July 5, 2011

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

Re: Docket No. FDA-2011-F-0172, RIN 0910-AG57

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

The American Cancer Society Cancer Action Network supports the Food and Drug Administration's (FDA) proposed regulations for menu labeling at chain restaurants and urges the FDA to strengthen certain provisions to better provide consumers with information to support their making healthy food choices. The American Cancer Society Cancer Action Network[SM] (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.

Nutrition and physical activity factors, including overweight and obesity, contribute to one third of all cancer deaths.[1] Overweight and obesity are clearly associated with increased risk for cancer of the breast (postmenopausal), colon, endometrium, esophagus and kidney.[2] There is also highly suggestive evidence of a link between overweight and obesity and cancers of the pancreas, gallbladder, thyroid, ovary, and cervix, and for multiple myeloma, Hodgkin's lymphoma, and aggressive prostate cancer.[3] As a result of this clear relationship diet and weight status have with certain types of cancer, ACS CAN supports multi-faceted population-based policy approaches to improving nutrition and physical activity by removing barriers, changing social norms, and increasing awareness.

ACS CAN strongly supported the passage of the Affordable Care Act (Public Law 11-148; ACA), which contained a number of meaningful public health and health care system reforms that will benefit families affected by cancer by emphasizing prevention, expanding access to meaningful coverage, and improving quality of life for cancer patients and survivors. Section 4205 of the ACA, which amends sections 403 and 403A of the Federal Food, Drug, and Cosmetic Act (FDCA), requires chain restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items

1 American Cancer Society. *Cancer Prevention and Early Detection Facts & Figures 2011*. Atlanta: American Cancer Society, 2011.
2 Ibid.
3 Ibid.

to disclose nutrient content information for standard menu items appearing on restaurant menus and menu boards and requires vending machine operators that own or operate 20 or more vending machines to disclose nutrient content information for certain articles of food sold from vending machines. ACS CAN supports providing consumers with nutrition information that will allow them to make informed decisions about the foods and beverages they consume and promote awareness for making healthy choices. Requiring venues to include nutrition information on menus and menu boards is an integral part of a comprehensive approach to addressing obesity and ultimately preventing future cancer deaths.

Summary of Comments on Proposed Rule

Overall, FDA has proposed generally sound and clear regulations on how to fulfill the menu labeling requirements of Section 4205 of the ACA. We believe that the final rule, when implemented, will go a long way in providing consumers with calorie information to facilitate making healthy food choices and in increasing awareness of nutrition and healthy food options.

We disagree, however, with several of the proposed provisions. To adhere to the intent of Congress, we strongly urge the FDA to revise the definition of restaurants and similar retail food establishments covered by the law to include all venues that sell or serve restaurant or restaurant-type food. Exempting certain venues creates numerous inconsistencies, is not what Congress intended, and reduces the impact of the law. We also recommend that the FDA require labeling for alcoholic beverages for public health and legal reasons. We look forward to the results of FDA's consumer research on the labeling of variable menu items and the statement about suggested daily caloric intake, which should guide the agency's decision-making on the requirements related to these two items.

We further recommend that FDA provide technical assistance for covered venues, an education campaign for consumers about the availability and meaning of the calorie and other nutrition information, and ensure that the law is appropriately implemented and enforced within 6 months following publication of the final rule. FDA should also clarify that other nutrition labeling laws are not preempted except for those that relate to the specific venues and types of foods to which this law applies.

Specific comments on certain provisions are described in detail in the comments that follow.

Comments on Specific Provisions of Proposed Rule

Definition of "Restaurant or Similar Retail Food Establishment"

ACS CAN strongly encourages FDA to amend its proposed definition of "restaurant or similar retail food establishment" to include all retail establishments that offer for sale "restaurant or restaurant-type food", regardless of whether the sale of food is the primary business activity of the establishment. We recommend that the definition of "restaurant or similar retail food establishment" be broadened to include all venues that sell or serve restaurant or restaurant-type food for several reasons:

a) Calories count regardless of where they are consumed and what else the consumer is doing while eating.
b) Congress intended for Section 4205 to apply to a broad range of venues that sell food for immediate consumption, including some that the proposed rule exempts.
c) Chain retail establishments that serve food for immediate consumption have standard menu items and could easily comply with the law.
d) The "primary business activity" criteria makes application of the law inconsistent, and enforcement, therefore, difficult.
e) Similar facilities that sell the same types of food should be treated the same under the law.

A. *Calories Count Regardless of Where They Are Consumed and What Else the Consumer is Doing While Eating.*

Many different kinds of establishments sell prepared foods for immediate consumption. People need nutrition information about those foods whether that food is eaten sitting down at a table-service restaurant, while watching a movie, when shopping at a retail store or shopping mall, or taken back to their desk from a food cart. Calories count the same regardless of where they are eaten.

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." It does not matter to consumers if they are getting their pizza, burger, fries, or other foods from an amusement park, bowling alley, or a restaurant in which no entertainment is provided. All those calories count and contribute to their diet similarly.

Numerous food-service establishments offer other services or entertainment to their customers. Providing those services does not affect people's need for nutrition information. For example, though people may go to a movie theater primarily to see a movie, the movie theater also is a food-service establishment, selling many (often surprisingly) high-calorie foods and beverages through its concession stand. It is essential that theaters provide clear calorie labeling for their popcorn, sugary beverages, candy, and other offerings. Bowling alleys, amusement parks, stadiums, casinos, miniature golf food stands, and other entertainment venues that sell food also should provide nutrition labeling if they are part of a chain, regardless of the percentage of sales from food or floor space dedicated to eating or selling food. Menu labeling also should apply to hotels with standard menus for their restaurants or in-room dining and to cafeterias within hospitals, superstores, schools, and stadiums as long as they have 20 or more locations.

Many of the foods sold through the venues that the FDA has proposed exempting are similar to foods that will be covered in establishments that would not be exempt. It would be inconsistent if competing venues were exempted. For example, many movie theaters are diversifying their concessions and adding more menu options, such as ice cream, fresh baked

goods, pizza, hot dogs, and coffees.[4] For example, AMC is testing a dinner-house-type menu with seat-side ordering.[5]

Customers are also showing interest in health and nutrition at entertainment venues. AMC has added AMC Smart MovieSnacks to their menu.[6] Last year, Regal Entertainment Group started offering 100-calorie packs of popcorn, a diet soda, and a pedometer combo in New York and California. The Disney Corporation's efforts to offer healthier children's meals have been successful at their theme parks.[7] The company has changed the defaults for beverages to healthy choices, such as 100% juice, water, and low-fat milk, and offers fruits and vegetables as the default side dishes with children's meals. Those changes have been well-received; two-thirds of families stick with the healthy children's meal defaults. If movie and other entertainment customers are interested in healthy options, it is likely they also would be interested in having menu labeling.

B. The Proposed Definitions for "Restaurant" and "Similar Retail Food Establishments" Exclude Food Establishments that Congress Intended to Include

The FDA has stated that the statutory language referring to "restaurants and similar retail food establishments" is unclear, and has invited comments on its proposed definitions of these terms. We respectfully disagree with the FDA's proposed definitions. We believe they are too narrow, and exclude foods and retail food establishments that Congress intended to include within the scope of Section 4205 of the ACA, including retail food establishments such as general merchandise stores, amusement parks, movie theaters, bowling alleys, and the like, so long as they are part of a chain with 20 or more locations nationwide. We believe that the more appropriate definition for "restaurants and similar retail food establishments" is the one that FDA previously applied for "restaurants,"[8] which included any establishment that offered for sale food ready for human consumption, either on or off its premises.

The FDA's proposal to insert a "primary business activity" requirement into the definitions of "restaurant" and "similar retail food establishment" would result in excluding foods and retail food establishments that Congress intended to include within the scope of Section 4205. Congress's intent can be determined by examining the plain language of the Nutrition Labeling & Education Act (NLEA), and how its terms have been understood, including by the FDA itself.

