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August 1, 2017

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

Re: Docket No. FDA-2011-F-0172

Dear Sir or Madam:

The American Heart Association (AHA) strongly objects to the Food and Drug Administration's (FDA) decision to delay the compliance date for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (menu labeling) until May 7, 2018. We urge the Agency to revoke the extension and allow menu labeling to take effect immediately.

A one-year delay is not needed. Retail food establishments have been given ample time to comply with the menu labeling requirements. It has been seven years since the law mandating menu labeling was passed, and two-and-a-half years since the release of the final rule. Stakeholders had multiple opportunities to provide input on the development of the rule and related guidance documents, and to seek clarification from the FDA on specific implementation issues. In addition, retail food establishments have already been given extra time to comply; with the compliance deadline moved from December 2015 to December 2016 and then May 2017, before the Agency's latest action.

Delaying menu labeling is also contrary to the public interest. Requiring food establishments to post calorie counts and make additional nutrition information available allows consumers to make informed, healthier choices. This is extremely important given the impact that diet has on cardiovascular and overall health. Among modifiable risk factors, poor dietary habits are a leading cause of death and disability.¹ Poor nutrition is associated with increased risk of obesity, heart disease, stroke, diabetes, and cancer; and has been estimated to contribute to over \$33 billion in medical

costs and \$9 billion in lost productivity.² By delaying menu labeling, the Agency is limiting consumers' ability to make informed decisions at retail food establishments, even though foods prepared outside the home account for one-third of all calories Americans consume.³

And, as we explain below, the one-year delay is unlikely to achieve the Agency's goal to reduce regulatory burden and costs. For these reasons, we disagree with the FDA's decision and urge you to reverse course and implement menu labeling immediately.

Reducing Regulatory Burden and Costs

According to the FDA's announcement extending the compliance deadline, the Agency took this action to "consider how we might further reduce the regulatory burden or increase flexibility."⁴ As noted above, we do not believe that this is a realistic goal.

Covered retail food establishments should have been prepared to comply with the menu labeling requirements *before* the FDA announced the compliance date extension. The FDA did not indicate that it would delay menu labeling until four days before the May 5th deadline; and the official notice of delay was not published until the day before retail food establishments were scheduled to comply. Given the late date of the FDA's announcement, retail food establishments would have already had to analyze their prepared foods and menu items, update their menus to reflect calorie counts, and conduct any necessary staff training. Accordingly, any costs associated with implementing menu labeling should have already been incurred by covered establishments. The FDA itself acknowledged this in the Interim Final Regulatory Impact Analysis when it stated, "[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."⁵ As a result, delaying the compliance date is unlikely to result in any significant cost savings for retail food establishments.

Unfortunately, the delay could have a significant impact on another group of stakeholders: consumers. Providing calorie counts and other nutrition information can help consumers make healthier choices and encourage retail food establishments to improve their offerings. In the Regulatory Impact Analysis issued with the menu labeling final rule, the FDA quantified the estimated benefit to consumers at \$9.2 billion over 20 years. While another study estimated that menu labeling could prevent up to 41,000 cases of childhood obesity and save over \$4.6 billion in healthcare costs over 10 years.⁶

¹ U.S. Burden of Disease Collaborators. The State of US Health, 1990–2010: Burden of Diseases, Injuries, and Risk Factors. *JAMA*. 2013;310:591–608. doi: 10.1001/jama.2013.13805

² Centers for Disease Control and Prevention. 2008. Preventing Chronic Diseases: Investing Wisely in Health Preventing Obesity and Chronic Diseases through Good Nutrition and Physical Activity.

³ Lind BH and Guthrie J. Nutritional Quality of Food Prepared at Home and Away from Home, 1977-2008. U.S. Department of Agriculture Economic Research. December 2012.

⁴ 82 FR 20825.

⁵ Food and Drug Administration. 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; page 7.

⁶ Gortmaker, Steven L, et al. "Three Interventions that Reduce Childhood Obesity Are Projected to Save More than They Cost to Implement." *Health Affairs* 34.11 (2015): 1932-1939.

