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Regulatory Alert: FDA Releases Menu Labeling Guidance

Key Questions Addressed on Labeling Format and Covered Items

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On September 11, 2015, the U.S. Food and Drug Administration (FDA) released draft <u>guidance</u> on the Final Menu Labeling Regulation (the "Final Rule").¹ The Guidance addresses a number of key questions the food industry posed to FDA and provides a number of insights into FDA's views on compliance requirements. Please contact Erik Lieberman at <u>erl1@liebermanpllc.com</u> or 202.830.0300 if you have questions or would like additional information. Lieberman PLLC assists firms in menu labeling matters and other FDA and USDA regulatory issues.

Background

FDA issued a proposed rule on menu labeling on April 6, 2011.² On December 1, 2014, FDA issued the Final Rule.³ The regulation implements the menu labeling provisions of the Affordable Care Act (ACA).⁴ Compliance was required on December 1, 2015, but in response to industry concerns, FDA <u>extended the deadline</u> to **December 1, 2016.**⁵

Key Points

Additional written nutrition information required by the Final Rule satisfies requirements for restaurant-type foods with nutrient content claims, provided the written nutrition information includes amounts that are the basis for the claim.

If you offer a "Low-Fat Bran Muffin" the description of the product as "low fat" constitutes a nutrient content claim and under 21 CFR 101.10 (Nutrition Labeling of Restaurant Foods) you are required to provide full Nutrition Facts labeling, or information on the specific nutrient on which the claim is based (e.g. total fat). FDA states that the additional written nutrition information requirement under the Final Rule will satisfy the requirements of 21 CFR 101.10, provided that the written nutrition information includes information on the particular nutrient amounts that are the basis for the claim. As a reminder, written information on total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars and protein is required to be provided to consumers on request for standard menu items.

¹ 79 Fed. Reg. 71156 (December 1, 2014).

² 76 Fed. Reg. 19192 (April 6, 2011).

³ 79 Fed. Reg. 71156.

⁴ Section 4205 of the ACA. Codified in 21 USC §§ 343 and 343-1.

⁵ 80 Fed. Reg. 39675 (July 10, 2015).

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Corporate executive dining rooms, hotels offering complimentary foods and hospitals that do not charge consumers for foods are generally not covered.

Corporate executive dining rooms (where employees are not charged for the food) are not considered covered establishments subject to the Final Rule. Similarly, hotels that offer complimentary buffets and hospitals that provide food at no cost to the consumer and do not offer for sale standard menu items, are not considered covered establishments.

Cold, prepared deli items sold by weight, typically eaten over several occasions or stored are generally not covered.

Cold, prepared barbecue meat items offered from behind a deli counter sold by weight rather than by piece and generally reheated before consumption are not subject to menu labeling requirements. However, a two-piece barbeque chicken lunch or a slice of pizza routinely included on a menu or menu board, or offered at a hot self-service buffet would be covered.

Calorie declarations are not required by pictures of items if the name, price and calories of the item are listed elsewhere in the menu or no the menu board.

For example, on the menu/menu board, a plate with eggs, bacon, French toast, and grits is pictured and directly beneath that picture is the name of the standard menu item combination meal (e.g., Aunt Cora's French toast breakfast). If Aunt Cora's French toast breakfast is also listed in a separate section of the menu and includes the calorie declarations for the entire combination meal, then the calorie declaration would not be needed next to the picture of the combination meal.

Coupons can be considered menus subject to menu labeling requirements.

A coupon for a pizza that includes a phone number where an order could be made and states "1 large pepperoni and sausage pizza \$9.99" is considered a menu and is subject to the menu labeling requirements. Other forms of advertising and marketing that contain a name of an item, a price, and a mechanism by which a consumer can make an order selection at the time the consumer is viewing it may be considered menus and subject to the menu labeling requirements. Retailers should examine their marketing materials and websites to determine whether calorie disclosure is required pursuant to the Final Rule. A coupon attached to a takeout menu which already contains calorie information for the standard item listed on the coupon would not need a redundant declaration on the coupon.

Deli platters offered by supermarkets and other retail establishments are covered.

Sandwich platters, hors d'oeuvres platters, dessert platters and platters offering standard menu items are required to display calorie information.

Calorie information for combination meals may be declared for individual meal items or as a range.

You may declare calorie information for each side dish individually in a combination meal, or include a range of total calorie information. For example, the following methods are both compliant:

Cheeseburger with choice of French fries or fruit cup (600/900 Cal)

Cheeseburger (500 Cal) with choice of French fries (300 Cal) or fruit cup (100 Cal)

Digital menu boards only need to display the succinct statement of a 2,000 calorie diet and statement on availability of written nutrition information when displaying standard menu items.

The succinct statement and the statement of availability need only appear on rotating displays of such digital menu boards that list standard menu items. For example, a display of a picture of a food without a name or price would not need the statements.

Multiple panel menu boards, including digital menu boards are considered to be a single menu board if all panels are visible to consumers when they are placing orders.

For the purposes of the Final Rule, FDA considers a multi-paneled menu board to be a single menu board if the entire multi-paneled board is visible to consumers when consumers are placing order selections for the standard menu items listed on the board.

FDA suggests delivering written nutrition information to consumers who request it for delivery items.

Covered establishments that deliver food to consumers are required to provide written nutrition information upon request. The covered establishment should determine the most feasible way to provide this information to the customer for food that is delivered to meet the requirements of the Final Rule. For example, the covered establishment could deliver the written nutrition information with the standard menu item ordered by a consumer if the consumer requests the information.

Required written nutrition information may be provided via an app or on a website, but only if a computer or other device is made available to consumers to access it.

You can provide additional written nutrition information required to consumers using an app or Internet link, provided access to the written nutrition information is available on the premises of the establishment (e.g., at a kiosk or other electronic device available at the establishment) and the information is provided to the consumer upon request without the need for customers to supply their own electronic device.

Grab and go items may be labeled directly with calorie information and information on additional required nutrients to meet the requirements of the Final Rule.

A label or sticker with calories provided directly on the package of a "grab and go" food is considered by FDA to be a way of declaring calories on a sign adjacent to and clearly associated with the corresponding food, which is one compliant manner of providing calorie information for self-service items and foods on display (other acceptable manners include a sign on a sneeze guard or a single sign with information for

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multiple items visible to consumers when making selections). Labeling the product with calorie information in accordance with the Final Rule does not affect the exemptions from nutrition labeling under 21 CFR 101.9(j)(3) for restaurant-type foods. In other words, if a food that was previously exempt from nutrition labeling under 21 CFR 101.9(j)(3) is now covered under the menu labeling requirements, declaring the calories for such food, including declaring calories on the package of a "grab and go" food, to comply with the requirements for nutrition labeling in 21 CFR 101.11, would not cause such food to fall out of the exemption in 21 CFR 101.9(j)(3). As a reminder, written nutrition information is required for foods on display and self-service foods, in addition to foods appearing on menus and menu boards. A nutrition facts panel voluntarily placed on the label of a grab and go food will meet the requirements of additional written nutrition disclosure.

States may enforce menu labeling requirements.

In general, FDA is delegated with enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C). However, under section 310(b) of the FD&C Act, a state could enforce certain provisions of the FD&C Act, including the menu labeling requirements under certain circumstances. Alternatively, states or localities could establish menu labeling requirements that are identical to the federal requirements and enforce their identical requirements. FDA intends to work with state and local authorities, as appropriate to ensure that implementation and enforcement of the menu labeling requirements are uniformly applied.

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