



August 1, 2017

Anna K. Abram  
Deputy Commissioner for Policy, Planning, Legislation, and Analysis  
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  
Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments**

Dear Ms. Abram:

The American Cancer Society Cancer Action Network (ACS CAN) strongly supports immediate implementation of the menu labeling final rule that was published in the *Federal Register* on December 1, 2014. We oppose any delay or weakening of the existing menu labeling regulations and request that the U.S. Food and Drug Administration (FDA) revoke the one-year extension of the compliance date that was announced in the May 4, 2017 final rule. Extending the deadline until May 7, 2018 is contrary to the public interest and unnecessarily delays menu labeling implementation more than seven years after passage of the law.

ACS CAN is the nonprofit, nonpartisan advocacy affiliate organization of the American Cancer Society dedicated to eliminating cancer as a major health problem. ACS CAN supports legislative, regulatory, and policy efforts that will make cancer a top national priority and is committed to evidence-based public policy strategies that help prevent the one in five cancer cases caused by poor diet, physical inactivity, and excess weight.<sup>1</sup> Menu labeling is an important tool that gives consumers information that helps them make their own informed choices and encourages companies to offer and promote healthier options. ACS CAN supported the menu labeling requirements in the Affordable Care Act and has provided input to the FDA at each step of the implementation process, supporting timely implementation of the menu labeling requirements that allow consumers to easily make informed, healthy choices at chain restaurants and other similar retailers. Our prior comments to FDA on its [proposed rule on menu labeling](#) and [draft guidance for industry on implementing the menu labeling requirements](#) can be viewed on ACS CAN's website through these hyperlinks.

The remainder of this comment letter responds to the issues raised in the May 4, 2017 interim final rule and other policy proposals to weaken or delay implementation of menu labeling.

**Further delay prevents consumers from accessing useful information and will not save companies money.**

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<sup>1</sup> American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta: American Cancer Society, 2017.

Surveys have shown that consumers want menu labeling information and often use the information when it is available. A national poll found that more than 75 percent of Americans support calorie labeling at chain restaurants, supermarkets, and convenience stores.<sup>2</sup> Another nationally representative survey of 1,000 adults conducted in March 2017 found that 58 percent of adults say they use nutrition information at least sometimes when they eat away from home, including 62 percent of women and 73 percent of people with a college degree.<sup>3</sup> These findings are consistent with a Centers for Disease Control and Prevention (CDC) study in 17 states that found that among survey respondents who said they notice menu labeling in restaurants, 57 percent said they use the information in deciding what to order, at least some of the time.<sup>4</sup>

In addition, covered establishments have already invested the resources needed to comply with the rule. The issues raised in the May 4, 2017 interim final rule have already been clarified through the final regulations, final guidance, and technical assistance. Covered establishments have had ample time to comply and have been given additional time by both the FDA and Congress.

All covered establishments were required to be ready to comply with the rule by May 5, 2017. Therefore, all chain restaurants, supermarkets, convenience stores, and other covered food service establishments would already have had to analyze their prepared foods and menu items, redesign and update their menus, and train their staff, so no transition-related savings should be realized by further delaying the compliance date. As FDA acknowledged in the Interim Final Regulatory Impact Analysis, “[g]iven the imminence of the current compliance date (May 5, 2017), it is likely that many covered establishments have already incurred some or all of the initial costs needed to be in compliance.”<sup>5</sup> Delaying the compliance date is unlikely to result in any cost savings for businesses and if the requirements of the regulation are changed, chains that have begun implementing the existing requirements would likely incur additional costs.

The benefit to consumers and potential savings to the health care system of requiring immediate compliance, by contrast, are considerable. According to the FDA’s regulatory impact analysis issued with the final rule, the estimated benefit of menu labeling is \$9.2 billion over 20 years. The total cost of implementation is estimated at \$1.2 billion, providing a total net savings of \$8 billion over 20 years.<sup>6</sup> A Harvard study similarly found restaurant menu labeling could prevent up to 41,000 cases of childhood obesity and could save over \$4.6 billion in healthcare costs over ten years.<sup>7</sup>

**The FDA should continue to define “covered establishments” to which the menu labeling regulations apply from the consumer’s perspective and include all chain retail food establishments selling ready-to-eat foods, including restaurants, supermarkets, convenience stores, and movie theaters.**

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<sup>2</sup> Caravan ORC International. *Restaurant Calorie Content: ORC Study 721210*, May 2012. Conducted for the Center for Science in the Public Interest. Accessed at: <http://cspinet.org/new/pdf/restaurant-calorie-content.pdf>.

<sup>3</sup> International Food Information Council Foundation. 2017 Food & Health Survey. Available at <http://www.foodinsight.org/2017-food-and-health-survey>. Accessed June 19, 2017.

