

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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

COMMENTS OF THE  
CENTER FOR SCIENCE IN THE PUBLIC INTEREST

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Docket No. FDA-2011-F-0172

**Re: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments**

The Center for Science in the Public Interest (CSPI) strongly supports immediate implementation of the menu labeling final rule. We oppose any delay or weakening of the menu labeling regulations and request that the FDA revoke the one-year compliance date extension. 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.

CSPI is a nonprofit organization supported by approximately 500,000 members and subscribers to its *Nutrition Action Healthletter* in the United States. CSPI supported passage of the national menu labeling law which was a bipartisan compromise supported by public health organizations and the restaurant industry, and it built on the momentum of more than 20 state and local policies.

While the National Grocers Association (NGA), the Food Marketing Institute (FMI), and the National Association of Convenience Stores (NACS) have advocated for delaying and weakening menu labeling, many chains are already posting calories, showing that menu labeling is feasible. These trade associations also engage in public-facing efforts and partnerships to boost healthy eating, otherwise demonstrating their willingness and ability to meet consumer demands for healthier options. One week after the official delay for menu labeling due in part by NACS, the trade association heralded itself as “the first retail-association partner” of the Partnership for a Healthier America (PHA) in a commitment to increase healthy choices inside their stores.<sup>1</sup>

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<sup>1</sup> National Association of Convenience Stores (NACS). NACS Becomes First Retail Association to Make a Commitment with Partnership for a Healthier America, May 11, 2017. Accessed at: [http://www.nacsonline.com/Media/Press\\_Releases/2017/Pages/PR051117.aspx#.WVFhkevytpg](http://www.nacsonline.com/Media/Press_Releases/2017/Pages/PR051117.aspx#.WVFhkevytpg).

The food service industry has had ample time to implement menu labeling and many covered food outlets have already complied with the regulations. The delay and reopening of the menu labeling rulemaking denies consumers the ability to make their own informed choices about how many calories to eat. This comes at a time of high rates of nutrition- and obesity-related illness including diabetes, heart disease, and cancer. These diseases not only harm Americans, but also place unmanageable fiscal and public health burdens on the American public, businesses, and federal, state, and local governments.

The vast majority of the top restaurant, supermarket, and convenience store chains already are labeling calories. In a recent scan of the top 50 restaurant chains in 2016 (by revenue according to National Restaurant News), we found that all 50 had calorie information either on-line (e.g., posted per menu item, provided in PDF or other format, or via an online nutrition calculator) or in the restaurant. The examples below are from covered establishments, including supermarkets and convenience stores, that are already complying with the menu labeling regulations as finalized, showing that posting calories as currently required is feasible and already widely prevalent.

**Figure 1. Jewel-Osco, prepared foods with labeling on signs, Chicago, IL, May 2017**



Figure 2. Whole Foods Market salad bar with labeling on sneeze guard, Bethesda, MD, May 2017



Figure 3. Giant Food supermarket salad bar with labeling on sneeze guard, Washington, DC, May 2017



Figure 4. Whole Foods Market grab-and-go bakery items, Bethesda, MD, May 2017



Figure 5. Wegmans grab-and-go deli items, Fairfax, VA, April 2017



Figure 6. 7-Eleven, Washington, DC, May 2017



Figure 7. Whole Foods Market salad bar with labeling on signs, Bethesda, MD, May 2017



The remainder of this comment 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 will not save companies money and changes to the regulations will increase costs to companies.**

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.

The Administration states in the Regulatory Impact Analysis (RIA) for the delay that the goal of the delay is to save industry money. However, most covered establishments have already invested the resources needed to comply with the rule. Given that the menu labeling final rule was officially stayed on May 4, 2017, one day before the compliance date,<sup>2</sup> all chain restaurants, supermarkets, convenience stores, and other covered food service establishments would already have had to analyze their prepared foods and menu items (which the FDA estimated to cost \$30-135 million in the Regulatory Impact Analysis for the final regulations), redesign and update their menus (which FDA estimated to cost \$250-260 million), train their staff (estimated cost, \$30-65 million), and conduct any needed legal review (estimated cost, \$1.64-2.45 million),<sup>3</sup> unless they were planning to disregard the law. The RIA for the menu labeling final rule estimated that the bulk of menu labeling costs are the initial cost (87%), rather than the yearly recurring costs (12%). The FDA 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.”<sup>4</sup> As a result, delaying the compliance date is unlikely to result in any cost savings for them. If the rule is amended, food service establishments would have to spend an additional \$282-327 million to redo their menus, retrain their staff (given 100% turnover per year) and reconduct the legal review.

