This is the Domino's generic menu. To see prices, coupons and exactly what items are in your store, use the store locator. CONTINUE

PIZZAS

(PRICING AVAILABLE WHEN ORDERING)

DOMINO'S AMERICAN LEGENDS™

Wisconsin 6 Cheese

Roman tomato sauce, cheeses made with 100% real mozzarella, feta, provolone, cheddar, parmesan, asiago and sprinkled with oregano on a parmesan and asiago crust.

Customer Rating ★★★★☆ 4.2

Read all 116 reviews

S	M	L	XL
250	250	340	450

Honolulu Hawaiian Pizza

Sliced ham, bacon, pineapple and roasted red peppers with provolone cheese on a parmesan asiago crust.

Customer Rating ★★★★☆ 4.1

Read all 47 reviews

S	M	L	XL
260	250	350	450

Philly Cheese Steak Pizza

Tender slices of steak, onions, green peppers and mushrooms with provolone and American cheeses on a provolone crust.

Customer Rating ★★★★☆ 4.1

Read all 84 reviews

S	M	L	XL
250	260	330	430

Pacific Veggie Pizza

Roasted red peppers, spinach, onions, mushrooms, tomatoes and black olives with feta and provolone cheeses on a parmesan asiago crust.

Customer Rating ★★★★☆ 4.2

Read all 126 reviews

S	M	L	XL
230	230	320	410

Cali Chicken Bacon Ranch™ Pizza

Grilled chicken breast, white sauce, smoked bacon and tomatoes on a provolone crust.

Customer Rating ★★★★☆ 4.2

Read all 51 reviews

S	M	L	XL
300	320	430	560

Fiery Hawaiian™ Pizza

Sliced ham, bacon, pineapple, roasted red peppers, hot sauce, and jalapeños with provolone cheese on a parmesan asiago crust.

Customer Rating ★★★★☆ 4.2

Read all 3x reviews

S	M	L	XL
260	250	350	450

Buffalo Chicken Pizza

Grilled chicken breast, buffalo hot sauce and onions with provolone and American cheeses on a cheddar crust.

Customer Rating ★★★½☆ 3.5

Read all 44 reviews

S	M	L	XL
270	260	350	460

Memphis BBQ Chicken Pizza

Grilled chicken breast, BBQ sauce and onions with provolone and cheddar cheeses on a cheddar crust.

Customer Rating ★★★★☆ 4.1

Read all 32 reviews

S	M	L	XL
270	280	360	470

Calorie counts based on the items featured in the photos.

The Dietary Guidelines for Americans recommend a typical adult consume 2,000 calories daily, however, individual needs may vary.

AVAILABLE OPTIONS

Sizes

Small (11")
Medium (12")
Large (14")
X-Large (16")

Basics

Cheese
Sauce
Cheddar Cheese
Provolone Cheese

Toppings

White Sauce
Pepperoni
Italian Sausage
Sliced Sausage
Green Peppers
Black Olives
Pineapple
Mushrooms
Onions
Beef
Ham
Bacon
Salami
Philly Steak
Marinara Chicken
Jalapeño Peppers
Banana Peppers
Spinach
Roasted Red Peppers
Shredded Parmesan
Feta
Tomatoes
Extra Tomatoes
BBQ Sauce

Want to build your own pizza? Find your custom nutrition facts here!

Cal-O-Meter

LEGAL STUFF ▶ **Any Delivery Charge is not a tip paid to your driver. Please reward your driver for awesomeness. Our drivers carry less than $20.**

Cost of Compliance, Industrywide

- Gathered compliance cost estimates from 14 Working Group companies
  - Just these 14 companies' cost estimates total over $50 million at conservative, low end of range
  - Estimates did NOT include probable recurring costs
- Extrapolating to entire chain industry:
  - Estimated chain restaurant locations covered: 250,000 – 275,000
    - Source: Chain Store Guide analysis of current restaurant database, with 680 companies operating 20 or more locations under same trade name

Cost of Compliance, Industrywide

- Estimate of covered locations does NOT include companies headquartered outside U.S. but operating covered restaurants in U.S.
- Estimate also does NOT include "Similar Retail Food Establishments" (SRFE's) covered under the statute, such as:
  - Hotel/motel operators, on-site/contract feeders, movie theaters, bowling alleys, bookstores, convenience stores, grocery stores, schools & universities

Cost of Compliance, Industrywide

- Average cost per restaurant, based on size of chain
  - 20-4500 locations: $1333
  - 4501-9000 locations: $600
  - 9001+ locations: $1100
- Cost range from chain restaurant industry sample:
  - Collected cost estimates from representative sample of industry participants – 14 companies
  - $150 million at low end of range ($600 x 250,000)
  - $367 million at high end of range ($1333 x 275,000)
- Cost likely doubles, or more, when SRFE's are included

Combination Meals
Example: Variable Combination Meal - Option A

*If the primary writing lists a **Variable Combination Meal** (e.g. a Combination Meal offering more than one choice of entrée or side item(s) or drink), the restaurant may:*

A. Provide calories as a range reflecting the lowest and highest total meal calorie content among the variations available.

Example:

The SONIC® menu offers variability in each combination meal. In most of the meals, there is variability within each of the three components:

1. Entrée: choice of condiments on burgers, or choice of protein prep on chicken entrées (grilled or fried), etc
2. Side Item: choice of Tots or Fries
3. Soft Drinks: choice of fountain flavors

In this example, the low end of the range is a burger with mustard, Tots and Diet Coke®. The high end of the range is all three sauces, fries and root beer. A nutrition brochure is available upon request for guests.

NOTE: This visual example, with one modification, is currently in SONIC® Drive-In locations where menu labeling has been implemented. "(as pictured)" has been added to this image to compliment proposed "Variable Menu Item" language.

Combination Meals

Example: Variable Combination Meal – Option B

*If the primary writing lists a **Variable Combination Meal** (e.g. a Combination Meal offering more than one choice of entrée or side item(s) or drink), the restaurant may:*

B. Provide a median average if the calories for all variations within the Variable Combination Meal are within 20% of the median calorie value. If this is the chosen method, the term "Avg Cal" must be stated on the primary writing adjacent to the calorie disclosure.

Example:

As shown in Option A, the range for this combination meal is 910 – 1340. The median value is 1125. The median standard permits an Average Calorie disclosure if the low and high are not greater than 20% from the median value.

1. 20% of 1125 is 225
2. 1125 minus 225 equals 900
3. 1125 plus 225 equals 1350
4. Both the low and high are within 20% of median

NOTE: This visual example is for purposes of demonstrating calorie disclosure methods and not currently in use at a SONIC® Drive-In.

Combination Meals
Example: Variable Combination Meal – Option D

*If the primary writing lists a **Variable Combination Meal** (e.g. a Combination Meal offering more than one choice of entrée or side item(s) or drink), the restaurant may:*

D. Provide the calories on the primary writing for one specified variation of the Variable Combination Meal. If the restaurant or SRFE elects this option, then the restaurant or SRFE must:

i. Identify the items comprising the variation specified;

ii. Disclose calories for the other variations of the Variable Combination Meal in a separate writing (examples include, but are not limited to: an electronic kiosk, a nutrition brochure, a menu addendum, a nutrition poster or online nutrition application) available at the point of sale.

Example:

The "specified variation" chosen represents the entrée as pictured (with Mayo), the most popular side item (Tots) and a non-diet soft drink. Nutrition brochures would be available upon request to view other variations, as well as available online.

NOTE: This visual example is for purposes of demonstrating calorie disclosure methods and not currently in use at a SONIC® Drive-In.

Combination Meals

Example: Variable Combination Meal – Multiple Sizes

If a Variable Combination Meal is available in multiple sizes, calories may be provided on the primary writing for each size when a price is also provided for each size. If a Variable Combination Meal is available in multiple sizes, but only one size of meal and one price is provided, while the other size(s) are available via an "upsize or downsize" message and pricing adjustment, then calorie information for the Variable Combination Meal may be disclosed adjacent to the meal while the calorie adjustment range or average associated with the "upsize or downsize" action may be provided adjacent to the "upsize or downsize" message and pricing.

Combo Meal headline as shown on current SONIC® menu.

Example:

SONIC® combination meals are offered on the menu in two sizes: Medium and Large. The "Med. Combo" and price are shown in each combo meal image. The "Large" meal is offered via an "upsell" mechanism and price adjustment on the menu. Because there is variability in the upsell products (both in Side Items, as well as Soft Drinks) a range is provided to represent the incremental calories associated to upsizing. Nutrition brochures are available upon request to view detail within the range, as well as available online.

NOTE: This methodology for "upsell" disclosure is currently in use at SONIC® Drive-Ins where menu labeling has been implemented.

NRF's Chain Restaurant Division

nccr

NATIONAL RESTAURANT ASSOCIATION®

January 4, 2011

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

RE: Docket No. FDA-2010-N-0567; 75 *Federal Register* 68361 (Nov. 5, 2010) (Agency Information Collection Activities; Proposed Collection; Comment Request; Restaurant Menu and Vending Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010)

The National Council of Chain Restaurants ("NCCR") and the National Restaurant Association ("Association") have previously provided comments related to FDA's implementation of PPACA § 4205. We believe these comments contain information responsive to the issues raised by Docket No. 2010-N-0567. Accordingly, please find attached the following prior submissions of NCCR and the Association related to PPACA § 4205:

- Comments submitted on October 12, 2010 to Docket No. FDA-2010-D-0370 (Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010)

- Comments submitted on September 7, 2010 to Docket No. FDA-2010-N-0298 (Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines)

As should be clear from these comments, the Agency's estimates with respect to the hours and costs associated with the implementation of PPACA § 4205 disclosure requirements grossly understate the burden on affected companies. For example, just *one* of our members estimates that the total cost of implementation of PPACA § 4205 requirements will be

$7,880,475, with $5,473,230 of those costs being borne by small business franchisees. The time required to implement menu labeling will amount to significantly greater time than estimated by the Agency on a chain and per location basis, particularly when accounting for time associated with preparation of graphics, training, accommodation of changes to local requirements and menu board configurations, and other factors. A failure to account for such time will result in a significant underestimation of the time required for overall implementation, which will range from 6 to 18 months or more. We urge FDA to carefully reevaluate its estimates and ensure that decisions made with respect to the implementation of PPACA § 4205 requirements reflect the actual costs and time borne by industry.

