

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

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

Overall, the Center for Science in the Public Interest (CSPI)¹ supports the Food and Drug Administration's (FDA) proposed regulations for menu labeling at chain restaurants. Menu labeling is an important tool that allows people to make informed choices for a growing -- and often problematic -- part of their diets. The FDA has proposed generally sound and clear regulations on how to fulfill the requirements of Section 4205 of the Affordable Care Act (Public Law 111-148).

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 and to require labeling for alcoholic beverages. We also ask the FDA to provide more guidance on how to label variable menu items, serving sizes for calorie disclosures for foods on display, and enforcement in the final regulations.

Definitions

We strongly oppose the definition of restaurant or similar retail food establishment. For consistency and ease of application, the FDA should amend the proposed definition and, instead, use the tried and tested definition contained in the Nutrition Labeling and Education Act (NLEA):

Restaurant or similar retail food establishment means establishments that offer for sale directly to the consumer food for immediate consumption, consumed either on or off the premises where the food is purchased.

¹ CSPI, a nonprofit consumer organization supported by approximately 750,000 members and subscribers to its *Nutrition Action Healthletter* in the U.S., has worked since 1971 to improve health policies and conduct education programs in the areas of nutrition and food safety.

The FDA should delete the remaining proposed text requiring that the sale of food be the retail establishment's primary business activity based on how the establishment presents itself or uses its floor space. In addition to the proposed definition not being consistent with NLEA, it is at odds with the FDA's approach to vending 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 vending rule would apply to all vending operators with 20 or more machines (to all 10,000).

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.

We agreed with the FDA's examples of covered establishments in its draft guidance, which included table-service restaurants, quick-service restaurants, coffee shops, delicatessens, food take-out and/or delivery establishments, convenience stores, movie theaters, cafeterias, bakeries/retail confectionary stores, food-service vendors (such as lunch wagons, ice cream shops, mall cookie counters, and sidewalk carts), and transportation carriers (for example, airlines and trains). The FDA did not provide a convincing rationale for changing that definition in the proposed rule.

When drafting the menu labeling provision, Congress, advocates, and the restaurant industry all strongly agreed that menu labeling should be broadly applied to all establishments that sell food for immediate consumption.^{2,3} We looked at the establishments that were exempted from Nutrition Facts labeling by the NLEA as what we expected to be covered, anticipating that the NLEA-exempted establishments would be covered by menu labeling. The FDA's existing definition restaurants and similar establishments (establishments that offer for sale directly to the consumer food for immediate consumption, consumed either on or off the premises where the food is purchased) will continue to be used for enforcement of the NLEA, and also should apply to menu labeling. It would be confusing and difficult to implement and enforce a different definition for menu labeling.

Congress was lobbied to exempt grocery stores, convenience stores, movie theaters, and other establishments; it rejected those requests. Those exemptions were carefully considered, especially since different states and localities have applied menu labeling

² Harkin, DeLauro Respond to Proposed Menu Labeling Rules, 4/1/11, found at <http://harkin.senate.gov/press/release.cfm?i=332329>.

³ Harkin T, DeLauro R. Letter to FDA Commissioner Hamburg about menu labeling. June 17, 2011.

differently to those venues. In addition, Congress required menu labeling at restaurants and "similar" retail food establishments, not *identical* establishments. Congress gave no indication that food service must be the primary purpose of the establishment for it to be covered by the law.

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 unfair 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

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>

Customers are 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 nutrition labeling.

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 (see Figures 1 and 2 below).

Figure 1



Figure 2



Bowling alley and hotel room service menus often look similar to the menus of dinner-house-type restaurants (see Figure 3 below for an excerpt from a menu from an Arlington, VA movie theater).

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>

Figure 3: Excerpt from Movie Theater Menu

- MUNCHIES -	
MUNCHSKINS CHEESE AND BACON Potato Skins topped with Cheddar Cheese Bacon Bits & Sour Cream.	\$7.95
MUNCHSKINS ITALIAN Potato Skins topped with Mozzarella Cheese, Pizza Sauce and Pepperoni.	\$7.95
O.A.G. WINGS 1 Pound Buffalo Style, with Celery & Blue Cheese Dressing	\$9.75
O.A.G. MOZZARELLA STICKS (7) Battered Mozzarella Sticks with Marinara	\$6.95
NACHOS TACO A large order of Tortilla Chips, Cheese, Chili, Shredded Lettuce and Tomatoes Served w/ Jalapenos & Salsa. Extra cheese add \$0.60	\$7.95
NACHOS DELUXE A large order of Tortilla Chips, Cheese, Jalapenos & Salsa. Served w/ Sour Cream & Guacamole upon request. Extra cheese add .60	\$7.75
BUFFALO CHICKEN TENDERS Crispy Chicken Tenders Smothered in Buffalo Sauce. Served w/ Ranch & Celery.	\$9.95
CHEESE FRIES Signature Seasoned Fries topped w/ Bacon, Cheddar & Mozzarella	\$7.95
BASKET OF FRIES	\$5.25
TORTILLA CHIPS - with Nacho Cheese & Salsa Dip	\$4.99
POPCORN - Popcorn comes already seasoned	\$3.75
WRAPS	
Served w/ our signature-seasoned fries, coleslaw and pickle spear!	
CHICKEN TENDER WRAP Our crisp Chicken Tenders wrapped w/ Lettuce, Tomatoes, Cheddar Cheese & Honey Mustard wrapped in a Southwestern Wrap	\$9.75
BUFFALO TENDER WRAP SPICY!! Crisp Chicken Tenders wrapped w/ lettuce, Cheddar Cheese, Tomatoes, Buffalo Sauce and Ranch Dressing in a Southwestern Wrap	\$9.75
HAM & CHEESE WRAP Fresh sliced Honey Ham & Provolone wrapped w/ Lettuce, Tomatoes & Honey Mustard in a Flour Tortilla	\$8.95
GRILLED CHICKEN CAESAR WRAP Grilled Chicken Breast layered w/ Parmesan Cheese, Crisp Romaine & Caesar Dressing in a Flour Tortilla	\$8.95
BBQ CHICKEN CHEDDAR WRAP Grilled Chicken Wrapped w/ Lettuce, Tomatoes, Onions, Cheddar, BBQ & Ranch dressing in a Southwestern Wrap	\$9.25
MEDITERRANEAN CHICKEN WRAP Grilled Chicken, Romaine Lettuce, Feta Cheese, Black Olives, Onions, Green Peppers & a Balsamic Vinaigrette Wrapped in a Flour Tortilla	\$9.25

Likewise, the menus on many planes and trains look similar to those at sandwich shops (see Figure 4 for an excerpt from an Amtrak menu and Figure 5 for a menu from Delta Airlines).

Figure 4: Amtrak Menu



Café Acela
MENU



Panache!
**FRESH SANDWICHES,
SALADS & MORE**

Fresh Fruit Cup	4.00
Fruit & Granola Yogurt Parfait	4.50
Wrap Sandwich	6.75
Panini Sandwich	7.25
Artisan Sandwich	7.75
Kosher Sandwich	7.75
Vegetarian Entrée Salad	7.00
Gourmet Entrée Salad	7.50



HOT SANDWICHES

 Hebrew National Hot Dog	4.25
Vegan Burger	4.75
Flame Broiled Cheeseburger	5.75

HOT SNACKS, ENTRÉES & SOUPS

 DiGiorno Pizza (Cheese or Pepperoni)	5.75
 Legal Sea Foods	
New England Clam Chowder, 16 oz.	6.25
Chicken Teriyaki Rice Bowl	6.75

Figure 5: Delta Airlines Menu



LUNCH/DINNER

9:46am - 8:00pm
BASED ON LOCAL DEPARTURE TIMES

WESTBOUND FLIGHTS

FRUIT & CHEESE PLATE

An appetizing assortment of Brie, Colby Jack and White Cheddar cheeses accompanied by Granny Smith and Braeburn apple slices, mango chutney and crackers.