Yet, when the FDA announced the compliance extension, the Agency downplayed the benefits that menu labeling will provide consumers. Instead, the interim final rule framed the cost savings to covered establishments as the “principal benefit.”⁷ This concerns us greatly. The true benefit of menu labeling is that it will allow consumers to make informed, healthier choices; the Agency’s primary focus should not be on creating “benefits” or cost savings for retail food establishments. This is especially concerning when you consider that the cost savings to covered establishments are estimated between \$2 to \$8 million over 20 years depending on the discount rate applied,⁸ while the “foregone benefits” to consumers range between \$5 and \$19 million.⁹ We do not understand how the FDA can justify a compliance delay when the “foregone benefits” to consumers are dramatically higher than the cost savings to covered establishments.

We also question how the Agency determined the amount of cost savings that retail food establishments would realize under a one-year delay. According to the FDA, the Agency does “not have data to estimate how much covered establishments have already spent to become compliant or the proportion of establishments in compliance.”¹⁰ The FDA chose to “assume that 50 percent of covered establishments are already in compliance and therefore 50 percent of initial, upfront costs have already been incurred.”¹¹ Without any evidence to base these calculations on, it is impossible to have confidence in the FDA’s conclusion that retail establishments will save between \$2 and \$8 million. If the number of retail establishments prepared to comply with menu labeling is in fact higher – which is likely since the delay was only announced a few days before the scheduled compliance deadline – the actual cost savings to food establishments will be much lower.

A number of retail food establishments have expressed concern that the delay will not save them money and ignores the years of work that have already gone into implementation.¹² In fact, the delay and reopening of the rule could result in retail food establishments incurring *additional costs* if the menu labeling requirements are altered.

Delaying the rule also increases the likelihood that individual states or localities will develop their own menu labeling requirements in the absence of a federal program. New York City, for example, recently announced that it would begin enforcing the city’s calorie labeling requirements on May 22, 2017.¹³ It is our understanding that retail food establishments would prefer to implement uniform federal requirements rather than a patchwork of different state and local laws.

⁷ 82 FR at 20828.

⁸ Annualized cost savings: \$2 - \$6 million with a 3% discount rate, or \$3 - \$8 million with a 7% discount rate over 20 years.

⁹ Annualized foregone benefits: \$5 - \$15 million with a 3% discount rate, or \$6 - \$19 million with a 7% discount rate over 20 years.

¹⁰ FDA. Interim Final Regulatory Impact Analysis. Ibid. Page 7.

¹¹ Ibid.

¹² Bottemiller Evich H. Trump’s Delay on Calorie-Posting Rule Jolts Restaurants. Politico. May 27, 2017. See <http://www.politico.com/story/2017/05/27/trump-restaurant-calorie-posting-rule-238873>.

¹³ See <http://www1.nyc.gov/assets/doh/downloads/pdf/permit/cal-label-faq.pdf>.

In addition, reopening the rule to explore changes to “increase flexibility” appears unnecessary. The final rule and guidance document contain a number of provisions intended to give retail food establishments flexibility in how they implement menu labeling, such as providing several options for labeling self-service foods or foods on display, or allowing pizza chains to post calorie counts by the pie or by the slice. As the FDA itself has stated, “[b]ecause of the complicated market structure in the food industry... flexibility was built into the menu labeling final rule for all establishments.”¹⁴

Finally, the number of retail food establishments that already provide menu labeling, including many restaurants, grocery stores, convenience stores, and entertainment venues, demonstrate that labeling is feasible in a reasonable space and a reasonable cost.

Definition of Covered Establishments

While not specifically addressed in the interim final rule, we are aware that some retail food establishments have questioned the definition of a “covered establishment,” and have requested that the definition be modified to exclude certain types of establishments. AHA does not believe a change to the definition is necessary.

We believe the FDA correctly interpreted the statute when establishing the definition for covered retail establishments. The statute is very clear: menu labeling applies to “restaurants and similar retail food establishments.”¹⁵ If Congress had intended that the requirement only apply to “restaurants,” it would not have included “similar retail food establishments” in the law. Instead, Congress deliberately chose broad language. It is also important to note that when Members of Congress later requested that the FDA delay implementation from December 1, 2015 to December 1, 2016, the purpose of the delay was to give grocery and convenience stores more time to comply with the requirements; not to exempt them completely from the final rule.