We would be happy to provide more information regarding any aspect of these comments, or to provide additional comments on specific issues raised by Docket No. 2010-N-0567. We appreciate the ongoing opportunity to participate in the implementation of PPACA § 4205.

Respectfully submitted,

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NRF's Chain Restaurant Division

nccr

NATIONAL RESTAURANT ASSOCIATION®

October 12, 2010

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

RE: **Docket No. FDA-2010-D-0370 (Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010)**

Dear Sir or Madam:

The National Council of Chain Restaurants ("NCCR") and the National Restaurant Association ("Association") submit these comments in response to the Food and Drug Administration's ("FDA" or "Agency") "Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act ("PPACA") of 2010," published on August 24, 2010 (the "Draft Guidance").

We have previously submitted comments to the general docket that provide information relating to the size and complexity of the chain restaurant industry, the importance of menus as a method of communication for restaurants, the economic burden imposed on chain restaurants by menu labeling, the need for regulatory flexibility in the implementation of PPACA Section 4205, and address various specific aspects of the law. Herein, we limit our comments to issues raised in the Draft Guidance and incorporate our prior comments by reference.

Partial and Repeated Implementation

In the Draft Guidance, FDA takes the position that some of the menu labeling provisions in PPACA are self-executing (and thus effective immediately), and others are not effective until FDA issues a final rule. We believe this interpretation is incorrect, for the following reasons:

First, we continue to believe that the menu labeling requirements of PPACA are not, as a matter of law and congressional intent, self-executing. The PPACA § 4205 menu labeling requirements mandate the establishment of definitions and parameters through notice and comment rulemaking, as evidenced by the one-year requirement for issuance of a proposed rule

and quarterly reports to Congress on progress toward a final rule. 21 U.S.C. §343(q)(5)(H)(x) We are not aware of any provision of PPACA or its legislative history that suggests that Congress intended piecemeal and repeated implementation of these requirements. Partial implementation also yields absurd results: for example, the Draft Guidance *simultaneously* states that the law is effective immediately, *and* requests comments related to whether certain entities (i.e., bakeries in grocery stores) are covered by the law at all.

Second, this approach is confusing to consumers. Under FDA's Draft Guidance, consumers will be provided nutrition information for some menu items but not others, depending on factors such as whether the item is "variable," a distinction that is not relevant from a public policy perspective.

Third, it is confusing to restaurants and regulators with respect to the scope of preemption. For example, under the Draft Guidance, any state or local requirement regarding labeling of "variable" menu items will be, by definition, "not identical" to the federal requirement, and will thus be preempted. Yet, some state or local governments, such as California and Montgomery County, Maryland (among other jurisdictions) have indicated an intent to enforce menu labeling laws beginning on January 1, 2011 that require restaurants to provide a range of possible nutritional content for "variable" items. This means restaurants in these jurisdictions must either openly defy local regulators, or create separate menus for use in those jurisdictions. This dilemma, of course, is *precisely* the problem that Congress intended to solve through federal preemption.

Fourth, the Agency's approach is burdensome and costly. Partial and repeated implementation will require chain restaurants to design and produce one set of menus and menu boards to comply with the initial Draft Guidance requirements, and another to comply with changes to requirements adopted in rulemaking and later requirements such as labeling of "variable menu items" and inclusion of the statement regarding the daily caloric intake. As described at length in our initial comments, menu redesign is a costly and labor intensive process. For some chain restaurants, updating menu boards can involve redesigning and modifying literally thousands of physical boards across fifty states.

Finally, implementing the menu labeling requirement with a single effective date, and one that provides restaurants sufficient time, is fully consistent with how FDA has regulated labeling on packaged foods. For example, following passage of the Nutrition Labeling and Education Act of 1990 (NLEA), the most comprehensive food labeling reform in history, FDA provided the packaged food industry with a single effective date for implementation, not a staggered or phased-in effective date schedule for different provisions. This was done even though the final regulations consumed over 2,000 pages and could readily have been divided into different implementation phases. FDA took this approach because the Agency understood the enormous cost associated with revising every food label, and so the agency rightfully made every effort to minimize that cost through a single, uniform effective date. FDA routinely takes the same approach with more limited labeling changes, by allowing food companies to implement a new labeling requirement at the next uniform labeling compliance date, which occurs once every two years. FDA should take the same approach with menu labeling for restaurants, as the costs associated with it and the implementation challenges are at least as compelling, if not more so, as described above. FDA should also not lose sight of the fact that the menu labeling law is an

amendment to NLEA, and so the history of NLEA implementation is directly relevant. Accordingly, FDA should apply the same lessons it has learned over the decades with the packaged food industry in this regard and apply them to the restaurant industry as well, by providing a single, uniform effective date, following the issuance of final regulations.

For these reasons, a better approach would be to require a single implementation, after the issuance of the final rule. Such an approach would give FDA time to issue proposed standards for variable menu items and a proposed statement for caloric intake; it would eliminate confusion with respect to preemption by clarifying that state and local labeling laws are preempted until such time as the federal law is implemented by rulemaking, it would mitigate the high cost of compliance for chain restaurants, which could redesign and implement new menus only once; and it would allow FDA time to educate consumers about how to read and use menu nutrition information, and restaurants about how to comply with the requirements. To the extent FDA believes it can expedite the rulemaking required under PPACA §4205, and therefore speed implementation of these requirements, we would fully support such an effort provided we are given a reasonable opportunity to submit comments and, as noted, afforded an adequate period for implementation after publication of the final rule.

Timing of Implementation

If the Agency decides to persist with implementation prior to the final rule based on guidance, it should exercise its enforcement discretion until at least one year after the publication of the final rule. During the interim period, restaurants may make good faith efforts to comply with a final guidance in a manner consistent with scarce resources and other factors, such as the applicability of state or local requirements.

An implementation period of at least one year after the publication of the final rule is necessitated by the enormous analytical and logistical effort needed to comply with the menu labeling law. By way of example, chain restaurants will need to take many if not all of the following steps in order to implement the menu labeling law:

- Analyze FDA's final guidance and determine which of its menus and menu boards are considered "primary writings" and, as to each menu item, whether nutrition information must be provided.

- For each covered menu item, determine nutrient content in a manner that complies with FDA's "reasonable basis" standard -- i.e. by laboratory testing of item or its ingredients, by entering the item's ingredients into a nutrition database, or by using recipes or other methods. *See* 21 C.F.R. §101.13(q)(5)(ii) (defining "reasonable basis"). This effort alone is enormous. In the case of a nutritional database, for example, a restaurant will have to research available and recommended databases, purchase and install the database, identify and train appropriate personnel to use the database, determine the ingredients for each covered item, enter those ingredients (including multiple entries for items that use the same ingredient, but source that ingredient from different suppliers) into the database, and analyze the results for errors.

- Create nutritional handouts containing nutrition information that must be made available in writing upon request.

- Redesign any menu, menu board or other materials (including drive-through boards) that is the "primary writing" under FDA Guidance, to incorporate caloric information and required statements related to the availability of additional information. As noted in our initial comments, such redesigns are extremely costly and labor-intensive.

- Roll out new menus and menu boards simultaneously to chain restaurants nationwide. For many chain restaurants, this involves the simultaneous modification of materials and roll-out of new materials across literally thousands of locations nationwide.

- Ensure that reasonable steps are in place at each covered establishment to ensure that standard menu items are created via methods that conform to the "reasonable basis" for the nutritional information. This could require creation and distribution of recipes and/or training materials, and the training of staff that is often entry-level. Again, in many cases this will need to be done at thousands of locations.

- Create and implement a process whereby information related to menu items such as ingredients, supplier data, etc., is periodically updated, and these updates are reflected in future menus and menu boards.

Even for chains that have long provided nutrition information for some items and locations, this presents an enormous logistical challenge that will require the devotion of significant resources. Moreover, as we expressed in our initial comments, many restaurants will be starting from scratch, and thus will face a steep learning curve. It is important to remember that most chain restaurant companies are franchised. Therefore, far from being large corporate behemoths that, some would say, could simply "absorb" the cost of partial and repeated implementation of menu labeling, the reality is that these costs will be borne by thousands of small business entities. As noted in our comments to the general docket, each implementation will cost these small businesspeople in the range of several hundred to several thousand dollars per restaurant location, and, collectively, well over one hundred million dollars across the industry. A partial and repeated implementation scheme, as envisioned in the Draft Guidance, will greatly increase these costs.

An implementation period of not less than one year after the final rule would alleviate these problems to some degree. It would also allow FDA to assist chain restaurants by working collaboratively to identify and gauge challenges in determining and displaying nutrition information, to provide detailed Q&A and other guidance materials, to convene workshops on compliance, and take other steps that would ensure the roll-out of clear, consistent and accurate nutrition information across restaurants nationwide. Such an organized and collaborative process, implemented across a reasonable timeframe, might also encourage businesses not subject to the law to register for voluntary compliance, thereby ultimately expanding the amount of nutritional information available to consumers.

Definition of Menu / Primary Writing

In Section 4205, Congress defines "menu" as "the *primary* writing of the restaurant or other similar retail food establishment from which a consumer makes an order." In the Draft Guidance, however, FDA attempts to rewrite that definition by defining "primary writing" as "all forms of primary writing, such as dessert menus, beverage menus, and other specialty type menus" and by stating that "an establishment may have *multiple* types of menus, *any one of which* may be used by various consumers as the primary writing to make selections." *See* Question C1 and C2.

By defining "menu" as "the primary writing," Congress intended to *limit* the scope of materials that are treated as menus or menu boards for the purposes of PPACA Section 4205. Interpreting "primary writing" as any form of communication that any consumer uses to make an ordering decision, as FDA does in the Draft Guidance, does the opposite: it *expands* the scope of materials treated as menus, rendering the term "primary" meaningless. If Congress had intended this result, it could easily have defined "menu" as FDA does in Draft Guidance, or it could have left "menu" undefined and instructed the Secretary to promulgate a definition. Instead, Congress defined menu as "the primary writing" -- a singular writing. We believe FDA's expansive interpretation imposes a considerably more onerous burden on chain restaurants than Congress intended.