\$6.75

CHICKEN SALAD SANDWICH

This classic favorite starts with a flaky butter croissant and is filled with plenty of chicken salad with grapes, Boar's Head cheddar cheese slices and topped with fresh lettuce and tomato.



\$8.50

KIDS PB&J PLATE

Created specially for our young travelers and those young at heart! This summer special includes a half of a peanut butter and jelly sandwich on whole grain bread and is served with grapes, apple slices, carrot and celery sticks and a side of ranch dressing.



\$4.50

The FDA has proposed that if the establishment presents itself or has presented itself publicly as a restaurant it would be covered by Section 4205. That 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 space exemption (requiring a total of more than 50 percent of the retail establishment's gross floor area be used for the preparation, purchase, service, consumption, or storage of food) 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. It does not matter to customers if a food-service outlet is in a superstore or is stand alone -- calories count the same. 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. If a food service outlet is part of a chain of 20 or more, it should provide menu labeling whether that food service is its primary business or not.

In addition, even using the proposed floor-space exemption, we believe that movie theaters would be covered. Since many people purchase drinks and snacks and bring them to their seats, all the seating area should be considered as a place where people

are consuming food. Typically, more than 50 percent of the space in the 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 seems arbitrary, subjective, and hard to implement and enforce. People eating in theater seats is analogous to people reading and checking their email while drinking coffee at Starbucks.

An exemption based on the percentage of revenue derived from food sales similarly would lead to inconsistencies and enforcement difficulties. It would be difficult for the FDA and state and local enforcement partners to determine the percent of a company's revenue generated from food sales.

Prepared foods at grocery and convenience stores should be labeled, as the FDA has proposed. We support the FDA's conclusion that prepared food 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 unfair 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 brochures) 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.

Labeling of prepared foods is not regulation of different departments, as suggested by some grocers. It is regulation of certain foods, which is well within the FDA's authority. 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 above). In addition, Congress did not give 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 (for example, loaves of bread,

whole cakes, whole pizzas, and buckets of chicken) or are sold by weight (for example, deli salads). Just as those foods would be covered by menu labeling at restaurants, such foods from grocery stores also should provide calorie labeling.

Some grocers asked that grocery coops be exempt from the menu labeling regulations. However, the type of ownership of grocery stores, such as a co-op, is irrelevant to whether a store is considered a chain. The law clearly requires chains operating under the same name to provide calorie labeling, regardless of the type of ownership. Grocery store co-ops face a similar situation as that faced by independent franchise owners of chain restaurants.

Contractors/managed food service. FDA should make clear that food sold by contractors and managed food service should be covered if the establishments run by the company offer for sale substantially the same menu items using standardized recipes. For example, if a school food service (whether run by the school district or by a contract food service management company) uses a central kitchen or cooks the same menu and recipes for more than 20 schools, it should provide calorie and other nutrition labeling on any menu boards at school, on-line menus, menus sent home to parents, and for foods on display in the cafeteria line. 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 more than 20 planes should be covered.

We suggest some modest changes to the following definition proposed by the FDA:

- Food on display. The definition for food on display should clarify that the food might be either self-serve or served by restaurant staff, out in the open or behind glass. The definition could read:

Food on display means restaurant or restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption. It includes food that is served by restaurant staff or self-served by customers and foods with Nutrition Facts labels that customers cannot examine without assistance. Food on display can be behind glass or other material or in an open display accessible to consumers.

A calorie display tag is not needed if a customer can pick up an item and easily examine its Nutrition Facts label prior to purchasing it, such as packaged chips in an open rack. The FDA has proposed that packaged foods with Nutrition Facts labels must be labeled if listed on menus or menu boards. Similarly, if customers cannot examine the nutrition labels of foods on display without assistance, food display tags should be required.

- Variable menu items (see below).

We support the other definitions proposed by the FDA, including:

- Combination meal. We agree that a combination meal may be presented in ways other than words, and are pleased that the FDA has included representations such as numbers, pictures, or other depictions in the definition.
- Doing business under the same name. We support the proposed definition; we agree that the name is the same even if there are modest variations in the name.
- Menu or menu board. We support the FDA's proposal that any primary writing from which a customer makes ordering decisions is covered. Congress clearly did not intend for restaurants to only provide calorie postings on a single medium in each restaurant, as asserted by some restaurants. 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. Calories must be supplied again with the other nutrients required in written form, as required in Sec. 4205(b)(ii)(III). The FDA should make clear that covered menus include individualized order sheets, such as those used to take sandwich orders at Au Bon Pain (see Figure 6 below).

Figure 6: Breakfast Sandwich Menu from Au Bon Pain

Name/Initials _____ Dining In To Go **au bon pain.**

Many of our products contain nuts. Please check our website, aubonpain.com, for complete information

BREAKFAST SANDWICHES

WE NOW SERVE 2 FRESHLY CRACKED EGGS ON ALL OF OUR BREAKFAST SANDWICHES.

- NEW! Egg Whites & Cheddar** on a Skinny Bagel
 White Skinny Bagel Wheat Skinny Bagel
 Made with 3 egg whites
- Egg, Swiss & Broccoli** on Ciabatta
 Made fresh, available in our self serve warmer
- Smoked Salmon Wasabi** on Onion Dill Bagel
- Bacon, Egg & Cheddar Melt** on Ciabatta
- Sausage, Egg & Cheddar Melt** on Asiago Bagel
- Egg & Cheddar** on a Bagel
- Sausage & Egg** on a Bagel
- Bacon & Egg** on a Bagel
- Egg** on a Bagel
- Sausage** on a Bagel
- Bacon** on a Bagel

BAGELS

- Plain
- Sesame
- Jalapeño Cheddar
- Cinnamon Raisin
- Everything
- Onion Dill
- Asiago Cheese
- Honey 9-Grain
- Skinny White
- Skinny Wheat

Toasted Untoasted Butter

CREAM CHEESE

- Lite Plain
- Honey Pecan
- Veggie
- Sun Dried Tomato
- Herb

CREATE your own BREAKFAST SANDWICH

- Cheddar Pepper Jack 2 Freshly Cracked Eggs
- Swiss 3 Egg Whites (extra charge applies)
- Bacon Ham Sausage Smoked Salmon
- Bagel Croissant
- Toasted Bread (please specify) _____