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4 Watts A. "Getting Proactive: A Diverse Menu Serves the Customer and the Critic." Film Journal International. May 19, 2011. Accessed at http://www.filmjournal.com/filmjournal/content_display/columns-and-blogs/snack-corner/e3iea8f2ef4334a6533cc06cbe7e5ff38c2

5 Ziegler L. "Beyond Popcorn: Theaters Try Seat-Side Food Service." NPR. May 25, 2011. Accessed at http://www.npr.org/2011/05/25/136644440/beyond-popcorn-theaters-try-seat-side-food-service?ft=1&f=1006

6 Carollo K. "Movie Theatres to Sell Healthy Snacks." ABC News. April 8, 2011. Accessed at http://abcnews.go.com/Health/movie-theatres-sell-healthy-snack-pack-amc-sells/story?id=13311986

7 Disney Corporation. "Walt Disney Company – 2008 Corporate Responsibility Report." 2008. Available at http://Disney.go.com/crreport/childrenandfamily/positivedevelopment/kidshealthandnutrition.html

8 DHHS, FDA. "Guidance for Industry: A Food Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods, April 2008. Available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053455.htm, accessed on May 19, 2011.

Before Section 4205 was incorporated into the NLEA, the NLEA exempted two types of food from its nutritional labeling requirements. It exempted food "served in restaurants or other establishments in which food is served for immediate consumption or which is sold for sale or use in such establishments" ("restaurant food"). 21 U.S.C. § 343(q)(5)(A)(i) (2009). The NLEA also exempted food "processed and prepared primarily in a retail food establishment, which is ready for human consumption, which is of the type described [above], and which is offered for sale to consumers" but not for immediate consumption on the premises, and which is not offered for sale outside the establishment ("restaurant-type food"). 21 U.S.C. § 343(q)(5)(A)(ii) (2009). In interpreting the scope of the exemption delineated by these NLEA provisions, the FDA correctly defined "restaurants or other establishments" and "retail food establishment" as including institutional cafeterias, transportation carriers, delicatessens, caterers of ready-to-eat foods, lunch counters, cookie counters in malls, vending machines, convenience stores, and the like, because these kinds of retail food establishments served restaurant and restaurant-type food.[9] Thus, the FDA's prior interpretation of the word "restaurant" logically and properly tracked with the NLEA's language defining restaurant-food and restaurant-type food.

This NLEA language continues to provide the appropriate legislative context for what kinds of foods and retail establishments Congress intended to bring within the scope of Section 4205. When Congress amended the NLEA with Section 4205, the intent was to eliminate the old exemption for restaurant-food and restaurant-type food retailers, of whatever kind, that are a part of large chains, and not to eliminate it only for some smaller subset of these large chains.

As the FDA notes, the language of Section 4205 is not crystal clear on this point. Consistent with the purpose, structure and language of the NLEA as a whole, however, it is clear that "food" is the focal point of the law. Thus, the better, more accurate interpretation is that which tracks the unchanged language contained in 21 U.S.C. §343(q)(5)(A) (i) & (ii), as well as the new language in 21 U.S.C. §343(q)(5)(H) added by Section 4205. The FDA's former interpretation of "restaurant" is more consistent with the plain language of the NLEA, as amended by Section 4205, than the newly proposed definitions because the former interpretation focuses appropriately on the type of food being sold, not the type of retail establishment selling the food. The language of 21 U.S.C. §353(q)(5)(H) addresses: 1) food; 2) that is a standard menu item; 3) offered for sale in a restaurant or similar retail food establishment (part of a chain of 20 locations or more, etc.). The types of business entities that sell or serve food are important—they must sell food at retail, and must be part of a large chain, clearly. But they are largely referred to as descriptors for types, or forms, of food (e.g., labeling requirements vary depending on whether food is received in bulk containers, whether the food is in the form of raw agricultural commodities or raw fish, or whether the food is restaurant food. *See* 21 U.S.C. 343§(q)(3)-(5) (2011)). In other words, "food" is the main subject of the law; "restaurant" is used as an adjective to describe the types of food covered, as well as the types of businesses regulated.

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9 Ibid.

In contrast, the FDA's newly proposed definitions place undue emphasis on the physical operations of the business entity—whether it holds itself out as a "restaurant" or how much floor space it devotes to the sale of food. Rather, Congress intended that the menu labeling obligation attaches to restaurant and restaurant-type food sold to consumers at the retail level, regardless of who specifically sells it, with the exception that the retailer "is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items . . . ." 21 U.S.C. § 343(q)5(H)(i) (2011).

C. *Retail Establishments Exempted from the Law Sell Restaurant-Type Food and Could Easily Comply.*

It is feasible for bowling alleys, movie theaters, transportation venues, hotels, and others to provide accurate, accessible nutrition information. Restaurants are providing nutrition labeling for the same types of menu items that are sold in movie theaters, hotels, airlines, trains, and entertainment venues. Movie theaters in California, New York City, and the New York counties of Albany, Schenectady, Suffolk, and Westchester already are required to provide menu labeling and are doing so without any apparent problems. Bowling alley and hotel room service menus often look similar to the menus of dinner-house-type restaurants. Likewise, the menus on many planes and trains look similar to those at sandwich shops.

D. *The "Primary Business Activity" Requirement Would Lead to Inconsistencies in Application of the Law and Make Enforcement Difficult.*

The FDA proposes that only venues for which the sale of food is the primary business activity of the establishment meet the definition of "restaurant or similar retail food establishment" and are subject to requirements of Section 4205 if they are part of a chain of 20 or more locations. The proposed rule further states that "the sale of food would be considered to be a retail establishment's primary business activity if either (1) the establishment presents or has presented itself publicly as a restaurant . . . or (2) greater than 50 percent of a retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of food." The proposal that an establishment that presents or has presented itself publicly as a restaurant would be covered by Section 4205 would lead to inconsistencies in labeling that would be confusing to consumers and make the law more difficult to implement and enforce. For example, some bowling alleys list themselves under the restaurant section of the phone book, and others do not. However, there are no meaningful differences in the menus of bowling alleys listed as restaurants and those that are not. In addition, some have signage indicating that the bowling alley serves as a restaurant and others do not. The FDA and/or state or local health departments would have to determine how many outlets within a chain position themselves as restaurants, making the law difficult to enforce.

The floor area requirement for venues that do not publicly present themselves as restaurants also would lead to inconsistencies and inequities in menu labeling requirements. For example, a chain food store with a café would have to provide menu labeling, whereas a similar café in a chain electronic or department store would not. Similarly, if a chain fast-food outlet is in a hospital, it would have to provide calorie labeling. Yet, if the hospital instead chose to run its

own food service, that cafeteria would not have calorie labeling even if the hospital is part of a chain (system of hospitals). A chain snack bar in a shopping mall would be covered, but a snack bar in a chain movie theater or train would not. In addition, there would not be an easy way for FDA or state or local agencies that may be charged with enforcing the law to know the percentage of floor space used for food preparation, sale, service, or consumption, or if the alternative percentage of revenue criteria is used, what percentage of a retail establishment's revenue came from the sale of food without the retail establishment divulging that information to regulators. Retail establishments likely would not want to have to report confidential internal information on its sales or floor space breakdown, which would determine whether or not it would be subject to the calorie labeling requirements. However, without this information, the FDA or other entities charged with enforcement of the law would not know which venues should be subject to the requirements and which are not.

We believe that if a retail establishment that serves food is part of a chain of 20 or more, it should provide menu labeling for its restaurant and restaurant-type food whether that food service is its primary business or not.