However, if FDA continues on its current course, at a minimum, it should limit the scope of its current definition by clarifying that certain materials are *not* menus. For example, FDA should state in the final guidance that if the primary purpose of a piece of marketing material (which may appear in various places, such as a counter, dining table, window or wall) is to promote an item or subset of items, and such items are already on a menu or menu board and accompanied by required nutrition information, the marketing material is not a menu or menu board within the meaning of PPACA Section 4205.

Alternatively, FDA could adopt a more specific interpretation of "primary writing." One formulation might define "primary writing" as any writing that contains a listing of all or substantially all items sold by a chain restaurant, or all or substantially all items sold by a restaurant in a given category (such as breakfast, or dessert). This approach would have the practical effect of excluding promotional materials such as table tents and banners that are clearly not a "primary writing," and would lend at least some meaning to the term "primary."

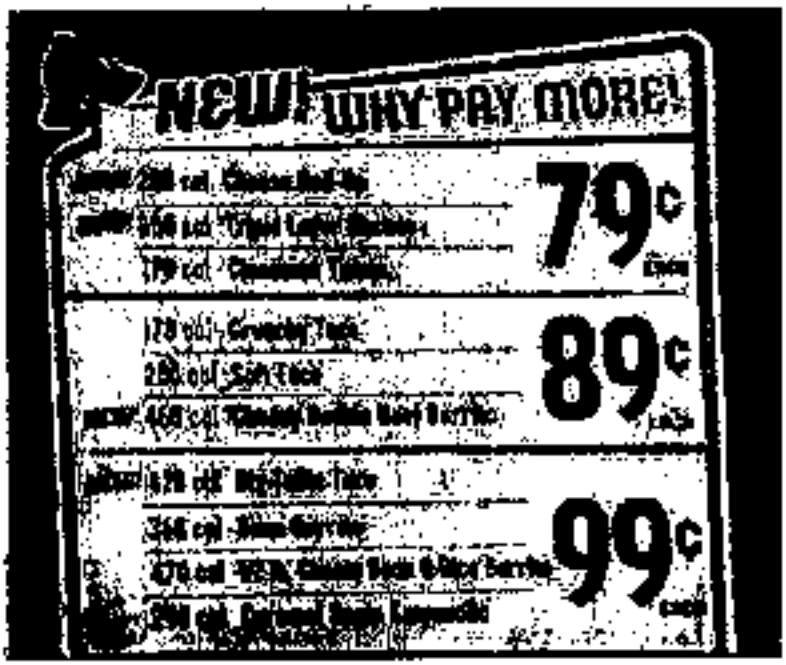
The Agency should also clarify that certain items are not "standard" menu items subject to menu labeling. The application of PPACA § 4205 to chain retail food establishments was driven in part by congressional recognition that such chains widely offer standard menu items across the full scope of their operations. In certain cases a single restaurant or market area in a restaurant chain may decide to serve a local or seasonal item. The final rule should clarify that such items are not subject to PPACA's provisions related to limited-time or test-market items; rather they are not "standard menu items" not subject to PPACA § 4205 labeling requirements.

Presentation of Menu Information

FDA's Draft Guidance requires that calorie disclosure be provided in the same type size as the name or price of a menu item (whichever is larger) and with the same color and contrasting background as the menu item. *See* Question C5. We understand, and share, the FDA's conviction that calorie information on menus should be easy for consumers to find, read and understand. However, the standards in the Draft Guidance relating to presentation of nutrition information do not achieve that goal and are seriously flawed.

There are myriad ways a restaurant may provide calorie information in a manner that is clearly readable and easily understandable by the consumer, without being forced to comply with requirements governing font size, color, contrasting backgrounds, etc. The adoption of a flexible standard will better accomplish the statutory mandate that information be "clear and conspicuous" than FDA's requirement that the font and color be the same size as the larger of the price or product name.

In some cases, a calorie listing that is smaller than the price, and in a different color or font, will actually be quite prominent and easy to read. Consider the following partial example of a menu board:



This example effectively uses different type-faces, colors and fonts to highlight various elements of information of importance to consumers. Rather than detract from the prominence of calories or other information elements, this structure makes it easier for consumers to quickly identify and use the information they need. Yet, although this example is perfectly "clear and conspicuous" as required by law, it would be impossible under the FDA standard because the calorie disclosure would have to be enormous. To be clear, our objection is not with the idea that calorie information is more or less important than price. Rather, the point is that presenting information all at the same size and color results in incoherence.

If FDA is concerned about potential minimization of calorie information, it should set a reasonable minimum requirement (e.g., type size not less than the smaller of the menu item or price), as was done in New York City, and then, in addition to the minimum standard, provide significant latitude for how restaurants structure and display disclosures consistent with the clear, conspicuous and adjacent standard. One example of such a standard is that adopted and applied in King County, Washington, prior to the passage of PPACA.[1] This standard required that the nutrition information be "easily readable, in a typeface similar to other information about each standard menu item, and in a font no less than nine point." See King County Board of Health Res. No. 08-02.2, at p. 8. The King County standard deterred abuse by including a subjective component (easily readable), a relative component (typeface similar to other information about the item), and an objective component (nine point font), yet still allowed restaurants considerable flexibility with respect to key design principles such as hierarchy and contrast.

Alcoholic Beverages

In the Draft Guidance, FDA took the position that alcoholic beverages are subject to menu labeling requirements because they are "food" as defined in the section 201(f) of the FFDCA. *See* Question B1 and B3 (citing 21 U.S.C. § 321(f)). The scope of FDA's jurisdiction with respect to alcoholic beverages, and the interplay between the role of FDA and the role of the Alcohol and Tobacco Tax and Trade Bureau ("TTB") is unclear, and we believe FDA should solicit further comment on this issue after TTB has provided a public position on the issue.

If FDA includes alcoholic beverages within the scope of menu labeling in the final guidance, it should provide guidance on how restaurants might calculate nutritional information for alcoholic beverages, because such information is not readily available from all suppliers. Unless FDA intends to require such suppliers to provide this information (which again raises the issue of jurisdiction), the menu labeling law could have far-reaching and unintended impact on the business of alcohol manufacture, supply and distribution, as well as on the products served in chain restaurants.

Again, the approach adopted by King County prior to PPACA serves as a useful model, as it allowed restaurants to calculate and display nutritional information on alcoholic beverages according to the following schedule:

Wine (5 ounces): 122 calories

Regular Beer: (12 ounces): 153 calories

Light Beer: (12 ounces): 103 calories

Distilled Spirits (1.5 ounces of 80 proof gin, rum, vodka or whiskey): 96 calories

[1] After the passage of PPACA, King County, (recognizing that its menu labeling law was preempted to the extent it was "not identical" to the federal requirements, modified its law.

The King County statute also allowed restaurants to "add to the menu the following statement: 'signature drinks of liqueurs with added ingredients may increase caloric content.'" This approach allowed restaurants to provide nutritional labeling for alcoholic beverages without making changes to suppliers or incurring costs of testing another companies' products.

Ready-to-Consume Food Sold by Facilities Within Grocery or Convenience Stores

FDA has requested comment on how facilities such as bakeries, salad bars, pizza bars, or delicatessens that are located within grocery stores or convenience stores, and that offer products that could be consumed immediately or could be purchased for future consumption, should be treated. *See* Question A5 and B6. Our view is that, for the purpose of menu labeling, such facilities are indistinguishable from their standalone counterparts, and thus any product offered by such a facility that meets the definition of a "standard menu item," and that is not otherwise subject to nutrition disclosure under NLEA requirements for packaged foods, should be covered by §4205.

Using FDA's example of a pizza bar at a grocery or convenience store, we see no reason why a pizza prepared in a covered grocery or convenience store that may be consumed immediately or taken home for immediate or future consumption should be treated differently than a pizza prepared in a restaurant (including for take-away or delivery), which could also be intended for immediate or future consumption. Accordingly, consistent with FDA's view that "establishments that offer comparable food items for immediate consumption [should be] treated comparably," (see Question A5) the pizza bar in this example should be required to disclose nutrition information.

Food Intended to Provide Multiple Servings

FDA has requested comment on how and whether foods intended to provide multiple servings, such as a whole cake or a loaf of bread, are covered by the requirements of Section 4205. *See* Question B6. Providing nutrition information for such items in a manner that is useful for consumers can be difficult to achieve, because the amount of nutrients is dependent on the size of serving selected by the consumer. Accordingly, the FDA should adopt a flexible standard for disclosing nutrition information for multi-serving items. Specifically, FDA should allow restaurants or similar retail establishments to provide either nutritional information for the entire product, or on a per-serving basis, but should not require both. Further, FDA should not attempt to specifically define serving sizes for the multiplicity of restaurant foods, but should allow flexibility for restaurants to define reasonable per serving declarations or use existing "reference amount customarily consumed" (RACC) designations for serving size when available.

Food on Display

The Draft Guidance requires restaurants or similar retail food establishments to provide nutritional information for food on display -- meaning food that is intended for immediate consumption on or off the premises, and visible to consumers -- on a sign adjacent to each item. *See* Question B5. This provision appears to target cafeteria-type settings, where customers are not ordering from a menu or menu board, and thus would not otherwise be provided with nutritional information. Some restaurants and similar retail food establishments, however, sell

food that meets FDA's definition for "food on display," but that is "ordered" from a menu or menu board, which often includes the name of the item, serving size options, and the price. FDA should clarify that in such situations, a restaurant or similar retail food establishments is only required to provide nutritional information on the menu or menu board, as applicable. This is consistent with FDA's position that nutrition information be provided at the point of ordering.

Variable Menu Items

We agree with the Agency's position that "FDA cannot require disclosure of nutrient content information for variable menu items until FDA issues a final rule." *See* Question B8. As we explained in greater detail in our previous comments, different restaurant chains face various challenges related to combination items due to factors such as inherent customization of certain menu items or large high-low ranges of available combinations that are of limited utility to consumers (e.g., 400 - 2800 calories). Accordingly, we reiterate that, when the FDA addresses this issue during rulemaking, it should provide restaurants with various options for representing nutrients in combination and variety items, such as allowing restaurants to label the calories of each component of a combination meal, provide a representative set of combinations with associated calorie information, or provide a range, median or average.

