July 5, 2011

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


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”) proposed rule implementing the restaurant menu labeling provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010 (“PPACA” or the “Act”). Our members strongly supported the adoption of a national menu labeling law, and we look forward to the orderly implementation of these requirements. However, as detailed below, we have grave concerns regarding certain of FDA’s proposed interpretations of the statutory menu labeling provisions. We appreciate the Agency’s commitment to working with stakeholders to ensure that implementation is consistent with the plain language of the law and the realities of the restaurant industry, and trust that FDA will carefully consider the comments provided herein and adjust the final rule accordingly. Without such changes, our members, who represent tens of thousands of small businesses across the country, would be subject to unnecessary burdens, inconsistent enforcement, and ambiguities that could foster litigation -- without a corresponding benefit to consumers. Such a result would be contrary to the clear intent of Congress in framing these requirements.
We previously submitted comments to the general docket on menu labeling established by the Agency. Those comments addressed various important aspects of the implementation of menu labeling, including 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, and the need for regulatory flexibility in the implementation of PPACA Section 4205. We incorporate those prior comments by reference.

Herein, we reiterate and build upon many aspects of our prior comments, while addressing the definitions, interpretations and tentative conclusions in the Proposed Rule, and responding to many of FDA’s specific requests for comments. Key issues addressed in our comments include:

- **Standard of Compliance**: FDA should adopt the “reasonable basis” standard of compliance that is specified in the statute, and that has governed voluntary nutrient content claims on restaurant menus for twenty years.

- **Establishments Covered**: the statute covers not only restaurant chains but also “similar retail food establishments.” FDA should interpret this term broadly to encompass most locations where consumers regularly consume away-from-home food.

- **Items Considered “Menus”**: FDA should ensure that in defining what constitutes a “menu” or “menu board,” it does not include “everything” that could be considered a menu, including the myriad types of advertisements and promotional materials that are not used as “primary writings” by restaurant customers.

- **Rules for Specific Items**: we include specific proposals for how FDA should define “standard menu item,” and how it should treat alcoholic beverages, variable menu items, food-on-display, and other issues.

- **Presentation on Menus**: FDA should allow flexibility for restaurants to present information in a way that is “clear and conspicuous” while also delineating certain objective criteria (font size, color, etc.) that will be presumed to comply.

- **Timing of Implementation**: given the scale of the undertaking and the likely bottlenecks that will arise as all restaurants update their menus simultaneously, we request that FDA allow at least one year for implementation of the final rule.

- **Flexibility in Updating Nutritional Information**: Due to factors outside the control of restaurants, such as ingredient availability and supplier formulation changes, nutrition values change periodically. FDA should adopt a flexible policy that allows restaurants to update menus in concert with regular menu cycles.

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1 75 Fed. Reg. 39026 (July 7, 2010).
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About the National Restaurant Association and National Council of Chain Restaurants

The National Restaurant Association, founded in 1919, is the largest 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 table service and quick service restaurant operators, chains, franchisees and independents. It also consists of allied members who are suppliers, distributors and consultants to the industry. 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, many of which in turn represent thousands of individual franchisee small businesses. NCCR is a division of the National Retail Federation, the world's largest retail trade group.

Introduction

The Proposed Rule takes a significant step toward establishing a menu labeling framework that is both useful for consumers and feasible for industry participants. However, the Proposed Rule suffers from a number of serious flaws, which stem primarily from FDA’s failure to account for and give sufficient weight to the realities of preparing food in a restaurant context, the myriad different types of restaurants and similar food establishments, and the importance of menus as a mechanism for communicating with customers. In some instances, the Proposed Rule exceeds FDA’s authority or directly contravenes the statute.

For example, Section 4205 requires FDA to determine restaurant compliance based on the “reasonable basis” compliance standard that has governed the manner by which FDA verifies the accuracy of nutrient content and claim information provided by restaurants for over 20 years. Under the Proposed Rule, however, nutritional disclosures made pursuant to Section 4205 would be evaluated for compliance using the “80/120” rule applicable to packaged food. This restrictive overlay to the reasonable basis standard is clearly contrary to the statute. Moreover, it fails to account for the exigencies of preparing food in a restaurant context, where factors such as customization by chefs and customers, variation in ingredients, and the simple fact that food served in restaurants is prepared and portioned by different people (not a piece of industrial food processing equipment), make it impossible to prepare food with the same degree of uniformity as packaged food.

Similarly, Section 4205 applies to “menus” or “menu boards,” which it defines as the primary writing of a restaurant from which a consumer makes an order selection. In the Proposed Rule, however, FDA defines “primary writing” in a broad manner that could be construed to include essentially any writing from which a consumer makes a selection. Such a
definition could include writings with just a few items, and advertisements, which would create a logistical nightmare and dramatically increase the cost of compliance. We propose that FDA adopt a more limited definition that gives content to the term “primary” and that clearly excludes advertising and promotional materials.

Elsewhere, the Proposed Rule fails to properly account for the sheer number of different ways in which food items are prepared and menus are presented at hundreds of thousands of restaurants across the country. For example, FDA proposes to allow one method -- the use of a range -- for labeling combination items (e.g., a meal consisting of a sandwich, chips, and drink) and variable menus items (e.g., a vanilla, chocolate or strawberry milkshake). While we believe that ranges are a valuable method of presenting nutritional information that should be part of a restaurant’s set of choices, there are many situations in which other methods such as providing an absolute value such as a median or average, or providing calories for a single “build” of an item that is representative of a finished version of the product that is typically ordered by customers, will be more useful to consumers and more feasible for restaurants. Accordingly, we propose that FDA adopt a broader set of options to conform the flexibility of the final rule to the complexities of the regulated conduct across our diverse industry.

The Proposed Rule is similarly inflexible with respect to the rules governing presentation of calorie information and required statements. FDA proposes, for example, to require the font size of the calorie declaration to be as large as the smaller of the price or the name of the item, and that the background color be the same as that of the item name or price. These rules are needlessly restrictive, particularly in light of other rules requiring that the calorie disclosure be adjacent to the name of the menu item, and “clear and conspicuous.” We propose that the FDA requires disclosures to be “clear and conspicuous,” but also state in the final rule that menus that declare calorie information in a font that is as large as the name, price, or the description of the menu item, whichever is smaller, are presumptively “clear and conspicuous” and comply with the statute.

FDA also proposes to determine whether a retail food establishment is “similar” to a covered restaurant based on whether more than 50% of its floor space is devoted to the sale of food. This interpretation will exclude many locations in which consumers regularly purchase food away from home, such as service stations and movie theaters. Assuming these entities meet the other requirements for being a covered establishment (i.e., more than 20 locations doing business under the same name, serving substantially the same menu items, etc.), we believe there is no basis for treating them differently from the restaurants with which they compete. We propose that FDA adopt a broader interpretation of “similar retail food establishment” that encompasses most locations where consumers routinely consume food away from home.

Throughout these comments, we endeavor to explain and provide support for critiques of FDA’s proposals, offer solutions, address specific areas where FDA has requested comments,
identify areas where we agree with the Proposed Rule, and provide research or other data where available. We appreciate the opportunity to participate in the process, and look forward to a successful implementation of the statute.

Comments

A. FDA Should Adopt a “Reasonable Basis” Compliance Standard.

In PPACA Section 4205, Congress enacted legislation that will, for the first time, mandate where, when, how, and by whom nutrition information must be posted on restaurant menus. Congress also dictated the legal standard by which FDA must determine compliance with these requirements. The Proposed Rule would impermissibly impose a far different standard, an option foreclosed by Congress.

Section 4205 states that “a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures,” and references FDA’s reasonable basis standard set forth in 21 C.F.R. § 101.10. The Proposed Rule purports to incorporate this decades-old standard, requiring in proposed section 101.11(c)(1) that a restaurant “must have a reasonable basis for its nutrient disclosures.” But the Proposed Rule would extend beyond Section 4205 by then imposing a compliance standard devised for pre-packaged foods found in section 101.9(g): Protein and dietary fiber added to the standard menu item (class I nutrients) must be present in at least their declared amounts, and protein, total carbohydrates, and dietary fiber naturally occurring in the food (class II nutrients) must be present at least 80 percent of their declared values. Calories, sugars, total fat, trans fat, cholesterol, and sodium must be present at no greater than 20 percent above their declared amounts. This so-called “80-120 rule” permits a narrow deviation between the posted calorie value and the amount of calories in the prepared restaurant menu item (and for all other nutrients that restaurants must furnish to consumers).

Restaurant foods are not prepared and sold in the same manner as pre-packaged food items. These fundamental differences account for the distinct compliance standard Congress has

2 Section 4205(b).
5 Id. (proposed 21 C.F.R. § 101.11(c)(3)(ii)).
6 Id. (proposed 21 C.F.R. § 101.11(c)(4)).
directed under Section 4205. FDA reached the same conclusion when it first adopted Section 101.10 in 1993. The question of an appropriate compliance standard for restaurants was decided by Congress. FDA cannot depart from an express statutory mandate that measures the accuracy of nutrition information by restaurants based on whether the restaurant holds a reasonable basis for the values furnished to consumers.

1. The Proposed Rule Is Inconsistent with Section 4205’s Statutory Language.

The proposal that restaurant nutrient-declaration compliance be judged using the standards for packaged foods contradicts the plain language of Section 4205 and therefore violates the Administrative Procedure Act. In proposing that restaurants be held to the packaged-foods 80-120 standard, FDA is interpreting the compliance standard articulated by Congress in Section 4205. But Section 4205 proposes a specific standard—the reasonable basis standard—and such a specific Congressional mandate does not permit an agency to impose a more rigorous standard than the one required by Congress.

An agency’s interpretation of its authorizing statute is analyzed under the framework developed in *Chevron, U.S.A., Inc. v. Natural Resource Defense Counsel.* 7 Under the *Chevron* analysis, courts ask, as a threshold, “whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter.” 8 The agency “must give effect to the unambiguously expressed intent of Congress.” 9

The express language in Section 4205 is unambiguous in adopting the pre-existing reasonable basis standard to determine compliance with the new mandatory nutrition labeling requirements:

(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other

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8 *Id.* at 842–43.
9 Only “if the statute is silent or ambiguous with respect to the specific issue, [does] the question for the court [become] whether the agency’s [interpretation] is based on a permissible construction of the statute.” *Id.* at 843. This *Chevron* “Step Two” inquiry is not at issue here because Congress’s intent is unambiguous. For the reasons set forth in this comment, FDA’s proposal contradicts established agency policy and practice and would, therefore, not withstand judicial scrutiny under the “Part Two” analysis.
reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.  

Congress chose to cite the very FDA regulation, and used express, parallel language found in Section 101.10. This reflects a clear directive to FDA which does not contemplate, nor permit, any deviation of the kind contemplated in the Proposed Rule. Indeed, in using language and incorporating only section 101.10, Congress could have, but chose not to, also apply the more exacting compliance standard under Section 101.9(g) applicable to pre-packaged foods, the only alternative compliance standard in title 21 of the C.F.R. relating to verification of nutrient levels in food.

As directed by Congress, proposed section 101.11(c)(1) memorializes the plain language of the statute (i.e., the reasonable basis standard). FDA inexplicably goes further, grafting on a compliance standard for package foods that Congress did not direct nor leave open to FDA the option to adopt. The Proposed Rule divides nutrients into Class I added nutrients and Class II naturally occurring nutrients. Class I protein or dietary fiber must be present at at least the declared amounts, and Class II protein, total carbohydrates, and dietary fiber must be present at at least 80 percent of the declared levels. Calories, sugars, total fat, saturated fat, trans fat, cholesterol, and sodium cannot exceed their declared levels by more than 20 percent. Food processors, using modern manufacturing equipment and methods, routinely produce hundreds of

10 Sec. 4205(b).

11 Section 101.13(q)(5)(ii) repeats the reasonable basis standard in the specific context of nutrient content claims made on restaurant menus, further clarifying that the reasonable basis standard may be relied on “[i]n lieu of analytical testing.”

12 C.f., Natural Resources Defense Council v. Thomas, 805 F.2d 410, 435–36 (D.C. Cir. 1986) (“Here it is Congress itself that has refused to give the agency any leeway in adjusting deadlines, and even under Chevron, in a contest between clear congressional intent and a more penumbral congressional purpose, the clear meaning of the statute wins.”).

13 See Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000) (“The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context.”); see also Sierra Club v. Environmental Protection Agency, 294 F.3d 155, 160 (D.C. Cir. 2002) (“We cannot but infer from the presence of these specific exemptions [enumerated in the statute] that the absence of any other exemption for the transport of ozone was deliberate, and that the Agency's attempt to grant such a dispensation is contrary to the intent of the Congress.”).

14 76 Fed. Reg. at 19235 (proposed section 101.11(c)(2)). Cf. 21 C.F.R. § 101.9(g)(3)

15 76 Fed. Reg. at 19235 (proposed section 101.11(c)(3)). Cf. 21 C.F.R. § 101.9(g)(4).