In addition, even using the proposed floor-space requirement, we believe that movie theaters would be covered by the law. Since many people purchase drinks and snacks and bring them to their seats, all of the seating area should be considered as a place where people are consuming food. This is no different than people purchasing food at the counter in a quick serve restaurant and bringing the food that they purchased to a table, the space for which would be included in the percent of a retail establishment's gross floor area used for food preparation, purchase, service, consumption, and storage. Typically, more than 50 percent of the space in a movie theater is occupied by the seating area. The proposed interpretation that multi-purpose seating areas used substantially for activities other than food consumption, such as seating in entertainment venues (e.g., shows, sport stadiums), would not be counted in the share of floor space devoted to the sale of food is arbitrary, subjective, and hard to implement or enforce. People eating in theater seats is analogous to people reading and checking their email while drinking coffee at Starbucks.

Also, if FDA decides to retain the primary business activity requirement, any floor space related to the preparation, purchase, service, consumption, or storage of alcoholic beverages should also be included in the calculation of the percentage of the retail establishment's gross floor space, or revenue under the alternative proposal, devoted to the sale of food. Alcoholic beverages are "food" as defined by the FDCA. *See* 21 U.S.C. §321(f) (2011).

E. The Proposed Definitions Raise Equal Protection Concerns

The FDA's proposed definitions also raise potential Equal Protection concerns because they could lead to irrational distinctions between similarly situated restaurant-food and restaurant-type food retailers. *See* U.S. Const. 14 Amend. § 1. The objective of Section 4205 is to allow consumers to obtain accurate nutritional information about restaurant-food and restaurant-type food from establishments that are part of a chain with 20 or more locations for the purpose of assisting them in making informed choices at the point of purchase. This nutritional information is equally relevant regardless of whether the food is purchased from a fast food

establishment in a shopping mall that is part of a chain of such establishments (within or outside malls) around the country; or whether it is purchased from a chain fast food purveyor in an amusement park that is part of a chain of similar outlets throughout the amusement park or a larger chain of locations throughout the country. Arguably, this information may be even more important for consumers in an amusement park, movie theater, or similar business, especially if that business prohibits consumers from bringing in their own food. In such circumstances, consumers are literally "captive" audiences and do not have other choices for obtaining food and drink.

The proposed definitions are likely to lead to a result where some chain restaurant-food purveyors will be required to provide nutritional information, while other, similarly-situated chain restaurant-food purveyors will not. This is precisely why the proposed approach raises potential Equal Protection concerns. For example, a Starbucks and a large chain general merchandise store's "Store X Café," located side-by-side within Store X are likely to be treated differently under the FDA's proposed definitions, despite the fact that both are "part of a chain with 20 or more retail locations doing business under the same name . . . and offering for sale substantially the same [restaurant-food and restaurant-type food menu items]." Yet, because Store X is a general merchandise store for which the "primary" business activity is *not* the sale of food as described in the Proposed Rule, its "Store X Café" likely would not have to comply with Section 4205's requirements while the Starbucks outlet would have to comply.

This disparate treatment of similarly-situated food retailers appears irrational, both from the consumer perspective and the business perspective. In contrast, the food-centered approach to the definition of "restaurant" and "similar retail food establishment" reflected in the FDA's 2008 Guidance[10] is logical as applied and consistent with the guiding principle that the labeling requirements should be viewed from the consumer's perspective—just as the FDA does in addressing how "menu" and "menu board" are defined for purposes of the Section 4205. This food-centered definition of "restaurant" is also more consistent with the National Restaurant Association's (NRA) understanding of the term. As the NRA notes on its website, "[S]ome of our members are restaurants operating within entirely different businesses. They are located inside hospitality businesses such as hotels and inside retail businesses such as grocery or convenience stores. They operate foodservice in schools, hospitals and workplaces."[11]

In addition to the proposed definition not being consistent with NLEA, it is at odds with the FDA's approach to vending machine labeling. The FDA has identified 10,000 companies that operate vending machines in the U.S. Although the FDA concluded that only 5,000 of those companies operate vending machines as their primary business, the proposed rule for calorie labeling of foods in vending machines would apply to all vending operators with 20 or more machines (to all 10,000).

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10 Ibid.

11 National Restaurant Association. "What We Do." Available at http://www.restaurant.org/aboutus/whatwedo/. Accessed on May 24, 2011.

Thus, the FDA should define "restaurant" and "similar retail food establishment" as a retail establishment that offers for sale food ready for human consumption either on or off its premises. We do not think that the FDA should retain the proposed "primary business activity" component for the definition of "restaurant" and "similar retail food establishment." This definition is consistent with the statutory language and history of the NLEA, including the language and history of Section 4205, and is consistent with real-world understandings of the term "restaurant."

Labeling of Restaurant and Restaurant-Type Food in Grocery, Convenience, and Superstores and by Managed Food Service

We support the FDA's conclusion that prepared foods sold at chain grocery and convenience stores are covered by menu labeling. Grocery stores sell a great deal of food for immediate consumption. It would be inconsistent if a stand-alone bakery had to provide calorie labeling, but the bakery in a grocery store did not. Grocery stores should provide calorie labeling for bakery items, prepared deli foods (such as potato salad, pasta salad, or sandwiches), prepared meals and side dishes, cooked pizza, fountain soft drinks, salad bars, and other food for immediate consumption. Although grocery stores sell many packaged foods that are covered by the NLEA, they also sell restaurant-type food, and should provide calorie labeling and nutrition information to their customers for those foods. The same is true for prepared foods in convenience stores, such as hot dogs, burritos, doughnuts, and fountain soft drinks.

In addition, it does not make sense for superstores to be treated differently than other grocery stores. Superstores that sell groceries and prepared foods should provide calorie labeling, just like other grocery stores, even if they also sell appliances, clothes and other non-food items.

The law does not allow an exemption from menu labeling for grocery or convenience stores based on an arbitrary percentage of total sales that are from food for immediate consumption, just as it should not exempt movie theaters or other retail food establishments that make money from activities other than food sales, as discussed previously. In addition, Congress did not provide an exemption for take-out foods. Industry assertions that the type of container the food is placed in or the provision of utensils should be an indication of whether a food must be labeled are erroneous. In addition, many restaurant foods are served in multiple servings, such as loaves of bread, whole cakes, whole pizzas, and buckets of chicken. Some restaurants also sell foods by weight, such as salad bar or buffet items. Just as those foods would be covered by menu labeling at restaurants, such foods from grocery stores also should provide calorie labeling.

In addition, FDA should make clear that food sold by contractors and managed food service should be covered if the establishments that are run by the company offer for sale substantially the same menu items using standardized recipes. For example, if a food-service-management company cooks the same recipes and has substantially similar menus at different workplace cafeterias or on college campuses, those cafeterias should provide calorie labeling. What is relevant to the law is that the company name is the same (i.e., ARAMARK, Compass Group, or Bon Appetit), not the name of the workplace or its cafeteria. If the majority of the menu items

and recipes are tailored specifically to an individual workplace, that workplace cafeteria would not be covered. Similarly, airlines that serve the same menu items or recipes on 20 or more planes should be covered.

Other Definitions Related to Covered Establishments

Doing Business Under the Same Name

We support FDA's proposed definition and agree that the name is the same even if there are modest variations in the name. We believe that the proposed definition should be broadened to include companies that have the same underlying name of ownership (parent company or contractor), regardless of the actual name of the restaurant or similar retail food establishment.

Offering for Sale Substantially the Same Menu Items

We support FDA's proposed definition of "Offering for Sale Substantially the Same Menu Items". We agree that restaurants and similar retail food establishments can still offer for sale substantially the same menu items even if the availability of some menu items varies within the chain and if some venues within the chain offer only a limited menu.