All retail food establishments that serve prepared, restaurant-type foods should be subject to menu labeling. It would be inconsistent to require calorie labeling at chain restaurants, but not for similar prepared foods at grocery and convenience stores and other retail food establishments. For example, it would not make sense to require a sandwich shop to provide calorie labeling, but to exempt premade or made to order sandwiches at a supermarket or convenience store. Similarly, it would be inappropriate to require a stand-alone bakery to comply, while the bakery in a grocery store is exempt. These are all part of the away-from-home eating experience where consumers need calorie information for what they are purchasing.

We also note that grocery and convenience stores are similar to and compete with more traditional restaurants. Consider the convenience stores located inside Sheetz gas stations. The stores offer a large array of prepared “Grab-n-go” foods such as hot breakfast sandwiches, fresh fruit, cheese, yogurt, and bakery items, as well as made to go foods, including hot dogs, burgers, sandwiches, wraps, pizza, chicken and fish platters, and sides.¹⁶ Some of the Sheetz locations allow customers to order online.

¹⁴ FDA. Interim Final Regulatory Impact Analysis. Ibid. Pages 10-11.

¹⁵ Sec. 4205. Patient Protection and Affordable Care Act.

¹⁶ See <https://www.sheetz.com/food>.

Sheetz even compares itself to a restaurant stating:

It's a popular belief that you can't get great-tasting food at a convenience store. At Sheetz, we like to turn such conventions on their heads. ***We have developed a food program that rivals any quick-serve restaurant you've ever visited.*** Our menu is made to order, or M•T•O® as we call it for short. We use only the highest quality ingredients and prepare your food especially for you, while you wait. Get exactly what you want, when you want it, 24/7. That's pretty convenient.¹⁷ (emphasis added)

Other convenience stores offer similar foods. For example, the Wawa brand of convenience stores "offer a large selection of fresh foods, available Built-to-Order® just the way you like or Ready-to-Go when you're in a hurry" such as breakfast sandwiches, soups, sides, sandwiches and hoagies, salads, wraps, and snacks.¹⁸ Or, 7-Eleven convenience stores that serve hot dogs, wings, taquitos, pizza, mini beef tacos, chicken tenders, mozzarella sticks, nachos, and more.¹⁹ These foods clearly qualify as restaurant-type foods.

Sheetz Convenience Store, Made to Order Counter & Kitchen, Chantilly, VA, July 2017



¹⁷ See <https://www.sheetz.com/food>.

¹⁸ See <https://www.wawa.com/fresh-food>.

¹⁹ See <https://www.7-eleven.com/eat-drink#snacks>.

Sheetz, Prepared Foods Display



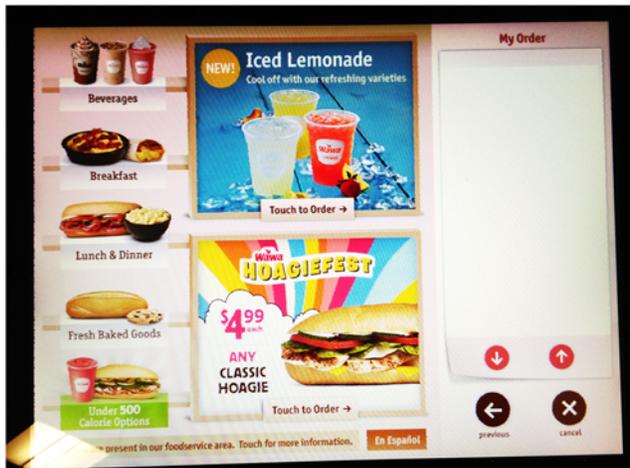
Sheetz, Electronic Ordering Kiosk



Wawa Convenience Store, Built-to-Order Counter & Kitchen, Chantilly, VA, July 2017



Wawa, Electronic Ordering Kiosk



**7-Eleven, Washington, DC, May 2017
Examples of Menu Labeling**



Grocery stores also offer prepared foods that are similar to those found in restaurants. The foods include items such as sandwiches, salads, soups, fried and rotisserie chicken, ribs, and meals consisting of an entrée and side(s). Depending on the store, these may be self-service foods or require a customer to order from a menu board. In addition to offering these foods, many grocery stores provide special seating areas for customers to immediately consume them. For example, Safeway and Vons offer all of these foods, as well as made to order breakfast sandwiches and hot and cold specialty sandwiches at their “Signature Café”.^{20,21} While Whole Foods stores may offer a variety of eating options such as “a deli, restaurant, salad bar, sandwich station, burger stand, pizza joint, BBQ shack, sushi venue, raw foods bar, taco bar, beer pub and wine bar.”²²

Safeway Signature Café, Falls Church, VA, July 2017



Safeway, Prepared Food



²⁰ See <http://www.safeway.com/ShopStores/Signature-Cafe.page>.