16 76 Fed. Reg. at 19235 (proposed section 101.11(c)(4)). Cf. 21 C.F.R. § 101.9(g)(5).
packages per minute on production lines that yield variations in nutrient levels of a magnitude that the so-called 80-120 rule recognizes.

Restaurants do not operate in this fashion, a determination that Congress made when it elected to mandate a compliance standard far more flexible and realistic than that for pre-packaged foods. The proposal is not a reasonable interpretation of Section 4205. Under the Proposed Rule, a restaurant that obtains the information for its nutrient declarations from a cookbook—which the statute expressly says constitutes a reasonable basis—could nevertheless violate FDA’s regulations if a laboratory analysis determines a nutrient falls above the 20 percent threshold. FDA cannot promulgate a regulation that punishes conduct expressly permitted by the authorizing statute. That is, of course, the protection the Supreme Court ensured under the Step One test of Chevron.

Lastly, courts are clear that “[a]n agency may not disregard ‘the Congressional intent clearly expressed in the text simply by asserting that its preferred approach would be better policy.’” 17 “Nor [does a court] set aside a statute's plain language simply because the agency thinks it leads to undesirable consequences in some applications.” 18 Even assuming the agency explained why it proposes applying the 80-120 rule for restaurant foods, no amount of agency explanation can override Congress’s clear instruction to apply the reasonable basis standard as it is written in the statute.

By the plain language of the statute, Congress expressly directed FDA in what should be considered under a reasonable basis standard, taking account of the “standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, . . inadvertent human error, training of food service workers, variations in ingredients, and other factors.” 19 By including this language, Congress demonstrated its familiarity with the challenges involved in requiring nutrition labeling for restaurant food, identifying many of the same factors that led FDA to implement the reasonable basis standard in the first place (as discussed further below). Congress took the somewhat unusual step of incorporating an agency regulation into a federal statute. The plain language of the statute sets forth a compliance standard that is clear on its face, as originally drafted and applied by FDA. The Proposed Rule

17 Sierra Club, 294 F.3d at 161 (quoting Engine Manufacturers Ass’n v. Environmental Protection Agency, 88 F.3d 1075, 1089 (D.C. Cir. 1996).
18 Friends of Earth, Inc. v. Environmental Protection Agency, 446 F.3d 140, 145 (D.C. Cir. 2006).
19 Section 4205(b).
would place the judgment of FDA above that of Congress, an outcome that would not withstand judicial review.  

2. **Adopting the 80-120 Standard Would Contradict 20 Years of FDA Precedent.**

The reasonable basis standard, as adopted by Congress, was originally promulgated by FDA in 1993. FDA determined that restaurant food preparation is fundamentally different than pre-packaged foods and that a nutrition compliance standard must account for greater flexibility than is applied to pre-packaged foods. This approach has proved workable and reliable for both restaurants and inspectors, providing a readily available way to ensure nutrient declarations are accurate and supported. Even had Congress not foreclosed the possibility, sound public policy requires that FDA’s application of existing section 101.9(g) standards for packaged foods should not be extended to restaurants.

The agency has consistently recognized that restaurant foods are fundamentally different than packaged foods. The degree of consistency expected in manufacturing facilities is simply unattainable in the restaurant industry. Each order is prepared individually at a customer’s request, ingredients are obtained in many instances from multiple suppliers, and standardized recipes are hand prepared in hundreds, or even thousands of restaurants across the country. FDA guidance and rulemaking explicitly acknowledge the “variations unique to restaurant foods (e.g., methods of preparation)” and recognize that restaurant foods “are generally hand assembled and, therefore, subject to individual product variations.” In other words, “restaurant foods tend to be prepared or sold differently from foods from other sources.” These issues, according to the agency, present “difficult questions . . . as to how exactly to analyze restaurant food in a reasonable and cost effective manner.”

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20 We have not attempted an exhaustive discussion, but would be pleased to discuss further with FDA the additional legal infirmities of its proposed standard as judged against the Administrative Procedure Act and the Constitution.
23 *Id.* Question 1.
The reasonable basis standard was the agency’s solution to this problem: because “the way in which a restaurant determines the nutrient content of a food or meal, and the way in which nutrition information is communicated to consumers, may be different for restaurant foods than for foods from other sources. . . . [f]or compliance purposes, a restaurant is required to provide information on its reasonable basis for making a claim.” 25 Thus, when first considering restaurant labeling in the context of claims, the agency decided that “a restaurant food may bear a nutrient content claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the definition for the claim.” 26

To accommodate the wide range of sophistication, resources, and preparation methods found in the restaurant industry, the agency determined “[t]he reasonable basis can be provided in a number of ways,” including using FDA’s guidelines on nutrient levels in seafood, reliable cookbooks, and databases. 27 Importantly, FDA made clear that it was “not requiring that the firm conduct an analysis of the food in order to provide this information.” 28 To ensure compliance, restaurants are required to furnish the basis for the stated nutrient values to a regulator who then would “determine whether the basis cited by the restaurant reasonably supports its use of a nutrient content claim.” 29 FDA found this to be “an effective standard for verifying that such claims are truthful and not misleading and in accordance with FDA regulations,” especially given that state and local authorities frequently performed these inspections. 30 The Proposed Rule would retain this provision and hold restaurants and similar retail food establishments accountable by requiring information substantiating nutrient values, including the method and data used to derive the nutrient values.

This standard is designed “to provide flexibility for restaurants in determining compliance with FDA’s requirements for the claims regime and in providing nutrition labeling for foods that bear a claim.” 31 This flexibility is necessary due to the unique characteristics of

27 Id. at 2387–88.
28 Id. at 2389.
29 Id. at 2388. As applied to nutrient content claims by section 101.13(g)(5)(ii), part of having a reasonable basis for a nutrient claim entails ensuring preparation methods are “sufficiently constant” to provide reasonable assurances that preparation methods do not differ substantially from those used to form the reasonable basis, but the agency specifically disclaims imposing any requirements that restaurants carefully weigh or measure each individual portion. Restaurant Labeling Guide, Questions 73–74; see also 21 C.F.R. § 101.13(q)(5)(ii).
the restaurant industry. As the Associations have furnished in previous comments to FDA on the new law’s implementation, the complexity and other characteristics of our industry are unchanged. No amount of care, training or testing would enable restaurant foods to meet the pre-packaged food compliance standard, nor is such an outcome consistent with the plain language Congress used when it directed FDA to ensure compliance with the reasonable basis standard.

In the present proposal, FDA provides no factual basis or evidence which might suggest the circumstances that justified the original “reasonable basis” standard have changed. As explained above, Congress determined that FDA had it right in 1993 and requires that FDA continue this policy. Even if the agency could disregard Congress’s clear instruction to apply the reasonable basis rule, the preamble provides no justification for so abruptly abandoning this approach. Noticeably absent from the Proposed Rule are any factual findings by FDA that the manner in which restaurant foods has changed or that in some manner the prescriptive standard applicable to uniform, prepackaged foods is attainable or practical for restaurant foods. Absent detailed and reasonable findings that the 80-120 rule is feasible for restaurant foods, adoption of the proposed standard could not be defended in court as the product of reasoned decision-making by the agency based on the administrative record before it.

The preamble devotes exactly one sentence to explaining this change, noting merely that “the nutrients that are required to be declared in covered establishments are a subset of those required to be declared in the labeling of [packaged] food in § 101.9.” 32 But this explanation hardly justifies such a drastic change. The nutrients being disclosed under the previous labeling regime were also “a subset of those required to be declared” in packaged food under section 101.9, but, as the preceding explanation shows, the agency determined that hand preparation methods in restaurants led to a individual product variations and that, as a result, restaurants should not be held to the same standards as packaged foods. 33

33 As this discussion suggests, it is questionable whether the agency has provided adequate explanation for its decision to impose the 80-120 rule on restaurant menu labeling, see Motor Vehicle Mfr. Ass’n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983) (“[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a “rational connection between the facts found and the choice made.””) (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962))), nor is it clear that the agency has adequately explained its sudden decision to depart significantly from two decades of agency precedent, see id. at 42 (“[A]n agency changing its course . . . is obligated to supply a reasoned analysis for the change . . . .”). Far from presenting a reasoned analysis for its departure, the Proposed Rule barely makes mention of the sweeping change that adopting the so-called 80-120 rule would constitute, nor are there any findings that this novel approach would be attainable or practical as applied to restaurant and similar foods.
Indeed, agency guidance furnished in 1993 and updated three years ago poses the question at issue: Does FDA interpret the reasonable basis standard as allowing for imposition of the so-called 80-120 rule as found in section 101.9(g)? Leaving aside FDA’s tentative position in the pending proposal, FDA previously answered “no.” The Q&A states: “The above compliance criteria (21 C.F.R. 101.9(g)) were established to account for natural variations in the nutrient content of commercially manufactured and packaged foods that are subject to chemical analysis to determine compliance.” Under the section 101.10 reasonable basis standard, “FDA will not subject restaurant foods to chemical analysis to determine whether nutrient levels are properly declared.” Instead, the relevant inquiry under section 101.10 is “whether the restaurant’s basis for a claim or other nutrition information is, or is not, reasonable.” This is the approach adopted by Congress and is contradicted by the agency’s proposed reasonable basis standard.

FDA’s well-reasoned regulation was based on the simple notion that compliance standards must take account of the real-world manner in which restaurant foods are prepared and sold. The agency “does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants.” The agency points to no changes in facts or the law to justify departing from this approach, particular given that Congress has codified it.

3. The Proposed Rule Does Not Account for the Variability Inherent in Restaurant Food.

For many of the reasons identified by FDA over the past two decades, the reasonable basis standard is necessary to account for the variability inherent in restaurant foods. Restaurant foods are prepared fundamentally differently than packaged foods, and it is unrealistic for a restaurant to control the quantity of ingredients as precisely as would a packaged food manufacturing facility.

As FDA and Congress have observed, restaurant foods are subject to inherent variability. Meals are usually prepared by hand at each customer’s request using ingredients that are subject to variation based on season and locality. Menu items may be prepared from standardized recipes, but the food served in each establishment is prepared and portioned by different people.

34 Restaurant Labeling Guide, Question 25. Moreover, section 101.13(g)(5)(ii) specifically allows the reasonable basis standard to be used to substantiate nutrient content claims “[i]n lieu of analytical testing.”
35 Id. Question 25, 65–70.
36 Id. Question 71.
For various reasons, such as geography and quality assurance, restaurant chains may have multiple suppliers for a single ingredient, and the nutrition information for the same ingredient from two different suppliers can and does vary to some extent notwithstanding the effort by some restaurant chains to maintain a high degree of uniformity across all restaurants. This variability is compounded by the number of ingredients used in a restaurant food and the number of separate restaurants and cooks preparing those foods under similar but not always identical circumstances. Even highly standardized preparation methods using standardized ingredients are subject to unavoidable human variability. These factors introduce a different and greater degree of variability than exists in a typical manufacturing facility where hundreds of identical packages come off a line in a single minute. It is not practical to require restaurants to comply with a standard developed for precisely calibrated manufacturing machinery.

Moreover, the challenges associated with restaurant nutrition labeling have not changed since 1993. Restaurant food preparation techniques are fundamentally the same now as they were in 1993, 1996, and 2008 (when the restaurant labeling guide was last revised). This is not a situation in which the agency desired a more precise compliance standard but one was not scientifically feasible; rather, the industry was not then and is not now conducive to being judged using such a tight compliance standard.

For example, in the context of a small order of French fries, as few as five additional French fries per serving can cause the item to exceed the 80-120 standard. One additional squirt of mayonnaise on a grilled chicken sandwich will have the same effect. Restaurants are not factories, and such inherent and unavoidable variation associated with preparing restaurant food makes the 80-120 rule unworkable.

Applying the 80-120 rule to the restaurant industry would effectively require restaurants to perform analytical testing on each menu item at each restaurant on a frequent basis, imposing significant compliance costs the agency found just three years ago to be unnecessary and not warranted.\footnote{See \textit{id.} Question 65.} Even where expensive testing were routinely conducted, the manner in which restaurant foods are prepared and served would make the type of accuracy contemplated in the Proposed Rule unrealistic. Packaged food manufacturers must account for nutrient variation at a single point of manufacture, or at a handful of manufacturing facilities, but chain restaurants have hundreds or even thousands of “points of manufacture,” each of which would require laboratory analysis of each standard menu item offered. The impracticality of obtaining comprehensive laboratory testing underscores the fundamental differences between the restaurant and packaged food industries. Moreover, the tremendous costs associated with frequent analytical testing would be substantial. It is doubtful that many restaurants could afford
to bear such costs and clear that few, if any, could operate in compliance with the 80-120 rule, a standard not designed nor appropriate for restaurant-prepared foods.