Foods and Beverages Covered by the Law

Restaurant Food and Restaurant-Type Food

We agree with FDA's proposed definition of "restaurant food". We also largely agree with FDA's proposed definition of "restaurant-type food". However, we recommend that FDA remove the phrase "and not offered for sale outside of that establishment" from the definition. Some restaurants and similar retail food establishments offer for sale items that are sold in their restaurant for sale outside of that establishment. For example, some restaurants, such as T.G.I. Friday's and California Pizza Kitchen, offer frozen versions of some of their menu items for sale in grocery stores, supermarkets, and convenience stores. Some bakeries covered by the law may also offer some of their baked goods for sale in grocery stores or other restaurants. The same is true for certain chain ice cream stores. Items that are offered for sale both in venues covered by the law and in other venues that may or may not be covered by the law should still be considered restaurant or restaurant-type food when offered for sale in a restaurant or similar retail food establishment.

Standard Menu Item

We agree with FDA's proposed definition of "standard menu item" and their inclusion in this definition of items listed on menus or menu boards, self-service foods, and food on display. We agree that multi-serving foods can be considered standard menu items. The number of servings an item contains or the number of people that are intended to consume it should not impact whether or not a food or beverage meets the definition of a standard menu item and is required to have calorie labeling and nutrition information.

We also agree that food on display should be included within the definition of standard menu items covered by the law, even if these foods are behind glass, plastic, some other viewing apparatus, or behind the clerk. Food on display should be covered if the customer can view item before purchase, regardless of whether or not there is an ordinary expectation that the customer will do something else with the foods before consumption. For example, deli meats and cheeses should be covered, even though one may make them into a sandwich before consuming them. They still were sliced and prepared in the retail food establishment. In addition, take out foods that were prepared in a restaurant may still be heated up at home before they are eaten, and these foods also should meet the definition of restaurant or restaurant-type food.

We also agree with FDA's proposed definitions of custom orders, daily specials, food that is part of a market test, temporary menu items, and condiments. We agree that these items are exempt from the requirements of the rule.

For standard menu items, we agree that calories must be listed for each standard menu item as usually prepared and offered for sale. The total calorie number posted must include all of the components that are included in the standard menu item and that are listed in the menu description. Although condiments for general use are exempt from the calorie labeling requirement, any condiments that are put on or come with an item "as it is usually prepared and offered for sale", should be included in the calorie count for that item. For example, if a sandwich usually comes with mayonnaise, or a side of mayonnaise, the calories in that mayonnaise should be included in the calorie count, but if mayonnaise is placed on a counter for general use by all customers, the calorie information for that mayonnaise need not be provided.

All components in an item as it is usually prepared and offered for sale should be included in the calorie count. For example, if a menu selection lists that a salad comes with lettuce, beans, meat, salsa, cheese, and dressing, the calorie information on the menu or menu board should include the total number of calories in all of those components. The restaurant should be considered out of compliance if it does not include all those components. That is, the range listed cannot be for a salad with just meat and lettuce or just beans, salsa, and lettuce. A salad with just those items would be considered a custom order, and custom orders are not covered by the menu labeling requirements.

Alcoholic Beverages Should Be Included Within the Scope of the Requirements of Section 4205 and the Proposed Regulations

We respectfully disagree with the FDA's proposal to exclude alcoholic beverages from the requirements of Section 4205. We believe that alcoholic beverages should be covered by Section 4205 for both health and legal reasons and that calorie labeling for alcoholic beverages would not be too difficult or burdensome for the industry.

Alcoholic beverages are consumed regularly by 50 percent of Americans and infrequently by another 14 percent of Americans.[12] They also contribute a substantial portion of the total calories that the average American adult consumes. At 5 percent of total calories, they represent the fifth leading source of calories in American adults' diets.[13] Calories in alcoholic beverages count toward overweight and obesity just like calories in foods and other beverages.

Exempting alcoholic beverages from the menu labeling requirements would not allow people to be able to compare options and make informed choices. It might be confusing to customers if, within the beverage section of the menu, some drinks are labeled and others are not. For example, they would be able to see that the Cherry Limeade has 230 calories, but would not be able to tell that the Long Island Ice Tea (an alcoholic beverage) has about the same number (200 calories). The absence of calorie labeling for alcoholic drinks could give the impression that they are a lower-calorie choice than labeled beverages on the menu.

The calorie content of alcoholic beverages can vary widely. Consumers are likely to have difficulty identifying lower calorie options, as has been found for other restaurant foods.[14] For example, at TGI Fridays, the Fresh Mango Lemonade Shaker (410 calories) has twice the calories of the Lemon Twist Martini (200 calories). Individual drinks can pack a meal's worth of calories. The Mudslide at Applebee's has 880 calories. Failing to provide consumers with calorie information for alcoholic beverages will make it more difficult for them to follow the 2010 *Dietary Guidelines'* advice to "control total calorie intake to manage body weight."

In addition, *the American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention*[15] and the 2010 *Dietary Guidelines* both recommend that alcohol only be consumed in moderation, which is defined as up to one drink per day for women and up to two drinks per day for men. Providing Americans with information about the caloric content of alcoholic beverages may lead them to reduce their consumption in order to reduce their caloric intake, concurrently reducing their risk of certain types of cancer and other health risks associated with alcoholic beverage consumption.

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12 U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans 2010*. Available at www.dietaryguidelines.gov.

13 U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans 2010*. Available at www.dietaryguidelines.gov.

14 Backstrand J, Wootan MG, Young LR, Hurley J. *Fat Chance*. Washington, DC: Center for Science in the Public Interest, 1997. Burton S et al. "Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants." *American Journal of Public Health* 2006;96:1669-1675. Kozup KC, Creyer EH, Burton S. "Making Healthful Food Choices: The Influence of Health Claims and Nutrition Information on Consumers' Evaluations of Packaged Food Products and Restaurant Menu Items." *Journal of Marketing* 2003;67:19-34. Wansink B and Chandon P. "Meal Size, Not Body Size, Explains Errors in Estimating the Calorie Content of Meals." *Annals of Internal Medicine* 2006;145:326-332.

15 Kushi LH, Byers T, Doyle C, et al. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention: Reducing the Risk of Cancer With Healthy Food Choices and Physical Activity. *CA Cancer J Clin* 2006; 56: 254-281.

The final rule should also apply to alcoholic beverages for legal reasons. As the FDA correctly noted in the Notice, it is undisputed that alcoholic beverages are "food" as defined under the Federal Food, Drug & Cosmetic Act (FDCA) of 1938, 21 U.S.C. §§301 et seq. *See, e.g., Brown-Forman Distillers v. Mathews,* 435 F. Supp. 5, 12 (W.D. Ky. 1976). Thus, alcoholic beverages are also "food" for the purposes Section 4205. Further, it is undisputed that the FDA has authority to regulate labeling of alcoholic beverages with a low alcohol content, and to enforce the adulteration provisions of the FDCA with respect to all alcoholic beverages. Where confusion arises is regarding FDA authority to enforce the misbranding provisions of the FDCA over certain alcoholic beverages, based on one federal trial court opinion from 1976, which involved ingredient labeling. This case, *Brown-Forman Distillers v. Mathews,* 435 F. Supp. 5 (W.D. Ky. 1976) held that the Federal Alcohol Administration Act (FAAA)[16] demonstrated an "implied intention" by Congress to remove the FDA's authority to impose ingredient labeling requirements on distillers, vintners, and others regulated by the FAAA.

The *Brown-Forman* case is not controlling or even relevant for a number of reasons.

First, the new menu labeling law includes clear language exempting certain foods from its requirements, and the law does not exempt alcoholic beverages. 21 U.S.C. §343(q)(5)(H)(vii) (2011). Because the statute explicitly sets forth which foods it exempts, there is no need to imply an intention by Congress to include additional foods, such as alcoholic beverages. The federal menu labeling law demonstrates Congress' intent to give the FDA, not the Alcohol and Tobacco Tax and Trade Bureau of the Treasury Department (TTB), authority to specifically require the disclosure of calorie and related nutrition information by restaurants and similar retail food establishments for all foods except those specifically exempted.