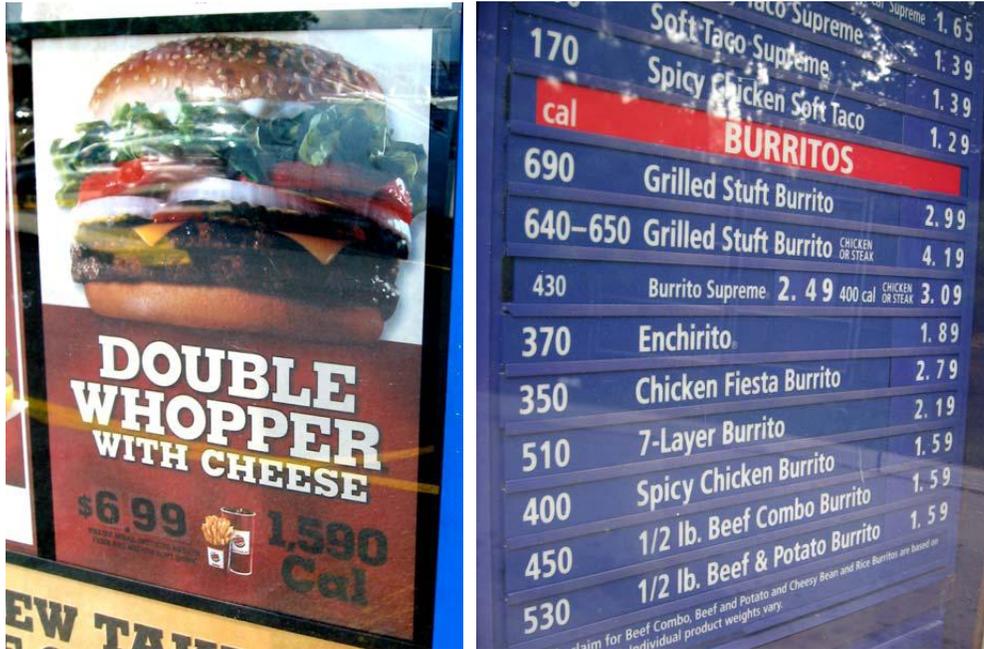
We agree that stanchions are not allowed as an alternative to drive-through menu boards. The law clearly requires calories to be posted directly on drive-through menu boards in Section (H)(ii)(II)(a). Stanchions or separate signs can be hard to read (see Figure 7 below). It is important that the calorie information and other ordering information, like product descriptions and price, all be in the same place so that customers can easily view and consider all the information together. Having different information in different locations is especially challenging when trying to read the information from a car, where customers have limited mobility and field of vision.

Figure 7: Drive-through Menu Board and Stanchion with Calorie Labeling in New York City



Even given different zoning laws around the country, drive-through menu boards have ample room for calories (though marketing messages and photos of menu items may need to be altered to accommodate the calorie postings)(see Figure 8).

Figure 8: Informed Eating on the Go: The drive-through menu boards below from New York City show that calorie information can be provided to customers through drive-thru menu boards.



We agree that specialty menus, beverage menus, children's menus, and all other menus from which people order must include calorie labeling. We also agree that Internet menus and take-out menus are covered, since a great deal of food is ordered to carry out and people often make ordering decisions off of Internet menus. As the FDA notes, some establishments may send out menus as a form of advertising. The rule should clarify that any establishment that takes orders by telephone, over the Internet, or by any other electronic means must include calorie labeling on any menus it sends out, regardless of whether the menu also serves as marketing. On airlines, product lists in airline magazines should include calorie labeling.

- Offering for sale substantially the same menu items. We support the FDA's interpretation that offering substantially the same menu items means that the recipes and preparation techniques are similar, even if the name of the menu item is different. For example, if a restaurant uses the same recipe for its ribs in all restaurants, but calls them Texas Ribs in one location and Tennessee Ribs in another, it is still the same menu item and should be labeled. We also support

that a chain is considered to have the same menu even if not all restaurants in the chain offer all items or if some add items to the core menu.

- Standard menu item. We support that the definition includes items on the menu or menu board or that are self-serve items or foods on display that are routinely available.
- Temporary menu item. We support the FDA's proposed definition and agree that the 60 days per year that the item appears on the menu do not need to be consecutive.

Applicability

Foods that come in multiple servings. We agree with the FDA that menu items must be labeled as offered for sale, even if they might provide more than one serving. The law is clear; calories must be posted per menu item as it is usually offered for sale. The FDA cannot allow and restaurants cannot choose to label items for only a fraction of a menu item. For example, the calorie count for an appetizer cannot be divided into four servings. It must be labeled as it is listed on the menu. We urge the FDA to clarify that standard menu items include items that might serve multiple people; a new paragraph should be added to Section (b)(2)(i)(A):

(5) For items that could serve more than one person, such as a large pizza or a bucket of chicken, calories must be listed per standard menu item as offered for sale and listed on the menu or menu board or as placed on display. In addition, restaurants and similar retail food establishments also may voluntarily provide nutrition information per serving.

Serving size information on packaged foods can be confusing. In one study, two-thirds of people could not correctly calculate the nutrition information in a 20-ounce bottle of soda that was labeled as 2.5 servings.⁸ People will have similar difficulties understanding the nutrition information for menu items if they are labeled as having more than one serving. In addition, it would be deceptive to label muffins, pastries, desserts, entrees, and other menu items as multiple servings, since they are often consumed by one person.

⁸ Rothman R., Housam R., Weiss H., et al. "Patient Understanding of Food Labels: The Role of Literacy and Numeracy." *American Journal of Preventive Medicine* 2006, vol. 31 (5), pp. 391-398.

People tend to finish what is on their plate when eating out. In one study, 69 percent of people said they finished their meal in a restaurant most or all of the time.⁹ Thirty percent of people said they base the amount of food they eat on how much they are served. Studies demonstrate that restaurant diners consume more food when they are served larger rather than smaller portions.¹⁰ In addition, it would be misleading to apply the small serving sizes on packaged foods to the often large portions served at restaurants.

Even for items meant for more than one person, it would be clearer to let diners determine how many people will share it and divide the calories accordingly. For example, if a pizza shop labeled a large pizza as three servings, but a family of four shared it, the math would get complicated. The same would be true of a baguette, a cake, or a bucket of chicken. Additionally, it is important that people be able to easily compare items on the menu without having to bring a calculator. For example, if the calories were listed for the whole menu item, it would be easier for a person to compare and choose between a chicken quesadilla appetizer and quesadilla entrée.

Items not required to be labeled. We support the FDA's proposal that condiments placed on the table or counter for general use, daily specials, temporary menu items, food part of a market test, and custom orders are not required to be labeled. We agree with the FDA's interpretation that the exemption for items not listed on the menu should be narrowly interpreted. It is clear that the law meant for condiments that are part of a standard menu item to be included in the calorie count of that menu item. Labeling of menu items as they are "usually prepared and offered for sale" is a central premise of the statute.

Leaving the condiments or sauces out of the nutrition analysis for the menu item would greatly affect the calorie counts of some items and would mean that the calorie number would not reflect how the item is usually prepared and offered for sale. Condiments and sauces should be included whether they are an ingredient in a standard menu item (such as mayonnaise on a sandwich) or provided automatically accompanying an item. For example, a chicken sandwich platter that is served with a small container of mayonnaise must include the mayonnaise in the calorie count. This should be specified in the final rule.

9 American Institute for Cancer Research. *Awareness and Action: AICR Surveys on Portion Size, Nutrition, and Cancer Risk*. Washington, D.C.: AICR, 2003.

10 Diliberti N, Bordi PL, Conklin MT, Roe LS, Rolls BJ. "Increased Portion Size Leads to Increased Energy Intake in a Restaurant Meal." *Obesity Research* 2004, vol. 12(3), pp.562-568.