The 80-120 standard set forth in the Proposed Rule would cause still further problems. For example, a given menu item is comprised of many ingredients, and the suppliers of those ingredients periodically change, reformulate, or discontinue certain ingredients, necessitating a recipe change. As explained elsewhere in this and prior comments, however, restaurants update menus on a cyclical basis to coordinate new menu items, promotions, designs, and other factors, thus the restaurant’s menus or menu boards will not immediately reflect the change to the recipe and possible corresponding change to nutritional values. Under the proposed 80-120 standard, a restaurant in this scenario might be out of compliance the moment it first used a reformulated ingredient or changed or added a supplier. This is another example of a problem that exists to a much smaller degree (if it exists at all) for manufacturers of packaged foods.

FDA should continue to use the well-established reasonable basis approach required by Section 4205 and expounded through years of accumulated agency guidance. The reasonable basis standard provides large and small restaurants a straightforward way to establish their nutrition information and allows state, local, and federal regulators to easily verify a restaurant’s compliance.

In guidance issued less than three years ago, FDA assured the restaurant industry that it “does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants.” 38 FDA’s compelling rationale for its long-standing reasonable basis standard remains true today. Imposing a standard that cannot be met would not reflect sound public policy nor could it be defended as the product of sound, reasoned agency decision-making.

4. The 80-120 Rule Is Inconsistent with the Purpose of the Statute.

Imposing the 80-120 rule on restaurants would have consequences inconsistent with the statute and the established regulation. 39 First, the 80-120 rule would strongly discourage restaurants with fewer than 20 locations from voluntarily opting into the federal regulatory scheme. For one thing, many state and local restaurant labeling laws measure compliance using a standard akin to the federal reasonable basis standard; for another, even where no state menu labeling laws apply, a restaurant making voluntary nutrient content claims would be subject to the “reasonable basis” standard under 21 U.S.C. § 343(r). In other words, under the Proposed

38 Id. Question 71.
39 See 76 Fed. Reg. at 19192 (listing combating obesity by providing clearer nutrition information so that consumers may make healthier choices as one of the goals of the regulation).
Rule, small-chain restaurants opting into the federal rule would subject themselves to more potential for liability under the federal 80-120 standard and would thus be less likely to voluntarily participate in the federal restaurant-menu labeling scheme. In turn, there would be less national uniformity in menu labeling, consumers would see less consistent nutrition information on menus, and state and local inspectors would have to apply a more complex patchwork of regulatory schemes.

Next, the 80-120 rule imposes a tighter compliance range for foods with lower levels of nutrients that should be consumed in limited quantities, such as fat and cholesterol. Because the 80-120 standard measures compliance as a percentage of the declared nutrient level, the standard necessarily creates stricter compliance ranges for lower levels of nutrients than for higher levels. For example, for a salad with 3 grams of fat, a deviation of even a single gram of fat would throw the restaurant out of compliance. In practice, this means that a few extra drops of oil dripping off a measuring spoon would trigger a violation of the regulations. This creates a disincentive against developing and marketing low-fat, low-sodium menu items under an 80-120 rule, an outcome contrary to the purpose of the rule.

Lastly, holding restaurants to the 80-120 standard ensures violations will be inherent in the system because restaurants cannot control nutrient levels with the accuracy required by the regulations. Indeed, such a rule will inevitably result in sanctioning restaurants that are following industry best practices for ensuring the most accurate menu labeling possible; unfortunately, the nature of the restaurant industry simply does not allow for the type of accuracy the Proposed Rule would require. Even the best actors would be prone to violations due the variability inherent in hand-prepared foods. These are not the consequences Congress envisioned, nor a result it ensured when it expressly adopted the reasonable basis standard without the overlay of the 80-120 rule added on by FDA’s Proposed Rule.

Applying the so-called 80-120 rule to restaurant foods is directly contrary to Congress’s unambiguous intent in Section 4205 and contradicts twenty years of agency practice in adhering to the reasonable basis standard, with no meaningful explanation for this abrupt shift. While it is appropriate to include in the final rule the reasonable basis standard and the requirement that inspectors be provided documentation to substantiate those reasonable bases, we strongly object to the proposal to judge compliance using the 80-120 rule, which does not take account of the inherent variability in the nutrients of restaurant foods or the unique challenges of preparing food in a restaurant setting.

It is appropriate for FDA to establish reasonable parameters by which it will evaluate compliance with the reasonable basis, as provided for by current regulations and several features of the Proposed Rule. For example, Section 101.13(q)(5)(ii), FDA currently requires that that when the reasonable basis standard is relied upon in support of a nutrient content claim, the restaurant must provide upon request the specific information relied upon and “reasonable
assurance of operational adherence to the preparation methods or other basis for the claim.” The Proposed Rule similarly would provide affirmative tools, from record access to sworn statements by a restaurant representative. FDA can and should ensure that the reasonable basis standard is effectively enforced. It cannot, of course, impose a compliance standard different from that expressly chosen by Congress.

In 1990, sweeping food label reform legislation adopted by Congress expressly exempted restaurant foods from the mandatory nutrition labeling requirements. In 1993, FDA promulgated final rules that preserved this exemption unless a restaurant made a nutrient content claim. In that instance, FDA created Section 101.10 as a flexible compliance standard against which the accuracy of nutrition claims and information would be judged. Congress expressly adopted this standard and it is now the law of the land. This FDA rulemaking does not provide the appropriate forum by which the agency or stakeholders can question the wisdom of Congress in ensuring a compliance standard that is realistic, enforceable and directly serves the consumers’ interest in gaining greater access to calorie and other nutrient information. FDA must abandon that portion of the Proposed Rule that goes beyond the plain meaning of the language used by Congress to preserve and mandate the reasonable basis standard.

B. Scope of Establishments Covered

Section 4205 applies to foods “offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering substantially the same menu items.” See Section 4205(q)(5)(H)(i). It also applies to restaurants or similar retail food establishments that voluntarily register to become subject to the Federal requirements. Id. § (q)(5)(H)(ix).

1. FDA Should Adopt a Broader Definition of “Similar Retail Food Establishments.”

FDA proposes to define a retail food establishment as “similar” to a restaurant if it “offers for sale restaurant-type food” and its “primary business activity” is the sale of food consumers. In turn, FDA proposes to consider the sale of food to consumers an establishment’s “primary business activity” if either “(1) the establishment presents or has presented itself publicly as a restaurant (through consumer-, industry- or investor oriented materials), or (2) greater than 50 percent of the establishment’s gross floor area is used for the

preparation, purchase, service, consumption or storage of food (including all floor space, with the exception of multi-purpose seating areas in entertainment venues).”

Alternatively, FDA proposes to define “primary business activity” as sale of food to consumers if over 50% of the establishment’s revenues are generated by the sale of food. FDA also proposes a separate, alternative, definition of “similar retail food establishment” meaning “a retail establishment where the sale of restaurant or restaurant-type food -- as opposed to food in general -- is the primary business activity of that establishment.”

FDA has invited submission of alternative definitions of “similar retail food establishment,” and requested specific comments on a range of issues such as whether outside seating should be included in computation of floor space, and whether a revenue-based approach is preferable to the floor-space computation and if so whether 50% is the appropriate threshold. It has also requested “other suggested alternative criteria for identifying the primary business activity of an establishment.” FDA also requested comments on whether facilities that exist within larger establishments (such as a concession stand in a movie theater) should be included within the definition of restaurants in the final rule.

We believe the Proposed Rule arbitrarily and unjustifiably excludes establishments that are not only similar to, but actually function as, restaurants, and that have publicly announced their intention to offer restaurant-type food.

- **Movie theaters**: Many national movie theater chains have recently expanded their dining options in a concerted effort to incorporate restaurant-type dining into the experience of a “night out at the movies,” and thereby increase sales and revenues. These theater chains are typically large companies; they offer a

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48 See, e.g., Lauren E. Schuker, The WALL STREET JOURNAL, *Double Feature: Dinner and a Movie; to upgrade from dirty carpets and tubs of popcorn, theater chains try full menus, seat-side service* (Jan 5, 2011); Ron Ruggless, Nation’s RESTAURANT NEWS, *Theater Giant AMC expands dining options* (Nov. 17, 2010); Laura Ziegler, NPR, *Beyond Popcorn: Theaters try seat-side food service* (May 25, 2011).
selection of standard menu items; and consumers order the food from menus and menu boards. It is thus incongruous to exclude these theater chains on the basis that they are not “similar” to restaurants.

- **Service Stations**: many service stations situated along interstates sell restaurant-type food in restaurant-like environments complete with menus, menu boards, combination meals and self-service beverage counters. Nonetheless, the Proposed Rule would exclude them because they devote significant square footage to selling general merchandise. To illustrate that these establishments are indistinguishable from restaurants (and to show the asymmetry of excluding them from the statute), we include images of menus and menus boards as Exhibit 1 to this comment.

- **Convenience stores**: FDA’s “alternative” definition of “similar retail food establishment” would exclude convenience stores. The Proposed Rule notes that FDA received comments to the effect that “food in convenience stores is not standardized and that the foods differ depending on the techniques and preferences of the store employees preparing the foods.” These comments contrast convenience store food with food sold at restaurants that is “typically standardized and prepared in a homogeneous manner as dictated by corporate policy.” However, like restaurants, “similar retail food establishments” will only be covered by the Act if they satisfy the other requirements, *i.e.*, if they “offer[] for sale substantially the same menu items” and also “offer for sale menu items that use the same general recipes and are prepared in substantially the same ways with substantially the same food components, even if the name of the menu item varies.” Thus if ready-to-eat food sold by a given convenience store truly “differ[s] depending on the techniques and preferences of the store employees typically preparing the foods,” then such food will not be covered by Section 4205 and calorie disclosures will not be required. On the other hand, if (as is likely) the food items are in fact consistent across chains, subject to centralized ordering, pricing, etc., then there is no reason to think they will be any less “standardized” than comparably standardized items at other retail food establishments such as chain restaurants.

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Retail food establishments within large retail establishments: many large general merchandise stores contain establishments selling restaurant-type food in a designated portion of the store, often in a food-court setting. These establishments are typically indistinguishable from standalone restaurants and, assuming they otherwise would be subject to the statute, their presence within a generalized retail environment should not operate to exclude them from providing nutritional information.

Excluding these and other regular away-from-home dining experiences from calorie labeling leaves a large swath of regular retail food consumption experiences unregulated, which is confusing for consumers and inconsistent with the purpose of the Act. FDA should take a consistent position with respect to the potential impact of away-from-home dining on calorie consumption.

In addition, the current definition of “similar retail food establishment” in the Proposed Rule will be difficult to administer and enforce. For example, establishments in a food court within a mall or retail store might argue that they are not subject to the law based on the percentage of square footage of the mall or retail store, as opposed to the food-selling establishment. Others might argue that although they serve food with the intent that it be consumed immediately, they do not hold themselves out as a restaurant. FDA should adopt a clearer policy, such as the one we propose below.

Proposal

We propose that FDA adopt the definition of “similar retail food establishment” set forth in the August 24, 2010 Guidance. Under that definition, establishments that sell food intended for immediate consumption, either on or off the premises where the food is purchased, are considered “restaurants or similar retail food establishments.” Further, food that is intended for immediate consumption includes food on a menu or menu board or on display or provided for self-service, carry-out, or delivery.

Under this proposal, labeling would be required at table service restaurants, quick service restaurants, coffee shops, delicatessens, food take-out and/or delivery establishments (e.g., pizza take-out and delivery establishments), convenience stores, movie theaters, cafeterias, bakeries/retail confectionary stores, food service vendors (e.g., lunch wagons, ice cream shops,

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54 Id.
mall cookie counters, and sidewalk carts), and transportation carriers (e.g., airlines and trains). Labeling would also apply to facilities in grocery stores including in-store cafes, food courts, bakeries, salad bars, pizza bars, and delicatessens.

This approach will provide consumers with more nutritional information, minimize consumer confusion by preventing the anomalous result of similar food being calorie-labeled in one dining context but not another, and maintain a level playing field among food purveyors.

2. **Doing Business Under the Same Name**

FDA proposes to define businesses “doing business under the same name” as businesses “sharing the same name, where the term ‘same name’ includes names that are either exactly the same, or are slight variations on each other due, for example, to the region, location or size.”\(^{55}\)

In the Proposed Rule, FDA has provided the following examples of restaurants that would be considered to operate under the same name:

For example, a quick-service restaurant, “Joe’s Burgers New York Ave.,” located on New York Avenue, might have another location on Pennsylvania Avenue called “Joe’s Burgers Pennsylvania Ave.”

As another example, a dine-in restaurant with the name “ABC” might have an outlet in an airport called “ABC Express” that offers take-out.

