

Regulatory Alert: FDA Menu Labeling Public Meeting Recap

Agency Reveals Thinking on Key Compliance Issues

July 14, 2016

On July 7th and 8th, the U.S. Food and Drug Administration (FDA) held a public meeting on the final menu labeling regulation at the Center for Food Safety and Applied Nutrition (CFSAN) in College Park, MD. The meeting consisted of a series of presentations by FDA and public Q&A followed by private appointments with industry members. Erik Lieberman of Lieberman PLLC attended the meeting and asked several questions. Lieberman also sat down with the leadership of FDA's menu labeling team to discuss important industry issues in further detail. This regulatory alert shares some of the key takeaways from the meeting. Please keep in mind that FDA has taken positions verbally in public meetings that it has later walked back. Regardless of this fact, we think the following points are important for industry to be aware of:

A. Recordkeeping and Certifications

The final menu labeling rule requires two certifications for each standard menu item:

- (1) A statement signed and dated by a responsible individual, employed at the covered establishment or its corporate headquarters or parent entity certifying that the information contained in the nutrient analysis is complete and accurate; and
- (2) A statement signed and dated by a responsible individual employed at the covered establishment (e.g. retail establishment) that the covered establishment has taken reasonable steps to ensure that the method of preparation (e.g. types and amounts of ingredients, cooking temperatures) and amount of a standard menu item offered for sale adhere to the factors on which its nutrient values were determined.

21 CFR 101.11 (c)

Erik Lieberman asked the FDA panel about ongoing obligations to update the certifications (e.g. when a recipe changes). FDA stated that certifications only need to be provided to FDA upon the request of the agency, and there is not an ongoing certification requirement. The agency stated that covered entities will have several weeks to provide this information to FDA. The agency also indicated that there is not an ongoing recordkeeping requirement under the rule—information substantiating nutrient information need only be provided several weeks after a request is made by the agency. This would indicate that the agency does not intend to review information substantiating nutrient values during the course of an inspection.

B. Cold Menu Items

FDA stated to Erik Lieberman that cold menu items normally consumed hot are excluded from the scope of menu labeling regardless of whether or not they appear with a sign that could be considered a menu or menu board. This exclusion is considerably broader than the exclusion expressed in the final menu labeling guidance which stated that cold prepared foods that are (1) 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 would not be considered restaurant food and thus not covered under menu labeling.

C. Calories from Fat

One insightful attendee pointed out that while menu labeling requires calories from fat to be provided as part of the additional written nutritional information that must be made available to consumers upon request, the new nutrition labeling final rule prohibits calories from fat from appearing on the Nutrition Facts label. FDA states in the final menu labeling guidance that the use of a Nutrition Facts label that meets the requirements of 21 CFR 101.9 would meet the menu labeling requirements for providing additional written nutrition information. As 21 CFR 101.9 no longer allows calories from fat to appear on the label, FDA was asked how they intend to reconcile this discrepancy. The agency stated that it would require them to issue another rulemaking to reconcile the discrepancy which will take time. They did not commit to doing so, but indicated they would look at that issue. In the meantime, they advised covered establishments to provide calories from fat information for menu items covered under the rule. If FDA does not take action to change the rule, we believe it would be appropriate to request enforcement discretion on this matter.

D. Enforcement

FDA intends to partner with the states to conduct enforcement.

E. Websites

FDA stated that a website must be intended for use by consumers to order items for it to be considered a menu under the regulation (and thus have to have calorie information posted among other things). A mere list of items with prices on a web page without a mechanism for ordering the items would not be considered a menu even if the footer on the page had a phone number for a store or a link to "find your nearest store." This would not be considered a mechanism for ordering by the agency

On the other hand, if a page had items whereby consumers could add them to an electronic shopping cart and pay for them online, or a page contained the names of items and/or pictures of items and prices along with a phone number preceded by the words "Order now," FDA would consider the page to be a menu.

F. Rotisserie Chickens and Racks of Ribs

Hot rotisserie chickens and racks of ribs are generally covered under the menu labeling rule. FDA views them as multi-serve restaurant-type foods.

G. Birthday Cakes

Retailers generally provide consumers with a form for ordering birthday cakes whereby they select the type of cake, type of frosting and other toppings from a list. FDA views this a menu thus calorie information is required.

H. Separately Owned and Operated Sushi Bars within Stores

Many retailers have arrangements where a separate company operates a sushi station within a retail store. The sushi station may or may not operate under a separate banner/signage and the sushi they package and label may or may not bear branding distinct from that of the retailer. FDA stated that if the sushi station is owned and operated by an entity that differs from the owner of the retail store, the owner of the sushi station will be held responsible for menu labeling compliance (if they are covered) regardless of whether there is a separate banner for the sushi station or separate branding on labels. If the owner of the sushi station has less than 20 outlets or the sushi station does not otherwise meet the requirements for being a covered establishment, the sushi station will be exempt from menu labeling requirements.

I. Fresh-Pressed Juices

FDA stated that fresh juices produced in-store would not be covered if they are sold from endcaps or shelves with other single bottles of juice where they are not intended to be sold to accompany a meal, or as a grab and go item. The agency said they would be covered if they are intended to accompany a meal item or sold as a grab and go item.

Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or need additional information.