

E-ALERT | Food & Drug

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FDA RELEASES FINAL RULES ON NUTRITION LABELING FOR MENUS IN CERTAIN RESTAURANTS AND VENDING MACHINES

Today FDA released two long-awaited final rules on nutrition labeling, one requiring chain restaurants and retail food establishments to disclose nutrition information for standard menu items,¹ and the other outlining similar requirements for vending machines.² The final rules clarify how FDA will implement and enforce the requirements contained in section 4205 of the healthcare reform legislation signed into law on March 23, 2010.³ As detailed below, the final rules contain a number of significant changes from the proposed rules the agency issued in April 2011.

Intended to help consumers make informed and healthier dietary choices, the healthcare reform legislation mandates nutrition labeling for standard menu items sold by chain restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering substantially the same menu items. Similar but distinct requirements apply to vending machines. The federal requirements create national uniformity for menu labeling requirements by explicitly preempting state and local nutrition labeling laws for chain retail food establishments (and vending machines) that are not identical to the federal requirements.

Key provisions of both final rules are summarized below.

Definition of “Restaurant or Similar Retail Food Establishment”

The final rule departs from FDA’s proposal and defines “restaurant or similar retail food establishment” to mean a retail establishment (other than a school) that offers for sale restaurant-type food. Under this broad definition, the menu labeling requirements will apply to food service facilities located within entertainment venues (such as movie theaters and amusement parks), which would not have been covered under the proposed rule.

The proposed definition of “restaurant or similar retail food establishment” contained a primary business test, which would have limited the menu labeling requirements to establishments whose primary business activity is the sale of food. FDA eliminated the primary business test from the final rule in response to comments asserting that food in entertainment venues is similar to food in chain restaurants, and that covering entertainment venues would create a level playing field and help consumers make informed and healthful dietary choices.

¹ See Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014), available [here](#).

² See Calorie Labeling of Articles of Food in Vending Machines, 79 Fed. Reg. 71,259 (Dec. 1, 2014), available [here](#).

³ For additional information about this legislation and FDA’s rulemaking process, see our previous client alerts, Nutrition Labeling for Chain Restaurant Foods Established by Healthcare Reform Legislation (Mar. 23, 2010), available [here](#), and FDA Issues Proposed Rules on Nutrition Labeling For Menus in Certain Restaurants and Vending Machines (Apr. 6, 2011), available [here](#).

Thus, the scope of the final rule applies to bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues (such as amusement parks, bowling alleys, and movie theaters), food service vendors (e.g., ice cream shops and mall cookie counters), food take-out and delivery establishments, grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants—if they sell “restaurant-type food.”

Definition of “Restaurant-Type Food”

Under the final rule, “restaurant-type food” is food that is usually eaten on the premises, while walking away, or soon after arriving at another location, and is either:

- (1) served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments, or
- (2) processed and prepared primarily in a retail establishment, ready for human consumption, of the type described in (1), and offered for sale to consumers, but not for immediate human consumption in such establishment, and which is not offered for sale outside such establishment.

FDA established this refined definition of “restaurant-type food” to better reflect the type of food sold in restaurants and avoid covering foods more commonly considered to be groceries. “Restaurant-type food” thus includes, in addition to food sold or served in restaurants, foods such as a pizza slice 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 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 at a deli counter; salads plated by the consumer at a salad bar; cookies from a mall cookie counter; bagels, donuts, rolls offered for individual sale).

“Restaurant-type food” does not include foods that consumers usually store for use at a later time or customarily further prepare (even if these items may be ready for immediate consumption). Thus, the menu labeling requirements do not extend to 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); foods sold by weight that are not self-serve and are not intended solely for individual consumption, either prepacked or packed upon consumer request (e.g., deli salads sold by unit of weight such as potato or chicken salad); and foods that are usually further prepared before consuming (e.g., deli meats and cheeses).

Alcoholic Beverages

The final rule covers alcoholic beverages that are standard menu items listed on menus and menu boards but exempts alcoholic beverages on display that are not available for self-service. Although the proposed rule would have exempted alcoholic beverages altogether, FDA ultimately included certain alcoholic beverages to enable consumers to compare beverage options and make informed selections.

Variable Menu Items

“Variable menu item” means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item, such as a milkshake that is available in vanilla, chocolate, or strawberry flavors, or a pizza prepared with a selection of toppings. The final rule keeps

the proposed rule's definition of "variable menu item," but changes the requirements for declaring the caloric content of these items.

The final rule requires the calories for variable menu items to be declared (1) with a slash between the two calorie declarations where only two options are available (e.g., "150/250 calories") or (2) as a range where there are more than two options (e.g., "100-250 calories"). Calories declared as a range must be in the format "xx-yy," where "xx" is the caloric content of the lowest calorie variety, flavor, or combination, and "yy" is the caloric content of the highest calorie variety, flavor, or combination.⁴ Additional requirements apply to variable menu items when the menu lists toppings that can be added to the item (e.g., pizza or ice cream).

