

MEMORANDUM

From: Steven B. Steinborn
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Date: May 2, 2016

Re: **FDA Issues Final Guidance on Menu Labeling**

The Food and Drug Administration (FDA) has published its final guidance on the menu labeling final rule. ^{1/} This development is significant because it triggers the compliance date for the law, which will be one year from the date that FDA publishes a notice in the *Federal Register* advising the public that the guidance is available. ^{2/} FDA expects to publish this notice in early May, meaning the compliance date for the final rule would be in early May 2017. (As of this writing the notice has not yet been published.)

The guidance document is comprised of questions and answers, with many of the questions having been submitted to the agency by the food industry. FDA is providing additional flexibility in a few areas, particularly for “grab and go” items sold in grocery stores; and for declaring calories for combination meals based on the individual components of the meal, where they are specifically listed, rather than using a range with the total possible calories. This memorandum summarizes some of the key highlights of the guidance, particularly where the guidance provides clarifications not offered in the final rule or preamble. ^{3/}

Covered Establishments

- **Food Not “Offered for Sale”.** FDA clarifies that an establishment that offers food at no cost to the consumer – such as an executive dining room that offers food at no cost to its employees, a hotel that offers a complimentary breakfast, or a hospital that provides food at no cost to the consumer – would not be subject to the menu labeling law. (Question 5.4)
- **Catered Events and Catering Menus.** Menu labeling would not need to be provided at an off-site catered event because the off-site location is not a restaurant or similar retail food establishment that offers for sale standard menu items. However, the catering menu itself, from which the customer makes purchase selections for the catered event, would need to

^{1/} A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11): Guidance for Industry (April 2016), <http://www.fda.gov/downloads/Food/GuidanceRegulation/Guidance-Documents/RegulatoryInformation/UCM461963.pdf>. We are also attaching a “Change Pro” version of the final guidance which shows all changes from the September 2015 draft guidance.

^{2/} The 2016 omnibus spending bill directed FDA to not use any funds to begin enforcing the menu labeling final rule until one year after the date that the agency publishes its final guidance.

^{3/} See HL Memorandum, *FDA Issues Final Rules Requiring Nutrition Labeling for Menus and Vending Machines*, Dec. 3, 2014; 79 Fed. Reg. 71156 (Dec. 1, 2014).

bear calorie labeling, assuming that the catering establishment otherwise meets the definition of a covered establishment. (Question 5.5)

- Mobile Vendors or “Hawkers”. Mobile vendors or “hawkers” that walk through stadiums or arenas and offer food and beverage for sale from a tray or bag are not required to declare calories because they do not have a fixed location or site. (Question 5.9)

Covered Menu Items

- Items Offered Only at Select Establishments. If a menu item is only offered at a few locations, or is only offered through a catering menu but not through the regular menu, that menu item is still subject to the calorie labeling requirements as long as it is a standard menu item at the particular establishment. The fact that a single menu item is not offered at 20 or more locations does not mean that the item is exempt. (Question 5.15)
- Items Offered at Grocery Stores.
 - According to FDA, the intent of the menu labeling rule is to cover the food “most like the food offered for sale in restaurants.” If a food involves additional preparation, such as reheating, before consuming, and is typically eaten over several eating occasions or stored for later use, the food would generally not be covered. For example, cold, prepared barbecue meat items offered from behind a deli counter sold by weight rather than by piece, and that are generally reheated by the consumer before being eaten, are not covered. (Question 5.12)
 - The guidance also states that “Cold prepared foods that: (1) are sold from behind a deli counter; (2) do not appear on a menu or menu board; and (3) require further preparation by the consumer before consumption,” including sliced meats and cheeses on display behind a deli counter, are not considered restaurant-type food and are not subject to the menu labeling requirements. (Question 5.97)
 - Additionally, items sold from bulk bins or cases in grocery stores that are meant to be eaten over several eating occasions and stored for later use, such as loaves of bread and bags or boxes of dinner rolls, are not considered restaurant-type food and would not require calorie declarations. (Question 5.3)

Definition of Menu

- Coupons and Marketing Materials. The guidance explains that while advertising and marketing materials, including coupons, generally would not be considered menus or menu boards, calories are required for a coupon or other material that states the name and price of a standard menu item and includes a phone number or web address where the customer can place an order. (Questions 5.17 and 5.18)

Declaration of Calories

- Multi-Serving Items with Sauces. FDA has added a Q&A on multi-serving standard menu items that are usually prepared and offered for sale with sauce(s). The Q&A does not specifically address the question of how to handle calorie declarations for the sauce if the menu item comes in discrete units but the sauce comes in a single unit (e.g., mozzarella sticks and marinara sauce). This was a key open question from the final rule. The guidance does explain that the calories for the sauce(s) must be included in the calorie declaration. If the options for the sauces are individually listed on the menu or menu board as part of the

multi-serving standard menu item, then the calorie declarations for each sauce would also need to be included. If the sauce options and their calories are already individually declared elsewhere on the menu or menu board, then calorie declarations for each individually listed sauce would not need to be repeated. (Question 5.20)