The benefit to consumers and potential savings to the health care system of requiring immediate compliance, by contrast, are considerable. Studies show that providing nutrition information at restaurants can help people make lower-calorie choices and improve restaurant offerings.<sup>5</sup> According to the FDA’s regulatory impact analysis issued with the final rule, the

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<sup>2</sup> The interim final rule extending the compliance date was published in the Federal Register on May 4, 2017 (82 FR at 20825), one day before covered establishments were required to comply with the final rule.

<sup>3</sup> Food and Drug Administration. Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Final Regulatory Impact Analysis FDA–2011–F–0172. November 2014. Accessed at

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/UCM423985.pdf>.

<sup>4</sup> 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.

<sup>5</sup> Center for Science in the Public Interest. Summary of Findings: Influence of Nutrition Information Provision, October 2008. Accessed at: <https://cspinet.org/resource/summary-findings-influence-nutrition-information-provision>.

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>

Yet, when the FDA announced the one-year compliance deadline 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.”<sup>8</sup> This concerns us greatly. The true benefit of menu labeling is that it will allow consumers to make informed, healthier choices. This is especially concerning given that the cost savings to covered establishments of not implementing menu labeling are estimated between \$2 to \$8 million over 20 years depending on the discount rate applied<sup>9</sup> while the “foregone benefits” to consumers range between \$5 and \$19 million.<sup>10</sup> The FDA cannot justify a compliance delay when the “foregone benefits” to consumers are so dramatically higher than the cost savings to covered establishments.

Many national restaurant chains have had menu labeling for years as a result of state and local laws, beginning almost a decade ago with the passage of the first two menu labeling laws in New York City<sup>11</sup> and Seattle/King County, Washington<sup>12</sup> that went into effect in 2008. The restaurant industry has since favored uniform federal requirements over the patchwork of different state and local laws.<sup>13</sup> These food establishments have demonstrated that labeling is feasible in a reasonable space and at a reasonable cost without liability risks.

**“Covered establishments” must include all chain retail food establishments selling ready-to-eat foods, including restaurants, supermarkets, and convenience stores.**

It would be inconsistent to require calorie labeling at chain restaurants, but not for similar prepared foods at supermarkets and convenience stores, movie theaters, stadiums, and more. Despite claims from supermarket and convenience store trade associations, these food

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<sup>6</sup> Food and Drug Administration. Final Regulatory Impact Analysis: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishment, November 2014. Accessed at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/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* 34.11 (2015): 1932-1939.

<sup>8</sup> 82 FR at 20828.

<sup>9</sup> Annualized cost savings: \$2-\$6 million with a 3% discount rate, or \$3-\$8 million with a 7% discount rate over 20 years.

<sup>10</sup> Annualized foregone benefits: \$5-\$15 million with a 3% discount rate, or \$6-\$19 million with a 7% discount rate over 20 years.

<sup>11</sup> Center for Science in the Public Interest. “NYC Trans Fat, Calorie Labeling Initiatives Approved.” December 5, 2006. Accessed at: <https://cspinet.org/new/200612052.html>.

<sup>12</sup> Center for Science in the Public Interest. “In Seattle, Menu Labeling is ‘in’, Trans Fat is ‘out’.” July 20, 2007. Accessed at: <https://cspinet.org/new/200707201.html>.

<sup>13</sup> National Restaurant Association. Menu Labeling, May, 2017. Accessed at: <http://www.restaurant.org/advocacy/Menu-Labeling>.

establishments are similar to and compete with restaurants.<sup>14,15</sup> For example, it does not make sense for a stand-alone bakery to have to provide calorie labeling, but for the bakery in a grocery store to be exempt.