Section (b)(ii) should be rewritten to read:

(ii) The labeling requirements in this paragraph (b) do not apply to daily specials, temporary menu items, custom orders, food that is part of a customary market test, and items such as condiments that are placed on the table or counter for general use. Condiments and sauces included as an ingredient or standard accompaniment to a menu item must be included in the nutrition information calculated for that item.

We strongly oppose the exemption for alcoholic beverages from menu labeling.

Only drinks that are ordered by customers at the bar and that are not listed on the menu should be exempt. We supported FDA's conclusion in the draft guidance on menu labeling issued in August 2010 that alcoholic beverages are covered by Section 4205 (www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm223266.htm). The FDA wrote:

Meat and poultry dishes and alcoholic beverages are considered food as defined in the FFDCFA (see Question B.1). Therefore, the nutrition disclosure requirements in section 4205 apply in cases where these foods are listed on a menu or menu board or are otherwise covered under section 4205, even though they may be regulated by other agencies in other circumstances.

The FDA's proposed exemption of alcohol thwarts Congress' intention to require nutrition information for all items listed on menus and menu boards. Congress provided very specific and limited exemptions in Section 4205(H)(vii). Alcohol is not one of those exemptions.

As the menu-labeling bill moved through Congress, alcohol producers lobbied to exempt alcoholic beverages. Congress chose to reject those requests,¹¹ after careful consideration and a close examination of several state and local menu labeling laws that specifically exempted alcohol.

We disagree with the FDA's assertion that it does not have authority to require menu labeling for alcohol. The FDA already exercises authority to label some alcoholic beverages, including low-alcohol wines, ciders, and beverages that make dietary claims (for example, light beers), and has a long history of working collaboratively with the Alcohol and Tobacco Tax and Trade Bureau of the Treasury Department (TTB), which shares authority over alcohol.

The proposed rule states that "at least one court has held that TTB [Treasury] has exclusive jurisdiction over the labels it regulates" under the Federal Alcohol

11 Harkin, *DeLauro Respond to Proposed Menu Labeling Rules*, 4/1/11, found at <http://harkin.senate.gov/press/release.cfm?i=332329>.

Administration Act, citing *Brown-Forman Distillers v. Mathews*, 435 F. Supp. 5 (W.D. Ky. 1976). However, that decision is not controlling for a number of reasons. First, the *Brown-Forman* case was interpreting 27 U.S.C. §205(e), a provision of the Federal Alcohol Administration Act (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, Section 4205 imposes requirements upon large chain restaurants, retail food establishments and vending machine owners and operators. Section 4205 (b)(H). Thus, the *Brown-Forman* case, and the labeling regulations in the FAAA are not applicable to many, if not all, of the establishments that are covered by Section 4205.

Second, even if the *Brown-Forman* interpretation of the FAAA provisions at issue in that case may be applicable in some way to some restaurants or similar retail food establishments, the case has been superseded by Section 4205, a much more recent and specific enactment. The *Brown-Forman* case was rendered decades before the enactment of Section 4205 of the Affordable Care Act, which gives the FDA new, explicit authority to require nutrition labeling at chain restaurants for all foods, with certain limited exemptions of which, as noted above, alcoholic beverages is not one.

The Federal District Court found in 1976 that it was Congress’s “implied intention” to exempt alcoholic beverages from the misbranding provision of the 1938 Food, Drug and Cosmetic Act. The decision in *Brown-Forman* has been superseded by the new menu labeling statute passed by Congress, when it chose to give the FDA, not TTB, new authority to specifically require the disclosure of calorie and related nutrition information by restaurants and similar retail food establishments for all foods but those specifically exempted. As the court concluded in the *Brown-Forman* case, “a basic rule of statutory construction to be applied to resolve a conflict between two different enactments each of whose literal terms cover a specific subject, is that ‘where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one’” 435 F. Supp at 13. Here, the specific statute, Section 4205 of the Affordable Care Act, takes precedence over the general provisions of the Federal Alcohol Administration Act and the *Brown-Forman* court’s interpretation of the misbranding provisions of the Federal Food, Drug, and Cosmetic Act as they existed in 1976.

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). 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 the *Brown-Forman* case was correctly decided, the reach of the implied exemption found by the *Brown-Forman* case is limited to the facts of that case. 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 BATF 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). At the time, it appeared to the court that there were reasonable arguments for why ingredient labeling for alcoholic beverages should be handled differently from ingredient labeling for other foods, supporting its holding that Congress impliedly intended to grant 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 "hinder current international trade negotiations." *Brown-Forman*, 435 F. Supp. at 17. Those reasons are irrelevant to the federal menu labeling requirements. To stretch this holding to a new law dealing specifically with nutritional disclosures for food, and which explicitly exempts certain foods (*not* alcoholic beverages) would give undue weight to a mere implication. Thus, the *Brown-Forman* case cannot be relied upon as limiting the FDA authority in the menu labeling context.

Because TTB has authority over alcoholic beverage labeling only, unless the FDA includes alcohol in the nutritional disclosure requirements of the menu labeling rule, there will be no federal regulation of this component of menus.

FDA's position on alcohol, and its claim that it lacks jurisdiction, also contrasts markedly with its assertion of authority to require labeling of meat and poultry menu items, for which labeling is regulated by the U.S. Department of Agriculture (USDA). The FDA has no more authority -- and no less -- to require labeling of meat and poultry than it has to require labeling of alcoholic beverages.

Some have argued that the FDA should wait for the TTB to require nutrition labeling on the packages of alcoholic beverages before the FDA requires menu labeling of alcoholic

beverages. However, it has been almost four years since the TTB proposed alcohol packaging labeling rules, and many more years since those rules were requested by advocates -- and still, no final rule has been issued. In addition, the TTB has not considered requiring calorie disclosures for restaurant menus as a part of those efforts. Given the urgency of the national obesity problem, restaurant diners should not have to wait for packaged product labeling to get information that Congress directed the FDA to require in restaurants now.

As the FDA pointed out in the proposed rule, alcohol (as well as meat and poultry) is included within the definition of “food” for the purposes of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., of which Section 4205 is now a part. See, e.g., *Brown-Forman Distillers v. Mathews*, 435 F. Supp. 5, 12 (W.D. Ky. 1976). In the Affordable Care Act, Congress gave the FDA express authority to label all food items on menus and menu boards. "except for food described in subclause (vii)." That list of exemptions does not include alcoholic beverages.

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 (see Figure 9 for an example from a Philadelphia menu, and note that Philadelphia also requires saturated fat, trans fat, carbohydrates, and sodium to be listed on menus).

