² See generally 79 Fed. Reg. 71243-44.

⁸³ See Guidance, *supra* note 8, at page 35.

When Must Covered Establishments Be In Compliance with the Menu Labeling Rule?

FDA’s final guidance was published in May 2016 and additional guidance was published in May 2018. Compliance has been required since May 7, 2018 although, as noted above, FDA intends to engage in “educational enforcement” for the first year that compliance is required.