Americans increasingly purchase ready-to-eat food from supermarkets and convenience stores, which sell a great deal of restaurant-type food for immediate consumption through their bakeries, delis, buffets/hot bars, salad bars, and cafés. 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>16</sup> People need nutrition information about 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 FDA should consider the definition of “covered establishments” from the consumer perspective, just as it has determined that the definition of menus and menu boards “should be interpreted from a consumer’s vantage point.”<sup>17</sup> It does not matter to consumers if they are getting a slice of pizza from a supermarket, a convenience store, a bowling alley, or a restaurant. The calories count and contribute to their diet similarly. And people want foods from all these venues to be labeled. A national poll found that 80 percent of Americans support calorie labeling at chain supermarkets, the same level of support as for restaurant calorie labeling.<sup>18</sup>

When drafting the menu labeling statute, 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>19,20</sup> While the Nutrition Labeling and Education Act of 1990 (NLEA) required nutrition labeling for most packaged food products, the law did not cover prepared foods.<sup>21</sup> Menu labeling thus was intended to fill a gap left by the NLEA, which exempted 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

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<sup>14</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>15</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>16</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>17</sup> 76 FR 19192 at 19202; 79 FR 71156 at 71177.

<sup>18</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>19</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>20</sup> Harkin T, DeLauro R. Letter to FDA Commissioner Hamburg about menu labeling. June 17, 2011.

<sup>21</sup> Federal Food, Drug, and Cosmetic Act of 1938. Public Law No. 75-717, 52 Stat. 1040, Sec. 403(q)(5)(A).

purchased. This definition should apply to menu labeling. It would be confusing and difficult to implement and enforce a different definition of restaurants and similar establishments for different nutrition labeling laws.

Congress explicitly chose to cover menu labeling at restaurants and “similar” retail food establishments—and has repeatedly rejected industry requests to exempt supermarket and convenience stores. The House of Representatives removed an exemption from the Commonsense Nutrition Disclosure Act (H.R. 2017) in 2016.<sup>22</sup> The bipartisan agreement from Senators Lamar Alexander (R-TN) and Patty Murray (D-WA), the chair and ranking member of the Senate Committee on Health, Education, Labor and Pensions (the committee with jurisdiction over menu labeling) along with 30 other senators, requested that the FDA delay implementation from December 1, 2015 to December 1, 2016 to provide more time for supermarkets and convenience stores to comply with labeling, not to exempt them from the requirement. The FDA also addressed concerns about covered establishments in the final regulations, taking into account different business practices and operations, including doing business under the same name and offering for sale substantially the same menu items, and carefully considered the supermarket and convenience store industries request to exempt them from labeling during the comment period.<sup>23</sup>

The law also 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. Grocery store co-ops are situated similarly to independent franchise owners of chain restaurants and should be subject to the same requirements.

**Consistent with the final rule, the FDA should consider the need for calorie information 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.**

The FDA considered industry and consumer concerns regarding the definition of menu and menu boards in the final rule. The FDA agreed that “primary writing” should be interpreted from the perspective of consumers. The regulations do not require a specific kind of menu or menu board; each food service establishment may decide how to present its items to customers. However, calories must 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 writing from which customers make order selections in the establishment, then the menu through the kiosk must 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.

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<sup>22</sup> See All Actions on H.R. 2017 at <https://www.congress.gov/bill/114th-congress/house-bill/2017/all-actions>.

<sup>23</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>.

We do not support exempting food service establishments from providing calorie information inside the restaurant/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.

Pizza chains and other establishments that offer delivery service should post calories on their menu boards just like other chain restaurants, as Congress intended. While some consumers use online menus, others use paper menus at home, drive-thru menu boards from their car, or menus and menu boards in a restaurant. All menus should list calories so consumers can see the information when and where they are deciding what to order. Pizza chains in Vermont, California, Seattle, and other states and municipalities are already posting calorie information on menus—demonstrating it can be done in a reasonable space and at a reasonable cost.