²¹ See <http://www.vons.com/ShopStores/Signature-Cafe.page>.

²² See <https://www.wholefoodsmarket.com/blog/where-quality-meets-convenience>.

It is important to note that grocery and convenience stores have become an increasingly popular place for consumers to purchase ready-to-eat foods. As grocery stores have expanded the variety of ready-to-eat entrees and meals in their prepared foods departments, sales of prepared foods have increased at a rate of 4 to 4.5% each year, compared with 2 to 2.5% growth each year for other grocery products.²³

As discussed above, it would be inconsistent to exempt grocery and convenience stores or other establishments that serve restaurant-type foods from menu labeling. Consumers need nutrition information about ready-to-eat foods whether the food is eaten while seated at a table-service restaurant, while watching a movie or a ballgame, taken home from a grocery store hot bar, or carried home from a convenience store. The calories count and contribute to their diet similarly, and consumers want information on foods from all of these venues. A national poll found that 80% of Americans support calorie labeling at chain grocery stores, the same level of support as for restaurant calorie labeling.²⁴

Calorie Disclosure Signage for Self-Service Foods

According to the Federal Register notice, the FDA continues to receive many questions about calorie disclosure signage for self-service foods, including buffets and grab-and-go foods. These questions are one of the reasons why the Agency chose to delay the compliance deadline.

We are surprised that retail food establishments continue to have questions about self-service foods. The Agency dedicated 12 pages in the final rule and an additional seven pages in the April 2016 guidance document to address how retailers should label self-service foods. In addition, covered establishments had multiple opportunities to seek additional clarification from the FDA during webinars and public workshops. We believe the FDA provided ample information to implement menu labeling for self-service foods.

We also believe that the FDA provided food establishments with an appropriate amount of flexibility by giving them several options to label self-service foods. According to the guidance document, calorie information for self-service foods or foods on display can be placed on a sign adjacent to and clearly associated with the food; on a sign attached to the sneeze guard; or on a single sign or placard listing the calorie declaration for several food items along with the names of the food items, so long as the sign or placard is located where a consumer can view it while selecting that item. These are reasonable options.

We are, however, concerned by reports that some covered establishments want the FDA to modify the rule to allow for the posting of calories on a menu board that is not located near the displayed item, such as posting the calories on a sign near the cash register. We strongly oppose this request. Posting calories in a location that is not visible to consumers as they make food selections would defeat the purpose of menu labeling. Consumers must be able to see the calorie

²³ U.S. Department of Agriculture. Retail Trends, October 12, 2016.

<https://www.ers.usda.gov/topics/food-markets-prices/retailing-wholesaling/retail-trends/>

²⁴ Caravan ORC International. Restaurant Calorie Content: ORC Study 721210, May 2012. Conducted for the Center for Science in the Public Interest. <https://cspinet.org/resource/poll-data-re-support-calorie-labeling-supermarkets-vending-machines-movie-theaters>

information when comparing products in order to make an informed choice. Thus, we urge the FDA to deny this request.

In addition, numerous food establishments have already complied with menu labeling and are successfully providing calorie counts for self-service foods using one of the three options provided by the FDA, as the examples below show. These establishments were able to understand and implement the requirements outlined in the final rule and guidance document. We believe other establishments should be able to do the same, and see no reason to delay implementation because of reported uncertainty around self-service foods.

