

FDA Answers Questions on When and How to Comply with New Restaurant Menu Labeling Law

On August, 24, 2010, the US Food and Drug Administration (FDA) published draft guidance interpreting the new restaurant menu labeling law in section 4205 of the Patient Protection and Affordable Care Act (PPACA) of 2010. The Agency also issued final guidance addressing the preemptive effect of the law. These documents, while technically non-binding, provide FDA's views on many questions restaurant owners have been asking since the provision became law on March 23, 2010.

Section 2405 amends section 403 of the Federal Food, Drug, and Cosmetic Act to require all chain restaurants and "similar retail food establishments" with 20 or more locations to provide calorie information for "standard menu items" on menus and menu boards, and to make other nutritional information available in writing on the premises. The law also affects companies that operate 20 or more vending machines.

When do the new rules go into effect?

One critical outstanding question was the extent to which the law was self-executing, rather than dependent upon the promulgation of regulations. Another was the effective date of preemption provisions, leading some States and localities (e.g., Massachusetts and Davidson County Tennessee) to repeal their menu labeling laws, and others (e.g., Philadelphia) to continue enforcing theirs.

In the FDA's view, while the preemption afforded by PPACA Section 4205 was immediate with respect to state and local requirements that are not identical to the federal law, certain major provisions of Section 4205—including calorie information on menus and menu boards and the requirement to provide other nutritional information in writing—also became effective upon enactment on March 23, 2010. FDA stated, however, that it would exercise its enforcement discretion and give restaurants time to comply before it begins to enforce the law. The extent and timing of that discretion will be articulated in the final guidance on current menu labeling requirements. This position is highly controversial and contrary to the industry's view on congressional intent and the statutory requirement that FDA promulgate regulations to carry out the provisions of the law.

FDA also addressed several implementation questions in draft guidance on which it is seeking comment.

Who must comply?

In addition to chain vending machine operators, section 4205 applies to chain restaurants and "similar retail food establishments," a term it does not define. In its draft guidance, FDA takes a

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broad view that the term encompasses at least “coffee shops, delicatessens, food take-out and/or delivery establishments (e.g., pizza take-out and delivery establishments), convenience stores, movie theaters, cafeterias, bakeries/retail confectionary stores, food service vendors (e.g., lunch wagons, ice cream shops, mall cookie counters, and sidewalk carts), and transportation carriers (e.g., airlines and trains).” According to FDA, the law also covers “grocery stores [that] have cafés, food courts, or otherwise sell food that is for immediate consumption directly to consumers,” although FDA welcomes comments on how to regulate grocery stores “that offer foods that could be consumed immediately or could be purchased as traditional grocery items for future consumption, such as in-store bakeries, salad bars, pizza bars, or delicatessens.”

This broad interpretation should interest many companies that may not have been following this issue or that may have hoped to avoid these requirements.

Where does the calorie information go?

According to the statute, chain restaurants and similar retail food establishments must place calorie information on their “menu” or “menu board,” defined as “the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.”

FDA says it will interpret “primary” broadly to mean “all all forms of primary writing” including dessert and beverage menus, as well as internet and take-out menus. FDA seems to be interpreting the term “primary” from the consumer’s perspective, not the food service establishment’s. FDA’s interpretation appears to erase the word “primary” from the law, attempting to require calorie information on multiple menus and menu boards.

The calorie information must be adjacent to its corresponding food item. FDA would like to see it in the same size font as the menu item, or the price, whichever is larger. The menu or menu board must also inform customers that additional nutritional information is available.

What additional nutritional information is required?

In addition to standard nutritional information (calories, fat, cholesterol, sodium, carbohydrates, sugars, fiber, and protein), FDA signaled that it may require the amount of trans fat to be listed. Although not required yet, FDA may require additional nutrition information in implementing regulations.

Do the requirements of the law apply to alcoholic beverages?

Yes, in FDA’s view, the law does apply to alcoholic beverages.

What about made-to-order sandwiches and pizzas, or requests to “hold the mayo?”

Section 4205 applies to “food” that is a “standard menu item,” food sold at self-service facilities, and “food on display.”

Custom orders, such as a ham sandwich without the mayonnaise, are not considered “standard menu items” in FDA’s draft guidance.

The guidance treats other common items, such as pizzas or deli sandwiches that are assembled by choosing from a selection of standard toppings, as “variable items.” Variable items are exempt, but only for now. FDA will be proposing regulations covering them by next spring.

Where can I learn more?

FDA’s guidance documents cover many more details and are available [here](#). If you have questions, you can also contact your Arnold & Porter attorney, or:

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