

CONGRESS DELAYS FDA'S IMPLEMENTATION OF FINAL RESTAURANT MENU AND VENDING MACHINE LABELING REQUIREMENTS FOR CHAINS WITH 20+ LOCATIONS

By

[Valerie L. Haber](#), Miami Alcohol Law and Food Law Attorney

Through passage of its bi-partisan omnibus tax bill, the **Consolidated Appropriations Act of 2016** (the "Act"), Congress has substantially extended the time line for the U.S. Food and Drug Administration's enforcement of the agency's new rules on standard restaurant menu labeling. At this point, there is no date certain as to when compliance will be required. The FDA announced last year that it would give chain restaurants until December 1, 2016, to comply with its final regulation requiring chain restaurants to post calorie counts for the foods they sell. Chain restaurants, grocery stores that sell prepared foods, and other covered businesses with 20 or more locations are covered by the new administrative rule.¹ As a result of public concerns, the agency also issued a draft guidance document in September of 2015 that address some of the most common questions businesses have posed about the new rule.²

However, buried in the tax and spending bill recently passed by Congress and signed into law by President Obama as the Act is a provision extending that implementation time to "***the date that is one year after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling and standard menu items in restaurants and similar food establishments in accordance with federal regulations.***" Specifically, the tax law provision, codified as Section 747 of the Act, prohibits the FDA from spending any of the funds appropriated by Congress to implement, administer or enforce the agency's final rules relating to food labeling for menus until the requisite Level 1 guidance is published by the Secretary of Health and Human Services.

Background on the New Menu Disclosure Regulations

After several years of public comment and redrafting, the U.S. Food and Drug Administration (FDA) in 2014 issued two final rules requiring that calorie information be listed on menus and menu boards in chain restaurants, similar retail food establishments and vending machines with 20 or more locations. These new rules follow a set of federal menu labeling requirements that FDA previously proposed in response to concerns over obesity associated with the consumption of processed foods and "fast food" offered by quick-service restaurants, especially in the context of adolescent obesity.

¹ <https://www.federalregister.gov/articles/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food>

² <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm437403.htm>

Under the final regulations, all covered establishments must list calories for any alcohol beverage found on a menu or menu board. No calories will be listed for beverages that are not standard menu items; however, the Menu Labeling final rule also requires covered establishments to provide written nutrition information about total calories, total fat, calories from fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fiber, sugars and protein, when that information is requested by a consumer. The ability to request such information is to be noted on menus and menu boards.

FDA was authorized to promulgate both new rules by the Affordable Care Act ([Pub. L. 111-148](#)), which was signed into law on March 23, 2010. Section 4205 of the Affordable Care Act amended 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (FDCA) by, among other things, creating new clause (H) to require that certain chain restaurants and similar retail food establishments with 20 or more locations disclose certain nutrient information for standard menu items. FDA has the authority to issue new rules under sections 403(a)(1), 403(q)(5)(H), and 701(a) of the FDCA ([21 U.S.C. 343](#)(a)(1), 343(q)(5)(H), and 371(a)). Section 701(a) of the FDCA vests the Secretary of Health and Human Services, and, by delegation, the FDA with the authority to issue regulations for the efficient enforcement of the FDCA. The new regulations are intended to provide consumers with more nutritional information about the foods they eat outside of the home.

The two new rules, which are accessible in the Federal Register, are summarized as follows:

- **Menu Labeling final rule**: Applies to restaurants and similar retail food establishments if they are part of a chain of 20 or more locations, doing business under the same name, offering for sale substantially the same menu items and offering for sale restaurant-type foods. Restaurants and similar retail food establishments will have one year to comply with the menu labeling requirements.
- **Vending Machine final rule**: Requires operators who own or operate 20 or more vending machines to disclose calorie information for food sold from vending machines, subject to certain exemptions. Vending machine operators will have two years to comply with the requirements.

Food establishments covered by the Menu Labeling final rule will be required to clearly and conspicuously display calorie information for standard items on menus and menu boards, next to the name or price of the item. Exemptions from the new rule include (i) Seasonal menu items offered for sale as temporary menu items; and (ii) daily specials and condiments for general use typically available on a counter or table.

The two final rules are available in the Federal Register:

- [Final Rule: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments](#)
- [Final Rule: Calorie Labeling of Articles of Food in Vending Machines](#)

The Congressional Delay on Implementation

Although the new regulations were scheduled to go into effect on December 1st of 2015, delays by both the FDA and most recently the Congress have pushed implementation back by at least one year. This means that restaurants and other establishments covered by the rule, and by the menu labeling provisions of the Affordable Care Act (ACA), now have until at least December 1, 2016 to post calories and other information on their menus and menu boards, provide full written nutrition information in-store, and come into compliance with the rule's other requirements. Most likely, because of the language in the Act, implementation of the restaurant menu rule will be delayed beyond 2016 because of the time necessary for the Secretary of Health and Human Services to draft and publish Level 1 guidance with respect to nutrition labeling and standard menu items.

A non-binding guidance document has been issued by the FDA that provides answers to some of the more frequently asked and crosscutting questions that the agency has received to further assist covered establishments in complying with the rule. "[A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods -- Part II](#)" is intended to help restaurants and similar retail food establishments understand nutrition labeling requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations that may apply to them. Broadly, these requirements include the menu labeling provisions of section 403(q)(5)(H) of the FD&C Act [21 U.S.C. 343(q)(5)(H)] and the final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments we published on December 1, 2014 (79 FR 71156).

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[Valerie L. Haber](#) is a Miami alcohol beverage law and liquor license attorney and is an associate in the firm's [Alcohol Beverage Law](#) and [Food Law](#) Practice Groups. She concentrates her practice on advising all three tiers of the alcohol beverage industry including wineries, breweries and distilled spirits suppliers, distributors and retailers. Valerie's practice includes counsel relating to federal, state and local laws governing the sale, distribution, importation, manufacturing and marketing of alcoholic beverages, including beer, wine and spirits. Valerie works closely with national retailers, including restaurants, supermarkets, movie theater chains and other on and off-premise businesses, through all phases of development and licensing, including land use and zoning diligence and approvals. She also has experience drafting management and promotional contracts for alcohol industry members, including hotels and golf courses, and regularly advises clients on the legal risks associated with promotional activities. Valerie also assists clients with local liquor licensing, including restaurant, hotel, and occupational licensing.

For more information regarding the impact and implication of these rules, please contact GrayRobinson's [Food Law Group](#) at foodlaw@gray-robinson.com or (866) 382-5132.