Second, the *Brown-Forman* case was interpreting 27 U.S.C. § 205(e), a provision of the FAAA that is not relevant to most, if any, large chain restaurants and similar retail food establishments. The FAAA imposes certain obligations, including certain labeling obligations, on "any person engaged in business as a distiller, brewer, rectifier, blender, or other producer, or as an importer or wholesaler, of distilled spirits, wine, or malt beverages, or as a bottler, or warehouseman and bottler, of distilled spirits, directly or indirectly or through an affiliate." 27 U.S.C. §205 (2011). In contrast, the menu labeling law imposes requirements upon large chain retailers that sell restaurant-food and restaurant-type food, as well as vending machine owners and operators. 21 U.S.C. §343(q)(5)(H) (2011). Thus, these two laws address largely different economic actors. The U.S. Supreme Court has noted, "The courts are not at liberty to pick and choose among Congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed Congressional intention to the contrary, to regard each as effective." *Morton v. Mancari*, 417 U.S. 535, 551 (1974). Here, there is no need to pick and choose between the FAAA and Section 4205—both of these statutes are capable of co-existence because they apply to different groups.

16 27 U.S.C. §§201 et seq. (2011).

Third, the reasoning of the *Brown-Forman* court has been called into question by legal scholars, with good cause. *See, e.g.*, Iver P. Cooper, *The FDA, the BATF, and Liquor Labeling: A Case Study of Interagency Jurisdictional Conflict*, 34 Food Drug Cosm. L.J. 370 (1979); and Elaine T. Bysewski, *What's in the Wine? A History of FDA's Role*, 57 Food & Drug L.J. 545 (2002). As these commentators note, the FDCA's plain language as well as its legislative history demonstrate that Congress intended that the FDA should be able to regulate the labeling of alcoholic beverages, and in fact had done so prior to the *Brown-Forman* case. Yet, the *Brown-Forman* court minimized or simply ignored this history. Due to the vagaries of circumstance, this trial court opinion avoided appellate review and thus has stood as the sole decision touching on the issue for over 35 years. One questionable trial court opinion should not be given undue weight in driving the future of all alcoholic beverage regulation even remotely touching on "labeling."

Fourth, even assuming for the sake of argument that *Brown-Forman* was correctly decided, the reach of the implied exemption for alcohol found by that case is limited to its facts. That case dealt with the FDA's authority to impose *ingredient* labeling requirements on alcoholic beverages, not its authority to require *nutritional* disclosures by restaurants and similar retail food establishments. *Brown-Forman*, 435 F. Supp. at 17 (noting that the Bureau of Alcohol, Tobacco and Firearms or BATF (the TTB's predecessor) held six days of public hearings and reviewed over 1,000 written comments on *ingredient* labeling of alcoholic beverages, and referring to the five reasons that BATF decided to withdraw its proposed regulation, which all related to *ingredient* labeling). Based on the evidence before it at that time in 1976, it appeared reasonable to the court to treat ingredient labeling for alcoholic beverages differently from ingredient labeling for other foods. Thus, the court held that Congress impliedly intended to grant TTB's predecessor, the BATF, exclusive authority over this aspect of alcoholic beverages. For example, the court noted that the BATF found that ingredient labeling was determined to involve excessive costs both to the industry and consumers; that ingredient labeling would be "of little value and, in certain cases, even misleading"; and that ingredient labeling could even "hinder current international trade negotiations." *Brown-Forman*, 435 F. Supp. at 17. However, even if these reasons are still applicable today, which is questionable, they are irrelevant to the federal menu labeling requirements because they require *nutritional* disclosures by *restaurants* and *similar retail food establishments*. Thus, the *Brown-Forman* case cannot be relied upon as limiting the FDA authority in the menu labeling context.

FDA can address concerns about difficulties raised in comments about establishing calorie and other nutrient content by providing guidance for what is a "reasonable basis" for these disclosures for alcoholic beverages pursuant to 21 U.S.C. §343(q)(5)(H)(iv) and the relevant regulations.

Availability of Nutrition Information for Alcoholic Beverages

In addition to being supported by the law, providing calorie and other nutrition labeling for alcoholic beverages is feasible. Alcoholic beverage labeling is already provided on menus in many jurisdictions, including New York City and Philadelphia.

FDA's proposed rule suggests that it would be difficult for restaurants to provide nutrition information for alcoholic beverage because nutrition labeling has not been required for packaged alcoholic beverages. That assertion ignores the availability of multiple data sources for alcoholic-beverage calorie and nutrient information. Nutrition information from nutrient databases and menu analysis software could easily provide the required information and qualify as the "reasonable basis" required by Section 4205 for nutrient calculations. Chain restaurants would not need to rely on alcohol producers, including small alcohol producers. For example, the USDA nutrient database includes full nutrition information for regular beer, light beer, more than 30 types of wine (including composite values for table wine), and distilled alcoholic beverages from 80 to 100 proof.

Restaurants would not have to test each bottle of wine or micro-brewed beer for its nutritional value. While there is some modest variation in the calorie content of different wines or the same wines of different vintages, that variation should not pose a barrier to providing reasonable nutrition information to consumers. Many of the other foods that the FDA has concluded should be labeled in chain restaurants experience similar variations. For example, the calorie and fat content of cuts of meat may vary, depending on the season and what the animals are fed. The FDA has determined that the use of nutrition information from databases is acceptable for such foods. The FDA should make clear in the final regulations that the concept of reasonable-basis determinations applies equally to alcoholic beverages. That should help reassure restaurants and alcoholic-beverage manufacturers that the feared burdens of alcohol labeling will be insignificant.

In applying menu labeling to alcoholic beverages, the FDA should not use the approach adopted by Seattle/King County, Washington. In King County, average calorie values for alcoholic beverages are listed, without adjustments for portion sizes or the addition of mixers. That compromise approach provides nutrition information that is too generic to be useful to consumers. Restaurants should be required to adjust the calorie content of alcoholic drinks to the portion sizes they serve and include the calories for mixers, which can add significantly to the drink's calories. For example, a shot of 90-proof rum contains 110 calories. Yet a strawberry daiquiri made with that rum might provide about 400 calories.

Calorie Declaration on Menus and Menu Boards

Definition of Menu or Menu Board

We support FDA's proposed definition of "menu or menu board" as "the primary writing of the restaurant or other similar retail food establishment from which a customer makes an order selection" and FDA's proposal to define "primary" from the perspective of the consumer. We agree that this should include all menus in the restaurant or similar retail food establishment, take out and delivery menus, and Internet menus.

We strongly agree with FDA's proposal that "primary writing" should be interpreted from the customer's vantage point. The customer needs to see the calorie information when they are

making their menu selection in order for it to be useful to them. Even if consumers cannot order online (must order by phone or in person), consumers may use an internet menu to make their menu selection and then call in their order. Or a customer may make their order selection online and have someone else actually travel to the restaurant to place and pick up their order. If a menu is posted online, we believe that it should be required to include calorie information and a link to the required additional nutrition information.

We also agree with FDA's tentative conclusion to disallow the use of stanchions at drive throughs because they inadequately convey calorie information. With a stanchion, a customer would have to look at one board for important food selection information, such as price, and another for calories. This would make viewing and using the calorie information difficult when customers have a relatively narrow field of vision and short time to view the menu.

Prominence of Calorie Information

We support FDA's proposal that calorie declarations on menus and menu boards must be made in the same color, or in a color as least as conspicuous as, the color of the associated standard menu item and have the same contrasting background as the background used for the name of the associated standard menu item. However, in contrast with FDA's proposal, we recommend that the calorie declaration be no smaller than the type size of the name or price of the associated standard menu, whichever is larger, rather than whichever is smaller as FDA proposed. It is important that the calorie information be clear and conspicuous in order for consumers to be able to notice, read, and use the calorie information in their food selection decisions. FDA's draft implementation guidance published on August 25, 2010 that was subsequently withdrawn on January 25, 2011 recommended that calories be declared in a type size at least as large of the name of the standard menu item or price, whichever is larger, and with the same prominence, i.e. same color and contrasting background as the name and price of the standard menu item. FDA has not provided a reason for its change in thinking.