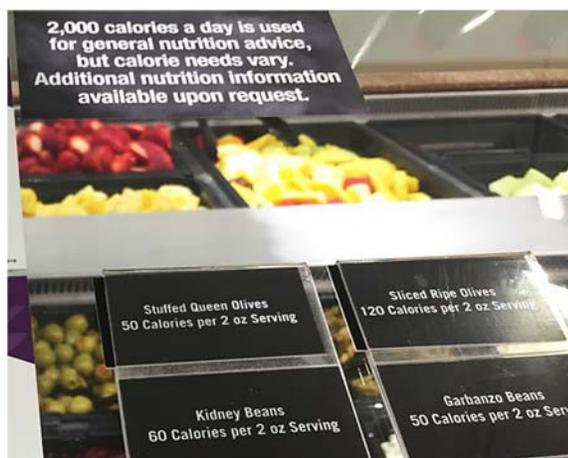
**Safeway, Falls Church, VA, July 2017
Self-Serve Buffet**



**Safeway, Falls Church, VA, July 2017
Bakery Case**



**Giant Food, Washington, DC, May 2017
Labeling on Salad Bar Sneeze Guard**



**Jewel-Osco, Chicago, IL, May 2017
Labeling on Signs at Hot Foods Buffet**



Methods for Providing Calorie Disclosure Information Other than the Menu

The FDA has also requested comments on methods for providing calorie disclosure information other than on the menu itself, and how different kinds of retailers might use different methods. By asking this question, it appears that the FDA is considering modifying the rule to exempt certain establishments from the requirement that they provide calorie counts on the menu or menu board. AHA would strongly oppose such a change.

While we support providing calorie information in multiple and innovative ways, all menus that customers use to make an order selection should be required to provide calorie labeling. This includes menus, menu boards, electronic menus (kiosks, tablets), drive-thru menus, takeout menus, and online menus. No menu that a customer may order from should be exempt.

We understand that some establishments have requested an exemption from the in-store menu or menu board requirement if 49% or fewer of their orders are placed in the store. We cannot overemphasize how much we oppose this request. This exemption would deny up to half of an establishment's customers access to calorie information. Again, this would be in direct conflict with the purpose of the menu labeling requirement.

Posting calorie information online only is not sufficient. Online menus will not help a customer who is ordering in the store. Customers who place an order in the establishment should not be penalized for not placing their order online. It is also important to remember that some Americans do not have ready access to the internet.

In addition, some online menus fail to provide consumers with calorie information at the appropriate time – when it could inform their selection. Consider the online menus for several major pizza chains. Domino's provides a calorie count by slice on its website, but the calorie information is not visible when the customer is selecting what to order. Instead, the calorie information does not appear until you select the "checkout" button to pay. Customers have to start their order over if they want to alter their selection after receiving the calorie information. To find additional nutrition information or to compare the calories between items, the consumer must locate the "nutrition" link at the bottom of the page. At other major chains, including Pizza Hut and Papa John's, the calorie count is not provided to the customer at any point during the order selection or at payment. Customers have to proactively search for that information and find the "nutrition" link at the bottom of the webpage. This is not a useful way to provide calorie or nutrition information. Pizza chains should improve their online menus to comply with the menu labeling requirements.

However, as noted above, online menus alone are not enough. Pizza chains and other establishments that offer takeout or delivery service must also post calories on their menu boards just like other chain restaurants, to accommodate those customers who place their orders in the store. Pizza chains in Vermont, California, Pennsylvania, Seattle, and other states and municipalities are already posting calorie information on menus – demonstrating that it can be done in a reasonable space and at a reasonable cost.

Pizza Hut, Ashland, VA, July 2017
Excerpt from Menu Board on Display at Order Counter

CREATE YOUR PIZZA FROM THE CRUST UP

CHOOSE A SIZE

LARGE (L) \$11.99 14" Cheese 8 Slices	MEDIUM (M) \$9.99 12" Cheese 8 Slices	PERSONAL PAN PIZZA® (P) 6" Cheese \$4.29 6" 1-Topping 4 Slices (Add 0-50 Cal/Slice) \$4.29
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CHOOSE A SAUCE
(CAL/SLICE)
CALORIE RANGE VARIES DEPENDING ON PIZZA SIZE

CLASSIC MARINARA	Add 0-10 Cal
PREMIUM CRUSHED TOMATO	Add 0-10 Cal
CREAMY GARLIC PARMESAN	Add 15-40 Cal
BARBEQUE	Add 5-20 Cal
BUFFALO	Add 0-10 Cal

CHOOSE A CRUST
(CAL/SLICE)

HAND TOSSED	M 120 L 160 Cal
THIN 'N CRISPY™	M 100 L 130 Cal
ORIGINAL PAN™	P 100 M 150 L 220 Cal
SKINNY IT UP*	L 120 Cal
ORIGINAL STUFFED CRUST™	L 220 Cal \$2.00 MORE