FDA has requested comments on the issue of “whether the relevant term should be understood instead to refer to the underlying name of ownership, such as the name of a parent company, or the name of the entity conducting corporate business on behalf of the establishment, such as the name of a contractor operating an establishment, regardless of the public name used by individual establishments.”\(^{56}\)

We agree with FDA’s proposed definition of “doing business under the same name.” Further, we believe the relevant inquiry should not be whether the restaurants are owned by the same parent company, because it is possible (and indeed not uncommon) for a parent company to own several small and unrelated restaurant chains. We also believe a definition focusing on parent companies would run afoul of the plain language of the Act, because by definition the restaurants would not be “doing business under” the name of the parent company. There are many different corporate and governance structures in the restaurant industry. A common or affiliated corporate name or business relationship is not a clear, reliable or necessary way to

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determine if common restaurants are similar in a manner that allows for the posting of the same nutritional information is practical. FDA should give effect to the ordinary meaning of the language chosen by Congress and consider entities as related for purposes of nutrition labeling if they operate under the same name.

3. Offering for Sale Substantially the Same Menu Items

FDA is proposing that “offering for sale substantially the same menu items” means “offering for sale menu items that use the same general recipe and are prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies.” Again, FDA has provided examples, such as where two chain restaurants make the same sandwich but one calls it the “Bay View Crab Cake” and the other calls it the “Ocean View Crab Cake” or when two restaurants offer the same menu except one is more limited than the other.

We agree with FDA’s proposed definition of “offering for sale substantially the same menu items.” As described in more detail below in the comment discussing the proposed definition of “standard menu item,” we believe that whether the necessary controls and economies of scale exist to make menu labeling feasible is determined in large part by whether a menu item is regularly offered in a consistent fashion across all the restaurants in a given chain.

C. Definition of Menu / Primary Writing

Section 4205 defines “menu” or “menu board” as the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection. In turn, the Proposed Rule defines “primary writing” to mean “any writing of the covered establishment that is the primary writing from which a consumer makes an order selection.” FDA goes on to explain that this definition includes “breakfast, lunch and dinner menus; dessert menus; beverage menus; children’s menus; other specialty menus; electronic menus; and menus on the Internet."

1. FDA Should Adopt a Definition of “Menu” the Does Not Impose Unnecessary Costs on Participating Restaurants and Establishments.

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59 See Section 4205(a)(5)(H)(xi) (emphasis added).
We are concerned that FDA’s proposal is susceptible to the interpretation that it covers “all” writings. FDA’s proposed definition of primary writing -- “any writing of the covered establishment that is the primary writing from which a consumer makes an order selection” -- reads identically when expressed as follows: “any writing of the covered establishment that is the primary writing from which a consumer makes an order selection.” That is, FDA has read the word “primary” out of the statute.

If the proposed rule were interpreted in this fashion, it could impose significant logistical challenges and unnecessary costs on restaurants. For example, many casual dining restaurants offer table-top stands with flappable pages that feature some or all of the restaurant’s dessert offerings. In most cases, all of the items included on the table stands are also on the dessert section of the main menu (or a standalone dessert menu) that the consumer receives from the server at the table. If a restaurant must calorie label and update the table top pieces as well as the main menu, it must undertake a redesign of those materials, which may entail a new layout to ensure that the information is aesthetically pleasing and “clear and conspicuous.” This design cost, as well as the new materials themselves, is thus entirely incremental to the labeling of the main menu.

Of course, this is only one example of innumerable similar situations that will arise for a single restaurant under the Proposed Rule. We highlight it to demonstrate that costs for a restaurateur will rise in direct relation to the amount of material covered by the statute. These costs are particularly burdensome given that in most if not all cases, the information will be redundant of information already displayed on the restaurant’s menus and menu boards.

These costs are all the more significant given that those bearing the burden will be small business owners, usually one- or two-store franchisees that create and pay for the promotional pieces themselves. In fact, many chains are networks of hundreds or thousands of family-owned, small businesses, who often have differing franchise agreements, standards they must adhere to, types of menu items they are allowed to sell, and even legal restrictions on whether the franchisor is allowed to provide compliance advice or tools for regulations like menu labeling. We believe the Comment submitted by the International Franchise Association on December 17, 2010, to Docket No. FDA-2010-D-0354, in response to the FDA’s Draft Guidance of August 24, 2010, aptly describes the many small businesses that will be impacted by the statute, and we incorporate it here by reference. The additional economic burden on small businesses explained in the IFA Comment, which could deter those businesses from hiring additional employees, will be exacerbated by FDA’s proposed expansive definition of “menu” and “menu board.”

Accordingly, we urge FDA to clarify that its definition of “menu” or “menu board” does not encompass all writings, and that writings with just a few items, and advertisements, are not “primary writings” under the final rule.

2. **The Proposed Rule Fails to Adequately Distinguish Advertisements.**
FDA tentatively concludes that “advertisements for food fall outside the scope of section 4205.”62 It also hints at a potential grounds for excluding some menus from coverage, stating that “take-out and delivery menus, which include all or a significant portion of items offered for sale and serve as the primary writing from which consumers make their order selections, would be menus under the proposed rule.”63 Despite these statements, however, the proposed regulations themselves make no mention of the exclusion of advertisements, much less the requirement that a menu that is also an advertisement contain “all or a significant portion of items offered for sale.”64

We agree that advertisements are not menus and thus fall outside the scope of Section 4205. We are concerned that without specific language to this effect in the final regulations, the statute could be construed to encompass many materials and pieces that list menu items but that are in fact used as advertisements. FDA has stated that enforcement may be conducted by state and local officials, and without a clear exclusion of advertisements, there is a risk that different regulators in different jurisdictions will apply the rule differently, resulting in inconsistent standards akin to those the statute sought to avoid in the first place.

We are also concerned that FDA may not appreciate the sheer number of different types of advertising materials that are employed by restaurants and similar retail food establishments subject to the Act. These include advertising materials such as table-top stands, translites,65 door hangers, pizza-box-toppers, tray liners, and many, many more. To illustrate the variety of pieces that fall into this category, we have included a list of these materials as Exhibit 2 to this Comment.

Proposal

We have previously submitted comments setting forth our view on the appropriate definition of “primary writing,” and many individual restaurant companies will submit separate comments expressing their own views. Consistent with those comments, we urge FDA to adopt a definition of “menu” in the final rule that gives content to the term “primary.”

In particular, FDA should include in the final rule a clear statement that advertisements and promotional material such as table top stands, newspaper ads and/or flyers, tray liners, point-

64 See 76 Fed. Reg. at 19202 (Apr. 6, 2011) (stating that “menus means the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection,” and making no reference to advertisements).
65 A translite is the outer transparency or graphic of an illuminated display box.
of-purchase marketing material and other advertisements are not “menus” under the statute. As described above, the exclusion of advertisements is crucial to the adoption of a workable rule for restaurants and similar retail food establishments.

In addition, we believe FDA should expand on its statement that such materials are menus that should be labeled if they “include all or a significant portion of items offered for sale.” Limiting labeling requirements, for example, to only menus listing over a percentage of standard menu items sold by the restaurant would have the practical effect of limiting the number of pieces covered, excluding many promotional items such as door hangers and pizza-box-tops, and creating an objective standard that could guide both restaurant behavior and enforcement.

D. Food Covered

1. Alcoholic Beverages

FDA tentatively concludes that Section 4205 does not apply to alcoholic beverages. It reasons that Congressional intent is unclear, given that Section 4205 is silent as to alcoholic beverages and that alcoholic beverage labels are already subject to regulation by the Tobacco Tax and Trade Bureau (“TTB”).66 Under the Proposed Rule, the portions of state and local menu labeling laws that include alcoholic beverages would not be preempted by the Federal law. Consequently, restaurant chains operating in jurisdictions with menu labeling laws encompassing alcoholic beverages would be required to comply with each local requirement, depriving those restaurants of the benefit of the preemption provision in the Federal law. Currently, alcoholic beverages are included in the menu labeling laws of New York City, Philadelphia, Seattle (King County, WA) and Oregon. Alcoholic beverages may be included in menu labeling in Maine and Massachusetts. Some state and local menu labeling laws currently under consideration would also include alcoholic beverages.

To address this concern, FDA should permit restaurant chains subject to the menu labeling regulation (or ones that opt in under the voluntary provision) to voluntarily provide calorie information for alcoholic beverages on menus. Restaurant electing to do so would benefit from national uniformity and preemption while providing calorie information at all locations; restaurant chains opting not to do so would be subject to state and local requirements.

Restaurant chains opting to provide calorie information should also be permitted to follow a simplified approach. Specifically, “opt-in” restaurants should be permitted to declare

66 76 Fed. Reg. at 19203 (Apr. 6, 2011). FDA does regulate certain beers and wine beverages containing less than 7 percent alcohol (“wine coolers” for example); those alcoholic beverages are within the scope of the FDA proposal.
calorie content generically for standard alcoholic beverages (beer, light beer, red wine, white wine, and distilled spirits) and not be required to disclose calorie content for each brand offered. Additionally, nutrient disclosures for alcoholic beverages should be limited to calorie content. Most other nutrients are not present in alcoholic beverages in material amounts, and because there is no nutrition labeling for alcoholic beverages, the inclusion of other nutrients raises serious compliance challenges and costs without commensurate benefit to the public.

The following is proposed language, which closely follows language used in Massachusetts and Seattle (King County) Washington:

As an alternative to posting calorie information for each individual alcoholic beverage of the types listed, such alcoholic beverages may be collectively labeled using the average calorie values for beers, wines, and spirits, as follows:

- Wine, 5 ounces: 122 calories
- Regular beer, 12 ounces: 153 calories
- Light beer, 12 ounces: 103 calories
- Distilled spirits (80 proof gin, rum, vodka, or whiskey), 1.5 ounces: 96 calories.

Covered food establishments that collectively label alcoholic beverages shall add to the labeling the following statement: “Signature drinks (beer, wine, spirits or liqueurs to which ingredients have been added) may have higher calorie content.”

These calorie amounts are drawn from USDA’s National Nutrient Database for Standard Reference. The USDA database also contains complete nutritional information for these alcoholic beverages, confirming that in most instances they are not substantial sources of nutrients that would be declared in a nutrition handout. Adopting these comparatively flexible requirements for declaring the caloric content of alcoholic beverages will encourage restaurants to provide consumers with calorie information, while at the same time respecting TTB involvement in regulation of alcohol.

67 The USDA database is available online, at http://www.ars.usda.gov/Main/site_main.htm?modecode=12-35-45-00.
2. Standard Menu Items

The mandatory nutrition labeling requirements established by Congress for foods sold by certain chain restaurants and similar retail food establishments apply only to a “standard menu items.” Although not expressly defined in the statute, “standard menu item” has a distinct meaning based on the plain meaning of the terms chosen by Congress and the context of the statute, and as illustrated by several statements made by FDA in the preamble accompanying the Proposed Rule. To avoid ambiguity or confusion, it is necessary for FDA to clarify the definition of “standard menu item” in the final rule.

FDA proposes that a “menu item” should be considered “a food item that is listed on a menu or menu board or that is offered as a self-service food or food on display.” In addition, FDA proposes to define “standard menu item” as restaurant or restaurant-type food that is “routinely included on a menu or menu board or that is routinely offered as a self-service food or food on display.”68 Essentially, then, FDA proposes that a menu item is “standard” -- and thus covered by the statute -- to the extent that it is “routinely offered” by a given chain restaurant or similar retail food establishment.

This definition of “standard menu item” is incomplete, and misunderstands the meaning of “standard” within the context of a chain of 20-plus restaurants or similar retail food establishments. That is, it is not the regularity with which a menu item is sold at a given restaurant that renders it “standard” within the context of a restaurant chain; rather it is the fact that the menu item is offered across many establishments in the chain, in substantially the same form, and is prepared according to the same recipe and using the same ingredients. It is these indicia of “standardization” that determine, for example, whether the item is prepared according to a standard recipe, whether the item will be included on standard menu cycles, and whether the ingredients for the item will be ordered and distributed in bulk. These are also the factors that allow restaurants or similar retail food establishments to accurately control nutritional content. Thus, they should be integrated into FDA’s definition of “standard.”

The Act recognizes this by providing, among other things, that restaurants and similar retail food establishments are not subject to the statute at all unless they “offer[] for sale substantially the same menu items.”69 In its proposed interpretation of this criterion, FDA states:

Establishments in the chain offer for sale menu items that use the same general recipes and are prepared in substantially the same

ways with substantially the same food components, even if the name of the menu item varies. Establishments can be offering for sale substantially the same menu items even if the availability of some menu items varies within the chain.\textsuperscript{70}

Definitions of other terms in the Proposed Rule also support this understanding of what makes a menu item “standard.” For example, FDA explains that “custom orders” (which are excluded from coverage under the statute) are orders that “require[] the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item.”\textsuperscript{71} Similarly, the discussion of a “variable menu item” contemplates that a “standard menu item” will have a basic, standardized recipe.\textsuperscript{72}

Specific examples offered by FDA also support this understanding of the meaning of “standard menu item.” For example, FDA’s discussion notes a hamburger, combination meal and a specific pizza build that regularly appear on a restaurant menu and would be considered “standard menu items.”\textsuperscript{73} Unstated, but important, is that such items are only subject to the nutrition labeling requirements if each is prepared from a fixed, standard recipe. When food items are standardized, nutrition values can be derived and nutrition labeling for the item across all restaurants or similar retail establishments is possible.