Figure 9: Beverage Menu with Calorie Labeling



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

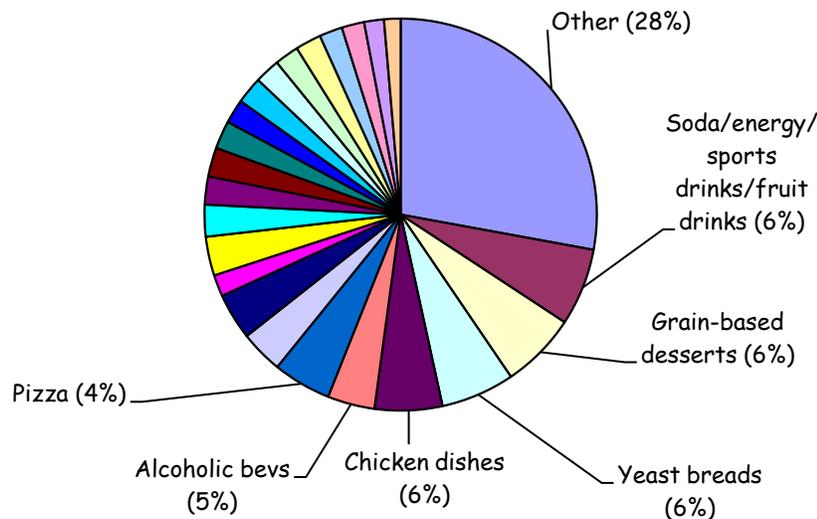
multiple data sources for alcoholic-beverage calorie and nutrient information (including from alcohol producers). Nutrition information from nutrient databases and menu analysis software could easily provide the required information and qualify as the “reasonable basis” required by Section 4205 for nutrient 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.

Important health reasons demand that alcoholic beverages be labeled. Alcoholic beverages contribute a substantial portion of average total calories consumed by Americans. At five percent of total calories, they represent the fifth leading source of calories in American adults' diets (see Figure 10). Failing to provide consumers with calorie information for alcoholic beverages will make it more difficult to follow the *Dietary Guidelines*' advice to “control total calorie intake to manage body weight.”

Figure 10: Leading Sources of Calories in Adults' Diets



It might be confusing to customers if, within the beverage section of the menu, some drinks are labeled and others are not. The FDA's proposed rule would not allow people to compare options and make informed choices. 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.

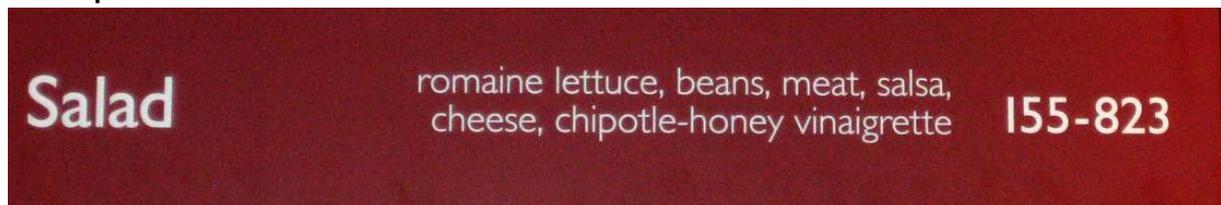
The calorie content of alcoholic beverages can vary widely. Consumers are likely to have difficulty identifying lower calorie options, as has been found for other restaurant foods.¹² For example, at TGI Fridays, the Fresh Mango Lemonade Shaker (410 calories) has twice the calories of the Lemon Twist Martini (200 calories). Individual drinks can pack a meal's worth of calories. The Mudslide at Applebee's has 880 calories.

12 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.

Nutrition information

We agree that calories must be listed for the 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. For example, the menu selection below lists that a salad comes standard with lettuce, beans, meat, salsa, cheese, and dressing. 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. The range on the menu below should be listed as 670-820 calories, not 155 to 823 calories (see Figure 11).

Figure 11: This is not an appropriate calorie posting, since the total calories listed do not include all the components included in the standard menu item.



It is vital that the calorie postings be clear and conspicuous. We urge the FDA to require that the calorie labeling be at least as large as the name or price associated with the item, whichever is *larger* (as opposed to the FDA proposal that the calories be as large as whichever is smaller). For the information to be useful, the calories must be prominent and easy to read. We agree that the color and contrasting background must all be comparable to the name and price of the item, making it as easy to see and read as other core ordering information.

Commas. The FDA should 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.

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.

Rounding calorie numbers is essential. It is essential that calorie numbers be rounded as the FDA has proposed and as is required for Nutrition Facts labels. Unrounded calorie numbers would imply a precision that is misleading. Also, it is more difficult to make comparisons between unrounded numbers.

Use of the term calorie or cal. We 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.

Reasonable basis determinations. We encourage the FDA to reflect the law and Congressional intent regarding reasonable basis determinations in the final rule. This was a significant point of discussion as Congressional leaders, advocates, and restaurant industry representatives negotiated the language in the Affordable Act. As a result Congress wrote the "reasonable basis" standard into the law. The method by which food establishments are expected to comply with and the FDA and state or local agencies enforce the menu labeling regulations should be consistent with that provision. This approach also is consistent with the FDA's current regulations for restaurant labeling claims. Companies should continue to be required to have documentation on how nutrient values are determined and how restaurateurs ensure meal preparation and service adheres to the recipe calculated.

Variable menu items and combination meals. The FDA should provide more direction to help ensure that restaurants and similar retail food establishments provide meaningful calorie labeling for menu items that come in multiple flavors and varieties and combination meals. Such labeling should be done in as uniform a manner across the industry as possible to make consumer use of the information easier and reduce confusion.

- The definition of variable menu items should be revised to the following:

Variable menu item means a standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item. It does not include foods, beverages, or meals that are listed as separate menu items but could be combined in a variety of combinations or that are different sizes of the same menu item.

The definition 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. Those items do not constitute variable menu items (see Figure 12).

Figure 12: The menu below would not be in compliance with the menu labeling law. The calorie content of each smoothie listed on the menu must be posted next to each variety of smoothie.



The FDA should 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. 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 example, the calorie postings in Figure 13 would not be in compliance with the law. Each option listed on the menu should be labeled as in Figure 14.

Figure 13: Not Allowed



Figure 14: Required Labeling

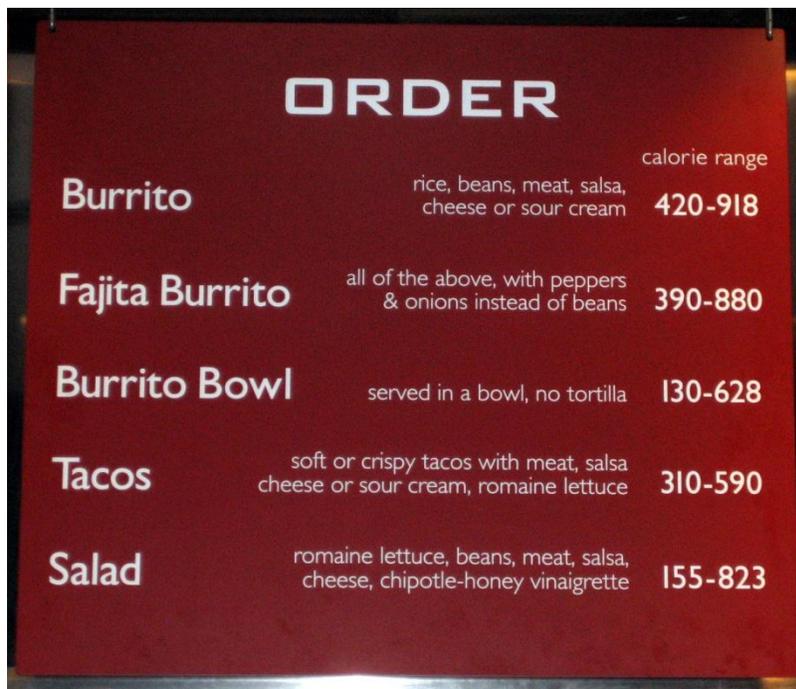


Figure 15: The following menu also would not be in compliance with the law. Each pancake flavor listed on the menu should be accompanied by the calorie count in that item.