Multi-Serving Items

Whereas FDA's proposed rule would have required covered establishments to list the total calories in each standard menu item, regardless of how many servings the item contained, the final rule provides an additional option for certain multi-serving menu items. The calories in multi-serving foods that are usually offered for sale divided in discrete serving units (e.g., slices of pizza) may be declared per serving, provided that the discrete serving unit (e.g., pizza slice) and total number of discrete serving units contained in the menu item are declared—e.g., "pizza pie: 200 cal/slice, 8 slices." As in the proposed rule, where a multi-serving food is not usually divided in discrete serving units, the covered establishment must declare the calories in the entire item. FDA noted, however, that an establishment could voluntarily declare calories per serving, in addition to the calories for the entire item.

The flexibility provided under the final rule is meant to address the many comments FDA received regarding multi-serving items. These comments described the variety of ways that covered establishments may choose to prepare and sell their food and illustrated the complexity of consumer eating habits and preferences. Providing the number of calories per discrete serving unit and the total number of serving units enables consumers to keep track of calories consumed and make informed dietary choices, FDA explained.

The final rule does not address how to declare the calories in a food that is both a variable menu item and a multi-serving item that is offered for sale divided in discrete serving units (e.g., a dozen bagels, where the consumer may choose among several bagel varieties).

Succinct Statement Concerning Suggested Daily Caloric Intake

The statement "2,000 calories a day is used for general nutrition advice, but calorie needs vary" must be posted prominently and in a clear and conspicuous manner on menus and menu boards. FDA noted that this statement is designed to enable consumers to understand, in the context of a total daily diet, the significance of the calorie information provided on menus and menu boards.

The final rule's statement closely tracks FDA's original proposal.⁵ The agency disagreed with several comments that wanted the statement to provide more information, such as the calorie intake values for different ages or the factors that impact caloric needs. Including "calorie needs vary" obviates the need to provide more detailed information, explained FDA. The agency also rejected a suggestion

⁴ Different rules apply if the menu lists all the flavors/varieties for an entire individual variable menu item (e.g., "soft drinks: Lemon Lime, Cola, Diet Lemon Lime, Diet Cola"). In that case, the covered establishment must declare separately the calories for each listed flavor/variety, but can group together varieties with the same number of calories (e.g., "Diet Lemon Lime or Diet Cola (0 cal); Cola or Lemon Lime (150 cal)").

⁵ The statement in the proposed rule was: "A 2,000 calorie diet is used as the basis for general nutrition advice; however, individual calorie needs may vary."

that the statement note the recommended calories per meal, because consumers should decide how to allocate calories among meals. FDA's approach with respect to this statement may provide insight into how the agency ultimately may handle the revision of the footnote in the Nutrition Facts Panel (NFP) on packaged foods that is intended to provide a context for the total diet, which is currently under consideration by FDA as part of its rulemaking to update the NFP.

For menus and menu boards targeted to children, the final rule allows covered establishments to substitute or supplement the succinct statement with the following statements:

- "1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years, but calorie needs vary" or
- "1,200 to 1,400 calories a day is used for general nutrition advice for children ages 4 to 8 years and 1,400 to 2,000 calories a day for children 9 to 13 years, but calorie needs vary."

Unlike the general statement, the children's statement provides the calorie intake values for specific age groups (presented as a range, not a single number). FDA justified this inconsistency by noting that because of the broad variability in the daily caloric needs of children, additional information is necessary to adequately enable parents and possibly some children to understand the significance of the calorie information in the context of their total daily diet.

Effective Date of Final Rule

Although many of the menu labeling provisions in the healthcare reform legislation became effective at the time the law was signed, FDA previously announced that it would exercise enforcement discretion until the final rule became effective. This final rule will go into effect on December 1, 2015. FDA decided that a one-year implementation period was more appropriate than the 6-month timeframe in its original proposal, given the difficulties in implementation (including updating menus and menu boards).

Vending Machines

The healthcare reform legislation also requires vending machine operators who own or operate 20 or more vending machines to provide calorie declarations for items that do not display nutritional information at the point of purchase. Under the final rule, the vendor may provide the calorie information in a sign in, on, or adjacent to the vending machine. The sign need not be attached to the vending machine, as long as the prospective consumer can simultaneously see the calorie declaration and either the food, its name, price, selection button, or selection number. The vending machine final rule becomes effective December 1, 2016.

If you have any questions concerning the material discussed in this client alert, please contact any of the following members of our Food & Drug Practice Group or visit our food and beverage practice website:

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