

## FDA Expediting Menu Labeling Implementation and Enforcement

The Food and Drug Administration (FDA) is expediting the enforcement of the Healthcare Reform law's food menu labeling provisions. The agency issued proposed [guidelines](#) clarifying the types of establishments and products subject to the new law and announcing that it will determine its enforcement timetable after the promulgation of a final policy. The policy could be finalized as early as December.

The Healthcare Reform law mandates food establishments (including restaurants, bakeries, mobile food carts, take out/delivery establishments, deli's, grocery stores, corporate caterers, coffee shops, bars, convenience stores and theatres) with 20 locations or more to display calorie information and that vending machine companies with 20 or more also disclose calorie information. Even though restaurant chains with less than 20 establishments are not required to adhere to the new law, those establishments may follow the guidelines and register with the FDA.

### Labeling Requirements Could Be Effective Before a Final Rule

Certain provisions took effect immediately when President Obama signed the Healthcare Reform law in March, including:

- (1) Mandatory disclosure of the number of calories in each standard menu item on menus and menu boards;
- (2) Making additional written nutrition information available to consumers upon request;
- (3) Requiring a statement on menus and menu boards about the availability of the additional written nutrition information; and
- (4) Requiring calorie information (per serving or per food item) for most self-service items and food on display on a sign adjacent to each item.

Typically, the agency enters into rulemaking and industry gets at least a year to comply. The agency is planning to continue with a rulemaking (a proposed rule expected to be issued by March 2011) to decide issues, including the scope of establishments subject to the rule (e.g., salad bars at grocery stores), the succinct statement of suggested daily intake that is required on menu boards, the labeling of trans fats, and other issues that are not clear under the law.

The current heightened interest in obesity prevention is seen as driving the expedited implementation and enforcement of menu nutrition labeling. FDA will not immediately enforce the draft policy, but will set a compliance timeframe in a final guidance, which the agency hopes to publish in December. The proposed guidelines request comment on the appropriate timeframe for enforcement to begin. We expect that FDA will rely on the States to enforce the law.

### FDA Guidance on Menu Nutrition Labeling

FDA clarifies in the proposed guidelines that the new requirements apply to chain restaurants even if they are franchised or establishments that offer "substantially the same menu items." FDA defines food that is "substantially the same" as products prepared using the same approximate recipe with the same

components and similar name. Corporate caterers that develop menu items to suit particular client needs are not subject to the menu labeling guidelines.

Surprises in the proposed guidelines include the requirement for nutrition information displays for meat and alcoholic beverages, despite that these products are regulated by other Federal agencies. Additionally, menu labeling requirements apply to any form of communication that a consumer may use to make a food selection, including menu items listed on the internet.

### **Guidance on Nutrition Information Format**

The agency announces some guidelines for the implementation of the law. For example, calorie disclosures can use either “calories” or “cal” on menus and the listed caloric amount should be the same size or larger as the menu item name and set against a contrasting background.

The nutritional information insert must include total calories, total fat-derived calories, fat content, saturated fat, cholesterol, sodium, carbohydrate level, the amount of sugars, total protein, and dietary fiber amounts. The agency also recommends the listing of trans fats, but is not required under the law.

### **Recommendations to Stakeholders**

*Stakeholders who fall squarely into the guidelines should prepare to comply with the self-implementing menu labeling requirements as well as those requirements that may be coming in future regulations. Stakeholders should evaluate their menu and customer preferences. Some restaurants who are already labeling calories are finding reduced sales of their higher calorie offerings and increased sales of their lower calorie offerings. Others are learning that new lower calorie offerings are flopping because customers expect and enjoy a higher calorie product. Stakeholders may wish to develop a strategy for introducing the calorie disclosures to their customers. They should know how their menu items compare to their competitors and be prepared to be a target for groups that are monitoring the labeling to highlight restaurant menu items that could be characterized as contributing to obesity, particularly childhood obesity.*

*Stakeholders who do not fall squarely into the guidelines should consider working with FDA and possibly Congress to develop sensible labeling requirements for their establishments.*

### **Womble Carlyle’s FDA Regulatory Practice**

Womble Carlyle’s [FDA Practice Group](#) is led by [Peggy Binzer](#), who has extensive experience in implementing nutrition labeling regulations and in strategically working with the FDA. Peggy has worked with dozens of food manufacturers in implementing the Nutrition Labeling and Education Act (NLEA), the law that requires nutrition labeling of foods. In addition, she spent over seven years as Counsel for FDA’s Office of Nutrition Products and Labeling and maintains strong relationships with FDA. Finally, she served as Senior FDA Counsel on the Senate Health Education Labor & Pensions Committee, the Senate Committee with jurisdiction over FDA’s implementation of restaurant labeling.

Womble Carlyle’s [Restaurant Team](#) includes lawyers from across a variety of disciplines who have joined together to address the unique and diverse needs of restaurant owners and operators, whether they are franchisors, franchisees, or independents. We represent restaurateurs in every aspect of their businesses, including business organization, corporate finance, acquisitions and divestitures, supply chain management, anti-trust, franchising, distribution, FDA regulatory compliance, intellectual property, real

estate, green practices, labor and employment, tax, bankruptcy, and dispute resolution. For more information about our Restaurant Team, please click [here](#).

For more information about the matters described in this Client Alert, please contact [Peggy Binzer](#) at (202) 857-4546 or [PBinzer@wcsr.com](mailto:PBinzer@wcsr.com) or one of our other [Restaurant](#) professionals.

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