

January 5, 2018

Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2011-F-0172; Menu Labeling: Supplemental Guidance for Industry; Draft Guidance

We respectfully submit the following comments on the Food and Drug Administration's (FDA) proposed Menu Labeling: Supplemental Guidance for Industry, which pertains to the agency's requirements for chain restaurants and similar retail food establishments to post nutrition information. Menu labeling is an important tool that allows consumers eating out to make informed choices for a growing—and often problematic—part of their diets, and we support the Guidance overall.

Given that the delay in the compliance deadline occurred with a single day's notice, many covered food establishments had already complied with the regulations in anticipation of the previous implementation date of May 5, 2017 (81 FR 96364). Indeed, the vast majority of the top restaurant, supermarket, and convenience store chains already are labeling calories, showing that posting calories as currently required is feasible. A recent scan of the top 50 restaurant chains (by revenue according to Nation's Restaurant News) found that all 50 had calorie information either online (*e.g.*, posted per menu item, provided in PDF or other format, or via an online nutrition calculator) or in the restaurant.¹ We encourage the FDA to finalize the guidance as soon as possible to facilitate implementation by May 7, 2018 (82 FR 20825).

The issues raised in the Draft Guidance largely reinforce clarifications that have already been made through the final regulations, previous guidance, and technical assistance. We do, however, suggest a few modifications to the Guidance. Specifically, our comments address the following topics:

The Final Guidance Should Clarify Salad Bar Signage be Visible to Consumers Selecting Any Item

We encourage the Guidance to further clarify in Section 3 that if the establishment chooses to use a single sign or placard by the salad bar, the sign must be visible from the whole salad bar (*e.g.*, both sides) and that it must be where a consumer can easily view the calories while selecting that item. The FDA should also encourage labeling calories for salad bars on a sign adjacent to the item (*e.g.*, food tags) or attached to the sneeze guard as the preferred method.

The Final Guidance Should Further Clarify the Definition of “Covered Establishments”

We request that the FDA amend its answer to Section 8.2 that determining whether the convenience store is a covered establishment depends on additional factors—namely, that franchisees should not be able to evade compliance with a merely superficial change in operating title. For instance, if a gas station chain with more than 20 locations doing business under the same name offers for sale substantially the same menu items that are restaurant-type food at all locations, then that gas station chain should be covered establishments. If the same gas station chain operates Bob's Corner Market (under a different name) and Bob's Corner Market offers for sale substantially the same menu items as other chain locations, Bob's Corner Market should be considered a covered establishment *even if Bob's Corner Market has fewer than 20 locations under that name.*

¹ Center for Science in the Public Interest. Supplemental Comment on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments; Docket No. FDA-2011-F-0172. August 2, 2017.

That is because there is no difference between the restaurant-type food offered for sale at a chain gas station or a chain-owned, -operated, or -franchised venue operated as Bob's Corner Market, and therefore the FDA should consider Bob's Corner Market a variation of the name of the business. Should FDA fail to clarify this aspect of the rule, it leaves open the possibility that businesses will rename subsidiaries merely to evade compliance.

When Making Combinations, the Final Guidance Should Clarify that Consumers Must Be Able to View All Standard Menu Items at the Same Time

In Section 5.3, the final Guidance should clarify that if establishments do not declare the total calories for standard menu items that can be combined for a special price, consumers must be able to view the calories for the standard menu items while choosing the combination (for example, by listing all of the standard menu items on the same menu or menu board (as shown in Figures 14 and 15)). Consumers may have more difficulty using the calorie information if standard menu items that can be combined are listed on separate menu pages or menu boards.

The Draft Guidance Is Consistent with Rules Requiring Pizza Chains to Label Calories Inside the Restaurant

The Guidance is consistent with the law and regulations (21 CFR 101.11) that calorie labeling is required inside pizza chains and other establishments that offer delivery service. Section 5.4 makes it clear that establishments that label calories online also must do so in-store. As mentioned in Section 5.2, establishments are not required to have a menu board. Indeed, there are a variety of ways establishments can provide calorie labeling in lieu of a menu board (*e.g.*, hand-held paper or laminated menus on the counter, or electronic devices such as in-store tablets or kiosks). However, if restaurants have a menu or menu board, calories must be posted on the menu or menu board.

