The Food and Drug Administration (FDA) has issued the long-awaited final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments (SRFEs), effective December 1, 2015. The rule, according to FDA, “will fill a critical information gap and help consumers make informed and healthful dietary choices.” In addition, the new “federal standards will help avoid situations in which a chain restaurant has to meet different requirements in different states.” This memorandum provides a top-line summary of several of the most important new requirements implementing the first-ever mandatory, uniform nutrition labeling rule for covered restaurants and SRFEs.

I. Scope: Who and What Foods are Covered

A “covered establishment” is a restaurant or SRFE with 20 or more locations, doing business under the same name, offering for sale substantially the same menu items, and selling restaurant-type foods. The key attribute of “restaurant-type foods” is that they are usually eaten on the premises, while walking away, or soon after arriving at another location. Examples of covered restaurants and similar SRFEs include sit-down and quick-service restaurants, drive-through windows, food take-out and/or delivery establishments, bakeries, cafeterias, coffee shops, grocery and convenience stores, delicatessens, and food service facilities located within entertainment venues (e.g., movie theatres). Vending machines are also covered under a separate regulation.

Examples of foods that fall outside the new rule include:

- food sold by unit of weight that are not self-serve and are typically intended for more than one person (such as deli salads; either pre-packed or packed upon customer request);
- food sold in transportation vehicles (e.g., trains, airplanes, and mobile food trucks);
- food sold in schools covered by the National School Lunch and School Breakfast Programs;
- food purchased in a grocery store that are eaten on several occasions or stored for later use (e.g., whole cake, loaves of bread, bags or boxes of candy, cookies, or bread/rolls); foods that customarily require additional preparation before consumption (such as deli meats and cheese); and,
- certain food bought from bulk bin cases (such as dried fruit and nuts).

Alcohol beverages are covered by the rule to the extent they qualify as restaurant-type foods and as standard menu items. Alcohol beverages that are foods on display and not self-service foods, such as bottles of liquor and mixers behind the bar, are exempt.

II. Required Nutrition Labeling Information

A. Minimum Mandatory Requirements

Covered entities must comply with three basic requirements:

- Disclose calories for standard menu items on a menu or menu-board, or on signs adjacent to foods on display and self-serve foods that are standard menu items. Use the term “Calories” or “Cal” as a column heading or adjacent to the number of calories for each standard menu item.
- Post a statement concerning suggested daily caloric intake (“2000 calories a day is used for general nutrition advice, but calorie needs vary”), with optional statements for menus and menu boards targeted to children;
- Post a statement advising that written nutrition information for standard menu items is available upon request (for specified nutrients, including calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, and protein). This information may be provided on a counter card, sign, poster, handout, booklet, looseleaf binder, electronic device, or in a menu.

The calorie information must appear on menus and menu boards, defined as the “primary writing of the covered establishment from which a customer makes an order selection,” which includes conventional menus, children’s menus, electronic menus and menus on the Internet. Detailed requirements govern the prominence and placement of calorie and other required information are found throughout the final rule.

Generally, calories are determined based on how the standard menu item is usually prepared and offered for sale. The number of calories must appear adjacent to the name or price, in a type size no smaller than the type size of the name or price of the item (whichever is smaller), in the same color, or a color at least as conspicuous as that used for the name of the menu item, and with the same contrasting background or background at least as contrasting as that used for the name of the menu item.

B. Special Labeling Requirements

The rules recognize the varied ways in which covered menu items are sold, with special rules adopted for variable menu items, multi-serving foods, combination meals, beverages and other product types and configurations (such as those with added toppings or multiple sizes).
For a multiple-serving item, 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 (e.g., pizza slice) and total number of discrete serving units are declared on the menu or menu board (and the menu item is typically sold in discrete serving units) (e.g., “pizza pie: 200 cal/slice, 8 slices”).

Combination meals sold as a standard menu item must declare the total calories for the included items. How the calories are posted depends on how many choices are listed. When three or more foods are included a calorie range is permitted (e.g., 300-650 calories). When two items are combined (e.g., sandwich with chips) a “slash” is used to separate the two calorie values (e.g., 350/150 calories).

Specific requirements are set-out for individual variable menu items (e.g., a standard menu item that comes in different flavors, varieties, or combinations), where calories may in certain circumstances be declared in a range. Similar requirements are specified regarding added toppings that may have varied calorie amounts (e.g., toppings for pizza, ice cream).

For beverages that are not self-service, calories must be based on the full volume of the cup served without ice, with certain exceptions allowing for a fixed amount less than the full volume of the cup or if the beverage is dispensed with a standard amount of ice.

C. Self-Service or Food on Display

Calories for standard menu items that are self-service or a food on display must be on signs adjacent to such foods.

- Calories per displayed food item (e.g., bagel, slice of pizza), or if not a discrete unit then per serving (e.g., scoop, cup), and the serving or unit used to determine the calorie content, must be declared.
- The calorie information may be placed on 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 calorie information above each specific food; or a single sign or placard listing the calories for several food items along with the names of the food items, so long as it is located where the consumer can view the information while selecting the item.
- Other requirements are specified.

III. Compliance Standard – Determination of Nutrient Content

An establishment must have a “reasonable basis” for its calorie and other nutrient declarations, including nutrient databases, cookbooks, lab analyses, “or other reasonable means.” An establishment must take “reasonable steps” to ensure that the method of preparation (e.g., types and amounts of ingredients, cooking temperature) and amount of the standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

The regulation provides the parameters by which a reasonable basis must be established. A responsible individual must certify that the information relied upon is complete and accurate and that the reasonable steps described above are taken. Documentation verifying calorie values must be made available to FDA upon request. The regulations specify the types of documentation needed, depending on the basis for the nutrient declarations.
The new rule states that a failure to comply with the rule will render the food “misbranded.” Selling a misbranded food is a “prohibited act” which carries civil (e.g., injunction, seizure by court order) and criminal penalties. FDA indicates its plan to issue guidance on compliance and to develop concrete enforcement plans over the next year, likely including coordination with states and localities. FDA advises in the preamble that it will consider a tiered approach to enforcement (e.g., first infraction versus repeated violations treated differently). Enforcement ultimately will be considered on a case-by-case basis depending on the specific facts, according to the FDA preamble.

IV. National Uniformity/Federal Preemption; Opt-in For Small Operators

Although not directly addressed in the regulation, the underlying statute mandating nutrition labeling makes clear that states and localities may not impose nutrition labeling requirements for food sold in “covered establishments,” as defined in 21 C.F.R. 101.11(a), which includes (1) chain restaurants and retail food establishments that are covered by the federal menu labeling rule, and (2) establishments that voluntarily comply, i.e., restaurants or SRFEs that are not subject to the requirements but that voluntarily elect to be subject to the federal requirements by registering biannually. See 21 U.S.C. 343-1(a)(4). FDA reinforces this point in the accompanying preamble.

FDA also explains it interprets the preemption provision such that states and localities may establish nutrition labeling requirements for food that is not covered by federal nutrition labeling laws. Specifically, states and localities can establish different or additional nutrition labeling requirements for establishments that are not covered by the federal menu labeling regulations and that are also exempt from nutrition labeling requirements for packaged foods under 21 U.S.C. 343(q)(5)(a)(i) and (ii). FDA gives the example that state and local nutrition labeling requirements for food sold in schools or transportation carriers would not be preempted.

Separately, entities not covered by the regulation can “opt-in” by voluntarily registering biannually with FDA to comply with the federal labeling requirements. This option is available to a restaurant or SRFE that is not part of a chain with 20 or more locations doing business under the same name and offering substantially the same menu items. Entities that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.