Conversely, calorie and nutrition labeling is not feasible for foods sold locally or nationally that do not share a common base recipe, whether or not they are “routinely offered” at a given restaurant. For such non-standardized items, the amount of calories and other nutrients would have to be determined on a case-by-case basis, which would not only be impractical and cost-prohibitive, but difficult in the absence of a standardized recipe.

Accordingly, FDA should define “standard menu item” based on its plain meaning, by reference to the factors that make an item “standard” in the context of chain restaurants and similar retail food establishments, and in a manner that is consistent with other terms and exclusions in the statute and Propose Rule. Defined thusly, FDA should reiterate that whether a menu item is self-serve, appears routinely on a menu, or is offered as part of a buffet, nutrition labeling only applies if the menu item is a “standard menu item.”

\textsuperscript{70} 76 Fed. Reg. at 19201 (Apr. 6, 2011) (emphasis added).
\textsuperscript{71} 76 Fed. Reg. at 19204 (emphasis added).
\textsuperscript{72} 76 Fed. Reg. at 19214 (“FDA tentatively concludes that it is more reasonable to require written nutrition information for the basic preparation of the pizza (e.g., plain, deep-dish 12” pizza) and then provide the additional written nutrition information for each possible topping.”) (emphasis added).
\textsuperscript{73} 76 Fed. Reg. at 19203.
Proposal

We propose that FDA define “standard menu item” to mean “a menu item that appears on the menus of substantially all restaurants in a chain, that uses the same general recipe and that is prepared in substantially the same way with substantially the same food components, even if the name of the menu item varies.” We further propose that for any restaurant or similar retail food establishment that prints and distributes a single, standardized menu for all restaurants or establishments, or all restaurants or establishments in a given region, the term “standard menu item” be interpreted to refer to menu items that appear on those centrally printed and distributed menus.

Adopting this definition would harmonize the definition of “standard menu item” with the criteria for being considered a “covered establishment,” and would ensure that the law applies only to those food items that are themselves subject to the type of standardized and centralized processes that allow them to be consistently prepared. Conversely, it would ensure that menu items that are not prepared using the same recipe or in substantially the same way with substantially the same components, i.e., menu items that are not “standard,” are not subject to the menu labeling law.

However, if FDA determines that menu items listed on menus of only some restaurants within a chain can nonetheless be considered “standard menu items,” we propose allowing restaurants and similar retail food establishments to provide nutritional information in writing at the point-of-sale for such items. If this or a similar solution is not permitted, restaurants will be required to include in nutrition brochures many menu items that are sold in a small percentage of restaurants, which is confusing to consumers and costly for restaurants.

3. Multiple Servings

Standard menu items sold at covered restaurants and similar retail food establishments can take a number of forms, including an item or grouping of items commonly consumed by a single individual (such as a burger, or a combination meal such as sandwich, side dish and beverage); large format items that provide multiple servings (such as a whole pizza or family-style platter of pasta); and self-service or on-display items that permit customers to select the quantity of the items for purchase.

PPACA section 4205(q)(5)(H)(ii) requires that covered chain restaurants and similar retail food establishments disclose on menus and menu boards the number of calories contained in a standard menu item “as usually prepared and offered for sale.” Section 4205(q)(5)(H)(iii) requires, in the case of self-service food or food that is on display, that these establishments list calories “…per displayed food item or per serving.” In addition, Section 4205(q)(5)(H)(v) directs the Secretary to establish regulations for nutrient disclosure for standard menu items that come in different flavors, varieties or combinations but which are listed as a single menu item.
In the Proposed Rule, FDA interprets these provisions to require that, in the case of multi-serving items, calories must be disclosed for the entire item without regard to the number of servings. Thus, for example, FDA proposes that a covered establishment selling a whole rotisserie chicken is required to display the amount of calories for the entire chicken. We do not believe this interpretation is either required by the statute or serves the best interests of consumers, who do not typically consume an entire chicken as one serving.

FDA has frequently adopted the view that calorie disclosure is most appropriately provided on a per serving basis. In its October 2009 Guidance for Industry: A Food Labeling Guide for packaged food products, FDA directs that nutrition disclosure for multi-serving products be done on a per serving basis using Reference Amounts Customarily Consumed (RACC). Similarly, FDA’s April 2008 Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods outlines the view that per serving or per unit information is an appropriate means of providing nutrition information for restaurant foods:

Q. Should a restaurant provide nutrition information on a ‘per serving’ basis, or can the information be declared by other units or measures, such as ‘per item’ or ‘per unit?’ For example, if a restaurant sells whole pizza and pizza by the slice, how should nutrition information be declared?

A. Generally, nutrition information should be presented on a per serving basis. Nutrition information on a per unit basis could be appropriate when a single unit may also be a single serving. However, the basis for the information must be clearly communicated to consumers.

It is especially important that the basis be declared when a food is available in more than one size serving (e.g., pizza that is available whole and by the slice), or soup that is available by the cup or by the bowl. The restaurant may provide additional information, such as ‘8 slices per medium 16-inch pizza, 1 slice contains…’ to help consumers put nutrition information in context.

Conversely, it would be misleading to present the information on a per item basis when a serving generally contains more than one item of the food, for example, if a single serving of cookies contains more than one cookie.\textsuperscript{76}

Consistent with this position, FDA should permit restaurants to display calories for multi-serving items on a “per unit” or “per serving” basis. This would align the Proposed Rule with FDA’s historical position and be consistent with the statutory requirement that calories be disclosed for a standard menu item “as usually prepared and offered for sale” so long as the disclosure is truthful and non-misleading in relation to the item as offered for sale.

In implementing these requirements, FDA should allow covered establishments to disclose either the amount of calories contained in the whole product or the number of servings and calories per serving. Thus, for example, a restaurant selling a four-serving family-style platter of pasta could comply either by disclosing that the whole product contains 2,000 calories, or by disclosing that the product consists of 4 servings, 500 calories per serving. In both instances, the disclosure reflects a truthful and non-misleading measure of the calorie content of the product “as usually prepared and offered for sale.” Similarly, information on a product such as a whole pizza could be disclosed for the entire pizza, or on a per unit (slice) basis, provided that the context for the disclosure clearly refers to the product as prepared and offered for sale (e.g., 8 slices, XX calories per slice).

This information should be permitted in any manner that clearly associates the product and the calorie information, such as suggested in the example below:

<table>
<thead>
<tr>
<th>Medium</th>
<th>Large</th>
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<td></td>
</tr>
<tr>
<td>(8 slices)</td>
<td>Cal/slice</td>
</tr>
<tr>
<td>Pizza X</td>
<td>8.99</td>
</tr>
</tbody>
</table>

Covered establishments should have the flexibility to provide per serving disclosure using common qualitative units of division of the product, such as per slice or per item. In those circumstances in which a quantitative per serving measure is needed, establishments should be permitted to use either FDA’s RACC for the food item or a common household measure that has

general consumer relevance and is clearly identified for the consumer (e.g., per cup or per ounce).

4. Variable Menu Items and Combination Meals

Section 4205(q)(5)(H)(v) requires that FDA establish, by regulation, standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, that are listed as single menu items. FDA proposes to define the term “variable menu item” to mean “a standard menu item that comes in different flavors, varieties and combinations, and is listed as a single menu item.”77 Examples of “variable menu items” include a milkshake available in vanilla, chocolate and strawberry, or a pizza prepared with a section of topping. For such items, the Proposed Rule requires that calories be declared as a range of lowest to highest value (i.e., “xx-yy”).78

In addition, FDA proposes to define the term “combination meal” to mean a “standard menu item that consists of more than one food item.”79 Combination meals may be variable menu items (such as where a consumer can order fries, salad, or onion rings as a component of a meal), in which case they must be declared with a range. Or, they may be “fixed,” meaning that the customer has no choice as to which flavors, varieties, or combinations of items are included. “Fixed” combination meals are subject to calorie disclosures applicable to any other standard menu item.

FDA has requested comments on whether these proposals are appropriate or would be misleading to consumers. FDA has also requested comment and research on options that it considered but did not propose, and whether any other options are preferable, either individually or in combination with one another.

We believe that by providing only a single option for variable menu items and combination meals containing variable items -- providing a range -- the Proposed Rule does not provide the flexibility restaurant chains need to declare calories for variable and combination items in a manner that is not confusing. As we have explained elsewhere in this comment and in prior comments, restaurants food takes every conceivable form and is served in innumerable configurations, and menus and menu boards vary widely in terms of size and the type of options represented. A one-size-fits-all approach to variable and combination items is thus bound to result in unclear or even absurd declarations in some cases. A better approach would be to set

forth several options that are permissible, and to allow restaurants to choose the option that best fits with their business and menu.

A few examples make this clear. For a combination item where the consumer has many different choices, but the end products ranges from 400 to 700 calories, a range may provide a useful non-misleading benchmark for consumers, while at the same time allow the restaurateur to save valuable menu or menu board space. In other situations, such as where the calorie amounts of the possible combination or variations fall within 20% of one another, use of a single value such as a median or average may be best, both in terms of menu space and clarity for consumers. In fact, FDA has previously found that single-value declarations offer benefits to consumers. Accordingly, restaurants should be permitted to use a single value at least in defined situations.

Finally, in some situations, presenting a single “build” of an item will be more useful than either a range or a single value. For example, where a certain configuration of an item is far and away the most popular, but other possible configurations would create a very broad range, it makes sense to provide the calorie information for the most popular “build” of the item. We recognize that this option presents certain risks, i.e., that restaurants or similar retail food establishments serving “build as you go” items might be tempted to select a lower calorie “build” as the featured build and provide the calorie count for that build alone, even if the restaurant’s business model assumes that customers will change and add to that basic build. We do not support this practice, and if FDA adopts this option it should specify that any such declaration of a “build” should be representative of a finished version of the product that is typically ordered by customers.

We suggest the following regulatory approach, which would provide flexibility for a restaurant chain to determine which approved method will communicate the nutritional information most effectively.

- For **Variable Menu Items**, calories should be disclosed by:
  - Providing 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

80 See, e.g., 56 Fed. Reg. 60366, at 60373 (opting to require single-value declaration instead of ranges under the NLEA because absolute values are “more informative, and less confusing, for consumers); 58 Fed. Reg. 2208, at 2218 (opting to use an absolute value for Daily Recommended Values, instead of a range, because “the information must be presented in a readable format and in a manner that does not overburden or overwhelm consumers.”)
o Calorie-labeling the flavors, components or toppings that make up that variable menu item elsewhere on the primary writing; or

o Displaying 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 selects this option, the “build” must be representative of a finished version of the product that is typically ordered by customers, and cannot be merely a rarely ordered base product to which additional fixings are added. The restaurant or similar retail food establishment must also 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.

- For **Fixed Combination Meals**, calories should be disclosed by:
  
o Providing total calories for the Fixed Combination Meal adjacent to the meal on the primary writing; or

  o Providing calories for each item or component of the Fixed Combination Meal elsewhere on the primary writing.

- For **Variable Combination Meals**, calories should be disclosed by:
  
o Providing calories as a range reflecting the lowest and highest total meal calorie content among the variations available; or

  o Providing a median or 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

  o Providing calorie information for each item of the Variable Combination Meal elsewhere on the primary writing; or

  o Providing the calories on the primary writing for one specified variation of the Variable Combination Meal. If the restaurant or similar retail food establishment elects this option, then it must:
    
    ▪ Identify the items comprising the variation specified;

    ▪ 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.

a. Multiple Sizes

FDA also requests comment on complexities that may be raised by certain variable menu items. For example, some menus with combination meals list an option to increase the size of components of those meals for a discounted additional price. FDA seeks comment on whether those listings should be labeled with the number or range of calories they add to the standard combination meal.

We propose the following standard:

- 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 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.

b. Internet Menus

FDA also recognizes that the Internet may allow for the use of different methods for disclosing calories and/or other nutritional information, if applicable. For example, interactive menus online may present opportunities for more innovative ways of providing tailored calorie information, e.g., providing a calorie tracker in the ordering frame that tallies calories as customers make order selections. FDA requests comment on this issue.

We request the FDA keep in mind the industry’s need for flexibility with menu items disclosed on a website. Because technology changes so rapidly, the technology available in just a few years may be vastly different from what is available now, and an inflexible standard may not appropriately address any future technology available. It is important that the industry have
flexibility to develop, adapt and utilize new technologies, as long as calorie information is clearly disclosed to the customer and easily accessible. For example, not all menu information listed on a website is static (such as a PDF of a menu or a listing of menu items on a web page); many restaurant chains use interactive website devices, such as an interactive nutrition calculator or ordering function in which the customer engages in a process to select specific items.

5. Food-on-Display and Self-Service Food

FDA proposes to define “food on display” as food that is visible to the customer before the customer makes an order selection. This definition includes food packaged at the customer’s request, such as a slice of pizza sold at a counter or an entrée item served on a buffet line, or pre-wrapped by the establishment for direct customer selection, such as a sandwich prepared on the premises and displayed in a case. FDA also tentatively concludes that “food on display” includes food that is behind a glass counter or another viewing apparatus for the purposes of showing a serving or meal suggestion.