<sup>4</sup> Lee-Kwan, SH, Pan L, Maynard, L, et al. Restaurant Menu Labeling Use Among Adults – 17 States, 2012. *MMWR* 2014;63:581-584.

<sup>5</sup> FDA. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date and Request for Comments. Interim Final Regulatory Impact Analysis. April 2017; p. 7.

<sup>6</sup> FDA. Final Regulatory Impact Analysis: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishment, November 2014. Available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM423985.pdf>.

<sup>7</sup> Gortmaker, Steven L, et al. Three Interventions that Reduce Childhood Obesity Are Projected to Save More than They Cost to Implement. *Health Affairs* 2015; 34(11): 1932-1939.

For menu labeling to be effective in helping consumers make more informed choices, the information needs to be available in the venues where people are purchasing ready-to-eat foods. Whether the food is eaten at a table-service restaurant, while watching a movie, taken home from a supermarket hot bar, or carried out from a convenience store, the calories count and contribute to the diet similarly. It would be inconsistent to require calorie labeling at chain restaurants, but not for similarly prepared foods at other retailers such as supermarkets, convenience stores, movie theaters, and stadiums, which sell the same types of foods as restaurants and increasingly compete with them.<sup>8,9</sup> Supermarkets have expanded the variety of ready-to-eat entrees and meals in their prepared food departments and sales of prepared foods have grown 4 to 4.5 percent each year, compared with 2 to 2.5 percent growth each year for other grocery products.<sup>10</sup>

When drafting the menu labeling statute, key members of Congress, consumer and public health advocates, and the restaurant industry all strongly agreed that menu labeling should broadly apply to all retail food establishments that sell food for immediate consumption.<sup>11,12</sup> While the Nutrition Labeling and Education Act of 1990 (NLEA) required nutrition labeling for most packaged food products, the law exempted prepared foods from restaurants and similar establishments that offer for sale food for immediate consumption or food consumed either on or off the premises where the food is purchased.<sup>13</sup> Menu labeling must fill in this gap.

The FDA also already considered and addressed concerns about covered establishments in the December 2014 final regulations, including different business practices and operations. The law clearly requires chain establishments operating under the same name to provide calorie labeling, regardless of the type of ownership, such as a co-op or franchise.<sup>14</sup>

**The FDA should continue to require that calorie information be located on or adjacent to the name of the food on a menu, menu board, or food label for self-service foods or foods on display and not in a separate part of the establishment.**

Under the December 2014 final rule, calorie information must be posted clearly and conspicuously for self-service foods and foods on display so that customers can use the calorie information at the point of selection. We oppose the FDA modifying the rule to allow for the posting of calories on a menu board or sign not in close proximity to the displayed item, such as posting the calories on a sign near the cash register. Posting calories in a location that is not visible to people as they are making food selections would significantly limit access to and the usefulness of calorie information for consumers. Information on a single menu board by the cash register would do people little good as they try to compare among options and make informed choices at the bakery department, salad bar, hot bar, or deli. In addition,

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<sup>8</sup> Meyer Z. Why Grocerants Are the New Trend, Taking Bite out of Restaurants. *USA Today*, April 5, 2017. Accessed at: [www.usatoday.com/story/money/business/2017/04/05/grocerants-take-bite-out-restaurants/99723098/](http://www.usatoday.com/story/money/business/2017/04/05/grocerants-take-bite-out-restaurants/99723098/).

<sup>9</sup> Blank C. C-Stores Eating Your Lunch: Improved Foodservice Offerings Helping Convenience Stores Steal Business from Quick Service. *QSR Magazine*, Jan 2014. Accessed at: <https://www.qsrmagazine.com/exclusives/c-stores-eating-your-lunch>.

<sup>10</sup> United States Department of Agriculture. Retail Trends, October 12, 2016. Accessed at: <https://www.ers.usda.gov/topics/food-markets-prices/retailing-wholesaling/retail-trends/>

<sup>11</sup> Harkin, DeLauro Call on Administration to Issue Strong Menu Labeling Rule. August 15, 2014. Available at <https://www.help.senate.gov/ranking/newsroom/press/harkin-de-lauro-call-on-administration-to-issue-strong-menu-labeling-rule>. Accessed August 1, 2017.

<sup>12</sup> Harkin Statement on Menu Labeling Rule Announced by White House. November 25, 2014. Available at <https://www.help.senate.gov/ranking/newsroom/press/harkin-statement-on-menu-labeling-rule-announced-by-white-house>. Accessed August 1, 2017.

<sup>13</sup> Federal Food, Drug, and Cosmetic Act of 1938. Public Law No. 75-717, 52 Stat. 1040, Sec. 403(q)(5)(A).

<sup>14</sup> FDA. Menu Labeling Final Rule: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments. December 1, 2014. Accessed at: <https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf>.

once customers have made their selections, it would be difficult to change their mind based on the calorie information and put salad bar items or other prepared food options back.