Format of Calorie Declarations

We agree with the FDA that calorie postings must be directly adjacent to the menu item name or price. It must be clear which calorie number goes with which menu item. This proximity is essential to making the calorie information easy to find and use.

We also agree that the word "calorie" or "cal" must be adjacent to the calorie number. People are not accustomed to having calorie labeling in restaurants. Without this identifier, it might be unclear what the number means.

We support FDA's proposal for rounding numbers in calorie declarations, as is required for calorie information in the Nutrition Facts Panel. Unrounded calorie numbers would imply a precision that is misleading. Also, it is more difficult to make comparisons between unrounded numbers.

Additionally, we recommend that the FDA add to the final regulations that calorie numbers over 1,000 must include a comma to make it easier for people to read the numbers. People are accustomed to seeing commas after the thousands place. Menus should comply with that standard way of presenting numbers. For example, calories should be posted as 1,220, not as 1220. A new subparagraph under (2)(A) should be added before subparagraph (2)(A)(4) on variable menu items:

(4) Calorie numbers over 1,000 must include a comma after the thousands place.

Variable Menu Items

We believe that further research is needed to determine the most effective way of labeling variable menu items, which are defined in the proposed rule as standard menu items that come in different flavors, varieties, or combinations but are listed as a single menu item. In the proposed rule, FDA listed several options for calorie declarations for variable menu items that were considered and proposed that the second option, requiring calories for variable menu items to be presented in a range, be the required format. We are concerned, for combination meals in particular, that the potential range of calories for some variable menu items could be too large to provide consumers with any useful information to facilitate their selection of healthier options. For example, a ¼ lb single hamburger combination meal at Wendy's could range from 575 calories, with a garden side salad and diet coke, to 1,030 calories, with a small fries and small diet coke. That is a range of nearly 500 calories, all for the small size meal. Using wide ranges for variable menu items does not provide consumers with useful information to allow them to know the relative number of calories that each flavor or combination contains, or how many calories would be in a particular flavor or combination.

FDA noted in the proposed rule that it plans to conduct consumer research to evaluate how well consumers understand the caloric information presented in each of the formats for variable menu items that FDA considered and whether mixed formats on a single menu or menu board might be confusing. FDA further noted that it plans to make the results of their consumer research available to the public prior to publication of the final rule and will allow sufficient time for stakeholder comment on the research results. ACS CAN is pleased that FDA plans to conduct research on potential formats of presenting calorie information for variable menu items and looks forward to reviewing the results of this research as soon as it is made public. We recommend that FDA include in the final regulations the option for displaying calorie information for variable menu items that is most useful to consumers and best allows them to select healthier items or combinations of items among the available options.

In addition to basing the requirement on the results of consumer research, we recommend that FDA provide additional direction and requirements for labeling of calorie information for individual flavors and items in a combination meal whenever possible. FDA should clarify that variable menu items do not include a food item that is listed on the menu in different sizes. Each size of a menu item listed on the menu, menu board, or display tag must be accompanied by a calorie posting. For example, calorie information should be provided for all serving sizes of soft drinks or French fries.

The FDA should also make clear in the final rule that variable menu items do not include items that are listed on the menu that can be put together in varying combinations. The law requires all items listed on the menu to be labeled. For example, calories must be posted for each pizza topping, sandwich component, omelet selection, sundae toppings, or salad ingredient or dressing that is listed on the menu or that is on display. For self-service food or food on display, calories should be provided for each flavor or item. We also recommend that calorie information for very low or no calorie beverages be listed separately from other caloric beverages, whenever possible.

For variable menu items appearing on the menu or menu board that are self-service foods or food on display with no clearly identifiable upper bound, such as an all-you-can-eat buffet, we agree that the menu or menu board include a statement, adjacent to the name or price of the item, referring customers to the self-service facility for calorie information, e.g.; ``See buffet for calorie declarations.'' This statement should appear in a type size no smaller than the name or price of the variable menu item, whichever is larger, and in the same color or a color at least as conspicuous as that name or price, with the same contrasting background as that name or price.

Succinct Statement Concerning Daily Suggested Caloric Intake

The law requires menus and menu boards to include a succinct statement regarding suggested daily caloric intake to enable diners to put the calorie labeling for menu items into the context of a daily diet. The contextual statement is required by law to be succinct. The statement also should be clear, easy to comprehend, and help people understand how the calories posted on the menu compare to recommended calorie intakes.

FDA noted in the proposed rule that it intends to conduct consumer research to evaluate consumer response to the potential statements listed in the proposed rule and intends to make the results of the research available to the public prior to publication of the final rule and to allow sufficient time for comment. ACS CAN is pleased that FDA plans to conduct research on potential statements about recommended daily caloric intake and looks forward to reviewing the results of this research as soon as it is made public. It is important that individuals be able to put the calorie information that they will see for menu items within the context of their daily caloric needs.

We agree with the proposed rule that 2,000 calories is the appropriate number to use for a statement regarding calorie needs for adults. Using the same daily calorie recommendation for menus and for the Nutrition Facts Panel would minimize consumer confusion. The 2,000 calorie number is suitable for the U.S. population given that two-thirds of American adults are either overweight or obese.[17] Because the majority of the U.S. adult population is overweight or obese, the statement about calorie needs should steer the population toward a calorie intake that would promote weight loss for most adults. If the calorie basis for Daily Values on

17 Flegal KM, Carroll MD, Ogden CL and Curtin LR. Prevalence and Trends in Obesity Among US Adults, 1999-2008. *JAMA* 2010; 303(3):235-241.

the Nutrition Facts Panel is changed for packaged-food labeling, the FDA also should adjust this statement on menus and menu boards to make it consistent.

In developing the final regulations for the succinct statement concerning recommended calorie intake, we recommend that FDA consider the above recommendations as well as the results of their consumer research. FDA should require that the statement shown to be most useful to consumers in understanding the context of the calorie information and their approximate calorie needs in achieving or maintaining a healthy weight be used.

We support the FDA's proposal for placement of the succinct statement on each page of the menu and once on the menu board in a font no smaller than and as prominent as the calorie postings. That should help to ensure that the statement is as easy to see and read as other basic ordering information. We agree that the statement should be placed above the notice regarding the availability of the additional nutrition information.

Additional Nutrition Information

We support the FDA's proposal for the wording, placement and prominence of the statement regarding the availability of the additional written nutrition information. The proposal would make it as easy to see and read the statement as the other basic ordering information.

We agree that the menu items must be listed in the same order in the additional nutrition information as they are listed on the menu or menu board; otherwise the information would be unnecessarily difficult to use.

We also agree that it makes sense to round the nutrient disclosures in the same way as for packaged food labeling.

We agree with the FDA's proposal that trans fat be included among the nutrition information provided, given the detrimental health effects of trans fat and that trans fat is required to be listed on the Nutrition Facts Panel. We support removing complex carbohydrates from the list of required nutrition information. We also recommend that the weight of the product in grams be included with the additional nutrition information. Weight in grams is required on the Nutrition Facts Panel and is an important indicator of portion sizes, is needed to determine caloric or nutrient density, and is essential for determining if health and nutrient content claims are accurate.

For variable menu items, as defined in the proposed rule, we strongly support the FDA's proposal to require that the nutrition information be provided for each basic preparation of a menu item and separately for each topping, flavor, or variety. Under this proposal, the additional nutrition information that the law requires be made available would provide consumers with a way to obtain specific calorie information for items that FDA allows be listed as ranges or averages on menus or menu boards.