ADD INGREDIENTS

MEDIUM \$1.35 EACH	LARGE \$1.65 EACH
PERSONAL PAN PIZZA® 80¢ EACH	
CALORIES ARE BASED ON 1-TOPPING AMOUNT. CALORIE RANGE VARIES DEPENDING ON PIZZA SIZE (CAL/SLICE).	
PEPPERONI	Add 25-60 Cal
BACON	Add 15-45 Cal
BEEF	Add 50-80 Cal
GRILLED CHICKEN	Add 15-30 Cal
HAM	Add 5-15 Cal
ITALIAN SAUSAGE	Add 50-90 Cal
MEATBALL	Add 35-60 Cal
SALAMI	Add 10-35 Cal
SEASONED PORK	Add 45-80 Cal
BANANA PEPPERS	Add 0 Cal
BLACK OLIVES	Add 5-20 Cal
DICED ROMA TOMATOES	Add 0 Cal

SIGNATURE

LARGE (L) \$16.99

HUT LOVERS® FAVORITES SPICY Enjoy the Pizzas. C

MEAT RECIPES

- SUPREME**
M 210-270 Cal | L 240-390 Cal/Slice
Pepperoni, seasoned pork, beef, mushrooms, green bell peppers and red onions.
- SUPER SUPREME (\$1 MORE)**
M 260-310 Cal | L 290-450 Cal/Slice
Pepperoni, ham, beef, seasoned pork, Italian sausage, red onions, mushrooms, green bell peppers and black olives.
- MEAT LOVER'S®**
M 260-310 Cal | L 290-450 Cal/Slice
Pepperoni, Italian sausage, ham, bacon, seasoned pork and beef.
- BACON SPINACH ALFREDO**
M 210-260 Cal | L 230-360 Cal/Slice
Bacon, mushrooms and spinach. With creamy garlic Parmesan sauce and salted pretzel crust finisher.
- PEPPERONI LOVER'S®**
M 250-300 Cal | L 290-440 Cal/Slice
50% more pepperoni.
- FOUR PEPPER PEPPERONI**
M 180-240 Cal | L 220-340 Cal/Slice
Pepperoni, jalapeño peppers, Peruvian cherry peppers, banana pepper and green bell peppers. With premium crushed tomato sauce.

PRIMO MEATS

And, as both Congress and the FDA have already made clear, retail food establishments can have more than one form of menu or “primary writing”, and each form is required to include a calorie declaration.

Distinguishing Between Menus and Other Information Presented to the Consumer

In the Federal Register notice, the FDA states that it has received questions about how to distinguish a menu from advertisements and other marketing materials. The Agency then continues to say that further consideration and clarification is needed.

The FDA, however, has already established clear criteria for distinguishing menus from advertisements and other marketing materials. In the final guidance document, the Agency explains that establishments should consider whether a customer can use the document or other form of communication to order (i.e., does it include the name or image of the standard menu item and the price, and can the customer order from it?). The guidance document provides several examples to illustrate how the criteria work. For example, an ad or coupon that states, “Try our large cheese pizza for only \$9.99” would not be considered a menu because a customer cannot order from it. However, if the ad or coupon includes a phone number or website, the calorie declaration must be provided because a customer could order from it.

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, if a coupon is part of a takeout menu that list calorie counts, the coupon itself does not need to list the calories since the takeout menu would be the primary way of ordering. The final guidance makes these distinctions between menus and other communications with consumers clear; no further changes or delay are needed.

Closing

In closing, AHA is extremely disappointed that the FDA delayed the compliance deadline for menu labeling – again. As explained above, we do not believe that a one-year delay is necessary. It is unlikely to achieve significant cost savings or reduce regulatory burden, but it will deprive consumers of valuable nutrition information that would allow them to make informed, healthier decisions.

In addition, the FDA has already answered the questions raised in the interim final rule, and we do not believe additional clarification or change is needed. Numerous establishments, including restaurants, grocery stores, convenience stores, pizza chains, and movie theaters, were able to successfully implement menu labeling without this additional delay.

We urge the Agency to put public health first and revoke the compliance date extension. Covered establishments should be directed to immediately implement the menu labeling final rule.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Thank you for your consideration of our comments.

Sincerely,



John J. Warner, MD
President
American Heart Association