The FDA should ensure that restaurants post calorie ranges as infrequently as possible. Posting wide ranges of calories for a single menu item is not informative to customers and does not allow them to make informed choices. For example, a menu listing that the calories for a burrito could range from 400 to 900 calories does not allow a person to make an informed choice (as shown below in Figure 16).

Figure 16: Posting a Wide Range of Calories Is Not Informative to Customers



We support a hybrid approach combining averages and ranges for labeling variable menu items (a variation of the FDA's proposed option 3), to maximize the utility of the calorie information for consumers while minimizing the burden and taking into account space constraints for restaurants. We oppose the proposed option 4 (using slashes). The slashes seem confusing. Given that consumers are not used to getting nutrition information on menus, it would be unclear what the numbers mean and how they correspond to the variety of options available.

Section (b)(2)(A)(4) should be revised to the following:

(4) For variable menu items:

(i) the calories must be declared as a range, in the format "xx-yy" where "xx" is the caloric content of the lowest calorie variety, flavor, or combination, and "yy" is the caloric content of the highest calorie variety, flavor, or combination, except that:

(a) Very low or no calorie beverages should be listed separately from other caloric beverages.

(b) The mean value for calories for all flavors, varieties, or combinations of the menu item should be listed if the calories for all the flavors, varieties or combinations are within 40 calories of each other and all the variable items are under 400 calories, or if the calories for all flavors, varieties, and combinations are within 80 calories of each other and one or more variety is over 400 calories.

(c) If the variable menu item appears on the menu or menu board and is a self-service food or food on display, and there is no clearly identifiable upper bound to the range---e.g., all-you-can-eat buffet---then the menu or menu board must 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 must appear in a type size no smaller than the name or price of the variable menu item, whichever is smaller, 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.

(d) If there is a standard or default option for a combination meal, calories should be posted for that option. The standard or default includes 1) the option depicted on the menu or menu board or 2) the meal including a side dish, beverage or specific combination

that comprises more than a majority (more than 50 percent) of the sales of that meal.

(ii) If calorie ranges are used, the calories for the menu options that are included in that range must be disclosed, either on the menu, through signs for foods on display, or through the device used to provide the other nutrition information required in Section (H)(ii)(III).

Use means for items that contain similar amounts of calories. For menu items that come in different flavors, varieties, or combinations, but that are listed as a single menu item, the mean value for calories for all flavors, varieties, or combinations should be listed on menus or menu boards if the calories for all flavors, varieties or combinations are within 40 calories for items where all varieties are under 400 calories or are within 80 calories for items where at least one variety is over 400 calories. For example, rather than listing Coca-Cola soft drinks as 200-240 calories (per 16 oz. serving), a multiple listing for Coke, Sprite, Fanta Orange, Mello Yello, Minute Maid Fruit Punch, and Pink Lemonade would be listed as 210 calories.

Listing the mean would be easier for restaurants to post and easier for customers to read and use than ranges. We recommend a 40 calorie range, since that is the basis for low-calorie claims. We suggest a cut-off point of 400 calories, which is 20 percent (a high amount according FDA food labeling principles) of a 2,000 calorie diet.

To the greatest extent possible restaurants should disclose on the menu or menu board the calories for each menu choice that is responsible for the range. That could be accomplished in a number of ways, depending on the type of menu and the choice of options that contributes to the need for a range:

- If a menu item that comes in different varieties is on display, the calories would be listed on a placard adjacent to the item, as required by law. For example, muffins would be listed on the menu board as 420-630 calories. The basis for that range would be explained because each muffin in the bakery case would be accompanied by a display tag listing the calories for each type of muffin.

- Often menu items include a main dish with a choice of sides or toppings, and those sides and toppings are described on the menu. The menu should list calories for each side and for the main dish in the description on the menu. For example, a menu would read:

Pancake Combo 1,200-1,420 calories \$8.20

Two pancakes (600 calories) served with two eggs (200 calories), hash brown (300 calories), and your choice of two bacon strips (100 calories) or two pork sausages (320 calories).

However, if the main dish (for example, a steak omelet) had a description of its ingredients, such as steak, green pepper, tomato, etc., that were not choices but the standard ingredients for the main dish, the calories for those ingredients would not have to be listed. For example, it could be listed as:

The Big Steak Omelette 1,490 calories \$10.59

Tender strips of steak, hash browns, green peppers, onions, tomatoes and cheddar cheese. Served with salsa.

- If a menu item is not displayed or the variable components of the menu item are not listed on the menu, nutrition information for each individual flavor or variety or each individual menu item that could be chosen as part of a combo meal should be provided with the other nutrition information required by Section (H)(ii)(III), which is discussed below. As the FDA proposed, signage would alert customers to the availability of that nutrition information.

For combination meals, the standard or default options should be used to calculate the calories posted on the menu or menu board. For example, if the meal depicted on the menu board is shown with fries, then calories for the meal should be calculated including fries. In addition, if more than a majority (more than 50 percent) of a certain meal is usually sold with a particular type of beverage or side dish, those items should be included when calculating the calories. For example, if the majority of combo meals are sold with full-calorie soft drinks, the calories for the meal including a full-calorie soft drink should be posted.

- Upgrades to larger sizes of side dishes or beverages that are listed as a separate item on the menu or menu board should be accompanied by a statement of the calories provided for the whole meal including the large beverage and side dish. That deal would constitute a separate menu item that should be labeled. For example, if a menu board lists that for an additional 49 cents a combo meal could include a large order of fries and large drink, instead

of the standard medium sizes, that offer should be accompanied by a listing of "1,330 calories" (the calories in the burger plus the large side and beverage).

Succinct statement to help people put restaurant calorie labeling in context of a day's diet. 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.

We agree with the proposed rule that 2,000 calories is the appropriate number to use for the adult statement. Using the same daily calorie recommendation for menus and for Nutrition Facts labels would minimize consumer confusion. This number is suitable for the U.S. population given that two-thirds of American adults are either overweight or obese and just 45 percent of adults meet physical activity recommendations.¹³ Using the lower end of calorie recommendations, rather than the upper end, would be protective of the population and help reduce the number of people who might be encouraged to overeat by the statement.

It is true that recommended calorie intakes vary for individuals based on gender, weight status, and activity levels. However, there is no need to include that obvious fact in the succinct statement. A qualifier that individual calorie needs vary is not used on food labels for Daily Values and would only clutter menus.

Thus, we recommend that the following statement be used on menus, menu boards, and the additional nutrition information required in Section (H)(ii)(III) and ask that the FDA include this statement among the others it tests in its consumer research.

Most adults should eat less than 2,000 calories a day, or less than 600 calories per meal.

We suggest 600 calories for a meal, because in addition to eating three meals, most people consume snacks. We suggest adding a per-meal reference because focus groups conducted by the New York State Department of Health to help plan their menu labeling education campaign found that participants overwhelmingly preferred per-meal calorie budget messaging over daily calorie budget messages.¹⁴ Participants were less

13 Macera CA, Jones DA, Yore MM, et al. "Prevalence of Physical Activity, Including Lifestyle Activities Among Adults -- United States, 2000--2001." *MMWR* 2003, vol. 52(32), pp. 764-769.