The FDA has already provided considerable flexibility for labeling foods on display at supermarkets and restaurants, including allowing calories to be placed on a sign adjacent to and clearly associated with the food, attached to the sneeze guard, or on a single sign listing the calories for all items as long as it can be seen while selecting the item.

**Similarly, the FDA should continue to define menus and menu boards from the perspective of the consumer. To that end, calorie labeling should be required on all menus that customers use to make food selection decisions including in-store, drive through, printed takeout and delivery, and online menus.**

After considering comments from industry and consumer groups regarding the definition of menus and menu boards that are required to have calorie information, the FDA determined in the December 2014 final rule that the “primary writing . . . should be interpreted from a consumer's vantage point.”<sup>15</sup> While the regulations do not require a specific type of menu or menu board, calories should be posted on the menu in the same medium that is used to present food items to customers to make their selections. For instance, if an electronic menu displayed at a kiosk is the primary medium from which customers make order selections in the establishment, then the menu through the kiosk should include calories for each standard menu item. Similarly, if there are in-store menu boards that customers use to order, the menu boards should include calorie information for all standard menu items listed.

We do not support exempting food service establishments from providing calorie information inside the restaurant or store if 49 percent or fewer orders are placed from in-store menus or menu boards. This would deny up to half of an establishment's customers access to calorie information, since online menus are unlikely to help a customer ordering in the store.

Congress clearly did not intend for restaurants to provide calorie postings only on a single medium in each restaurant or store, as asserted by some food service establishments. For example, Congress required calorie postings directly on drive-through menus, though most restaurants also have menus inside their restaurants. In addition, the law requires the information to again be posted for foods on display or in a self-serve arrangement, even if those items are also listed on the menu or menu board.

**Serving sizes must be standardized for the nutrition information to be meaningful. Therefore, it is essential for calories to be listed for each item as typically prepared and offered for sale.**

Posting the total calories per menu item enables consumers to more easily compare different types of food items, such as nachos, chicken wings, salads, or pizza, and leaves it up to the individual—not the restaurant—to determine how many people will share the item. It would be deceptive to label breakfast pastries, entrees, desserts, and most menu items as multiple servings, since those items are most often consumed by one person. Arbitrary serving sizes would make it difficult for customers to determine total calories and to compare calories. For example, if serving sizes are left up to the discretion of the establishment, a restaurant could list calories for one-half of one appetizer, one-third of another appetizer, and one-tenth of another. FDA has already provided flexibility to allow calories to be labeled per slice of pizza, if the number of slices is also indicated.

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<sup>15</sup> Ibid.

**The FDA has already addressed additional concerns raised in the May 2017 interim final rule, including how to distinguish menus from advertisements and how to address the natural calorie variations in foods. No further changes to the rule are needed.**

The FDA clarified in its final guidance that it considers whether a customer can use the document or other form of communication to order (e.g., does it include the standard menu item and price?) in determining whether it should be considered a menu and must have calorie information. However, if customers use a menu or menu board to order at an establishment, the displays, posters, coupons, and other marketing materials on display at the establishment would not count as menus.

Similarly, the FDA has already provided food retail establishments with considerable flexibility for variations and accuracy of nutrient declarations. The final regulations explained that a covered establishment needs to have a reasonable basis for its nutrient declarations, which can be determined through a wide range of approaches from menu analysis software to cookbooks to any other reasonable means. The guidance further states, “Where variations in portion size may occur, such variations can be taken into consideration when determining the calorie content for the menu item, for example, by basing the nutrient declarations on the average size of a piece of fish or beef.”<sup>16</sup>

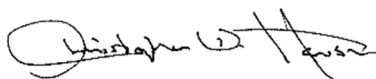
## **Conclusion**

Seven years after the passage of the national menu labeling law, the FDA has already addressed the issues raised in the interim final rule and provided food retailers with sufficient time, guidance and flexibility to implement the requirements. As FDA noted, “[b]ecause of the complicated market structure in the food industry... *flexibility was built into the menu labeling final rule* for all establishments” (emphasis added).<sup>17</sup>

Therefore, we strongly urge the FDA to put the public’s health first by revoking the menu labeling compliance date extension and proceeding with immediate implementation of the menu labeling regulations as finalized.

If you have questions about our comments or we can provide any additional information, please contact Melissa Maitin-Shepard, Senior Analyst, Policy Analysis & Legislative Support, at 202-585-3205 or [melissa.maitin-shepard@cancer.org](mailto:melissa.maitin-shepard@cancer.org).

Sincerely,



Christopher W. Hansen  
President  
American Cancer Society Cancer Action Network

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<sup>16</sup> FDA. 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. Available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm461934.htm>. p. 43.

<sup>17</sup> FDA. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date and Request for Comments. Interim Final Regulatory Impact Analysis. April 2017; p. 10-11.