

# FDA Seeks Public Comment on Nutritional Disclosures in Retail Food Outlets

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Last week, the Food and Drug Administration (FDA) took the first steps needed to implement the new restaurant food labeling requirements of the Federal Food, Drug & Cosmetic Act (FDCA), requesting public comment on a number of regulatory issues that will affect compliance burdens and liability risks for companies subject to the new requirements. Submissions responding to the FDA notice can be made until September 7, 2010.

The new labeling requirements were established under FDCA amendments adopted as part of the recently enacted health care reform legislation (i.e., section 4205 of the Patient Protection and Affordable Care Act of 2010). The amendments expanded the scope of mandatory nutrition labeling requirements under FDCA section 403(q)(5)), and require restaurants and other retail food establishments with at least 20 or more locations to provide "clear and conspicuous" calorie information to consumers. More specifically, companies subject to the new requirements must:

- Declare the number of calories provided by each standard menu item as it is typically prepared, and
- Present the required calorie information in terms of suggested caloric intake in the context of an overall diet.

As discussed in greater detail in [our analysis of the recent FDCA amendments](#), the new restaurant labeling requirements raise a number of significant issues that merit consideration as FDA develops implementation policies. Further clarification is needed with respect to the scope of "retail establishments" that will be subject to the new requirements and the standards governing the calculation and representation of calorie information. For example, the extent to which the new requirements should apply to in-store delis, salad bars, vending, and other ready-to-eat foods sold through grocery stores, gas stations, and other retail establishments, and distributors of food that serve more than 20 retail establishments or privately operated cafeterias (e.g., corporate, schools) is unclear. Further, standards must be set regarding calorie calculation to achieve the standardization goal of the amendment.

## Opportunity for Comment

Through the docket, the FDA is providing industry an opportunity to inform the implementation of the new legislative requirements for mandatory or voluntary menu, menu board and vending machine labeling. The FDA is specifically seeking information relating to the following issues:

### **Chain Retail Food Establishments**

- What types of restaurants or similar retail food establishments and the nature of their food service activities are potentially impacted by the new law, including the number of retail chains subject to mandatory or voluntary compliance with the new law?
- What are the current practices regarding use of menus or menu boards within the restaurant or similar retail food establishment industry? To what degree is space on menus or menu boards a consideration?
- What are the current practices with respect to the format and manner of nutrient content disclosures concerning food items that appear on retail food service menus or menu boards?
- What are the considerations in the disclosure of calorie content information for food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display?
- What are the issues to be considered in developing a succinct statement about a suggested daily caloric intake that is required to appear on menus and menu boards?
- What are the methods related to presentation of nutrient content (ranges, averages, or other methods) for standard menu items that come in different flavors, varieties, or combinations but which are listed as a single menu item, such as soft drinks, ice cream, pizza, etc., or combination meals such as children's combination meals?
- What are the factors to consider with respect to determining what foods or categories of foods might be exempt from the menu labeling requirements because, e.g., they are condiments and other items placed on tables or counters for general use; daily specials, temporary menu items, or custom orders; or other food that is part of a customary market test?
- What information is available about the size of chain retail food establishments (e.g., based on annual revenue or on number of locations)?

### **Determination of Calorie Content of Foods Offered by Chain Retail Food Establishments**

- What information is available about standardization of recipes and methods of preparation?
- What information is available about variation in serving size and formulation of menu items.
- To what degree does inadvertent human error factor in?
- What information is available about training of food service workers?
- To what degree are ingredient variations a factor?

### **Vending Machine Operations**

- What is the scope of potential chain vending machine operators that are or could be subject to section 4205 and those who might voluntarily choose to comply?
- What are the current practices within the vending machine industry with respect to the availability to prospective purchasers of Nutrition Facts panel information or otherwise providing visible nutrition information at the point of purchase?

- What are the possible mechanisms for displaying products' Nutrition Facts panels or otherwise providing visible nutrition information at the point of purchase?
- What are the factors to consider with respect to availability and use of space on vending machines?
- What are the considerations in requiring caloric content disclosure about food items sold from vending machines?
- What information is available about the size of chain vending machine operators (e.g., based on annual revenue or on number of locations)?

## **Implementation and Enforcement**

- What information is available about implementation, including information about options for inspection and enforcement?
- What information is available about inspection and enforcement mechanisms in state and local nutrition labeling programs?

Should you wish to address any of the questions above in a response to FDA or for further information about the new nutrition labeling requirements please contact one of the Kelley Drye attorneys listed below.

## **Kelley Drye & Warren LLP**

Kelley Drye's team of [Food and Drug](#) lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

For more information about this Client Advisory, please contact:

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