Congress clearly did not intend for restaurants to provide calorie postings only on a single medium in each restaurant/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 also are listed on the menu board.

**Calorie information must 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 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 that is 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 options and make informed choices at the bakery department, salad bar, hot bar, or deli.

The FDA has already provided considerable flexibility for labeling foods on display. According to the FDA's final guidance, there are several options for the placement of calories for foods on display: 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. This applies to all self-service foods (e.g., salad bars, buffets, hot bars, grab-and-go, non-packaged foods in coolers, etc.), not only at supermarkets but also at restaurants.

**Serving sizes must be standardized for consumers to make use of nutrition information.**

**It is essential for calories to be listed for each item as typically prepared and offered for sale.**

Without standardization of serving sizes, people will have difficulty understanding and using the nutrition information for menu items. Posting the total calories per menu item enables

consumers to more easily compare different types of food items, such as nachos, chicken wings, 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 muffins, 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, such as between appetizers, which could have calories listed for one-half, one-third, or one-tenth of the item if serving sizes as left up to the discretion of the establishment.

Further, the FDA already addressed the pizza industry’s concern about serving sizes and provided them the additional flexibility to label calories per slice of pizza, as long as the number of slices is also indicated.

**The FDA already has provided food retail establishments with considerable flexibility for variations and accuracy of nutrient declarations, and no changes in the requirements are needed.**

The final regulations specified that a covered establishment must simply 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 calorie and other nutrition information should be consistent with the specific basis used to determine the nutrient values and the covered establishment must take reasonable steps to ensure that the method of preparation and amount served are consistent with the factors on which its nutrient values were determined.

The FDA guidance states (page 43), “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.”

**The FDA has established valid criteria distinguishing menus from advertisements and other marketing pieces in its final guidance, and no further changes are needed.**

The FDA considers whether a customer can use the document or other form of communication to order in determining whether it should be considered a menu (e.g., does it include the standard menu item and price?). For example, an advertisement, poster, or coupon that states, “Try our large pepperoni and sausage pizza for only \$9.99,” would not be considered a menu for calorie labeling because a customer cannot order from it. However, if the document included the phone number or website, the calorie declaration must also be provided because a customer could order from it. Similarly, if the document could be used by the customer to order online or in-store, it would need to be labeled.

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 lists the 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.

**Many states and localities have required calorie labeling for almost a decade and not a single restaurant chain has faced a lawsuit.**

States and local agencies charged with enforcing calorie labeling laws thus far have worked with food retail establishment to correct any problems before levying fines. Fines are usually reserved for retail food establishments that are unwilling to correct problems or after repeated violations. The FDA had indicated that it would take a similar approach, with the agency publicly stating that it would focus on technical assistance and education rather than enforcement during the beginning stages of implementation.<sup>24</sup>

**National uniformity.**

Preemption of state and local authority is disfavored, particularly in areas of law—like public health—where state and local governments historically and traditionally have had broad authority to regulate. The menu labeling rule makes clear that while Section 4205 restricts state and local authority to impose menu labeling requirements on restaurants and similar food establishments that are not identical to the national requirements, Congress clearly intended that state and local governments retain the remainder of their traditional authority in this area and the rule allows states and localities to enforce requirements that are the same as the national requirements.

The regulation of restaurants and similar food establishments has traditionally been the province of state and local governments, which oversee restaurant sanitation and food-handling requirements, as well as the location and many aspects of the operation of restaurants through zoning and licensing requirements. The menu labeling final rule therefore takes an appropriately narrow view of the preemptive effect of Section 4205.

