

## E-ALERT | Food & Drug

April 6, 2011

### FDA ISSUES PROPOSED RULES ON NUTRITION LABELING FOR MENUS IN CERTAIN RESTAURANTS AND VENDING MACHINES

Today FDA published in the Federal Register two proposed rules regarding calorie labeling on menus and menu boards in chain restaurants, retail food establishments, and vending machines.<sup>1</sup> The proposed rules provide detail as to how FDA will implement and enforce the requirements contained in section 4205 of the healthcare reform legislation signed into law on March 23, 2010<sup>2</sup> and supplant a 2010 FDA Draft Guidance regarding implementation of the menu labeling provisions.<sup>3</sup>

The healthcare reform legislation mandated nutrition labeling for standard menu items<sup>4</sup> sold by chain restaurants with 20 or more locations doing business under the same name and offering substantially the same menu items. The requirements apply to menus and menu boards (including drive-in menu boards), self-service food and food on display, and vending machines. The requirements explicitly preempt State and local nutrition labeling requirements for chain retail food establishments that are not “identical” to the Federal requirements, thereby creating national uniformity for menu labeling requirements.

Key provisions of the proposed rule regarding menu labeling in chain restaurants and retail food establishments are summarized below.

#### DEFINITION OF “RESTAURANT OR SIMILAR FOOD ESTABLISHMENT”

The proposed regulations would define “restaurant or similar retail food establishment” to mean a retail establishment that offers for sale restaurant or “restaurant-type” food, where the sale of food is the primary business activity of that establishment. The sale of food is the retail establishment’s primary business activity if either:

- (1) the establishment presents itself, or has presented itself publicly as a restaurant (e.g., through consumer, industry or investor-oriented materials), or
- (2) greater than 50 percent of that retail establishment’s gross floor area is used for the preparation, purchase, service, consumption, or storage of food.

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<sup>1</sup> See Proposed Rule, 76 Fed. Reg. 19192 (Apr. 6, 2011) (Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments), available [here](#); Proposed Rule, 76 Fed. Reg. 19238 (Apr. 6, 2011) (Calorie Labeling of Articles of Food in Vending Machines), available [here](#).

<sup>2</sup> For additional information about this legislation, see our previous client alert, Nutrition Labeling for Chain Restaurant Foods Established by Healthcare Reform Legislation (Mar. 23, 2010), available [here](#).

<sup>3</sup> FDA withdrew its Draft Guidance, Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010, on January 25, 2011. See 76 Fed. Reg. 4360 (Jan. 25, 2011). For additional information about this guidance, see our previous client alert, FDA Issues Draft Guidance Regarding Implementation of the New Federal Menu Labeling Requirements (Aug. 25, 2010), available [here](#).

<sup>4</sup> The requirements do not apply to custom orders, daily specials, food that is part of a customary market test, and temporary menu items.

For the second criterion, gross floor area would include all floor space, wall to wall, including areas under built-in counters, cooking equipment, seating, and similar furniture. Multi-purpose seating areas used substantially for activities other than food consumption, such as seating in entertainment venues like shows and sport stadiums, would not be counted in the share of floor space devoted to the sale of food.

Under this interpretation, FDA stated that restaurants and similar retail food establishments would likely include table service and quick-service (or fast food) dining establishments, cafeterias, pastry and retail confectionary stores, coffee shops, snack bars, ice cream parlors, and grocery stores and convenience stores that sell restaurant or restaurant-type food, but would not include most movie theaters, amusement parks, general merchandise stores with in-house concession stands, hotels, and transportation carriers.<sup>5</sup> As an alternative to using percentage of gross floor area as an indicator of the primary business activity of an establishment, FDA considered an approach based on the percentage of the business's revenue attributable to the sale of food. Here, the second criterion would be whether more than 50 percent of the establishment's revenues are generated by the sale of food. Under this option, FDA stated that grocery and convenience stores would likely not be covered because it would not count the floor space used to sell food that is not restaurant or restaurant-type food in determining the primary business activity. FDA is seeking comment on this alternative means, whether 50 percent is the appropriate threshold, and any suggestions for alternative criteria for identifying the primary business activity of an establishment.

## FACILITIES LOCATED INSIDE LARGER ESTABLISHMENTS

Many facilities that sell restaurant or restaurant-type food are located within larger retail establishments, such as a coffee shop in a bookstore or a quick-service counter in an establishment selling a range of packaged foods. FDA stated that some of these facilities would be considered separate retail establishments, while others would be considered part of their larger retail establishments. This would turn on whether the facility selling the restaurant-type food also has locations outside of the larger retail establishment.