We agree that the additional nutrition information must be provided for food on display, including salad bars and buffets. Many restaurants have menu items that are not listed on menus, but are on display, and it is important for consumers to be able to obtain nutrition information for these items.

With respect to the format of the additional written nutrition information, the information should be clear and easy to read and comprehend. The information should be provided in a font size and style to make it easily readable and presented using a contrasting background. We also support requiring that the information about the required nutrients be presented in the order in which the nutrients are listed in the proposed rule. This is the order in which consumers are used to seeing these nutrients listed in the Nutrition Facts Panel.

We do not recommend that FDA require nutrients that are particularly important to consumers with specific diseases, such as obesity or diabetes, to be highlighted using bold text or placed in a separate table. The most important nutrient for individuals who are overweight or obesity to pay attention to is calories, and this information will already be provided on the menu or menu board. The majority of people who will request to see the written nutrition information will likely be individuals who are interested in information about the amount of specific nutrients other than calories that certain items contain. Different people have different dietary needs, concerns, and health conditions and will therefore have different nutrients of concern. Other than calories and serving size, it would not be appropriate for FDA to require that certain nutrients be highlighted in the Nutrition Facts Panel over others.

The written nutrition information should be readily available immediately before or at the point of purchase, the place and time where the consumer makes their menu selection. It should not be provided in a format that requires people to leave their place in line or leave their table to access it. The nutrition information also should not be provided in a format that greatly hinders the speed of ordering. For example, the additional nutrition information should not be provided via a poster at the back of the restaurant.

The format should allow people to make comparisons between menu items. For example, information provided through a computer kiosk or website on which only one or a small number of menu items could be viewed at a time would not satisfy this requirement. Making comparisons between items is a key way that people use nutrition information. People not only want to know that a Burger King Tendergrill Garden Salad with fat-free ranch dressing has 290 calories, but also that it has 310 fewer calories than the Tendercrisp salad with regular ranch (which has 600 calories).

The additional nutrition information should also be required to include the succinct statement about recommended daily caloric intake to help people put the calorie information into context. People who are interested in comprehensive nutrition information may look at the calorie information primarily from the brochure or other device used to provide the additional nutrition information. It would be helpful to them to be able to put the calorie information into context when using the calorie listings from the brochure.

Display of Calories for Self-Service Foods or Foods on Display

We support FDA's tentative conclusion in the proposed rule that when a self-service food or food on display already has an adjacent sign with the name and/or price, calories must be provided on that sign in the same color or at least as conspicuous a color and no smaller a type size than the name or price, with a contrasting background. We recommend that there not be the option to instead provide a separate sign with the calorie information adjacent to the food item. Calorie information should be provided in the most clear and conspicuous manner possible, and it could be confusing for there to be multiple signs for each food item.

We also support FDA's proposal that self-service food or food on display without an adjacent sign with its name or price be required to have an adjacent sign with its calorie information labeled clearly and conspicuously. The FDA should specify that calorie information must be easy to read from the point where someone is choosing his or her food. It also should be clearly apparent which sign goes with each item, by proximity and by including the name of the product.

Calorie and other nutrition information should be provided for the portion size of the menu item as offered for sale. For example, calories should be posted at the fountain-soda dispenser for each size beverage available. Scones, muffins, and other items should be labeled for the size of the item as sold. For self-serve items that consumers can serve in varying amounts, such as items at a buffet or salad bar, nutrition declarations should be per item for a food or beverage that comes in discrete items and the usual serving is one item, such as for an ear of corn or a baked potato. When a single item is not a typical serving size, the size of the serving utensil should be used as the serving size, whenever possible, or the standard serving size of the item for packaged foods. The serving size for items that do not come in a standard size should be included on the sign with the calorie declaration for the item.

FDA notes in the proposed rule that some packaged foods required to bear nutrition information under NLEA would meet the definition of "self-service food" or "food on display". We support FDA's tentative conclusion that packaged food that is self-service food or food on display doesn't require calorie labeling as long as the consumer can examine the calorie information on the Nutrition Facts Panel prior to purchase. However, we agree that calorie labeling would still be required for standard menu items listed on menus or menu boards and for variable menu items that are combination meals that include a packaged food, such as a combo meal that includes a sandwich, packaged chips, and a drink. We also agree that foods that are covered by this law that voluntarily provide nutrition information on the package still must comply with the calorie labeling requirements in this law, but the nutrition information on the package would suffice for the additional nutrition information that is required to be made available, as long as the consumer could examine the nutrition information on the package immediately prior to or at the point of purchase.

Timeline for Implementation

We strongly support the FDA's proposal to enforce the final menu labeling regulations six months following publication of the final rule. Many local menu labeling laws were implemented and enforced approximately six months after enactment, including in Seattle/King County, WA; Montgomery County, MD; and the New York State counties of Westchester, Albany, and Ulster. Most large chains have already analyzed the calorie content of their menu items because they have outlets in cities or states that already require menu labeling or they already voluntarily provide nutrition information to their customers. Even for those that have not, menu analysis should be underway already and menu redesign should be possible within six months after publication of the final rule. We recommend that FDA provide chains subject to this law with tools and technical assistance, subject to the availability of funds, to facilitate compliance.

Consumer Awareness, Technical Assistance, and Enforcement

To ensure that the law has the greatest possible impact, ACS CAN encourages the FDA to put strong enforcement mechanisms in place to ensure compliance with the law. We encourage the FDA to make information about the requirements of law publicly available to retail food establishment and vending machine owners and operators and consumers. Research shows that consumers want more information about the calorie and nutrient content of the foods they may choose to consume. More than 70 percent of respondents in a 2009 national survey indicated that they desired restaurant calorie labeling.[18]

To make menu labeling as useful as possible, the FDA, working together with state and local health departments, public health and nutrition organizations, and the National Restaurant Association and its affiliates, should mount a comprehensive promotion and education campaign to alert consumers to the availability of the nutrition information in restaurants and give tips on how to use it to make healthier menu selections. Some observers have suggested that Nutrition Facts labels have not been as effective as they could be because of the lack of a sustained, attention-getting education program. Consumers should be informed about menu labeling through public health communications campaigns that make use of various forms of media including restaurant signage, television and radio advertisements, the Internet, and social media campaigns.

Information and support for the retail food industry would help to ensure compliance with the law. ACS CAN recommends that training and technical assistance be made available for retail food establishment owners who are subject to the law or who may voluntarily register to become subject to the law. This information and assistance should be available in multiple formats and through multiple vehicles. Training and technical assistance should include information about the requirements of and who is subject to the law, requirements for mandatory and/or voluntary registration, information about resources and acceptable means

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18 Kolodinsky J, Reynolds TW, Cannella M, Timmons D, and Bromberg D. U.S. Consumer Demand for Restaurant Calorie Information: Targeting Demographic and Behavioral Segments in Labeling Initiatives. *Am J Heal Promot* 2009; 24(1): 11-14.

for determining calorie and nutrient content, examples of ways to comply with the law, and answers to questions frequently asked by retail food establishment and vending machine owners and operators.

A well-articulated and credible enforcement regime is essential in order for the menu labeling law to be able to accomplish the purpose for which it was enacted. Because the federal menu labeling law may supplant several actively enforced local and state regimes, the need to ensure proper enforcement is especially important.

The FDA can support enforcement of the law in several ways:

A. *FDA should support development and enforcement of state and local nutrition labeling requirements.*

The FDA should support state and local initiatives to enact "identical" restaurant labeling requirements. For reasons of familiarity, tradition, and established practice, local and state authorities are more likely to enforce their own laws than they are to enforce the federal law. Thus, the FDA should encourage and facilitate state and local enactment of new menu labeling laws and amendment of existing menu labeling laws by providing technical assistance to jurisdictions that are working to enact "identical" disclosure requirements in their laws or amend their existing law to make it "identical". The FDA could provide this assistance in various ways, including: 1) making staff available upon request to help assess proposed language for potential conflicts with the federal law; and 2) providing model legislation. The FDA should reiterate in their technical assistance that the *language* of the state or local measure need not be the same as the federal law in order for the relevant labeling requirements to be considered "identical." 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. *See* 21 C.F.R. 100.1(c)(4).