The statute preempts only state and local menu labeling requirements that are “of the type” set out in Section 4205 and not “identical” to the federal law. State and local governments retain their authority to enforce menu labeling requirements that are “identical” to the national menu labeling requirements and impose non-“identical” labeling requirements on restaurants and other retail food establishments that (1) are not part of a national chain with 20 or more outlets and (2) have not agreed to comply with the federal law by registering with the FDA. The word “identical” does not mean verbatim in wording but rather in effect—state or local requirements that are worded differently from the federal requirements may still be “identical” under Section 4205. As several court opinions have made clear, “identical” means that the language used is substantially the same as the parallel language found in the Federal Food, Drug, and Cosmetic Act (FFDCA), and that differences between them do not result in “materially

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<sup>24</sup> Black, J. “Pizza Chains Are Making a Desperate Push to Avoid Posting Calories on Menus.” *Washington Post*, April 7, 2017. Accessed at: [https://www.washingtonpost.com/lifestyle/food/pizza-chains-are-making-a-desperate-push-to-avoid-posting-calories-on-menus/2017/04/06/080a8d5e-18b0-11e7-bcc2-7d1a0973e7b2\\_story.html](https://www.washingtonpost.com/lifestyle/food/pizza-chains-are-making-a-desperate-push-to-avoid-posting-calories-on-menus/2017/04/06/080a8d5e-18b0-11e7-bcc2-7d1a0973e7b2_story.html).

different requirements.”<sup>25</sup> In other words, a court should analyze the phrasing in terms of equivalence. “As long as Plaintiff's state law claims do not impose different requirements than the FFDCa or FDA regulations, these claims are not preempted.”<sup>26</sup>

The final rule's uniformity provisions are limited to calorie and other nutrient labeling requirements in covered establishments. The language and intent of the statute, together with Executive Order 13132, underscore the validity of the FDA's determination that the rule not create a regulatory vacuum. The only state and local provisions that must be the same as the national requirements are those that explicitly require the type of menu labeling set forth in section 4205 at a covered establishment. For example, since the law does not cover chains with less than 20 outlets, states and localities could enact laws to cover them. In addition, the FDA made clear in the final rule that state or local requirements for statements in food labeling providing for warnings concerning food safety are not preempted.

In the face of the obesity epidemic, state and local governments are motivated to implement a variety of systems, policy, and environmental changes to promote healthy eating and active living, and to make healthy behaviors the default choice. It is especially important that their ability to experiment not be curtailed by an inappropriately broad reading of Section 4205's preemptive language.

## Conclusion

The FDA has already answered the questions raised in the interim final rule and food retail establishments have had seven years to prepare for national menu labeling. In addition, the FDA has already provided covered establishments with sufficient flexibility and guidance to implement the rule. According to the FDA, “[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>27</sup>

Therefore, we strongly urge the FDA to revoke the compliance date extension and move forward with implementing the menu labeling regulations as finalized. Americans want calorie labeling when eating out and have been waiting long enough. The final menu labeling regulations provide well-defined nutrition labeling requirements that are applied in a fair manner to all covered establishments. The regulations as written provide clear, conspicuous, and accessible calorie labeling that allows consumers to make their own choices about what to order when eating out. Changing the labeling requirements at this late date would penalize the many chains that have already complied with the law, undermine people's ability to make informed choices about their health, and interfere with the FDA's obligation to implement the rule.

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<sup>25</sup> See *Vermont Pure Holdings, Ltd. v. Nestle Waters N. Am., Inc.*, CIV.A.03-11465 DPW, 2006 WL 839486 (D. Mass. Mar. 28, 2006) (quoting H. Rep. No. 109-379 (Feb. 28, 2006)).

<sup>26</sup> *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F.Supp.2d 1112, 1121 (C.D.Cal.2009); See also *Reyes v. McDonald's Corp.*, 06 C 1604, 2006 WL 3253579 (N.D. Ill. Nov. 8, 2006) (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454, 125 S. Ct. 1788, 1804, 161 L. Ed. 2d 687 (2005)).

<sup>27</sup> FDA. Interim Final Regulatory Impact Analysis. Page 10-11.

We urge the FDA to put the public's health first, and to proceed immediately with implementing its carefully crafted final rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Margo Wootan". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Margo G. Wootan, D.Sc.  
Director of Nutrition Policy

A handwritten signature in black ink, appearing to read "Colin Schwartz". The signature is cursive and compact, with a horizontal stroke at the end.

Colin Schwartz, M.P.P.  
Senior Nutrition Policy Associate