14 Health Research Inc. and NYS Department of Health. *Menu Labeling Research and Creative Testing: Draft of Key Findings*. November 9, 2010.

aware and many could not calculate the distribution of a daily calorie budget between meals.

If the calorie basis for Daily Values is changed for packaged-food labeling, the FDA also should adjust the menu contextual statement to make it consistent.

Children's statement. We agree that the FDA should require the use of a different statement for children's menus. We recommend the following:

Most children 4-8 years old need about 1,500 calories a day, or less than 500 calories a meal.

Our recommended calorie limit for children was determined by dividing the mean average total calorie needs per day for sedentary children ages 4-8 years old (1,500 calories, as recommended by MyPlate, the Dietary Guidelines, and the Dietary Reference Intakes), by three meals per day. Our rationale for choosing 4-8 year olds is based on findings from the Rudd Center's Fast Food F.A.C.T.S. report showing that children's meals are most often purchased for children under age 6.¹⁵

Placement of the succinct statement. We support the FDA's proposal for placement of the 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 nutrition information. The proposal would make it as easy to see and read the statement as the other basic ordering information.

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

Rounding. It makes sense to round the nutrient disclosures in the same way as for packaged food labeling.

15 Rudd Center for Food Policy and Obesity, Yale University. *Fast Food F.A.C.T.S.* New Haven, CT: Rudd Center, 2010.

Trans fat and weight in grams should be included in the additional nutrition information provided. We agree with the FDA 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 Nutrition Facts labels. We support removing complex carbohydrates from the list of required nutrition information. We urge that the weight of the product in grams be included with the additional nutrition information. Weight in grams is required on Nutrition Facts labels 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 meals and main dishes.

Variable menu items. As discussed above, the additional nutrition information device provides a way that consumers could get calorie information for items listed as ranges on menus or menu boards. We strongly agree with the FDA proposal to require that the nutrition information be provided for each basic preparation and separately for each topping, flavor or variety. As for calorie labeling, using slashes to separate the nutrition information for different flavors of a menu item would be confusing. Given that consumers are not used to getting nutrition information in restaurants, it likely would be unclear what the numbers mean and how they correspond to the variety of options available.

Food on display. We agree that the additional nutrition information must be provided for food on display, including salad bars and buffets. The additional nutrient information would be important for people who have heart disease, high blood pressure, diabetes, or other conditions that are affected by the nutrients that are required to be listed. Many restaurants have menu items that are not listed on menus, but are on display.

Format of the additional nutrition information. The FDA should give more guidance about the format that companies could use to provide the additional nutrition information. The written materials should be easy to read; the information should be provided in a large enough font to be easily readable; food names and nutrients should not be in all capital letters (which are hard to read) or other difficult-to-read fonts; and information should be presented using a contrasting background.

The nutrition information should be readily available. 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 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.

Importantly, 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 more calories than the Tendercrisp salad with regular ranch (which has 600 calories).

Nutrition information on the Internet. Calories must be posted directly on Internet menus. The additional nutrition information on the Internet could be provided via a prominent link from the restaurant's Internet menu. Take-out menus could refer people to the Internet or to in-store nutrition information. Restaurants should not be required to provide the additional nutrition information with each carry-out menu.

We recommend that the FDA revise the language of (b)(2)(ii)(D) to read:

(D) The written nutrition information required in paragraph (b)(2)(ii)(A) of this section must be readily available upon request before ordering. It must be presented in a clear and conspicuous manner, including in a font type and size that are easily readable and that are on a contrasting background. It may be provided on a counter card, sign, poster, handout, booklet, loose leaf binder, or electronic device such as a computer, or in a menu, or in any other form that similarly provides written declaration of the required nutrient content information for all standard menu items in a manner that allows customers to compare the information between different menu items before ordering and without losing their place in line or having to leave the table. If the written information is not in a form that can be given to the customer upon request, it must be readily available in a manner and location on the premises that allows the customer to review the written nutrition information when ordering (i.e., the customer should be able to see and review both the menu/menu board and the additional nutrition information at the same time).

Succinct statement. The additional nutrition information should include the succinct statement 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.

Self-serve and food on display

We encourage the FDA to provide more guidance for the labeling of food on display.

Sec. 101.10(b)(2)(ii)(A) should be revised to read:

(iii) The following must be provided for food that is self service or on display.

(A) When a self-service food or food on display is already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the calories per item or per serving must be provided on the sign. When a self-service food or food on display is not already accompanied by an individual sign, adjacent to the food, that provides the food's name, price, or both, the covered establishment must place a sign adjacent to each food with the number of calories per item or per serving in a clear and conspicuous manner. The calorie information on the sign must be readable from the point where consumers are choosing their food, and it must be readily apparent which sign labels which item, both by proximity and by including the name of the product on the sign.

(1) Calories must be provided for each standard serving size offered, e.g., each beverage cup size offered for a fountain beverage dispenser or each container size available for a deli salad.

(2) For purposes of Sec. 101.10(b)(2)(ii)(A), "per item" means per each discrete unit offered for sale---for example, a bagel, a muffin, a sandwich, or a multi-serving food, such as a whole cake.

(3) If the item is not sold as a discrete unit, it can be labeled per serving.

For purposes of Sec. 101.10(b)(2)(ii)(A), "per serving" means:

(i) Per each scoop or container as dished up using the serving instrument provided, such as a ladle, cup, or measuring spoon, or per weight or container-size offered, such as a quarter pound of potato salad or a container of soup.

(ii) If the item is not served using a ladle or other measuring instrument or per container size, the item must be labeled in the common household measure closest to the Reference Amount Customarily Consumed (RACC) for that item, e.g., per cup or tablespoon.

We agree that the law makes clear that the calories should be provided next to each item, on a sign posted in immediate proximity to each displayed item. The law does not allow companies to provide the calories via a notebook or pamphlet next to the whole salad bar or buffet line.

If an item on display already has a sign listing the name of the product and/or the price, the calories must be posted on that sign. The calories should be posted with same prominence as the name or price, and use the word "calorie" or "cal".

If there is not already a sign for a food on display, we agree that restaurants and other food service establishments must place a sign adjacent to each food to post the calories. 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.

In addition, the 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. Deli items or prepared foods that restaurant or grocery store staff dish up into standard containers should have a sign posted next to each item with calorie counts for each container size available. For example, potato salad that is dished up into half pint, pint, and quart containers should list calories for one half pint of potato salad, one pint of potato salad, and a quart of potato salad.

For self-serve items that customers can dish up in varying amounts, the FDA should require companies to base their calorie determinations on their serving utensil size when possible. Calories should be listed per ladle of salad dressing or scoop of macaroni and cheese. If no such utensil is used, then companies should use the same serving sizes as for packaged food labeling described in standard household measures. For example, next to the lettuce on the salad bar, which is served with tongs, calories should be listed as calories per cup.

As discussed above (under definitions), foods on display should be labeled whether the food is accessed by the customer or a restaurant employee. The labeling requirement should include foods found at salad bars, buffet lines, cafeteria lines, and self-serve fountain soft-drink dispensers. The FDA should make clear that the labeling requirement also includes displayed foods, such as pastries or doughnuts at a bakery, doughnut shop, or grocery store; ice cream behind a glass case in an ice cream shop; burrito components that customers can see and choose at restaurants like Chipotle; and sandwich fixings at a deli.

