

FDA Menu Labeling Rules Have Long Reach

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With the U.S. Food and Drug Administration's release of final rules for menu and vending machine labeling on Nov. 25, 2014, the FDA significantly expanded its regulatory reach into restaurants and beyond. The long-awaited rules stem from the Affordable Care Act, the comprehensive health care reform law of 2010, and come more than three years after proposed rules were issued in April 2011. The broad expanse of the final rules, imposing requirements well beyond those in the proposed rules, and the potentially burdensome requirements surrounding certification of nutritional content, mean covered businesses should begin preparing now for the Dec. 1, 2015 compliance date.

Nutrition Labeling in Restaurants and Retail Food Establishments: The Basics

What Establishments are Covered by the Rules?

In a significant departure from the earlier proposed rules, the FDA's final rules expand the categories of covered establishments to potentially include not just restaurants, but also movie theaters, amusement parks, bowling alleys and other entertainment venues, convenience stores, coffee shops, bakeries, delis, grocery stores, supercenters and fitness clubs. Schools and businesses that sell food but do not have a fixed location, such as trains, airplanes and food trucks, are excluded.

The menu labeling rules apply to restaurants and "similar retail food establishments" that have 20 or more locations, doing business under substantially the same name and selling substantially the same menu items, regardless of type of ownership. Congress did not define "restaurant or similar retail establishment" in the ACA so, for the purposes of the final rules, the FDA defined the term to mean any retail establishment that offers "restaurant-type food." Restaurant-type food is food that is "[u]sually eaten on the premises, while walking away, or soon after arriving at another location" and either served in the establishment or processed and prepared primarily in the establishment. This definition eliminated the "primary business test" in the proposed rules, which would have limited coverage only to those establishments whose primary business is restaurant-type food or more than 50 percent of the business' revenue is generated from the sale of such food.



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The FDA's removal of the primary business test from the final rules was a surprise and industry has responded. Recently introduced legislation — the Common Sense Nutrition Disclosure Act — would narrow the scope of covered establishments by redefining “restaurant or similar retail food establishment” to include only those that “derive more than 50 percent of their total revenue from the sale” of restaurant-type food.

What are Covered Businesses Required to Do?

At the most basic level, covered establishments must post calorie amounts by each standard menu item. The posting must be made on menus and menu boards, and on signs adjacent to standard menu items that are self-serve or on display. Covered establishments must also post two prescribed statements on menus and menu boards: a succinct statement regarding daily caloric intake (“2,000 calories a day is used for general nutrition advice, but calorie needs vary”) and a statement regarding the availability of additional nutrition information (“Additional nutrition information available upon request.”). On menus targeted to children, businesses may voluntarily include a statement reflecting modified caloric intakes for children ages 4 to 13 years as a substitute for, or in addition to, the general succinct statement.

If requested by a consumer, businesses must provide detailed, written nutrition information for standard menu items, including total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fiber, sugars and protein for those items. The FDA allows flexibility in providing this information — it can be in a booklet or an electronic kiosk — so long as it is available to the consumer on the premises.

The rules provide specific requirements for the type size, location and other formatting of the caloric declarations and statements. Covered establishments must follow these requirements precisely. For some businesses, this may require revising menus created to comply with state or local menu labeling regulations. The federal rules expressly preempt existing state and local rules.

What Menu Items Must be Labeled?

The labeling requirements apply to standard menu items offered for sale in the establishment. “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.

In another surprising and significant departure from the proposed rules, the final rules include alcohol. Beer, wine and mixed drinks that are standard menu items are covered. But beer or bottles of liquor behind a bar or mixed drinks ordered from the bar that do not appear on a menu or menu board are not covered.

Other menu items excluded from the labeling requirements include condiments (unless listed on the menu), daily specials, temporary menu items (less than 60 days in a calendar year), custom orders and food offered for sale for less than 90 consecutive days as part of a market test. Certain foods that are typically intended for more than one person to eat and require additional preparation before consuming, such as pounds of deli meats and large-size deli salads, are not covered.