Many pizza chains are already labeling different sizes, varieties, and toppings on menus and menu boards, demonstrating that labeling can be accomplished in a reasonable amount of space and at a reasonable cost. As mentioned in Section 5.6, the FDA has already provided establishments with the flexibility to declare calories for the pizza per slice, provided that the number of slices per pie is included on the menu or menu board in a manner that clearly associates the calories per slice and the number of slices for each size of pie offered by the establishment (*e.g.*, pizza pie 200 cal/slice, 8 slices) (21 CFR 101.11(b)(2)(i)(A)). It is helpful that the Guidance provides seven additional examples for the pizza industry (Figures 16 through 22).

The Draft Guidance Clearly Distinguishes Between Menus and Advertisements

In Section 4.1, the FDA again clarifies the difference between menus or menu boards and advertisements. The FDA appropriately considers whether a consumer can use the document or other form of communication to order in determining whether it should be considered a menu.

The Final Guidance Should Reaffirm that the Type Size, Color, and Contrast of Calories Must be the Same or Similar to Standard Menu Items

We encourage the FDA to add to Section 5 or 5.1 that the calorie declarations must be in a type size that is no smaller than that used for the name or price of the standard menu item (whichever is smaller), the same or similar color that is at least as conspicuous as the standard menu item, and the same or similar contrasting background as the standard menu item (21 CFR 101.11(b)(2)(i)(A)(1)). The succinct statement and statement regarding the availability of the additional written nutrition information also has similar conspicuity requirements. (21 CFR 101.11(b)(2)(i)(C)(I)). These are all essential to ensure that calories are clear, legible, and provide the intended context for decisions by consumers.

The Draft Guidance Helpfully Reaffirms that Serving Sizes Must Be Easy to Understand and Items Be Listed as Typically Prepared and Offered For Sale

Section 5.7 is consistent with the law and regulations. For multiple-serving standard menu items that are not offered for sale in discrete units (e.g., “Family-Style Salad”), the calories declared must be for the entire standard menu item. In addition, an establishment can include the number of servings and the calories per serving as usually prepared and offered for sale (e.g., Family-Style Lasagna: 625 Cal/serving, 8 servings; 5,000 Cal). (21 CFR 101.11(b)(2)(i)(A)).

The Draft Guidance Appropriately Addresses Enforcement Issues and Describes the Compliance Support that FDA Will Provide

Section 6.1 is consistent with the FDA’s previous position that the first year of menu labeling implementation will focus on education and technical assistance. Section 6.2 provides clear examples of minor violations that would not result in fines or criminal penalties, such as missing a calorie declaration for a buffet item, minimal variations in ingredients or inadvertent error such as adding extra slices of pepperoni on a pizza, and not rounding the calories correctly. For such concerns, the FDA indicates that it will work with covered establishments on an appropriate time-frame to make corrections.

The Draft Guidance Reaffirms Flexibility to Determine Nutrition Information and Recordkeeping

Section 7.1 reaffirms that the reasonable basis standard for determining calorie counts provides flexibility for natural variation in ingredients. There are many ways that an establishment may determine the nutrition information of its standard menu items in addition to laboratory testing (21 CFR 101.11(c)(1)) (Section 7.2). Establishments can also keep the records of their nutrient information on site or at the corporate headquarters and will have 4-6 weeks to provide the information following a request (Section 7.3). Recalculation of nutrient information is required only if a standard menu item changes (Section 7.4).

The Draft Guidance Appropriately Requires Labeling of Beer if Listed on Menus or Menu Boards

Section 10.1 reaffirms that beer on tap is considered a food on display. Moreover, alcoholic beverages that are foods on display and are not self-serve are also exempt from labeling (21 CFR 101.11(b)(1)(ii)(B)). However, if a menu or menu board lists beers on tap as standard menu items, then the calories must be provided on that menu or menu board.

Conclusion

Again, we generally support the Guidance and encourage the FDA to make the clarifications suggested above. We urge the FDA to finalize the Guidance quickly to facilitate implementation for food service establishments by May 7, 2018.

Sincerely,

American Cancer Society Cancer Action Network
American Diabetes Association
American Heart Association
American Public Health Association
Center for Science in the Public Interest
Consortium to Lower Obesity in Chicago Children (CLOCC)
Consumers Union
Eat Smart Move More SC
Healthy Savannah
Interfaith Center on Corporate Responsibility
LiveWell Colorado
National Association of County and City Health Officials (NACCHO)

National Farm to School Network
National WIC Association
Nutrition Policy Institute
Public Health Institute
Real Food for Kids
UConn Rudd Center for Food Policy & Obesity