For example, if a coffee shop in a bookstore is part of a chain of coffee shops with locations outside of the chain of bookstores, the coffee shop would be considered a separate retail establishment. When determining the primary business activity of the coffee shop, only the representations of the coffee shop itself and the coffee shop's floor area would be considered; thus, the coffee shop in the bookstore would most likely meet the proposed definition of a restaurant or similar retail food establishment.

On the other hand, if a Superstore has a café that appears only in other locations of the Superstore chain, the café would be considered part of the Superstore. When determining the primary business activity of the Superstore, FDA would ask whether the Superstore as a whole presents itself as a restaurant and what percentage of the gross floor area of the superstore as a whole, including the café, is dedicated to the sale of restaurant-type food. Because the café would not be considered an establishment, whether the café independently presents itself as a restaurant or has greater than 50% of its floor space devoted to the sale of food would be irrelevant.

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<sup>5</sup> Although FDA has included grocery and convenience stores as meeting this definition, we note that there could be disagreement with this interpretation. In addition, it appears that there may be errors in the Federal Register publication. When describing the alternative option, FDA notes that it would not include grocery and convenience stores because it would not count the floor space used to sell packaged food in determining the primary business activity, even though the alternative option discusses the percentage of revenue attributed to sale of restaurant-type food.

FDA requests comment on whether such facilities within larger establishments should be included within the definition of restaurants and similar retail food establishments, particularly with respect to movie theaters, other entertainment-type venues, and superstores that offer restaurant or restaurant-type food.

## MULTIPLE SERVINGS

Although some comments stated that foods sold in multiple servings such as a bucket of chicken pieces or a full rack of ribs should declare calories on a per-serving basis rather than for the whole order, FDA disagreed with this approach. FDA noted that multi-serving foods that are routinely included on a menu or menu board would meet FDA's proposed definition of standard menu item. Because the statutory language requires that calories be declared for each standard menu item, FDA stated in its proposal that calories should be disclosed for the full standard menu items at covered establishments, regardless of how many servings are included in the item. FDA requests comment on this issue. We note that the agency's approach here seems somewhat inconsistent with its approach to self-service food or food on display, for which calories are disclosed per serving, or per item where the item represents one serving.

## 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. For variable menu items, the calories must be declared as a range, 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.

FDA noted that it considered a number of other options, including use of (1) a single value in the form of an average or median, (2) a range, (3) a hybrid combining averages and ranges, and (4) providing both numbers with a slash if only two options ("350/400") and using a range or hybrid if more than two options. FDA stated that its selection of the second option would give consumers a consistent format across all items, but noted that the range could be so wide for certain items that additional information would be necessary. FDA is seeking comment on whether the proposed method of declaring calories is appropriate and would not be misleading to consumers. FDA is also interested in comment and research on the other options that were considered and whether any of the other options individually or in combination would be preferable.

## SUCCINCT STATEMENT CONCERNING SUGGESTED DAILY CALORIC INTAKE

The statement "a 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may 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 the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided. FDA considered other statements, but ultimately decided that this sentence best met the principles FDA developed that (1) the statement should be succinct, (2) the statement should be in plain language that consumers can understand, (3) the total caloric value should be framed appropriately so that it is not viewed as a recommendation for daily intake for every consumer; (4) the statement should give consumers a means to compare the calorie declaration for a menu item to total calories, and (5) the statement should inform consumers that individual needs vary. FDA is seeking comment on the principles developed by the agency and whether FDA's proposed statement is adequately designed to enable the public to understand, in the context of a total daily diet, the

significance of the caloric information provided on menus and menu boards. FDA is particularly interested in comments with alternative suggested statements that are consistent with the principles identified above and requests that any such statements be accompanied by data, such as consumer research.

## EFFECTIVE DATE OF FINAL RULE

Although many of the menu labeling provisions in the health care reform legislation became effective at the time the law was signed, FDA previously announced its intention to exercise enforcement discretion until the final rule is published and in effect. FDA is proposing that the final rule become effective six months from the date of its publication. Because of the benefits of the rule, FDA would like to make the requirements effective as soon as possible. Recognizing difficulties in implementation, FDA has requested comment on whether a nine-month or one-year implementation timeframe would be more appropriate.

FDA has requested that comments on the proposed rule for restaurants and similar retail food establishments be received by June 6, 2011 and that comments on the proposed rule for vending machines be received by July 5, 2011. Comments can be submitted to Docket numbers FDA-2011-F-0172 (restaurants and similar retail food establishments) and FDA-2011-F-0171 (vending machines) at [www.regulations.gov](http://www.regulations.gov).

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