

Article

FDA Publishes Proposed Regulations on Menu Labeling Requirements



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In April 2011, the Food and Drug Administration (FDA) published proposed regulations to implement the menu labeling provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). Pub. L. No. 111-148, 124 Stat. 119; see [here](#). As drafted, the proposed regulations require certain chain restaurants to provide calorie and other nutritional information for their standard menu items to consumers.

The franchise community has been anxiously awaiting the release of the proposed regulations to assess how they may impact franchise systems that offer and sell food and beverages to the public. As part of its rulemaking process, the FDA seeks public comment on several issues related to the proposed regulations by June 6, 2011. While the FDA expects to issue final regulations by the end of the year, it has indicated that enforcement of the new requirements will not begin until mid-2012, at the earliest.

Background

The FDA's current nutrition labeling requirements, which were issued in 1993 (21 C.F.R. § 101.9 (1993)), apply only to packaged food and specifically exempt foods served in restaurants or prepared for immediate consumption. The dining habits of Americans have changed considerably over the years, however, and the FDA estimates that American consumers now receive one-third of their total calories from foods prepared outside of the home. The agency also reports that most people are either generally unaware of, or inaccurately estimate, the caloric content of restaurant foods.

In response to this trend and other issues related to health conditions such as obesity and diabetes, Congress amended the FDA's nutrition labeling requirements in March 2010, through Section 4205 of the Affordable Care Act. 21 U.S.C.A. § 343q-5. Section 4205 requires the FDA to issue regulations that establish: (1) requirements that caloric content information be posted on menus and menu boards; (2) standards for determining and disclosing nutrition content; and (3) processes to enable

restaurants not otherwise covered by the rules to opt-in to the menu labeling requirements.

The FDA published draft guidance in August 2010 (75 F.R. § 52426), which it subsequently withdrew in January 2011, in favor of releasing the proposed regulations as part of a formal rulemaking process. As discussed below, the draft rules not only attempt to interpret the meaning of various provisions contained in Section 4205, but also include suggested alternatives on which the FDA seeks public comment. This article discusses several of the key provisions that, if adopted, will impact restaurants and franchise operations.

What are "Covered Establishments"?

Section 4205 of the Affordable Care Act requires "covered establishments" to provide caloric content information on menus and menu boards, and other nutritional information upon request, for all standard menu items. A "covered establishment" includes "any restaurant or similar retail food establishment" that is part of a "chain" (a) with 20 or more "locations," (b) doing business under the "same name," and (c) offering for sale "substantially the same menu items." These provisions raise several questions concerning the scope of the law's application.

- To be a "restaurant or similar retail food establishment" within the meaning of the Act, the FDA's proposed rules contemplate that the business must (1) sell restaurant or restaurant-type food, and (2) either (a) publicly present itself as a restaurant or (b) dedicate more than 50 percent of its floor space for the sale of food. If adopted, these rules will apply to table service and fast-food restaurants, coffee shops, snack bars and ice cream parlors, but not to movie theaters, amusement parks, hotels, trains and airplanes. In addition, the FDA proposes that coffee shops in bookstores and other kiosks, counters and similar food facilities located within larger retail establishments or "superstores" be considered part of the larger retail establishment for purposes of

calculating the 50 percent floor space test, unless the food facility is part of a chain with locations outside of the larger establishment (such as a Starbucks mini-store located within a Barnes & Noble or Target).

- The FDA has not proposed specific definitions for the terms “chain” and “location,” and is instead assuming the common meanings for those words. However, the agency has requested comment on whether these terms should be specifically defined in the final regulations, especially within the context of various types of business structures, including franchising
- The proposed regulations indicate that doing business under the “same name” includes slight variations based on region, location or size, such as “Joe’s Burgers New York Ave.” and “Joe’s Burgers Pennsylvania Ave.,” but the FDA seeks comments on whether the regulations should instead refer to underlying ownership or contractual relationships, such as franchising, that link the establishments together regardless of the public name used by individual establishments
- The FDA proposes that the phrase “substantially the same menu items” should include menu items that (a) use the same general recipe, and (b) are prepared substantially in the same way using substantially the same food components, regardless of the name assigned to the menu items. To further clarify, if a restaurant with a limited menu offers standard menu items that are sold in a restaurant with a more extensive menu, then these two restaurants will be deemed to offer substantially the same menu items.

What are “Menu and Menu Boards”?