We support the FDA's proposal to allow general signage in close proximity to the foods on display alerting people to the availability of the other nutrition information and for the succinct statement about daily calories. We agree that the sign should be easily read when a customer is choosing the self-serve or displayed food.

Claims

We agree with the FDA that the requirements for substantiation of claims at restaurants are still in effect.

Enforcement and implementation

Timeline. 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 6 to 7 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 already have analyzed the calorie content of their menu items because they have outlets in cities or states that already require restaurant labeling. Even for those that have not, menu analysis should be underway already given the guidance from the FDA last summer. Menu redesign should be possible within six months after publication of the final rule.

Enforcement. Without a well-articulated and credible enforcement regime, the menu labeling law will not 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.

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, which should be made part of the Model Food Code.

As discussed below in the section on preemption, the FDA should reiterate in its 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).

State and local enforcement mechanisms need not be “identical”: 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.

Of course, not all states or locales can or will adopt labeling requirements “identical” to the federal provisions. With large 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 well have nationwide effect. However, the existence of smaller and regional chains confirms the need for a broad and readily accessible enforcement regime.

Support state and local enforcement of the federal law

Restaurant inspections are historically a state and local responsibility. The FDA's program of enforcement should rely on states and localities to carry out inspections and otherwise enforce the terms of Section 4205. The FDA should provide training, guidance 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. The President's proposed 2012 budget includes funds for the enforcement of the federal menu labeling law, apparently through contracts with state and local authorities. Alternative sources of funding -- including direction of penalties and fines to the inspecting authority -- should be considered as well. Devolving enforcement responsibility onto state and local governments without enhancement of their capacity or available resources would likely result, at best, in a patchwork of enforcement efforts.

The delegation of inspection authority to the states will need to be explicit. Although 21 U.S.C. §337 authorizes states to enforce the federal law in their own names, this option has proven to be of little or no utility to state authorities. Indeed, it is our understanding that this provision has rarely, if ever, been used in the decades that it has been in existence.

Coordinate efforts to enforce federal and state menu labeling regimes

We suggest several options for promoting compliance and coordinating enforcement efforts between federal and state/local authorities to be considered as the final rule is developed.

To promote compliance with the federal law and “identical” state or local requirements, we suggest that the FDA consider the following:

- The FDA should require that each *covered* chain register with the FDA. (This could be similar to the requirement that food facilities register with the FDA under 21 U.S.C. §350d.) This database should be made readily available to the public, particularly to state and local authorities (for example, through the FDA’s website). A local health inspector, particularly in a smaller city or town, is unlikely to know whether a local doughnut shop is part of a chain with only 3 -- versus 20 -- locations nationwide, for example. Having this kind of information collected in a database would help promote efficient enforcement. If the relevant information is already available in a public or private database, then the FDA should work to ensure that the database is accessible to those doing menu labeling inspections.
- The final rule should call for food establishments to provide to the FDA a copy of the written nutrition information required to be made available to customers. Requiring this information to be reported to the FDA would enhance compliance with the law, and is a logical extension of the FDA’s authority to enforce the law. This nutrition information could be collected as part of the registration process suggested above, and also should be made publicly available either separately or as part of the registration database described above, to aid state and local enforcement efforts.
- 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.
- The FDA could facilitate these compliance efforts, and ease the potential enforcement burden on state and local authorities, by developing a process for verifying the accuracy of the nutritional information provided by chains.

We believe that these approaches would not only enhance industry compliance, but would also promote more efficient enforcement. The FDA also could support state and local enforcement activities in the following ways:

- The FDA could use its authority under 21 U.S.C. § 372(a)(1)(A) to support enforcement activities by state and local authorities, including providing technical assistance and funding for these efforts.

- The FDA should set up a simple process for local health inspectors to report potential violations of the federal requirements -- for example, by supplying them with postcards to be filled in and sent to the FDA, with a tear-off receipt to be left with the restaurant manager.
- The FDA should develop a system for collecting and storing those and other reports of violations in a database that would be accessible to state and local authorities, to aid enforcement efforts.

Devise a regime of penalties for violation of the federal law

With respect to violations of the federal menu labeling law, the FDA should detail the penalties for noncompliance and direct any funds from fines or penalties to support inspection programs enforcing the federal law.

Preemption

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 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 proposed rule therefore takes an appropriately narrow view of the preemptive effect of Section 4205.

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.

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. The proposed rule is 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, as noted earlier, 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. As several court opinions have made clear, “identical” means that the language used is substantially the same as the parallel language found in the FDCA, and that differences between them do not result in “materially different requirements.”¹⁶ 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 FFDCFA or FDA regulations, these claims are not preempted.”¹⁷

Taking into account the diversity of state and local enforcement methods mentioned above, the rule might therefore read:

The specific words 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.

We support the proposed rule’s reading of the preemptive scope of Section 4205 as 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 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 set forth in 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. As another example, if the FDA decided to exempt alcoholic drinks from menu labeling, labeling for alcoholic beverages would not be preempted. The localities

¹⁶ 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)).

¹⁷ *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)).

and states that have already passed menu labeling provisions and others that might pass laws in the future could require labeling of alcohol drinks.

Including an explicit statement about the scope of the law's preemptive effect 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 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.

Warning statements are not preempted by the statute. The proposed rule correctly recognizes that state and local requirements for warning statements about the safety of food are explicitly *not* preempted by Section 4205. The final rule could usefully clarify the scope of such exempted warnings. Given the flexibility necessary to meet new and emerging health threats, and to react swiftly to developments in scientific research, the exemption should be construed broadly enough to include at least consumer advisories, warnings in the form of symbols, allergen warnings, and similar alerts. The FDA should clarify that the exemption for statements providing a warning about the safety of a food or food component relates to the overall safety of the product, not just to microbiological contamination of food. Information about safety concerns regarding foods, unsafe food additives, or components of food that contribute to chronic disease are not preempted. For example, a state or locality could require a warning notice about high levels of sodium in menu items that have the potential to contribute to high blood pressure and heart disease.

The savings clause for warnings appears in a section, 4205(d), of the Affordable Care Act, designated "Rule of Construction," that is not codified. Because the absence of the Rule of Construction from the text of the United States Code may lead to confusion in properly interpreting the statute, we urge the FDA to set forth the Rule of Construction in the Code of Federal Regulation. The lack of a codified statement of a similar rule of construction in the NLEA has led to confusion and to court decisions that have not taken that rule into account—presumably because litigants and courts were unaware of it. (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.

In the notice, at page 152, the FDA requested comments on an “alternative view” of possible preemption. That alternative would violate recent directives from all three branches of the federal government that preemption in this area should be narrowly construed. We agree, instead, with the proposed rule’s carefully focused reading of preemption in Section 4205.

Develop a Strong National Promotion and Educational Campaign

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. The reductions in calories purchased in restaurants could be augmented by a vigorous promotion and education campaign.

Conclusion

Overall, we support many aspects of the proposed menu labeling regulations. However, we strongly urge the FDA to revise the definition of restaurants and similar retail food establishments and to remove the exemption for alcoholic beverage labeling. We also ask the FDA provide more guidance on how to label variable menu items, serving sizes for calorie disclosures for foods on display, and on enforcement in the final rule.

For more information contact, Margo G. Wootan, D.Sc., Director of Nutrition Policy, Center for Science in the Public Interest, mwootan@cspinet.org, 202-777-8352.