Preemption

As recognized in FDA Guidance, the uniformity provisions in PPACA § 4205(e) took effect immediately upon enactment, and apply to any current or future state or local menu nutrition labeling requirement. Federal preemption means that states and localities cannot enforce any menu labeling requirement that is "not identical to" the national requirements. This means that states and localities may not enforce their own menu labeling provisions that are either broader in scope than the Federal law (e.g., require posting of nutrition information other than calories) or which are more specific in application (e.g., require particular font size, color/contrast).

In our previous comments, we commended FDA for acknowledging this fact, and urged the Agency to ensure that states and localities understand that any state or local menu nutrition labeling requirement that is not identical to the requirements of 21 U.S.C. § 343(q)(5)(H) (and in particular goes further than what will be required under Federal law either in scope or specificity) is now preempted. Without affirmative efforts by FDA, we noted, such jurisdictions may continue to challenge industry, forcing companies to resolve these issues in court in order to ensure that there is one uniform federal standard. We also requested that FDA seek to prevent new jurisdictions from enforcing menu labeling laws not previously in force, which would further disrupt an orderly implementation of national requirements and create confusion among consumers.

These concerns are fast becoming reality: as of January 1, 2011, several state and local jurisdictions, such as California and Montgomery County, Maryland, have announced that they will begin enforcing menu labeling laws that are "not identical" to the federal standard. For example, these jurisdictions will require covered entities to provide nutritional information for "variable" menus items, the labeling of which is not currently required under federal law;

pursuant to the Draft Guidance. These requirements are "not identical" to the federal requirements currently in effect, and are accordingly preempted.

Moreover, as a practical matter, this means that restaurants will have to create one set of menus to comply with these state and local laws, and then another set of menus in the event that the FDA's final guidance differs from them in any respect. And, if this were not enough, these state and local laws also differ significantly from one another: For example, the Montgomery County law applies to alcoholic beverages, but the California law does not apply to alcoholic beverages; the Montgomery County law does not apply to groceries, convenience stores, or movie theaters, while the California law applies to each of these entities.

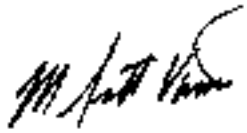
If the Agency continues on its current course with respect to implementation by guidance, FDA should resolve this dilemma by clarifying that compliance with the federal law as outlined in final guidance should be deemed compliance with any applicable state or local law. This is what Congress intended when it adopted nationwide preemption, and when it allowed states to pass and enforce menu labeling laws only so long as they did not impose requirements that are "not identical" to the federal requirements.

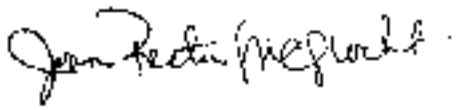
* * *

NCCR and the National Restaurant Association appreciate this opportunity to provide comments on FDA's Draft Guidance. We look forward to working with the Agency to implement the law in a manner that benefits consumers, respects the realities of a complex chain restaurant industry, and achieves the implementation of a uniform national approach to menu labeling requirements.

We would be happy to provide more information regarding any aspect of these comments.

Respectfully submitted.





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NATIONAL RESTAURANT ASSOCIATION®

September 7, 2010

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

RE: **Docket No. FDA-2010-N-0298; 75 *Federal Register* 39026 (July 7, 2010) (Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines)**

Dear Sir or Madam:

The National Council of Chain Restaurants ("NCCR") and the National Restaurant Association ("Association") welcome this opportunity to respond to the Food and Drug Administration ("FDA" or "Agency") notice and request for comments on the implementation of Section 4205 of the Patient Protection and Affordable Care Act ("PPACA") (codified at 21 U.S.C. § 343(q)(5)(H)). We strongly supported the passage of menu labeling legislation, and look forward to working with FDA to facilitate the efficient and effective implementation of the law, including commenting on the recently issued final and draft guidance documents and participating in the upcoming rulemaking required to carry out PPACA § 4205 menu labeling provisions.

NCCR is the leading trade association exclusively representing chain restaurant companies. For more than 40 years, NCCR has worked to advance sound public policy that best serves the interests of both chain restaurants and the millions of people they employ. NCCR members include the country's largest and most respected quick serve and casual dining companies. NCCR is a division of the National Retail Federation, the world's largest retail trade group.

The National Restaurant Association, founded in 1919, is the leading business association for the restaurant industry, representing more than 380,000 member restaurant establishments. The Association's membership base consists of many different facets of the industry including chains and independents, table service and quick service restaurant operators, chains, franchisees

and independents. It is also consists of allied members who are suppliers, distributors and consultants to the industry.

Executive Summary of Comments

NCCR and the National Restaurant Association believe the Agency must carefully consider a range of issues in implementing the menu labeling requirements of PPACA § 4205:

- The restaurant industry is very diverse, which presents serious challenges in implementing menu labeling requirements. Chain restaurants operate under many different business models, communicate with consumers in various ways, and face important constraints due to factors such as size of establishment, types and number of foods offered, and local requirements such as zoning laws limiting size and placement of drive-thru menu boards.

- As Congress recognized in framing PPACA § 4205, restaurants will need regulatory flexibility and a significant period of time for menu labeling implementation due to the nature of hand-preparation of restaurant foods, physical and logistical issues associated with menu and menu board changes, determinations of nutrient content, and training of personnel.

- Menus play various roles, and are an extension and representation of each company's brand. The chain restaurant industry puts enormous effort into developing menus, which often reflect the results of market research, consumer feedback, and complex business processes. Menu labeling should not disrupt industry's ability to communicate effectively with consumers.

- The cost of PPACA § 4205 implementation will be significant, totaling several hundred million dollars. Given that franchisees often bear the costs associated with menu changes, a large proportion of that burden will fall on the shoulders of small business owners.

- Congress, while mandating immediate preemption of state and local laws to stop the continued proliferation of varying and burdensome restaurant nutrition labeling requirements across the nation, did not intend to require industry to implement menu labeling requirements nationally prior to FDA's finalization of a rule establishing a truly uniform approach across the country. Although restaurants may implement these provisions on a voluntary basis now, attempting to require implementation based on general statutory language and guidance followed by a second implementation in accordance with the final regulation would be contrary to law, confusing to our customers, and an undue burden on the industry.

I. General Issues and Principles

NCCR and the National Restaurant Association believe the following issues and principles should be considered by FDA in its implementation of PPACA § 4205 requirements. Detailed responses to FDA's specific requests for information are provided in Section II. In both sections we address aspects of the draft and final guidance documents issued by the Agency on August 24, 2010.[1] However, NCCR and the Association plan to submit additional comments on those documents to the respective dockets.

- **FDA Should Consider the Diversity of the Restaurant Industry**

The restaurant industry is large, complex and multi-faceted. Consequently, the opportunities and challenges associated with providing nutrition information vary from chain to chain based on factors including the type of restaurant (e.g., quick-service, delivery, casual dining, etc.), the method of communication (e.g., menu, menu board, drive-thru, phone or website ordering, etc.), the type of food offered (e.g., a few highly customizable items versus many individual items), the presence or absence of state and local regulations (e.g., zoning ordinances governing placement of outdoor menu boards, other required disclosures not preempted by PPACA § 4205, etc.), the presentation of menu selections (e.g., the prevalence of combination items versus a fixed menu of items), and many other issues.

Chain restaurants maintain highly individualized practices -- which are driven by consumer preferences and expectations -- related to the size, format and appearance of menus and the number of menu items offered. For example, some chains make limited or virtually no changes to standard menu items each year. Other chains make changes to menus on a regular basis, as often as monthly or even weekly. While some chains have as few as 10 menu items, others offer hundreds of menu items that may be customized per consumer orders in many different ways. FDA should be mindful of the diverse nature of the industry in promulgating regulations; a comprehensive understanding and appreciation of the industry's diversity will help in creating regulations and guidance to ensure effective communication of nutrition information to restaurant consumers.

- **Menus Play a Critical Role In the Restaurant Industry**

While nutrition can play an important role in food choices for some consumers, it is critical to understand that restaurant menus play a number of vital roles in communicating information of importance to consumers. Restaurant menus are not merely a list of items for

[1] FDA, *Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010* (August 24, 2010) ("Draft Guidance"); FDA, *Guidance for Industry, Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws*, (August 24, 2010) ("Guidance").

sale; they are one of the primary methods restaurants use to reach, communicate with, and retain customers. As a result, a restaurant's brand and value proposition is at stake every time a consumer reads a menu. Restaurant menus are the focus of intense efforts, and often reflect the results of market research, consumer feedback, and business processes, to say nothing of the substantial cost of producing menus. Menus and menu boards often are designed to aid consumers in quickly and easily locating various types of menu offerings and relevant information, improving the consumer experience and promoting efficient employee handling of orders by patrons. The use of pictures, descriptors, color, and text of varying fonts and sizes can be integral to menu readability and assisting consumers in identifying information of interest to them. Many restaurants employ extensive processes related to menu design, production and updating to ensure, among other things, uniform brand image and positioning, and coordination across individual restaurants. Unexpected disruptions or unrealistic timelines will impose significant costs that could easily be avoided. In short, FDA regulations should recognize that menus are an integral part of each restaurant business, and are nothing less than an extension and representation of a company's brand.

- **Need for Flexibility in Implementing Menu Labeling**

Because of the extraordinary diversity of the restaurant industry and the importance of menus, a one-size-fits all approach to implementing PPACA § 4205 is not appropriate, as a requirement that is relatively easy to implement for one restaurant chain may be highly burdensome for another. In enacting PPACA § 4205, Congress was well aware of the complexity and diversity of the restaurant industry, and of the corresponding need to consider these factors in implementing regulations. In fact, these concerns have informed FDA regulation of restaurants since its implementation of the Nutrition Labeling and Education Act of 1990, when, in response to industry comments and in recognition of the unique manner in which restaurant foods are prepared and sold, FDA established unique, flexible regulatory requirements. For example, in determining that restaurants are bound to the nutrient content claim definitions (developed for pre-packaged foods), FDA adopted measures to preserve flexibility, including the "reasonable basis" standard for menu item nutrient declarations. In enacting a national uniform menu labeling law, Congress has expressly invoked and adopted its prior findings related to the unique challenges presented by the preparation of food in a restaurant setting, including mandating that FDA, in developing implementing regulations, consider a range of variable factors inherent in the restaurant food preparation and service. 21 U.S.C. §343(q)(5)(H)(x)(II)(aa).