FDA is proposing to define “self-service food” as food that is available at a salad bar, buffet line, cafeteria line, or similar self-service facility. This definition covers food that the customer serves himself or herself, such as food at hot and cold food bars or beverages in a self-service beverage machine in a restaurant. For self-service beverages, FDA proposes that “the self-service beverage dispenser itself must have calorie declarations for each flavor or variety offered, such that the calorie declaration is clearly associated with its corresponding flavor or variety.” FDA considers self-service food to be a subset of food on display.

FDA proposes that, if restaurants provide signs adjacent to items stating the name and price of the item, they must place calorie information on the signs, in a type size no smaller than the type size of the name or the price of the item whichever is smaller in the same color, or a color at least as conspicuous as that name or price, with the same contrasting background. The Proposed Rule also requires that, where self-service or on-display items appear on both menus boards and signs adjacent to the items themselves, restaurants or similar retail food establishments label the items both on menu board, and on the adjacent signs.

We agree with FDA’s definition of “food on display” and “self-service”; however, we disagree with a number of the proposed requirements on the basis that they contradict the statute, and fail to take account of the special challenges associated with labeling self-service food and food on display.

First, as we have stated in prior comments, nutrition labeling of self-service foods presents unique challenges. In the context of salad bars or other cafeteria-style service options offered by many covered establishments, the consumer will 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. Based on these practical challenges, we believe the FDA should allow nutrition labeling for self service food in a flexible manner, such as via a handout or placard.

Second, requiring restaurants to label such food on both menu boards and in display cases is inconsistent with the plain language of the Act. Section 4205(q)(5)(H)(iii) specifically addresses “food on display” and reads.

. . . SELF SERVICE AND FOOD ON DISPLAY: Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility . . . a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

By its plain language, Section 4205 specifies that for items on display, calories are to be provided adjacent to the item. Nothing indicates such items should also be declared on menus and menu boards. Furthermore, requiring labeling only adjacent to such items is consistent with FDA’s emphasis on providing information at the point of ordering, and with the statutory directive that restaurants label their “primary writing.”

Third, and similarly, requiring disclosure of additional information for “self-service” and “food on display” contravenes the Act. Section 4205(q)(5)(H)(iii) says nothing about disclosing additional nutrition information; this is telling, because this requirement is expressly spelled out for other standard menu items. Specifically, Section 4205(q)(H)(i) states that covered establishments must “disclose the information described in subsections (ii) and (iii).” Subsection (ii)(I) then requires covered establishments to disclose calories and make required statements on menus; subsection (ii)(II) requires the same disclosures on menu boards; subsection (ii)(III) requires additional information to be disclosed in writing, and subsection (ii)(IV) requires menus and menus boards to state the availability of the information described in subsection (ii)(III).

As described above, however, subsection (iii) is a standalone section dealing with “food on display” and “self-service food” that does not require restaurants to provide additional nutritional information. Id. § 4205(q)(5)(H)(iii). Thus, under the plain language of the statute as well as numerous canons of statutory interpretation, such as expressio unius est exclusio alterius
and the general rule that specific provisions govern general ones, section 4205 does not require nutrition information in writing for self-service foods.

Fourth, we believe the obvious space constraints associated with using small signs to label food on an item-by-item basis within a display case or on a buffet justifies more flexibility with respect to the presentation of information. For example, FDA proposes that information on signs adjacent to self-service food be as large as either the price or item name. However, many existing signs for food-on-display state only the name of the item, so the Proposed Rule will effectively require the calorie information be as large as the name of the item itself. This result will be burdensome for restaurants, create a cluttered and confusing experience for consumers, and will foreclose many methods of disclosing calorie information in a manner that is “clear and conspicuous.” FDA should permit covered establishments to declare calories for self-service food or food on display in any manner that is “clear and conspicuous.”

Fifth, with respect to beverages, we believe the Proposed Rule fails to recognize the space constraints associated with self-service beverage stations, which are designed to take up minimal space while allowing several consumers to use them at once or in rapid succession. We request that FDA allow restaurants and similar retail food establishments flexibility in how they label self-service beverage areas, and allow calories to be posted on the dispenser labels on the beverage towers themselves, or on a sign posted in close proximity to the self-service beverage station.

Finally, items-on-display are often different “flavors or varieties” of one another, as in a display case containing different flavors of ice cream or doughnuts. The Final Rule should clarify that FDA restaurants may disclose nutritional information for such items by using a range-per-serving (or other options) as described above.

6. Custom Orders

Section 4205(q)(5)(H)(vii)(bb) exempts daily specials, temporary items appearing on the menu for less than 60 days per calendar year, or custom orders. We agree with FDA’s proposed definition of a “custom order” as a food order that is prepared in a specific manner based on an individual consumer’s request, which requires the covered establishment to deviate from its usual preparation of a menu item.

7. Daily Specials

Section 4205(q)(5)(H)(vii)(bb) exempts daily specials, temporary items appearing on the menu for less than 60 days per calendar year, or custom orders. We agree with FDA’s view that a daily special is a menu item prepared and offered for sale on a particular day, and that neither a standard menu item offered at a special price, nor a combination meal that includes a standard
menu item should qualify for the daily special exemption if the item is otherwise commonly offered.

8. Market Tests

Section 4205(q)(5)(H)(vii)(cc) excludes food that is part of a customary test market appearing on the menu for less than 90 days, under terms and conditions established by the Secretary. FDA proposes that “a customary test market” refers to a test in a single covered establishment for a period of less than 90 consecutive days.83

FDA should clarify that, in the case of a food that is part of a customary test market in more than one location of a chain at a time, the 90 consecutive day test period is applied independently at each location. In addition, it is common for such products to be subject to iterative tests with changes in recipe or other product features between tests. In these instances, FDA should note that each material modification of the product results in a new food item and a new 90-day period would begin for the subsequent testing of the revised product.

These clarifications are necessary given the complexity and variety of testing practices. For example, some restaurants use a multi-phase process, in which (for example) alpha testing occurs in 5 stores in 1 market; if it is successful beta testing proceeds in 20 stores in additional markets; if that too is successful then a full test is launched across all restaurants. Significantly, as the performance of a menu item is evaluated, it is subject to change. Test results may lead to changes in product makeup, including size, shape, taste profile, and preparation. Therefore, the underlying nutritionals are also subject to change. From start to finish, the testing of a product easily takes 6 months.

We believe that in light of these complexities, FDA should build substantial flexibility into the final rule governing market tests.

9. Condiments

Section 4205(q)(5)(H)(vii) exempts from nutrition disclosure certain categories of foods. Clause (aa) of that section exempts items not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use). FDA proposes that this exclusion should apply to many condiments that are available for use by any customer in the covered establishment, regardless of the customer’s particular order or food selection, and presents as examples items such as salt and pepper placed on tables and large ketchup and mayonnaise dispensers. Likewise, this exemption should apply to salt and pepper, ketchup, mayonnaise, and other items.

mayonnaise, taco sauce and similar condiments provided on a “to go” basis to carry-out and drive-through customers for later application as desired by the customer.

We agree with FDA’s proposal that condiments as used by the covered establishment in the typical preparation of a standard menu item should appropriately be included in the calorie disclosure for that item (e.g., mustard and ketchup applied in the normal course of preparation of a burger that is a standard menu item). In contrast, however, sauces or similar condiments provided as a convenience for optional use or application by the customer should not be included if these products are used at the discretion of the consumer. For example, in the case of a burger and French fries served with a ramekin of ketchup on the side for optional use by the customer, the ketchup is not an element of the standard preparation of the menu item and should not be included in the calorie disclosure, just as the ketchup would not be included if it were provided to the customer via a bottle placed on the table for customer use. The application of other condiments or other non-menu elements during preparation at the request of a customer (e.g., extra mustard; addition of jalapeno peppers), would constitute a custom order and be exempt from further disclosure.

10. Temporary Menu Items

The Proposed Rule adopts the view that self-service food and food on display that do not appear on menus or menu boards would not be considered temporary menu items or food that is part of a customary test market. FDA should clarify its interpretation with regard to these foods. FDA has noted that menu and menu boards can come in “…different forms, e.g., booklets, pamphlets, or single sheets of paper”. In the case of a self-service food or food on display, FDA has tentatively concluded that when these foods are “… already accompanied by an individual sign, adjacent to the food, that provides the food’s name, price, or both, listing calories per displayed food item or per serving on that sign satisfies…” the calorie disclosure requirement. Thus, a sign for these foods is treated as the functional equivalent of a menu or menu board. As such, we encourage FDA to make clear that self-service food and food on display that is accompanied by an individual sign adjacent to the food with the food’s name, price, or both, would be eligible for exclusion from calorie disclosure if those items otherwise qualify as temporary menu items or food that is part of a customary test market.

E. Information that Must Be Declared

As we have consistently expressed throughout the comment period, menus and menu boards are one of the keys methods by which restaurants communicate with their customers. Accordingly, restaurants go to great lengths, and have a great incentive, to ensure that their menus are easily readable, reinforce their brand, and contribute to creating a positive guest experience.
Critical elements in designing menus and menu boards include type size, color of type, color of background, and font. Used properly, these elements allow restaurants to present large amounts of important information, such as item name and price (and now calories), without sacrificing readability. In the Proposed Rule, the FDA proposes several requirements related to font size and color that are designed to ensure that restaurants present calorie information in a manner that is clear and conspicuous. Given that restaurants have a built-in incentive to ensure that menus are clean and readable, we believe more flexible standards will better accomplish the statutory mandate, as described below.

1. **Font Size**

Section 4205(H)(ii) requires that restaurants disclose calories in a “clear and conspicuous manner.” To satisfy this requirement, FDA proposes to require restaurants to list calorie information in a type size that is at least equal to either the name of the menu item, or the price, whichever is smaller. This approach, FDA suggests, “fulfill[s] the requirements of the statute and providing consumers with easily readable information.”

We believe this standard is preferable to the standard set forth in the Proposed Guidance that was subsequently withdrawn. Under that standard, FDA had proposed to require restaurants to list calorie information in a type size that is at least equal to either the name of the menu item, or the price, whichever is larger. We appreciate FDA’s recognition that its initial proposal was not feasible; however, the current definition still excludes many design possibilities that would also communicate calorie information in a manner that is “clear and conspicuous.”

Accordingly, instead of adopting a rigid definition based on minimum size font, FDA should simply require that disclosures be “clear and conspicuous,” as stated in the statute. However, as a safe harbor, FDA should provide that a menu or menu board listing calorie information in a type size that is as large as the name, price, or description of the menu item, whichever is smaller, (and, per our proposal in section 2 below, that presents the calorie information in the same color, or in a color at least as conspicuous as the color of the name of the associated standard menu item, with the same contrasting background, or a background at least as contrasting, as the background used for the name of the associated standard menu item on the menu or menu board) is presumptively “clear and conspicuous” and in compliance with the font requirements.

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“Clear and conspicuous” is an administrable standard, particularly when it is paired with such a “safe harbor” construct. For example, the FTC requires that certain disclaimers in advertisements be “clear and conspicuous,” in order to be effective.\textsuperscript{86} In determining whether a given disclaimer meets the standard, the FTC considers the advertisement from the perspective of a reasonable consumer and takes into account factors including proximity of the disclaimer to the claim it is qualifying, prominence of the disclosure, and whether other parts of the advertisement distract attention from the disclosure.

Here, Section 4205 already requires that the calories disclosures be “adjacent to the name of the standard menu item, so as to be associated with the standard menu item” and the FDA rules related to color (discussed below) help ensure that the calorie information is noticeable. Accordingly, the risk of unclear disclosures is quite small, particularly compared with the benefit to restaurants that may require additional flexibility.

**Proposal**

We propose that FDA require calorie information to be declared in a manner that is “clear and conspicuous” without requiring a specific font size relative to price, name or description of the item. However, to provide guidance for enforcement, we propose that FDA state in the final rule that menus and menu boards that declare calorie information in a font that is as large as the name, price, or description of the menu item, whichever is smaller (and, per our proposal in section 2 below, that present the calorie information in the same color, or in a color at least as conspicuous as the color of the name of the associated standard menu item, and with the same contrasting background, or a background at least as contrasting, as the background used for the name of the associated standard menu item on the menu or menu board) are presumptively “clear and conspicuous” and comply with the statute.

In combination with the requirement that the calorie information be adjacent to the name of the item, and other rules related to presentation, this will meet the statutory requirement while providing restaurants with flexibility to communicate information as clearly as possible, while taking account of the particular design, lay-out, form and other factors that come into play across numerous restaurants that cannot be anticipated nor accounted for in a single regulation. The added measure of flexibility does not relieve a restaurant from ensuring that the information is of sufficient prominence in context to ensure that consumers can readily identify and make use of it.