- Calorie Declarations on Internet Menus. The calorie declaration requirements for internet menus are generally the same as for printed menus. The agency clarifies that calories may not be listed on a webpage or screen that is separate from the associated menu item listed on the internet menu. (Question 5.23)
- Placement of the Term “Calories”. The term “calories” or “cal” can appear adjacent to the number of calories for each standard menu item, or as a column “header” over the listing of calories for each standard menu item. Per the guidance, it also can appear at the beginning of a list of the standard menu items. (Question 5.29) For example:
 - MOCK SANGRIA – A blend of sparkling apple cider, fresh fruit and fruit juices. \$5.99
 - Calories: Berry 190, White Peach 230, Black Raspberry 80
- Combination Meals. If the items in a combination meal are listed individually, the calories can be listed separately for each component, rather than as a total (range) for all items in the combination meal. FDA recognizes that such an approach provides more specific information to consumers. (Question 5.43)
- “Grab and Go” Items.
 - For “grab and go” items that are subject to menu labeling but exempt from packaged food nutrition labeling, such as a packaged sandwich, a yogurt parfait, or a package of sushi prepared at the retail establishment, FDA explains that calories can be provided on the package itself, without triggering the need for a full Nutrition Facts Panel. FDA clarifies that the calories declared on the package should be declared for the entire package, rather than “per serving.” Similarly, the additional written nutrition information would need to be provided for the entire package, unless the establishment voluntarily provides a Nutrition Facts Panel on the package itself. (Questions 5.93 and 5.96)
 - If an establishment adds calorie labeling on the package itself of a “grab and go” item, the succinct statement (“2,000 calories a day is used for general nutrition advice, but calorie needs vary”) and statement of availability of additional written nutrition information could be placed on the label itself as well. Alternatively, these statements could be placed on a sign or menu board that can be read as the customer is selecting the food. If the additional written nutrition information is provided on the label via a Nutrition Facts Panel, no statement that the additional written nutrition information is available upon request would be needed. (Questions 5.94 and 5.95)

Additional Written Nutrition information

- Use of an App or Internet Link. An establishment can use an application or internet link to provide the additional written nutrition information, but this information cannot replace the requirement that the written information must be available at the covered establishment for consumers without their own electronic device. This means that in addition to providing the app or link, an establishment would also have to either (1) provide a kiosk or electronic

device on premises for use upon request, or (2) make printed nutrition information available on premises, in addition to providing the link or application. (Question 5.74)

Enforcement and Recordkeeping

- Recordkeeping and Submission of Records to FDA Upon Request. FDA explains that for the recordkeeping provisions, the required records should be maintained as long as the standard menu items are offered for sale at the covered establishment. Upon request, such records must be submitted to the agency within a reasonable period of time, which FDA considers to be “about 4-6 weeks after the request is made.” (Question 6.4)
- Records for Temporary Items and Market Test Items. For items that are exempt because they are a temporary menu item (offered for sale for less than 60 days per calendar year) or part of a customary market test (for less than 90 consecutive days), FDA recommends that covered establishments keep records on the dates that the item was first and last offered for sale. (Question 6.4, but labeled as part of Question 6.5)
- Changes in Recipe or Method of Preparation. The agency expects that when changes are made to a recipe, method of preparation, or way of serving a menu item (such as changes in portion size), the covered establishment will make any necessary changes to the nutrient values on the menu, menu board, or additional written nutrition information at the same time. If an establishment is unable to update these materials prior to the recipe change, FDA advises requesting further guidance from the agency by emailing CalorieLabeling@fda.hhs.gov. (Question 6.5)
- Records Access to Recipes or Formulations. FDA makes clear that the agency views its recordkeeping authority as extending to the recipe or formula for a standard menu item, if it is relied upon as a basis for nutrient declarations. (Question 6.8)
- Sample Signed Statement. The guidance provides an example of language to use in the signed statement that must be provided upon request by FDA by a reasonable individual at the covered establishment (Question 6.14). The sample language is:
 - “I, (name of the responsible individual), certify that (name of the covered establishment) has taken reasonable steps to ensure that the recipe for (name(s) of standard menu item) that was used to determine the calorie declaration and other nutrient values was followed to prepare (name(s) of standard menu item). The ingredients were properly measured, the specified cook times and temperatures were followed, and the specified portion sizes were served to the customer.”
- State and Local Enforcement. FDA explains that although the agency is charged with enforcing the menu labeling requirements, a state could also enforce the menu labeling requirements under certain circumstances. ^{4/} States and localities can also establish menu labeling requirements identical to the federal requirements and enforce their identical requirements. FDA explains that it intends to work with state and local authorities, as appropriate, to ensure that implementation and enforcement of the menu labeling requirements are uniformly applied. (Question 6.24)

^{4/} Section 310(b) of the Federal Food, Drug, and Cosmetic Act states that a state “may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 343(q) of this title if the food that is the subject of the proceedings is located in the State.” 21 U.S.C. § 337(b). The State must give notice to FDA that it intends to bring such a proceeding and may not bring such a case if FDA is pursuing its own enforcement action pertaining to the food.

Alcoholic Beverages

Section 7 of the guidance is devoted to questions specific to menu labeling for alcoholic beverages. The guidance generally treats alcoholic beverage the same as other individual variable menu items, such as soft drinks that come in different flavors or varieties. There are no specific exemptions that would allow calories for alcoholic beverages to be grouped together (unless the nutrition values are the same after rounding) or declared by ounces. The final guidance includes new details on when the reasonable basis can be based on nutrition information on alcoholic beverage labels consistent with Alcohol and Tobacco, Tax, and Trade Bureau (TTB) rulings. (Question 7.10) FDA also provides additional clarification that beers on tap are exempt from menu labeling unless they are listed on a menu or menu board. (Question 7.5 and 7.6)

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Please contact us if you have any questions or if we can be of assistance.