As noted in our comments below, regulatory flexibility is critical as the implementation period for regulations promulgated to carry out PPACA § 4205 labeling requirements is considered. Restaurants will need a significant period to implement these requirements due to physical and logistical issues associated with menu and menu board changes, determinations of nutrient content, and the need to train personnel. That period should commence from the issuance of final regulations, when the specific requirements associated with implementation are available to the industry.

- **Menu Labeling Presents a Significant Economic Burden on the Chain Restaurant Business**

Although the restaurant industry strongly supports menu labeling, it does come with a cost. We are still in the process of gathering estimates from companies in the industry regarding the cost to comply with PPACA § 4205, and expect to provide more detailed information shortly. However, the economic burden on industry is clearly significant. Data collected to date indicate that there is a wide range of expected compliance costs depending on the type of restaurant, the segment represented, its size, whether the restaurant concept has menus, menu boards, drive-thrus or all of the above. However, most medium to large chains expect to spend several million dollars to conform their systems with federal menu labeling requirements. Our research indicates that some 250,000 to 275,000 restaurant chain locations across the United States would be covered by the regulation. Thus, the cost of implementation will multiply to several hundred million dollars. Given that in many franchised restaurant models the costs associated with menu, menu board and drive thru replacement are the responsibility of the franchisee, a significant proportion of these costs will fall on the shoulders of small business owners.

The above estimate does not include "similar retail food establishments" which are also covered by PPACA § 4205. When added, these establishments would likely expand the cost of compliance by another several hundred million dollars. Clearly, the regulatory implementation of menu labeling warrants appropriate treatment as a significant rulemaking under applicable law and FDA policy, and given the economic situation we find ourselves in today, efforts should be made to minimize the economic impact of PPACA § 4205 implementation on the restaurant industry.

- **Ensuring Broad National Uniformity with One Implementation of PPACA § 4205 Requirements is Essential**

In enacting menu labeling requirements, Congress recognized that a uniform, national approach to menu labeling is essential to ensuring consumer understanding and facilitating implementation by industry. As recognized in FDA's Guidance, upon enactment, the uniformity provisions in PPACA § 4205(c) took effect immediately and apply to any current or future state or local menu nutrition labeling requirement. Federal preemption means that states and localities cannot enforce any menu labeling requirement that is "not identical to" the national requirements. This means that states and localities may not enforce their own menu labeling provisions that are either broader in scope than the Federal law (e.g., require posting of nutrition information other than calories) or which are more specific in application (e.g., require particular font size, color/contrast). This limitation on state and local governments is necessary to assure achievement of the congressional intent of a nationally uniform set of menu labeling requirements.

We commend FDA for acknowledging this fact, and urge the Agency to ensure that states and localities understand that any state or local menu nutrition labeling requirement that is not identical to the requirements of 21 U.S.C. § 343(q)(5)(H) (and in particular goes further than what will be required under Federal law either in scope or specificity) is now preempted. Without affirmative efforts by FDA to educate state and local jurisdictions as to the scope of preemption, such jurisdictions may continue to challenge industry, forcing companies to resolve

these issues in court in order to ensure that there is one uniform federal standard. FDA should also seek to prevent new jurisdictions from enforcing menu labeling laws not previously in force, which would further disrupt an orderly implementation of national requirements and create confusion among consumers. Unnecessary court battles will only add to the costs of implementation for all those involved and slow the progress of the restaurant industry in providing information to the public.

Contrary to FDA's Draft Guidance, we believe the statute does not permit FDA to require industry to move forward with nationwide implementation of menu labeling before a final regulation implementing 21 U.S.C. §343(q)(5)(H) is issued. Rather, Congress specifically tasked FDA to develop and implement regulations to "carry out" the requirements of the law through a rulemaking process providing specific parameters for compliance, including a one-year requirement for issuance of a proposed rule and quarterly reports to Congress on progress toward a final rule. 21 U.S.C. §343(q)(5)(H)(x). Unlike the preemption in place under PPACA § 4205(c), the menu labeling requirements of the statute are not self-executing. Various significant aspects of the statute require the establishment of definitions and parameters through notice and comment rulemaking. This indicates that Congress, while intending immediate preemptive effect to prevent the continued proliferation of varying and burdensome restaurant nutrition labeling requirements across the nation, did not intend to mandate that industry implement 21 U.S.C. §343(q)(5)(H) menu labeling requirements nationally prior to FDA's finalization of a rule establishing a truly uniform approach across the country.

The approach taken in FDA's Draft Guidance is contrary to what we believe was the congressional intent, as well as the terms of statute, and would prejudge the outcome of the rulemaking. Moreover, attempting to require national implementation of the PPACA § 4205 based on general statutory language with guidance followed by a second implementation in accordance with the final regulation would be confusing to our customers. A clear example is contained in the FDA Draft Guidance document. Implementation prior to completion of the regulatory process would produce menus/menu boards with at best only partial information, as variable menu items would not be labeled. Premature implementation will also place enormous and unnecessary cost burdens on the industry, especially franchisees that operate small businesses. This massive implementation effort should occur only once, after the issuance of final rules interpreting the requirements of PPACA § 4205.

Implementing the menu labeling requirement in a single process with sufficient time for implementation is fully consistent with how FDA has long regulated labeling on packaged foods. For example, following passage of the Nutrition Labeling and Education Act of 1990 (NLEA), the most comprehensive food labeling reform in history, FDA provided the packaged food industry with a single effective date for implementation, not a staggered or phased-in schedule for different provisions. FDA took this approach because FDA understood the enormous cost associated with revising every food label, and so the agency rightfully made every effort to minimize that cost through a single, uniform effective date. FDA routinely takes the same approach with more limited labeling changes, by allowing food companies to implement a new labeling requirement at the next uniform labeling compliance date, which occurs once every two years. FDA should take the very same approach with menu labeling for restaurants, as the costs and implementation challenges associated with menu labeling are at least as compelling, if not more so. In the restaurant setting, not only would this rule affect hundreds of thousands of retail

establishments, but many locations would be instituting this labeling for the very first time, and the changes affect not just menus but also training of many thousands of restaurant workers. Accordingly, FDA should apply the same lessons learned over the decades with the packaged food industry in this regard, by providing a single, uniform effect date, following the issuance of final regulations.

Rather than attempting to implement PPACA § 4205 requirements prior to final regulations, and to the extent certain state and local jurisdictions continue to maintain and enforce menu labeling requirements identical to the requirements of 21 U.S.C. §343(q)(5)(H), we believe all restaurants -- including those chain restaurants and similar retail food establishments that will be subject to the final rule -- should have the option to choose to register under the voluntary menu labeling program under 21 U.S.C. § 343(q)(5)(H)(ix) and implement menu labeling requirements in such jurisdictions in general compliance with 21 U.S.C. §343(q)(5)(H). During this interim period, only voluntary implementation should occur for restaurants not subject to an identical state or local law. If employed to assist in such voluntary, interim compliance, FDA guidance providing general parameters for implementation by restaurants in jurisdictions with identical requirements would be appropriate.

II. Specific Comments

FDA has requested specific comments on various issues associated with PPACA § 4205 implementation. With the exception of issues relating to vending machines, we hereby provide comments on each matter raised by FDA.

Chain Retail Food Establishments

- **The Types of Restaurants or Similar Retail Food Establishments and the Nature of Their Food Service Activities**

The U.S. restaurant and foodservice industry is large, complex, and fragmented. The industry has 40 different segments, including three major groups: commercial; noncommercial; and military restaurant services. Our restaurants include national and regional chains, many of which are franchised, as well as thousands of independent establishments. Of these different types of restaurants across the country, most consist of full service restaurants ("FSRs") and limited service eating places which include quick-service restaurants ("QSRs"); cafeterias and buffets; snack bars; non-alcoholic beverage bars; and bars and taverns.

FSRs, where waiter or waitress service is provided, usually feature a variety of main course items on the menu. Customer preferences drive sales and often result in "cooked-to-order" or customized menu items, product substitutions and varying serving sizes. FSRs include casual dining (full bar); family dining (limited bar) and fine dining establishments. Often, fine dining establishments rely on a greater range of suppliers, and change menu items seasonally (or even daily), which can add complexity. FSRs typically have customary (but not uniform) practices in terms of how menu items are conveyed, method of preparation and service, and consumption.

Most QSRs are "fast food" restaurants, but the category also includes fast casual restaurants which may offer different choices at a slightly higher price point without table service. The QSR market includes about 200,000 restaurants. Some may be freestanding or located inside other buildings. Companies may place kiosks, with limited or no seating, in tight spaces like airports or train stations. Most QSRs specialize in main dish categories, including hamburgers, sandwiches, chicken, pizza/pasta, Mexican food, Asian food or snacks. Many QSRs offer side dishes, desserts and beverages and some also provide breakfast items, children's menus or combo meal packages. QSRs may take orders from in store menu boards, or drive-thrus, or take phone and online orders for customer pick-up and delivery. Customers of QSRs consume about 60% of food purchased off-premises.

Chain restaurants also vary in terms of structure and geographic breadth. Some chains have 20 or more locations all in a close proximity, with the result that shipping costs for new menu boards are modest. Others have thousands of locations across all 50 states, which means shipping costs are significant and the logistics of ensuring coordinated shipments, posting and change-outs are complex and expensive.

Chain restaurants often operate under franchise models, which present unique challenges for PPACA § 4205 implementation. Some chain franchise companies own all their restaurants, while others have extensive franchisee ownership. Within that structure, contracts between corporations and franchise owners vary widely according to business model. For example, menu boards and menus may be designed by the corporate franchisor but sourced and produced by franchisees locally. In other models, the franchisee buys the menu boards and menus directly from the franchisor or from a supplier or suppliers prescribed by the franchisor. Similarly, in some franchise systems, franchisees have flexibility to make changes to the standard menu boards or menus, and in others, the franchisor controls this aspect of the restaurant with absolute discretion. In some franchise systems, the corporate franchisor pays for menus, while in other systems the franchisees pay for menu-related costs.

Certain restaurants create custom menu boards for franchisees to reflect the unique combination of items that the franchisee offers. In at least one major chain, each menu board must be manually created by hand, which will add yet another layer of complexity and cost to the implementation of calorie labeling. FDA regulations, implementation requirements and enforcement should recognize the varying control by franchisors over franchisee activities, including the fact that significant differences in menu offerings and practices exist at the franchisee level.

