

# PUBLICATION

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## FDA Mulls Enforcement Strategy for National Menu Labeling

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As we previously advised in a prior edition of Hospitalitas ("Congress Considers National Menu Nutrition Disclosure Standard for Chain Restaurants," 2009, Vol. 2), Section 4205 of the Patient Protection and Affordable Care Act (the Act) authorized the U.S. Food and Drug Administration (FDA) to establish and enforce national menu labeling standards applicable to certain chain restaurants and similar retail food establishments with 20 or more locations. Failure to comply with the new requirements would render a food misbranded under the Federal Food, Drug and Cosmetic Act (FFDCA), which could result in civil and criminal penalties.

Specifically, the Act requires that calories and nutrition information be disclosed to consumers on standard menu items, food on display and self-service food. Section 4205 also requires vending machine operators who own or operate 20 or more machines to disclose calories for articles of food. The legislation allows restaurants and retail food establishments with less than 20 locations and vending machine operators with less than 20 machines to opt-in to the regulatory regime by registering with the FDA.<sup>1</sup>

### **Purpose of the Legislation**

The legislation is the result of a political compromise reached between the national restaurant industry and public health and consumer groups on standardizing the way calories and nutrition information is disclosed on menu boards. In the wake of federal court decisions upholding the authority of state and local governments to regulate menu labeling, industry groups feared exposure to multiple and potentially conflicting labeling requirements by different states and municipalities. To that end, Section 4205 preempts state and local menu labeling that is not identical to the national menu labeling standards authorized by the Act.<sup>2</sup>

### **Key Requirements of Section 4205**

Under Section 4205, chain retail food establishments must meet the following requirements: (1) disclose the number of calories in each standard menu item on menus and menu boards; (2) make additional written nutrition information available to consumers upon request; (3) provide a statement on menus and menu boards about the availability of the additional nutrition information and (4) provide calorie information (per serving or per food item) for most self-service items and food on display on a sign adjacent to each food item. These requirements took effect on the date of enactment of the Act (March 23, 2010) but the FDA has stayed enforcement until it has decided on a final enforcement strategy.<sup>3</sup>

The FDA is also expected to issue no later than March 23, 2011 proposed regulations concerning a narrow set of issues specifically identified in the legislation, such as the standardization of recipes and methods of preparation, reasonable variation in serving size, ingredients, and formulation of menu items, space on menus and menu boards, inadvertent human error, the training of food service workers and "other factors" the FDA determines to be useful to the industry in meeting the calorie and nutrition labeling requirements.

### **Concerns about FDA Enforcement Strategy**

There is tremendous uncertainty among industry groups concerning the way the FDA plans to enforce Section 4205. The problem is in part caused by the way Congress drafted the statute. In delegating authority to the FDA, Congress usually requires the agency to conduct a formal rulemaking process subject to public notice and comment period. However, because Section 4205 took effect on March 23, 2010, the FDA may enforce these requirements prior to completing a formal rulemaking process. For the time being, the FDA has agreed to stay enforcement of these provisions until it has finalized what is in essence a pre-rulemaking guidance document to guide interim FDA enforcement. The FDA continues to solicit input on the document, including "the appropriate time period for enforcement after the issuance of final guidance."

If the FDA decides to enforce Section 4205 in a guidance document before completing a formal rulemaking, regulated restaurants may be forced to first comply with an agency guidance document for an as yet unknown time period. The FDA could then instruct restaurants to change mid-course and comply with a revised set of rules produced after a lengthy formal rulemaking process to be completed at some point in the future. Because such an enforcement strategy will lead to added compliance costs and potential confusion in the compliance, inspection and enforcement process, industry trade groups have told the FDA that issues being addressed in the guidance document and the rulemaking process should be covered simultaneously in one consolidated rulemaking procedure. Convincing the FDA to initiate a formal rulemaking relating to all aspects of Section 4205 is a top industry priority. In comments submitted to the FDA on September 7, the National Council of Chain Restaurants and the National Restaurant Association told the FDA that "attempting to require implementation based on general statutory language and guidance followed by a second implementation in accordance with the final regulation would be contrary to law, confusing to our customers, and an undue burden on the industry."

## The Road Ahead

It is too early to predict the regulatory compliance and enforcement strategy on which the FDA finally decides. Industry stakeholders will remain heavily involved in shaping the strategy and will not be shy about reaching out to key allies on Capitol Hill in ensuring that the FDA adopts an open and transparent notice and comment process so that industry is fully aware of all of its obligations under the law prior to FDA enforcement. In the interim, regulated restaurant operators should work with suppliers to make sure they are fully aware that once the menu labeling standards become fully enforceable, any alterations in the nutritional values of their products will have a big impact on menu labeling. Stay in contact with your counsel on the timing of the upcoming compliance materials.

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1. The FDA issued a notice in the Federal Register on July 23 informing restaurants with less than 20 locations and vending machine operators with less than 20 machines of the FDA registration process in the event they choose to opt-in to the national menu labeling regime. Vol. 75 Fed. Reg. 43182 (July 23, 2010)

2. On August 25, the FDA issued a draft guidance document notifying state and local governments of the legal impact of Section 4205 on their menu and vending machine labeling laws. Vol. 75 Fed. Reg. 52427 (August 25, 2010)

3. FDA Press Release, "FDA releases guidance on federal menu labeling requirements: Agency requests public comment on implementation of new provisions," August 24, 2010. The vending machine operator nutrition labeling requirements of Section 4205 also took effect on the date of enactment, and the FDA stay applies to these requirements as well.