A significant benefit of local statutory regimes is that they allow states and municipal governments to make use of their existing inspection and enforcement apparatus. We recommend that language be added to the final rule that makes express an assumption that is implicit in the proposed rule: that enforcement provisions included in state or local menu labeling laws -- for example, the administrative processes or remedies used to bring about compliance -- are not affected by Section 4205 and need not be "identical" to those of the federal regime. Such a statement would be fully consistent with a statute that explicitly contemplates the parallel existence and operation of state and local menu labeling regimes.

With many large nationwide chains there may be no need for enforcement to occur in every state or county, since a few jurisdictions actively enforcing the federal law or their own laws may have a nationwide effect. However, the existence of smaller and regional chains confirms the need for a broad and readily accessible enforcement regime.

B. FDA should support state and local enforcement of the federal law.

Restaurant inspections are historically a state and local responsibility. The FDA should provide guidance, training, and funding to states and localities to facilitate enforcement of the federal statute.

An approach analogous to the contractual regime used in food safety inspections could be employed. Indeed, local restaurant inspectors could add menu labeling inspections to their responsibilities, much as state and municipal food safety inspectors working under federal contract also inspect and enforce packaged food labeling under the NLEA. However, providing states and localities with this inspection authority should be explicit.

The President's proposed 2012 budget includes funds for the enforcement of the federal menu labeling law. Alternative sources of funding -- including direction of penalties and fines to the inspecting authority -- should be considered as well. Providing state and local governments with enforcement authority and at least partial responsibility without enhancement of their capacity or available resources would hinder their enforcement efforts.

c). FDA should require all covered chains to register with the FDA.

The FDA should consider developing and implementing additional measures to increase compliance with the requirements of the law. One strategy that we recommend includes requiring all owners or operators of food retail establishments and vending machines subject to the law to register with the FDA. FDA should then create a publicly-available database with this information. The law currently requires that food retail establishments and vending machine owners and operators voluntarily selecting to be subject to the law register with the FDA once every two years. However, FDA currently has no way of counting, tracking, or holding accountable venues for which compliance with the law is mandatory. Chains subject to the law should be required to provide the same information to FDA as chains that voluntarily choose to register. FDA could also track violations of the law in this same database. We also recommend that FDA set up a phone hotline and website through which consumers or state and local health department staff can ask questions or report possible violations of the law. This system would allow state and local public health departments and boards of health to know which retail food establishments are subject to the law, facilitate checks for compliance, and ensure that covered venues that are out of compliance can be held accountable.

The FDA, and any other federal, state, or local entities it empowers to enforce the law on its behalf should confirm that covered establishments meet all of the requirements for format, placement, and prominence of the required calorie and other nutrition information and ensure that the calorie and other nutrition information provided is accurate. As reflected in the statute and proposed rule, covered food establishments must have a reasonable basis to support their nutrient content disclosures. The final rule should clearly state that covered establishments are responsible for maintaining the accuracy of those disclosures, including keeping this information up-to-date as their menus change. FDA should develop a process for verifying the accuracy of the nutritional information provided by chains.

ACS CAN encourages all retail food establishments and vending machine operators to provide clear, simple calorie and other nutrition information to consumers regardless of whether or not they are required by any federal, state, or local law to provide this information.

Preemption

Preemption of state and local authority is disfavored in the public health arena, where state and local governments historically and traditionally have had broad authority to regulate. Requiring retail food establishments to disclose nutritional information so that consumers can make informed choices falls squarely within this traditional realm of state and local authority. The Proposed Rule recognizes that while Section 4205 restricts state and local authority to impose menu labeling requirements on restaurants and similar food establishments, Congress clearly intended that state and local governments retain the remainder of their traditional authority in this area.

We support the FDA's reading of the preemptive scope of Section 4205 as limited to calorie and other nutritional 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 Proposed Rule must not create a regulatory vacuum. The final rule should include an explicit statement that the scope of the law's preemptive effect is coextensive with the law's nutrition labeling requirements; that is, the only state and local provisions that are preempted are those that explicitly require the type of menu labeling required by Section 4205 at a covered establishment. For example, if the FDA decided not to cover theaters, hospitals, or other establishments in the final rule, then states and localities could enact laws to cover them. In addition, if the FDA decided to exempt alcoholic drinks from menu labeling, state or local menu labeling requirements for alcoholic beverages would not be preempted.

This interpretation would conform to the NLEA's and Section 4205's bar on implied preemption. 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 prevent chronic disease. It is especially important that their freedom to experiment not be curtailed by an inappropriately broad reading of Section 4205's preemptive language.

Additionally, the savings clause for warnings about the safety of food or a component of the food is included in a section designated "Rule of Construction" that is not codified. See Section 4205(d). The exclusion of the Rule of Construction from the text of the codified version may lead to confusion over how the statute should be interpreted. Thus, we urge the FDA to include the Rule of Construction in the CFR. The lack of a codified statement of a similar rule of construction in the NLEA has led to confusion and to court decisions that did not take that rule into account. *See, e.g., In re Farmed Raised Salmon Cases*, 142 Cal.App.4th 805 (Cal. Ct. App. 2006) (later overruled by California Supreme Court, which relied on the uncodified provision); *Cohen v. McDonald's Corp.*, 347 Ill.App.3d 627 (2004). Ensuring that the rule of construction is explicitly set out in the CFR could help to avoid similar problems with the menu labeling law.

The FDA is also correct that state and local governments retain their authority to 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.

We believe, however, that the final rule should more explicitly set forth the limitations on the preemptive effect of Section 4205. Given the presumption against preemption in public health matters, and specifically in areas affected by this statute, the final rule should contain a more explicit statement of non-preemption than what is included in the Proposed Rule. *See* Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (21 U.S.C. § 343-1 note (NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1(a)] of the [FDCA]"); *NYSRA v. NYC Bd. of Health*, 556 F.3d 114 (2nd Cir. 2009). *See also Memorandum for the Heads of Executive Departments and Agencies*, Office of the Press Sec'y, The White House (Executive Order 13132) (May 20, 2009).

For example, the final rule should explicitly state that 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. Thus, we suggest the following language be added: "The specific words of the state or local requirements need not be the same. State or local requirements that are worded differently from the federal requirements and/or provide for different enforcement schemes may still be 'identical' under Section 4205."

Conclusion

Overall, ACS CAN supports the FDA's proposed rule for menu labeling at chain restaurants and other similar retail food establishments. We strongly urge the FDA to revise its definition of venues covered by the law and to require labeling of alcoholic beverages. We believe that these two key recommendations would allow the regulations to have a larger impact on consumers' awareness of healthy options and ability to choose them, as well as the overall nutritional profile of foods and beverages available in the marketplace.

We thank the FDA for its work to implement the menu labeling requirement in Section 4205 of the ACA and respectfully urge that it issue a strong final rule in a timely manner and provide companies with six months to implement the regulations following publication of the final rule.

We look forward to working with you to provide consumers with calorie and other nutrition information for standard menu items offered for sale in chain restaurants and other retail food establishments. We believe that this information will increase consumers' awareness about the relative healthfulness of various food and beverage options, allow them to make healthier choices, and promote the introduction of or reformulation toward healthier menu options, all of which will promote improved health and reduced disease risk.

If you have any questions or we can provide additional information, please contact Melissa Maitin-Shepard at Melissa.maitin-shepard@cancer.org or 202-585-3205.

Thank you for your time and your consideration of our recommendations.

Sincerely,

Stephen Finan
Senior Director, Policy
American Cancer Society Cancer Action Network