PPACA applies to both restaurants and "similar retail food establishments," but does not define which businesses will be considered "similar retail food establishments" and thus subject to PPACA. As contemplated in FDA's Draft Guidance, we believe that "similar retail food establishments" should be defined broadly to encompass businesses such as convenience stores, grocery stores, cafes, bakeries, theaters, delis and grills located in convenience stores, concession stands located in stadiums, and other environments where food is sold by chain operators. Such a broad definition would prevent the anomalous result in which similar food is labeled with nutrition information in one dining context but not another, and would maintain a level playing field among food purveyors.

- **Current Practices within the Restaurant or Similar Retail Food Establishment with Respect to Standard and Non-Standard Menu Items and the Use of Menus or Menu Boards.**

As befitting an industry as diverse as that described above, chain restaurants provide consumers with information about menu items in a broad array of formats. Some chains produce written paper brochure menus, some printed menus, some only hard plastic menu boards, and others have electronic menu boards on a flat screen monitor. Some chains are a combination of sit-down restaurants with a drive thru, some are purely sit-down, and some are purely drive thru. Others are solely delivery, others purely take-out, and still others a combination of the two. The operation and regulation of each type of restaurant must always take account of limitations placed on restaurants by virtue of local ordinances and requirements, such as zoning limitations on menu boards.

PPACA defines "menu" or "menu boards" as "*the primary writing* of the restaurant or other similar retail food establishment from which a consumer makes an order selection." 21 U.S.C. § 343(q)(5)(H)(xi) (emphasis added). As noted, different restaurants use various primary means of communicating with consumers. For example, a restaurant that sells pizza for delivery or carry-out may communicate with its customers primarily by means of a website, while consumers eating at a casual dining restaurant overwhelmingly make ordering decisions based on an in-store menu. FDA's Draft Guidance incorrectly interprets the plain terms of the statute, ignoring the terms "the" and "primary" to attempt to require nutrition information on multiple menus and menu boards. To require a pizza delivery/carry-out to provide calorie information on in-store menu boards, which are extremely expensive and rarely utilized by consumers, or a casual dining restaurant to provide calorie information on delivery menus -- neither of which are "the primary writing" for consumer selections in each setting -- would impose an undue and unlawful burden on those restaurants. "The primary writing" clearly means one menu or menu board, and FDA should clarify that restaurants may lawfully designate one menu or menu board as its "primary writing", with labeling of other menus or menu boards permitted on a voluntary basis. FDA should also acknowledge that many restaurants use promotional material (e.g., tabletop tents) to advertise special items or deals, and such materials do not constitute "menus" or "menu boards" within the scope of PPACA § 4205.

Drive-thru menus present particular challenges. PPACA requires restaurants using drive-thru menu boards as their primary writing to list calories on those boards. 21 U.S.C. § 343(q)(5)(H)(ii). As noted, in some jurisdictions the size of drive-thru menu boards -- and therefore the amount of available space on them -- is limited by local zoning ordinances. Some state and local jurisdictions, such as New York City, have addressed this issue in part by allowing the use of stanchions for providing calorie information in drive-thru areas and similar settings. *See* N.Y. Health Code § 81.50(e)(3). However, the use of stanchions also requires available real estate and risks running afoul of local zoning regulations. As a result, other jurisdictions, such as California, have permitted restaurants to choose a variety of methods of providing nutrition information at drive-thru areas, including making the information available upon request. *See* Cal. Health & Safety Code § 114094(c)(4). In order to avoid imposing an undue burden on some restaurants, FDA regulations and enforcement discretion should recognize various options for furnishing information in these settings. In no case should the practical consequence of calorie disclosure requirements on drive-thru menu boards be a *de facto*

restriction (due to space limitations) on the number or variety of menu items that would otherwise be offered by the restaurant on such menu boards.

The application of PPACA § 4205 to chain retail food establishments was driven in part by congressional recognition that such chains widely offer standard menu items across the full scope of their operations. FDA should also recognize that in certain cases a single restaurant or market area in a restaurant chain may decide to serve a local or seasonal item. The final rule should clarify that such items are not subject to PPACA's provisions related to limited-time or test-market items; rather they are not "standard menu items" not subject to PPACA § 4205 labeling requirements.

Providing nutrition information for certain custom items (e.g., custom beverages) can be particularly burdensome, and such custom food items are not standard menu items subject to these requirements. For standardized beverages, such as coffee, orange juice, etc., FDA should allow but not require a standard disclosure per ounce.

- **Current Practices with Respect to the Format and Manner of Nutrient Content Disclosures Concerning Food Items that Appear on Retail Food Service Menus or Menu Boards**

Some chain restaurants currently provide written nutrient information to customers, and the use of printed brochures, wall posters, and websites to convey this information has increased over the years. Based upon that experience, we believe FDA's Draft Guidance is unduly prescriptive and burdensome with respect to font size, placement and other requirements associated with the declaration of calories and the "additional nutrition information is available upon request" statement. As framed in the Draft Guidance, these declarations would significantly change the look of menus, crowding out other essential information and altering the unique expression of the brand identity of the chain restaurant. Instead, FDA regulations should permit significant flexibility in achieving disclosures that meet the statutory requirements.

- **Considerations in the Disclosure of Caloric Content Information for Food Sold at a Salad Bar, Buffet Line, Cafeteria Line, or Similar Self-Service Facility, and for Self-Service Beverages or Food That Is on Display**

Self-Service Items (Salad Bar, Buffet Line, Etc.): Many chain restaurants offer salad bars or other cafeteria-style service options, where the consumer may select not only the food he or she will consume, but also the amount of that food. This makes effective nutrition labeling difficult, because the amount of nutrients is dependent on the size of serving selected by the consumer. Further, it is difficult to convey nutrition information in a self-service setting in a concise and easily understandable manner without cluttering an already crowded space. Accordingly, due to these challenges and the fact that consumers can control their own portion sizes effectively in self-service settings, the FDA should allow nutrition information for self-service food in a flexible manner, such as via a handout or placard. We note also that these foods are not subject to the obligation to provide additional nutrition information in writing for consumers on request.

Self-Service Beverages: Many chain restaurants include self service beverages as options that may be ordered with food items or combination meals. In many cases, the consumer reviews options on a menu board, then places an order at a cashier and pays, and then fills up his or her beverage. We believe labeling of beverage calorie content on the primary menu or menu board writing is appropriate, including for self-service beverages, and not where such beverages may be filled by the consumer.

- **Issues to be Considered in Developing a Succinct Statement About a Suggested Daily Caloric Intake that is Required to Appear on Menus and Menu Boards**

PPACA requires "a succinct statement concerning suggested daily caloric intake . . . to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu." *See* § 21 U.S.C. § 343(q)(5)(H)(ii)(I)(bb). We note that this is not the only statement required by the federal law: PPACA also requires a "prominent, clear and conspicuous" statement regarding the availability of nutrition information. See 21 U.S.C. § 343(q)(5)(H)(ii). Furthermore, an increasing number of states and localities are requiring restaurants to list other disclaimers and notices on menus, such as allergen disclosures. In light of the mounting number of required statements, FDA should consider the very limited space available on menus and menu boards, and the importance to consumers of other menu information. Specifically, to avoid requiring restaurants with limited menu space to fill that space with lengthy statements that may not be understood or easily viewed under the best of circumstances, FDA should keep the required statements brief, require them only on one page or the menu or one panel of the menu board, and allow restaurants to combine them with other required statements or disclosures.

In some cases menu space is available for additional information. Consequently, FDA should make clear that additional voluntary disclaimers are permitted to the extent they do not interfere with required information, such as a statement that actual nutritional content in items may vary from declared values due to factors such as variation in ingredients and portion size. A flexible approach to such statements will allow restaurants to strike the appropriate balance between communicating the required information and maintaining the readability of menus.

- **Methods Related to Presentation of Nutrient Content (Ranges, Averages, or other Methods) for Standard Menu Items that Come in Different Flavors, Varieties, or Combinations but which are Listed as a Single Menu Item, such as Soft Drinks, Ice Cream, Pizza, Etc., or Combination Meals Such as Children's Combination Meals.**

PPACA requires FDA to establish standards for "determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or combination meals, through means determined by the FDA, including ranges, averages, or other methods." 21 U.S.C. § 343(q)(5)(H)(v). The treatment of combination meals, flavors and varieties has been a recurring concern for restaurants attempting to comply with state and local menu labeling laws. Different restaurant chains face various challenges related to combination items due to factors such as inherent customization of certain menu items or large high-low ranges of available combinations that are of limited utility to consumers (*e.g.*, 400 - 2800

calories). To ensure that restaurants can both comply with PPACA and effectively communicate information to consumers, FDA should provide restaurants with various options for representing nutrients in combination and variety items, such as allowing restaurants to label the calories of each component of a combination meal, provide a representative set of combinations with associated caloric information, or provide a range, median or average. For example, customers in pizza restaurants may benefit from precise nutrition information on the core, standard pizza builds that they order by name from a website (e.g., Veggie Pizza, Deluxe Pizza, etc.), and further information and customization options could be provided in more detailed nutrition brochures.

Similarly, in achieving compliance with respect to food intended to serve multiple guests, we believe that listing calories "as is" or a reasonable per serving declaration for multi-serving items is a workable approach and is commonly allowed in many states and localities with menu labeling ordinances. FDA should not attempt to specifically define serving sizes for the multiplicity of restaurant foods, but should allow flexibility for restaurants to define reasonable per serving declarations or use existing "reference amount customarily consumed" (RACC) designations for serving size when available.

- **Factors to Consider With Respect to Determining What Foods or Categories of Foods Might be Exempt from the Menu Labeling Requirements Because, e.g., They are Condiments and Other Items Placed on Tables or Counters for General Use; Daily Specials, Temporary Menu Items, or Custom Orders; or Other Food That Is Part of a Customary Market Test**

PPACA states that it does not apply to (and thus labeling is not required for) items that are not listed on the menu or menu boards (such as condiments and other items placed on the table or counter for general use) . . . daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; . . . or such other food that is part of a customary market test appearing on the menu for less than 90 days, under the terms and conditions established by the [FDA]." 21 U.S.C. § 343(q)(5)(H)(viii)(I)(aa)-(cc). We believe the exemption for daily specials and items not listed on menus or boards is clear, and should be codified in regulations.