The proposed regulations raise additional questions concerning the materials on which nutritional information must be disclosed, as well as the appearance and content of the disclosure. Under the proposed regulations, a “menu” or “menu board” includes any writing (e.g., booklets, pamphlets or single sheets, including drive-through menu boards and counter displays) of the covered establishment that is the primary writing from the standpoint of the consumer.

The FDA has tentatively concluded that general advertisements for food fall outside the scope of Section 4205. Additionally, to the extent consumers can order food online, over the phone or by fax using an online menu, the menu posted to the Internet will also be considered a “primary writing.” Although the FDA has requested comments about the scope of the primary writing requirement, in light of the overall objective of giving consumers access to

nutritional information, the FDA will likely adopt a broad meaning to that term.

As for what information must be displayed on menus and menu boards, the number of calories contained in each standard menu item as usually prepared and offered for sale must appear adjacent to each menu item in a clear and conspicuous manner. The FDA has not specified a type size and font for all disclosures, but has requested comment on that issue. If the standard menu items come in different flavors, varieties or combinations (i.e., pizza, doughnuts, combination meals, etc.), the FDA suggests that the calorie content be disclosed as a range from the lowest to the highest number of calories.

The menus and menu boards must include the following declaration: “A 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual needs may vary.” The FDA has requested comment on this declaration, but the proposed regulations indicate that the statement is intended to improve the consumers’ understanding of the menu selections by providing context to their total daily diet.

The menus and menu boards also must include the following declaration: “Additional nutrition information is available upon request.” This additional nutrition information must include total calories from all sources, total calories from total fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, sugars and protein contained in each serving size or other unit of measure, and must be available in written format. For foods that can be ordered in different varieties, flavors and combinations, the nutrient information must be available for each variety, flavor and component. If the possible variations are so numerous that this requirement is impractical, then nutrition information may be provided based on standard preparation parameters with separate disclosures for each topping or other variable component.

What are “Standard Menu Items”?

Section 4205 requires that covered establishments provide calorie and other nutrition information for “food that is a standard menu item.” While the FDA seeks comment on the proposed definition of the term “standard menu item,” the proposed regulations suggest that this term apply to a restaurant or restaurant-type food that is served for immediate human consumption (or prepared but not for immediate consumption) and is routinely listed on a menu or menu board, or is routinely offered as self-service food or food on display.

For example, standard menu items include combination meals, variable menu items, self-service food and food on display, but do not include custom orders, daily specials, food that

is part of customary market tests and temporary menu items. The proposed regulations provide detailed interpretations of the meaning of each of these terms. Alcohol is also excluded because of the exclusive regulation over alcohol labeling by the Alcohol and Tobacco Tax and Trade Bureau.

Special Rules for Products on Display and Self Service Items

The proposed rules define (a) “food on display” as food that is visible to the customer before making an order selection, and (b) “self-service food” as food that is available at a salad bar, buffet line, cafeteria line or similar self-service facility, including self-service beverages. These items must be accompanied by an individual sign that lists calories per item or per serving (or per ounce in the case of beverages), and the FDA has proposed detailed rules for the declarations concerning these items.

Voluntary Registration

Section 4205 of the Affordable Care Act specifically preempts all state and local nutrition labeling requirements. Restaurants and similar retail food establishments that are not “covered establishments” within the meaning of the Act may voluntarily register with the FDA every other year and, after registering, will not be subject to any state and local nutrition labeling requirements other than those that are identical to the federal requirements.

Next Steps

Nearly everyone agrees that the long-awaited, proposed regulations represent a welcome change to the confusing web of state laws concerning nutrition labeling requirements. When the final regulations are issued, these rules should provide much needed guidance and uniformity in this area to franchise systems that offer and sell food and beverages to the public. However, for some franchise systems that have not been forced to comply with these types of labeling requirements in the past, the new rules may add an unwelcome new burden.

Franchisors should specifically focus on the proposed definition of a “covered establishment” because the final definition of that term and the related concepts will ultimately determine whether a particular franchise system is subject to these requirements. All franchise systems that offer and sell food and beverages to the public should carefully consider the impacts and alternatives raised by the proposed regulations and take advantage of the opportunity to provide comments to the FDA by the June 6, 2011 deadline. Comments may be submitted: (1) online [here](#), (2) by facsimile (301-827-6870), or (3) by mail, hand delivery or courier to: The Division of Dockets Management (HFA-305),

Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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