Alternatively, FDA should permit the type size of the descriptions of the menu items to be used for calorie declarations. Restaurants often use menu space to describe their menu offerings; these descriptions are important to restaurants and consumers alike, thus restaurants take pains to insure that the descriptions in their menus of their various offerings are easily read and understood by their customers. As a result, allowing restaurants list calories in font size as large as price, name-of-item, or description-of-item (whichever is smaller) would give restaurants greater flexibility while still ensuring that the information is “clear and conspicuous.”

2. **Color of Type and Background**

FDA proposes that “calorie declarations must be made in the same color, or in a color at least as conspicuous as, the color of the name of the associated standard menu.”\(^{87}\) We agree that this standard accomplishes the statutory goal that calorie information be “clear and conspicuous,” while providing restaurants with necessary flexibility. However, FDA has not extended this flexibility to the color of the background. Instead, FDA proposes that a calorie declaration must have the same contrasting background as the background used for the name of the associated standard menu item on the menu or menu board.

This approach to background color is impractical and needlessly restrictive. It is not uncommon for the background of a restaurant’s menu to consist of a particular scene or photo that is iconic to that restaurant chain. Such backgrounds consist of numerous colors, not simply one color, rendering compliance with the Proposed Rule difficult. Restaurants also seek to ensure that information conveyed on menus is clear and understandable. Having access to a full palette of background colors is critical to achieving this goal.

In fact, the option of using different contrasting background colors is, in many instances, a possible approach to improve readability and comprehension. Conversely, the requirement of using identical backgrounds will in some cases actually impede comprehension and stifle design. Restaurateurs believe different menu board designs might employ a wide range of colors to share calorie information and that the strong emphasis on same color is limiting.

To address these concerns, FDA should extend its proposal for typeface color to apply to background color, and modify the Proposed Rule to add the bolded language, as follows:

> FDA proposes in § 101.11(b)(2)(i)(A)(1) that a calorie declaration must be made in the same color, or in a color at least as conspicuous as, the color of the name of the associated standard menu item on the menu or menu board. Further, FDA proposes

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\(^{87}\) 76 Fed. Reg. at 19206 (Apr. 6, 2011).
that a calorie declaration must have the same contrasting background, or a background at least as contrasting, as the background used for the name of the associated standard menu item on the menu or menu board.

Alternatively, and to provide specificity, FDA should state in the final rule that a calorie declaration must have a background that is “at least as contrasting” as that used for the price, and also provide that menus using the same contrasting background as the menu item (i.e. menus that comply with the Proposed Rule) will be presumed to comply.

3. Stanchions

In the Proposed Rule, FDA tentatively concludes that “stanchions inadequately convey calorie information” and requests comments on the issue. FDA reaches its conclusion based on several concerns: that the statute requires calories to be disclosed on “the menu board” itself; that requiring consumers to look at more than one board may make it more difficult for them to comprehend the nutritional information; and that this may be particularly true in the drive thru context, where drivers have limited view out their windows and limited time to make their decisions.

These concerns are unwarranted. First, while the statute refers to menus and menu boards, it also gives FDA the authority to define those terms, meaning that FDA is permitted to incorporate stanchions into the definition of menu board in the context of a drive thru restaurant. Similarly, the statute charges FDA with ensuring that nutritional information is communicated in a manner that is “clear and conspicuous.” FDA could thus include stanchions as a method of communicating calorie information in a manner that is “clear and conspicuous” at drive-thrus.

Second, in many cases information conveyed on stanchions is more clear and conspicuous than on menu boards. At many quick-serve restaurants, every square inch of the menu board is spoken for, and limitations such as local zoning rules make expanding menu boards impossible. In these situations, placing dedicated boards near or at the point-of-ordering actually increases readability and comprehension, and at the very least offers an option that is equally viable to communicate in a “clear and conspicuous” manner.

Third, as might be expected, restaurants have a vested interest in customer satisfaction in the context of a drive-thru window. Uniformly, restaurants have concluded that clear and organized space, presented within the framework of a known and expected brand expression, is the most critical success factor for presenting information to consumers on menu boards. The

better organized the information, the higher the guest satisfaction in this critical “choose” stage of the consumer buying cycle. Significantly, stanchions adjacent or close to menu boards are viewed as “complete thoughts” if the information is relevant, well organized and clearly marked. If this were not true, stanchions would not be employed as they have been by many quick serve restaurants as a natural extension of overall menu choices.

Fourth, as quick serve restaurants with drive-thrus can attest, the time customers invest to consider their meal choices when ordering vary dramatically. There is no artificial limit, nor ‘deadline’, on how much time a customer invests to consider their options before ordering. Accordingly, FDA’s concern that consumers with limited time might not use stanchions is unwarranted.

Many state and local jurisdictions have recognized the utility of stanchions and allowed their use in connection with menu labeling laws. The jurisdictions include Albany County New York; King County, Washington; Montgomery County, Maryland; New Jersey; New York City, New York; Philadelphia, Pennsylvania; Schenectady County, New York; Suffolk County, New York; Ulster County, New York; Vermont; and Westchester County, New York. We are not aware of any concerns or consumers complaints arising from the use of stanchions in these jurisdictions.

If FDA bans the use of stanchions, it will force restaurants to shoehorn even more information into an already overcrowded, finite space. In turn, this will make all of the information more difficult to see and understand, including the calorie information FDA seeks to emphasize. We propose that FDA consider the current widespread use of stanchions as evidence that restaurants believe them to be valid methods of communicating with customers, and allow restaurants to use them to present calorie information in the context of drive-thru windows.

F. Additional Required Statements

FDA proposes that the 20-word Succinct Statement must appear on the bottom of every page of a menu. In addition, FDA proposes that the Nutrition Information Availability Statement must appear on the bottom of the last page of a two-page menu, or for longer menus that it either appear on every page or be linked via an asterisk to the statement on the first page. The Proposed Rule would also require that when the Succinct Statement and the Nutrition

Availability Statement appear on the same menu page, the Succinct Statement must appear above the Nutrition Availability Statement. 91

Taken together, we believe FDA’s proposals fail to adequately take into account the practical constraints, limitations and costs restaurants must address in designing and printing their menus, primarily due to the fact that both statements must appear on every page of a menu.

First, we are very concerned about the amount of space these statements will occupy on a menu. It would help if each statement were to be shortened; but shortened statements will not resolve our concerns if one or both of them still must appear on every page of a menu. Most restaurant chains already include various references (e.g. the FDA Food Code Consumer Advisory; footnotes as to daily availability of various menu items; footnotes referencing “net weight before cooking,” etc.). Menus become overly cluttered very quickly; and the very messages FDA wants to convey to consumers will get lost in all the “noise” at the bottom of each page of the menu.

Second, while we applaud FDA’s recognition that the Nutrition Information Availability Statement serves its essential purpose, even when it appears only once on a menu, we are concerned that requiring the placement of asterisks on each subsequent page in reference to a disclosure set forth on a previous page will only serve to confuse a reader (who, upon seeing an asterisk, has been trained since elementary school to look for the associated footnote at the bottom of the page on which the asterisk appears).

Third, FDA’s proposal that when the Succinct Statement and the Nutrition Availability Statement appear on the same menu page, the Succinct Statement must appear above the Nutrition Availability Statement, further limits flexibility. We believe the statements would be just as “clear and conspicuous” were they to appear side by side or in some other positioning on the page.

In light of the foregoing, we recommend that FDA adopt the position of many state and local jurisdictions (like California) that require statements similar to these statements to appear only once in a menu. While we appreciate that FDA has allowed the type size of both statements to be the type size of the smallest calorie declaration within the menu, if the statements are to appear only once, we believe a slightly larger type size (the type size most frequently used for the names of standard menu items in the menu) is an appropriate requirement.

Specifically, we propose that the portions of Section 101.11(b)(2)(B)(1) and Section 101.11(b)(2)(B)(2) relating to the Succinct Statement on menus be revised as follows:

(1) For menus, this statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the type size most frequently used throughout the menu for the names of standard menu items and in the same color or a color at least as conspicuous as the color most frequently used throughout the menu for the names of standard menu items and with the same contrasting background or a contrasting background at least as conspicuous as the background most frequently used throughout the menu for the names of standard menu items.

(2) For menus, this statement must appear on either the first page listing menu items or the last page of a menu.

Further, we propose that the portions of Section 101.11(b)(2)(C)(1) and Section 101.11(b)(2)(C)(2) relating to the Nutrition Information Availability Statement on menus be revised as follows:

(1) For menus, this statement must be posted prominently and in a clear and conspicuous manner in a type size no smaller than the type size most frequently used throughout the menu for the names of standard menu items and in the same color or a color at least as conspicuous as the color most frequently used throughout the menu for the names of standard menu items and with the same contrasting background or a contrasting background at least as conspicuous as the background most frequently used throughout the menu for the names of standard menu items.

(2) For menus, this statement must appear on either the first page listing menu items or the last page of a menu.

With respect to menu boards, we agree with the Proposed Rule, which states that the required statements must appear once at the bottom of a menu board. See, e.g., 101.11(b)(2)(B)(3); 101.11(b)(2)(C)(3). We ask FDA to clarify, however, that the required statements must only appear once per menu board, not once per panel of a menu board.

G. Proposed Effective Date

FDA is proposing that the Final Rule become effective six months from the date of its publication. The Proposed Rule explains that this time frame was chosen in order to deliver the
public health benefits associated with the law as soon as “practicable.”\textsuperscript{92} FDA also requested comments on other time frames that might be more appropriate.\textsuperscript{93}

We believe a six month implementation time period is not in fact “practicable” in light of the many tasks restaurants must accomplish prior to updating menus, the cyclical nature of menu updates in chain restaurants, and the sheer complexity of understanding and implementing the sweeping new requirements. Moreover, the number of firms currently operating in the marketplace that are capable of performing menu item testing and evaluation is quite limited, as is the number of menu and menu board vendors. Demand for these firms’ services will skyrocket all at precisely or near-precisely the same time, as the final rule will necessitate the creation of menus and signage for literally hundreds of thousands of restaurants and similar retail food establishments. For example, covered establishments will need to take many if not all of the following steps in order to comply:

- Digest the final rule. Restaurants must determine what materials are “primary writings,” which menu items are “standard menu items” under the Final Rule, which are custom, temporary, or otherwise excluded. Restaurants estimate that this process alone will take at least 4-6 weeks.

- For each covered menu item, determine nutrient content in a manner consistent with the final rule and ensure that the reasonable basis relied upon is sound and that adequate controls are in place to ensure the reliability of the nutrient values to be posted.

- Create materials containing complete nutrition information for all covered menu items to 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 the Final Rule to incorporate calorie information and required statements related to the availability of additional information.

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

\textsuperscript{92} 76 Fed. Reg. at 19219 (Apr. 6, 2011).

\textsuperscript{93} See 76 Fed. Reg. at 19219 (Apr. 6, 2011).
Ensure that reasonable steps are in place at each covered establishment to ensure that standard menu items are prepared consistently. 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.

Although restaurants have been on notice of the menu labeling law, there is much that cannot be done in advance of the Final Rule. For example, the definition of “menu” itself is not finalized; the font and color requirements are in flux and differ from FDA’s 2010 Guidance; FDA has proposed adding (trans fat) and removing (complex carbohydrates) from the required handout; and, the definition of variable and combination meals is not finalized. In fact, many establishments are not even sure whether or not they will be considered “similar retail food establishments” under the Final Rule.

This means that substantially all covered restaurants -- we estimate that there are 250,000 to 275,000 “covered” restaurant locations across the United States, not including any similar retail food establishments that are covered under the Final Rule -- will begin working on compliance at the same time. The number of laboratories available to test food items is quite low; some are already backlogged, and the onslaught of food items to-be-measured is sure to create a bottleneck. Similarly, the many industry participants use the same vendors to create menus or update signs, and these vendors will be overwhelmed, creating another delay. Accordingly, it is very possible that a six month time period will prove to be not only impracticable, but impossible for some restaurants. FDA might also take account of the substantial number of restaurants that already provide nutrition information voluntarily in many different ways. There is an obvious benefit to a single, national uniform approach. At the same time, in many ways consumers already are able to take advantage of the information in advance of when the final rule becomes effective.

Even for chains that have long provided nutrition information for some items and locations, extending nutritional labeling to all menu items nationally presents an enormous logistical challenge that will require the devotement of significant resources. As we have stressed in our prior comments, most chain restaurant companies are franchised. As a result, the costs will be borne by thousands of small business entities, many of whom will be dealing with these issues for the first time. Adopting a compressed timeframe for implementation will exacerbate these costs and create needless uncertainty for industry and regulators.

We propose that FDA adopt an implementation period of not less than one year after the publication of the final rule. Such a time period would allow restaurants to properly review the final rule, analyze covered food items, and incorporate nutrition labeling into a normal menu cycle. This last point is critical: as we have explained in prior comments, menu updates are
complex and heavily coordinated exercises that involve many considerations that are entirely distinct from nutritional content. Extending the time period to a year would allow most restaurants to incorporate calorie disclosures and associated redesigns with regular menu cycles, thus lessening the additional cost to some degree.