With respect to exemptions for temporary menu items and market tests, FDA should recognize that restaurants have highly individualized practices relating to such limited-time offerings. For example, some restaurants typically begin a test in several restaurants in a region, then (if warranted by the initial test), expand the test to a larger set of restaurants, and then (again, if warranted) offer an item system-wide. Other restaurants test items first in one restaurant or region, then in another, and then (if warranted) offer the item system wide. Still others adopt customized plans on an item-by item basis. Moreover, "test" menu items often evolve over the course of a market test, based on customer preferences (i.e. the results of the test). Regional tastes may significantly impact the initiation or expansion of market tests. Thus, FDA should adopt a flexible regulation that takes into account the variable and iterative nature of market tests.

Given the difficulties associated with providing test or variance item information nationally (which in certain cases would actually result in consumer frustration due to the

appearance on menus or menu boards of items for which they do not in fact have local access), we urge FDA to adopt an approach in which test or variance items that are sold at only 20% of a chain are not considered "standard menu items." Caloric information for such items could be provided in writing with other nutrition information.

The nature of the restaurant business also dictates that from time-to-time the composition of a menu item may change during a menu cycle due to, for example, ingredient changes at the supplier level, ingredient shortages, or product recalls. In such cases, only changes that affect the information presented on the menu should be permitted to be made during the next regular menu cycle, due to the expense involved in reprinting menus or modifying menu boards. For example, absent a flexible regulatory approach, if a supplier changes an ingredient and another supplier is unavailable (and thus the inputs to a product change for reasons beyond a restaurant's control) restaurants might be faced with incurring a large expense to alter menu boards or reprint menus for the sake of a small and transitory variance on one menu item. To avoid this scenario, a flexible regulatory approach that accounts for business cycles and contingencies is critical. In this scenario, for example, the item should not be considered a standard menu item subject to nutrition labeling, or restaurants should be afforded a grace period until the next menu cycle to update menus to conform to supplier changes and ingredient shortages.

With respect to "condiments and other items placed on the table or counter for general use", this exemption should be applied in a manner that accommodates the diversity of practices in the restaurant industry. For example, the same condiment that is placed on the table for general use in one restaurant, allowing the guest to use as much or as little as desired, may be served in a ramekin or small bowl on the entrée plate in another restaurant, also allowing the guest to use as much or as little as desired. Both restaurants should have flexibility not to add the nutrient information for that condiment or dipping sauce to the nutrient values for the dish.

- **Information About the Size of Chain Retail Food Establishments**

As noted, the number of chain restaurant locations covered by PPACA § 4205 is estimated at 250,000 – 275,000.[2] However, this number includes only chain restaurant companies operating 20 or more locations under the same trade name, and does not include "similar retail food establishments" encompassed by the statute but as yet undefined by regulation. Therefore, the potential universe of covered entities is much larger than our estimated 250,000 – 275,000 chain restaurants. Moreover, the statute provides a mechanism for restaurants to voluntarily opt-in to coverage, which could potentially enlarge the number of covered entities by several hundred thousand.

Commercial restaurants in the U.S. number over 550,000 restaurants, and the industry is far from monolithic. The industry is comprised of some of the largest companies in the country and also of thousands of small independent owners, with great diversity in business models. Large companies may have both corporate and franchisee owned stores, and companies may

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[2] Chain Store Guide Database of Chain Restaurant Operators, August 4, 2010. See Attachment A

issue franchises for an individual store or a geographical market. Some franchise chains have small, independent operators with only one or two locations. Others have franchisees with hundreds of locations across many states. Accordingly, PPACA § 4205 will affect businesses varying from relatively small chains, to "mom and pop" owners and franchise operators, to some of the country's largest companies. These variations affect factors such as economies of scale, supply chain, and menu cycles, and can have a major impact on how food, menus and nutrition information are provided to consumers.

- **Information About the Number of Retail Food Establishments That May Choose Voluntarily to Be Subject to Section 4205**

As has been mentioned previously, the restaurant industry is very diverse. The entire foodservice industry in the U.S. (including all types of venues and institutional settings) includes some 945,000 locations, with more than 70% of such establishments having just one unit. Some restaurants and restaurant companies have been providing nutrition information to their guests for years and, with the adoption of a flexible federal standard, will likely choose to participate in it. For others, the burden presented will be a critical factor, and the willingness to voluntarily participate in labeling will be determined by the flexibility of the federal standard.

- **Factors to Consider With Respect to Availability and Use of Space on Menus and Menu Boards**

As noted, the availability of space on menu and menu boards is extremely limited, and menus play multiple roles in communicating information to consumers. In certain scenarios, such as drive thrus, local requirements such as zoning laws may further limit available space. Contrary to the Draft Guidance, FDA should recognize that the caloric information and other required statements can significantly impact the readability of menus and menu boards. Thus, restaurants should be provided with flexibility in presenting caloric information in ways that satisfy the "clear and conspicuous" and "adjacent to the name of the standard menu item" requirement, without rigid font or size specifications. Statements regarding calorie intake and availability of other nutrition information should be succinct and required only once on the primary menu or menu board.

Determination of Caloric Content of Foods Offered by Chain Retail Food Establishments

We believe the statutory "reasonable basis" standard for restaurant menu item nutrient declarations reflects the important differences between the packaged food and hand-preparation restaurant industries. While many chain restaurants have standard ingredients and preparation techniques, anyone who has eaten at a chain restaurant recognizes that the specific prepared on can and does vary from experience to experience. Some chains have as many as 500,000 restaurant level employees across their franchised and company restaurants, and restaurants in the QSR sector may have over 100% annual turnover among employees. The industry faces the challenge of training millions of employees each year in how to function in their restaurants, including but by no means limited to how to hand prepare our products consistent with chain standards. While chain restaurants strive to produce a consistent customer experience in our food and other aspects of our operations, the specific product any customer receives will vary. That may be a function of the specific employee's training, their experience and skill in

preparing the product, the care with which they measure an ingredient, how busy the restaurant is at a particular time, and other factors. Even QSR products are hand-made in the restaurant, so there is necessarily significant variation within individual product preparations. Indeed, factors such as the type of equipment available in a given location (e.g., flat grills versus broilers) can introduce significant variation in food item nutrient content. FDA's approach to the "reasonable basis" standard, and use of enforcement discretion in nutrient declarations, must recognize these realities.

Implementation and Enforcement

- **Information About Implementation, Including Information About Options for Inspection and Enforcement**

For many restaurants, nutrition labeling will involve a steep learning curve and will require them to incur substantial costs in the form of education, planning and execution. Labeling will require restaurants to understand the final regulations and guidance issued by FDA and the application to their various menu offerings; analyze nutritional content of their products; design and produce menus and menu boards (including boards for drive-thrus); ship and install menus, menu boards and written nutritional information available on request; train staff in requirements and maintenance of disclosure materials, product preparation and other factors; and continuously update and maintain appropriate information on their products. Much of the restaurant-level work force is at an entry-level, and thus compliance with menu labeling requirements will involve an enormous training and implementation effort. Even for chains that have long provided nutrition information, the challenges associated with complying with a single, uniform national mandate will require the devotion of significant resources.

Accordingly, as was the practice with respect to the implementation of nutrition labeling on packaged foods, we believe FDA should require only one implementation of menu labeling after the issuance of final regulations, and allow a meaningful period -- e.g., not less than one year after regulations are finalized -- for restaurants and similar retail food establishments to implement the final rule prior to any FDA enforcement of these provisions. Concurrently, the Agency should provide Q&A and other guidance materials, convene workshops on compliance, and take other steps to assist industry in achieving compliance with the final rule. FDA should also adopt a reasonable approach to enforcement of menu labeling, incorporating opportunities for training, informal notices, and expedited dispute resolution, in recognition of the fact that uniform compliance at restaurant locations across the country will be difficult to achieve.

- **Information About Inspection and Enforcement Mechanisms in State and Local Nutrition Labeling Programs**

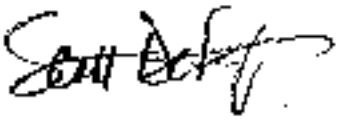
We believe it is important to ensure that state and local jurisdictions attempting to enforce laws that are identical to PPACA requirements do so in a uniform way that respects the judgments made by Congress in framing the statute, as well as FDA's interpretations adopted through rulemaking and guidance. As PPACA § 4205 is implemented, FDA should provide guidance and training to state and local jurisdictions to ensure that such entities do not attempt to adopt varying interpretations of federal requirements which would be preempted under the federal law.

* * *

NCCR and the National Restaurant Association appreciate this opportunity to provide comments on FDA's implementation of PPACA § 4205. We look forward to working with the Agency to implement the law in a manner that benefits consumers, respects the realities of a complex chain restaurant industry, and achieves the implementation of a uniform national approach to menu labeling requirements.

We would be happy to provide more information regarding any aspect of these comments.

Respectfully submitted,



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ATTACHMENT A

Chain Store Guide
Business Intelligence | Market Research

www.chainstoreguide.com

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325 7th Street, NW
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Washington, DC 20004

August 4, 2010

Dear Mr. Vinson:

Pursuant to our discussion regarding Section 4205 of the Patient Protection and Affordable Care Act of 2010 and its menu labeling requirements for chain restaurant operators, I am providing you with information derived from Chain Store Guide's Database of Chain Restaurant Operators.

As you are aware, Chain Store Guide has been in the business of collecting and disseminating information about retail and foodservice operators since 1925. Our current chain restaurant database contains information for more than 6,400 companies in the United States that operate two or more locations. Information is compiled using our in-house call center, and each company is completely updated at least once a year.

The criteria used to determine the number of companies and total locations that may be affected by the new menu labeling requirements include companies headquartered in the United States that operate a minimum of 20 restaurants operating as a singular concept. Analysis of the CSG database reveals 680 companies operating just over 292,000 locations worldwide that fall within these parameters.

It should be noted that perhaps as many as 50,000 of the total locations may be situated outside the U.S. borders. McDonald's, Subway, and Yum! Brands all have substantial numbers of international restaurants. The most recent information available reveals that these three companies have approximately 45,500 locations in foreign countries, most of which are operated by franchisees. Other restaurant chains such as Chili's, Applebee's, Ruby Tuesday, Hooter's, Popeyes Louisiana Kitchen, Domino's Pizza, and Papa John's Pizza also have international operations, but not at the same levels as the first three cited above.