Specific calorie labeling requirements apply to combination meals, multiple-serving menu items and menu items offered in different flavors or varieties (“variable menu items”). Generally, calories must be listed for each size, flavor, variety and combination option. If only two variations or options exist, calories must be declared for each with a forward slash between the two amounts. If three or more

variations or options are offered, calories must be expressed in a range from the lowest to the highest. Flavors and varieties may be listed together as a group if they have the same caloric content (e.g., diet beverages).

The rules also impose additional calorie labeling requirements for items on display or available for self-service (e.g., salad bars, bakery items or self-serve fountain beverages), even if they are also listed on a menu or menu board.

What is Considered a Menu or Menu Board?

Menus and menu boards are defined as “primary writings” of the business from which a consumer makes an order. The FDA makes clear that what constitutes a menu will be determined from the consumer’s perspective and will include drive-through menu boards and take-out menus. But the term potentially spans a broad range of other formats. The FDA notes that an establishment may have more than one “primary writing,” which is defined to include anything with a name or image of the food item, the price and a manner in which a consumer can order it (e.g., it is posted near a cash register or provides a telephone number or website to arrange pick-up or delivery).

How Must Nutrient Content of Menu Items be Determined and Substantiated?

Businesses must have a “reasonable basis” for nutrient content declarations and take reasonable steps to ensure that the method of preparation and serving amounts adhere to the factors on which nutrient values were determined. Upon the FDA’s request, a business must provide information substantiating nutrient values, including the method and data used to derive those values. Nutrient values may be determined based on nutrient databases, cookbooks, laboratory analyses, nutrition facts on packaged foods or other “reasonable” means. Notably, a business must provide two signed statements: (1) one signed by a responsible individual employed at the establishment or its corporate headquarters certifying that the information contained in the nutrient analysis is complete and accurate; and (2) another signed by a responsible individual employed at the establishment certifying that it has taken reasonable steps to ensure that the preparation and amount of the menu item adhere to the labeled nutrient values.

How Will the FDA Enforce the Final Rules?

Both the effective date and compliance date for the menu labeling rules are Dec. 1, 2015. Failure to comply with the rules will render the food misbranded under the Food, Drug, and Cosmetic Act. Although the FDA is somewhat vague in describing how it will enforce the rules, it expects enforcement to be similar to that involving other misbranded food and will be “considered on a case-by-case basis.” The FDA anticipates issuing guidance to assist covered establishments with compliance, and it may develop a protocol for checking the accuracy of nutritional information provided by establishments “once [the FDA] has had experience in evaluating compliance with the rule.”

Significantly, misbranding under the FDCA — even if unintentional — is a misdemeanor. The FDA cautions that “persons exercising authority and supervisory responsibility over a restaurant or similar retail food establishment can be held responsible for violations,” citing *United States v. Park*, 421 U.S. 658, 659 (1978). The FDA therefore has the discretion to hold criminally liable those with authority, including “responsible individuals,” with a duty to implement measures to ensure compliance, for menu labeling violations.

Calorie Labeling of Food in Vending Machines

Operators or owners with 20 or more vending machines must post calorie counts for all food items as vended. The calorie declarations must be made in close proximity to the food or selection button on the vending machine. A vending machine is defined to cover a variety of machines, including machines that sell packaged food or drinks, hot-and-cold cup beverages and bulk vending machines (e.g., small candies, gum or nuts). The FDA expressly excludes game machines from the rule, even if they dispense candy as a prize.

Unlike the final menu labeling rules, covered vending machine operators are not required to have a “reasonable basis” for calorie declarations. Still, vending machine operators must ensure that calorie declarations are truthful and not misleading under the FDCA. They may rely on the same types of resources as restaurants to determine calorie content, such as the food package’s Nutrition Facts Panel, nutrient databases, cookbooks or laboratory analyses.

The final vending machine labeling rules become effective on Dec. 1, 2016, giving operators or owners of covered vending machines two years to ensure compliance.

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