It should also be noted that the following types of business are not included in the above totals:

- Companies that franchise all of their restaurants from another entity, although their locations are accounted for in the franchisor's total.
- Multi-concept operators that have 20 or more locations under multiple trade names, none of which totals 20.
- Companies headquartered in another country but operating restaurants in the U.S.
- Companies such as hotel/motel operators, on-site/contract feeders (sports venues, prisons, business and industrial cafeterias, hospitals), movie theatres, bowling alleys, book stores, convenience stores, grocery stores, schools and universities, and many other types of nontraditional foodservice operations that may have 20 or more locations.

There are no definitive numbers available regarding the number of locations that could be affected if the above-noted exclusions were to be included. For example, Tim Hortons is a Canadian-based public company which at year-end operated 553 restaurants in the U.S. Canadian franchisor Pita Pit has nearly 200 U.S. locations. Movie theatre operator AMC Entertainment has almost 400 theatre complexes, and AMF Bowling Centers runs more than 300 bowling alleys. Depending on how the law is interpreted and/or

enforced, grocery and convenience stores with on-site foodservice may be subject to regulation, affecting potentially tens of thousands of additional locations. The CSG Database of Convenience Store Locations currently includes nearly 120,000 such stores in the U.S., many of which are providing ready-to-eat food and beverages to their customers.

While Chain Store Guide does not claim to include the entire universe of all restaurant operators in the U.S. that operate 20 or more locations, we are confident that our database covers at least 90% of the non-franchisees of this size.

If you have additional questions or data needs, please do not hesitate to contact me.

Linda P. Helman

Linda P. Helman, Senior Editor
Chain Store Guide

February 25, 2011

Jessica Leighton
Senior Science Advisor
Office of Foods
Office of the Commissioner
U.S. Food and Drug Administration
White Oak Office Building 1, Room 3226
10903 New Hampshire Avenue
Silver Spring MD 20993

Dear Jessica:

NCCR and NRA have attached what we believe is a sound proposal for the handling of variable menu items under the upcoming rulemaking implementing PPACA § 4205. In framing this approach, we have taken into account the critical interests of our customers as well as the practical industry realities highlighted repeatedly in our comments to the Agency.

The variable menu items offered by the restaurant industry are extremely diverse, and are the result of an enormous effort in terms of market research, consumer feedback, and complex business processes. Any given variable menu item -- and there may be many on a menu or menu board --may actually represent hundreds or even thousands of possible versions of that item. Such items may differ by size, toppings, crusts, type of meat, method of preparation or cooking, flavors, etc. In some cases, menu calorie declarations reflecting even a portion of those permutations would require a menu board covering much of the available space at the restaurant venue. Thus, in order to provide information on these items in a coherent manner that reflects the diversity of restaurant food choices, modes of service and presentation, we believe it is absolutely essential that the rulemaking permit a range of approaches to variable menu item declarations. These include averages and ranges, labeling of flavors, components and toppings individually rather than as potentially offered in each version of the variable item, and labeling of pre-set "builds" of variable menu items. Such a reasonable approach to variable menu item calorie declarations is critical to the successful implementation of PPACA § 4205, both for consumers and the regulated industry.

We look forward to discussing this further in our upcoming meeting, and we would be happy to convene a call sooner if you have any questions. We also plan to provide suggested language for combination menu items.

Thank you in advance for your consideration of this approach to variable menu items.

Sincerely,

M. Scott Vinson
Vice President
National Council of Chain Restaurants

Scott DeFife
Executive Vice President, Policy & Government Affairs
National Restaurant Association

VARIABLE MENU ITEMS

Variable menu items are menu items represented by a single price point or common size, but which differ by flavor, components, toppings or method of preparation. Examples include, but are not limited to: a medium 3-topping pizza for which crusts and toppings are variable; a 10-piece order of chicken for which a choice of light/dark meat, as well as cooking method, are variable; ice cream sundaes and shakes for which mix in candies, toppings or base ice cream flavors are variable; burgers for which toppings or protein choice are variable; and omelets, for which ingredients and toppings are variable.

Such items should be subject to calorie disclosure as usually prepared and offered for sale; or on the basis of a customary division of the menu item (e.g., a slice of pie or pizza); or by declaring the number of servings in the menu item and the number of calories per serving (e.g., family-style lasagna serves four, 400 calories per serving).

Calories for variable menu items should be disclosed on the primary writing utilizing <u>one</u> of the following methods:

- Provide an average or range, for each size or price point of the variable menu item on the primary writing, adjacent to the variable menu item. If "averages" are the chosen method, the term "Avg Cal" must be stated on the menu adjacent to the average declaration;

  or

- Calorie label the flavors, components or toppings that make up that variable menu item elsewhere on the primary writing;

  or

- Display the calorie amount on the primary writing for one pre-set "build" of the variable menu item. If the restaurant or similar retail food establishment (SRFE) selects this option, it must indicate on the primary writing which build that calorie count represents. For example, by indicating *"calorie counts are based on the pictured items"*, or if the item is not pictured, the calorie disclosure must have a text label indicating the product represented. The restaurant or SRFE must then calorie label the additional options available for the variable menu item in a separate writing (examples include, but are not limited to: an electronic kiosk, a nutrition brochure, a menu addendum, a nutrition poster or online nutrition application) available before or at the point of sale.

- Variable menu items should be distinguished from "custom orders," which are prepared in a specific manner for an individual consumer such that the restaurant or SRFE must deviate from its standard preparation of a menu item. Custom orders generally involve removing ingredients or adding ingredients that are not listed on the menu or menu board as options.

March 9, 2011

Jessica Leighton
Senior Science Advisor
Office of Foods
Office of the Commissioner
U.S. Food and Drug Administration
White Oak Office Building 1, Room 3226
10903 New Hampshire Avenue
Silver Spring MD 20993

Dear Jessica:

Following up on our letter of February 25, in which we outlined our recommendations for calorie disclosure of variable menu items in the upcoming rulemaking implementing PPACA Section 4205, NCCR and NRA enclose here our proposal for calorie disclosure for combination meal items. We believe this framework addresses the many diverse menu and menu board formats existing in the chain restaurant industry today, and will provide consumers with clear and simple information on calorie content that is easy to understand.

We reiterate our request to meet with you as soon as possible to further explain our recommended framework for calorie labeling for both variable menu items and combination meals. We hope to provide graphic illustrations to serve as visual aids so that you may see how our recommendations would appear on menus and menu boards.

Thank you in advance for your consideration of these recommendations, and please do not hesitate to contact either of us for more information.

Sincerely,

M. Scott Vinson
Vice President
National Council of Chain Restaurants

Scott DeFife
Executive Vice President, Policy & Government Affairs
National Restaurant Association

Combination Meal Menu Items

- "Combination Meals" are comprised of two or more food or beverage items bundled into one menu item at specified pricing (examples include: Burger + Fries + Soft Drink; or Appetizer + Entrée + Dessert).

- Combination Meals may be "Fixed" (e.g., a combination of specific entrée, specific side item(s) and specific drink) or "Variable" where one or more food or beverage items have variability in flavor, components, toppings, or method of preparation (e.g. a combination offering more than one choice of entrée or side item(s) or drink). Both Fixed and Variable Combination Meals may be offered in multiple sizes at corresponding prices

- Disclosure of calories of Combination Meals should be based on the Combination Meal as it is usually prepared and offered for sale (e.g., Scrambled Eggs + Home Fries + Coffee). If a Combination Meal allows for multiple servings, calories may be disclosed on the basis of the customary division of the menu item; or by declaring the number of servings in the menu item and calories per serving (e.g., Family-Style Lasagna + Tossed Salad + Garlic Bread, serves 4).

- If the primary writing lists a **Fixed Combination Meal** (e.g., a combination of specific entrée, specific side item(s) and specific drink), the restaurant may:

    A. Provide total calories for the Fixed Combination Meal adjacent to the meal on the primary writing. OR

    B. Provide calories for each menu item of the Fixed Combination Meal elsewhere on the primary writing.

    - If a Fixed Combination Meal is available in multiple sizes, calories may be provided on the primary writing for each size when a price is also provided for each size. If a Fixed Combination Meal is available in multiple sizes, but only one size of meal and one price is provided, while the other size(s) are available via an "upsize or downsize" message and pricing adjustment, calories for the Fixed Combination Meal may be disclosed adjacent to the meal while the calorie adjustment associated with the "upsize or downsize" action may be provided adjacent to the "upsize or downsize" message and pricing.

- If the primary writing lists a **Variable Combination Meal** (e.g. a Combination Meal offering more than one choice of entrée or side item(s) or drink), the restaurant may:

    A. Provide calories as a range reflecting the lowest and highest total meal calorie content among the variations available. OR

    B. Provide a median average if the calories for all variations within the Variable Combination Meal are within 20% of the median calorie value. If this is the chosen method, the term "Avg Cal" must be stated on the primary writing adjacent to the calorie disclosure. OR

C. Provide calorie information for each item of the Variable Combination Meal elsewhere on the primary writing OR

D. Provide the calories on the primary writing for one specified variation of the Variable Combination Meal If the restaurant or SRFE elects this option, then the restaurant or SRFF must:

i. Identify the items comprising the variation specified,
ii Disclose calories for the other variations of the Variable Combination Meal in a separate writing (examples include, but are not limited to, an electronic kiosk, a nutrition brochure, a menu addendum, a nutrition poster or online nutrition application) available at the point of sale.

n If a Variable Combination Meal is available in multiple sizes, calories may be provided on the primary writing for each size when a price is also provided for each size. If a Variable Combination Meal is available in multiple sizes, but only one size of meal and one price is provided, while the other size(s) are available via an "upsize or downsize" message and pricing adjustment, then calorie information for the Variable Combination Meal may be disclosed adjacent to the meal while the calorie adjustment range or average associated with the "upsize or downsize" action may be provided adjacent to the "upsize or downsize" message and pricing.

- Custom orders generally involve removing ingredients or adding ingredients to food or beverage items resulting in the restaurant or SRFE deviating from its standard preparation of the item. Any Combination Meal that includes a custom order food or beverage item does not require any nutrient disclosure.