Our member restaurants have indicated that the process of actually applying the changes - designing new layouts, obtaining reviews and approvals, production and kitting, etc. -- can easily take up to 24 weeks. But there is much to be done before the changes can even be determined. For example, our member restaurants estimate that the process of digesting the rule alone -- deciding what materials are “primary writings,” which menu items are “standard menu items” and which are custom or otherwise excluded -- will take at least four weeks. Moreover, even today, before any rush occurs due to the passage of the final rule, shipping times for menu boards can run up to eight weeks. All of these time frames assume that nothing goes awry and that the vendors necessary to conduct the evaluation and create the signage are able to absorb the massive influx of demand for their services; suffice it to say this is not necessarily a realistic assumption. In short, to have a realistic opportunity to comply with the final rule, restaurants require an implementation period of one year.

H. FDA Should Allow Flexibility In Updating Menus To Reflect Changes to Nutritionals.

Once the monumental task of complying with the final rule is complete, restaurants will continue to face challenges in addressing changes to labeling and other materials bearing calorie and other nutrition information. The task will be particularly daunting (and effectively unworkable) if restaurants are required to make system-wide changes to labeling each time a nutrient value changes. Because this is neither possible nor reasonably necessary to ensure that the objectives of the new law are met, we request FDA address this important issue in the final rule to ensure fair, consistent enforcement of the new law in a uniform fashion.

A number of factors, many outside the control of the restaurant, can cause changes in nutrient values. Restaurants deal with many different suppliers and other vendors who over time may modify the formulation of their products, which in turn will change the nutritional values of the restaurant’s standard menu item. This also occurs when the supplier or other vendor has simply updated its nutritional analysis but made no change in formulation. Other changes can be prompted by unexpected variations in source or availability of a given food or ingredient (e.g., recall, crop damage, commodity prices and availability). Reformulation of existing menu items in response to consumer feedback will inevitably impact the food’s calorie and other nutrient values. Significantly, modifications will occur over time to the levels of nutrients of concern (e.g., sodium, fat), as well as other modifications to increase the proportion of whole grains and other positive nutrients and ingredients.
Absent flexibility, and a clear and consistent enforcement and compliance standard, restaurants would be in an untenable position. Restaurants would incur substantial and repeated costs if forced to update nutritional information every time a change occurs to a menu item due to the host of factors identified above (and many others). And, for changes the restaurant can control, such as making existing menu items healthier, the substantial costs to making menu/labeling changes will delay innovations of great benefit to consumers unless FDA adopts a flexible, reasonable approach.

Moreover, if the final rule does not allow for flexibility in updating menus to reflect changes in underlying menu items, restaurants and similar retail food establishments will face significant inventory exposure problems. Specifically, for each menu item or promotional piece, a restaurant must choose a quantity to be printed. For example, a business owner might order 1,000 print menus for $2.00 apiece. Under the Proposed Rule, if there is a major change to one of the ingredients the next week that alters the calories, the business owner will be forced to decide whether to throw out $2,000 of out-of-date calorie labeled print menus, or risk being out of compliance. This dilemma will only be magnified if that same decision must be made across many additional “primary” writings. Restaurants might try to limit inventory exposure by ordering fewer menus and promotional pieces, but this too dramatically increases costs, as those restaurants will not qualify for substantial volume discounts available for ordering pieces in bulk. To avoid this result, FDA should adopt a flexible policy regarding updating menus and menu boards to reflect changes.

Proposal

To reflect the significant logistical challenges associated with keeping nutritional declarations on menus and menu boards current, and provide much-needed flexibility, FDA should state that nutritional values found to be not current will not be considered to raise a compliance issue if the restaurant can demonstrate that it has adopted and follows a reasonable program to monitor changing nutrition values, and that it updates its materials at reasonable intervals based on the manner and frequency in which it changes menu and other labeling.

FDA should permit restaurants and similar retail food establishments to update menus and menu boards at reasonable intervals that coincide with the typical cycle for changes to menus and labeling for the particular restaurant or similar retail food establishment and, at a maximum, nutritional values that require updating should be updated at least once yearly. FDA should clarify that any temporary inconsistencies resulting from periodic updating will not result in a violation of the law.

* * *

The National Council of Chain Restaurants and the National Restaurant Association appreciate this opportunity to provide comments on FDA’s Proposed Rule. We look forward to
working with the Agency to implement the law in a manner that benefits consumers, recognizes the realities of a complex, diverse industry, respects Congress’s clear statutory language, 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,

M. Scott Vinson
Vice President
National Council of Chain Restaurants of the National Retail Federation

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

325 7th Street, NW
Washington, DC 20004
Tel: 202-661-3059
Fax: 202-626-8185
vinsons@nccr.net

1200 17th Street, NW
Washington, DC 20036
Tel: 202-331-5938
Fax: 202-973-5374
sdefife@restaurant.org
NCCR / NRA COMMENT: EXHIBIT 1
FAJITAS
GRILLED CHICKEN OR STEAK FAJITA
Hot flour tortilla filled with either grilled Chicken or tender Steak served with your choice of toppings.

HOT DOGZ, NACHOZ, & SIDEZ
HOT DOG
The original hot dog

DELI DOG
1/4 lb. jumbo hot dog

NACHOZ & CHEESE
Regular or side

NACHOZ GRANDE
Regular nachoz with your choice of additional toppings

SIDEZ
HARD BOILED EGGS

COLESLAW

GOURMET PRETZELS
* Salted * Jalapeno filled * Cinnamon sugar

BREAKFAST
SMUFFINS
Served on an English Muffin with your favorite toppings.
* Egg * Sausage * Ham * Bacon * Steak

SMISCUITZ
Served on a hot flaky biscuit with your choice of toppings.
* Egg * Sausage * Ham * Bacon * Steak

SHMAGELZ
Served on a Flat, Wheat, Everything, Cinnamon-Raisin or LowCarb bagel
* Egg * Sausage * Ham * Bacon * Steak

PRETZEL MELT
Served on our signature pretzel roll.
* Egg * Sausage * Ham * Bacon * Steak

SHMONSTER
Double egg, Double meat and extra Cheese on any Breakfast Sandwich.
* Egg * Sausage * Ham * Bacon * Steak

BREAKFAST SIDEZ
Hashbrownz English Muffin
Bagel (Plain) Bagel with butter
Bagel with cream cheese Biscuit

PRETZEL MELTS
ROASTED TURKEY
Signature Pretzel Roll topped with Roasted Turkey and your choice of spreads, cheese and toppings

HAM
Signature Pretzel Roll topped with Ham and your choice of spreads, cheese and toppings

ROAST BEEF
Signature Pretzel Roll topped with Roast Beef and your choice of spreads, cheese and toppings

CLUB COMBO
Signature Pretzel Roll topped with Ham and Roasted Turkey and your choice of spreads, cheese and toppings

BACON
Signature Pretzel Roll topped with Bacon and your choice of spreads, cheese and toppings

CLASSIC SUBZ
ALL MADE TO ORDER 6 OR 12

CHEESE
Swiss, Yellow American, and Provolone cheeses with your choice of a wheat or white sub roll, spreads and customized toppings.

DELI
Bologna, Salami and Ham with your choice of a wheat or white sub roll, spreads and customized toppings.

HAM & CHEESE
Ham with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

ROASTED TURKEY & CHEESE
Roasted Turkey with our choice of a wheat or white sub roll, cheese, spreads and customized toppings.

CLASSIC ITALIAN
Pepper Ham, Cappicola and Salami with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

BLT
Bacon, Lettuce and Sliced Tomatoes with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

TUNA SALAD
Tuna Salad with your choice of a wheat or white bread, cheese, spreads and customized toppings.

CHICKEN SALAD
Chicken Salad with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

ROAST BEEF & CHEESE
Roast Beef with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

CLUB COMBO
Ham and Roasted Turkey with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.
**CLASSIC HOT SUBZ**
All made to order. 6 or 12 available toasted in selected locations.

**MEATBALL PARMESAN**
Italian meatballs topped with marinara sauce with your choice of a white or wheat sub roll topped with your choice of cheese and toppings.

**MADE TO ORDER STEAK**
Tender Steak with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

**MADE TO ORDER GRILLED CHICKEN**
Grilled chicken with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

**PEPPERONI PIZZA SUB**
Pepperoni with your choice of a wheat or white sub roll, cheese, spreads and customized toppings.

**SOUTHWEST STEAK OR CHICKEN**
A white or wheat sub roll topped with juicy steak or grilled chicken, your choice of cheese, shredded lettuce, salsa, sliced tomatoes and jalapeno peppers.

**CHICKEN CORDON BLEU**
A white or wheat sub roll with Grilled Chicken, Ham, your choice of cheese and honey mustard.

**SHMOKEHOUSE STEAK OR CHICKEN**
A white or wheat sub roll with your choice of Grilled chicken or juicy steak, your choice of cheese, BBQ sauce, bacon and coleslaw.

![Image of a menu page with different options]

**PERFECT SANDWICHEZ**

<table>
<thead>
<tr>
<th>DELI</th>
<th>Bolognese, Salami and Ham with your choice of bread, cheese, spreads and customized toppings.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAM &amp; CHEESE</td>
<td>Ham with your choice of bread, cheese, spreads and customized toppings.</td>
</tr>
<tr>
<td>TURKEY</td>
<td>Roasted Turkey with your choice of bread, cheese, spreads and customized toppings.</td>
</tr>
<tr>
<td>CHICKEN SALAD</td>
<td>Chicken Salad with your choice of bread, cheese, spreads and customized toppings.</td>
</tr>
<tr>
<td>ITALIAN</td>
<td>Pepper Ham, Cappuccio and Salami with your choice of bread, cheese, spreads and customized toppings.</td>
</tr>
<tr>
<td>TUNA SALAD</td>
<td>Tuna Salad with your choice of bread, cheese, spreads and customized toppings.</td>
</tr>
<tr>
<td>ROAST BEEF &amp; CHEESE</td>
<td>Roast Beef with your choice of bread, cheese, spreads and customized toppings.</td>
</tr>
</tbody>
</table>

**SALADZ**

<table>
<thead>
<tr>
<th>GARDEN SALAD</th>
<th>Your favorite garden-fresh salad blend with your choice of toppings and salad dressing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRILLED CHICKEN CAESAR</td>
<td>Fresh greens topped with Ham, Roasted Turkey, shredded cheddar cheese, your choice of toppings and choice of dressing.</td>
</tr>
<tr>
<td>TACO SALAD</td>
<td>Fresh greens, tortilla chips, chili sauce and Colby Jack cheese with our choice of toppings.</td>
</tr>
<tr>
<td>CLASSIC CHEF S SALAD</td>
<td>Roasted Turkey, shredded cheddar cheese, your choice of toppings and choice of dressing.</td>
</tr>
</tbody>
</table>

**WRAPZ**

<table>
<thead>
<tr>
<th>ROASTED TURKEY &amp; CHEESE WRAP</th>
<th>Roasted Turkey, shredded lettuce with your choice of spreads, cheese and toppings all wrapped in traditional lavash bread.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADE TO ORDER GRILLED CHICKEN WRAP</td>
<td>Grilled chicken, shredded lettuce and your choice of spreads, choice of cheese and toppings wrapped in traditional lavash bread.</td>
</tr>
<tr>
<td>MADE TO ORDER STEAK WRAP</td>
<td>Steak, shredded lettuce and your choice of spreads, choice of cheese and toppings wrapped in traditional lavash bread.</td>
</tr>
<tr>
<td>GRILLED CHICKEN CAESAR WRAP</td>
<td>Grilled Chicken, Romana blend, shredded Parmesan cheese and classic Caesar dressing with croutons wrapped in traditional lavash bread.</td>
</tr>
</tbody>
</table>

**MADE TO ORDER STEAK SALAD**
Tender strips of steak on your favorite garden-fresh salad blend with your choice of toppings and salad dressing.

**MADE TO ORDER CRISPY CHICKEN SALAD**
Garden-fresh salad blend topped with Crispy Chicken Strips, your choice of toppings and salad dressing.

**BURGERZ**

<table>
<thead>
<tr>
<th>MTO BURGERZ &amp; CHEESEBURGERZ</th>
<th>A gourmet burger on a toasted corn-dusted or wheat roll topped with your choice of cheese, and choice of toppings.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOUTHWEST BURGERZ</td>
<td>A gourmet burger on a toasted corn-dusted or wheat roll topped with your choice of cheese, shredded lettuce, jalapeno peppers and salsa.</td>
</tr>
<tr>
<td>SHMOKEHOUSE BURGERZ</td>
<td>A gourmet burger on a toasted corn-dusted or wheat roll topped with your choice of cheese, sliced bacon and BBQ sauce, and coleslaw.</td>
</tr>
<tr>
<td>CORON BLEU BURGERZ</td>
<td>A gourmet burger on a toasted corn-dusted or wheat roll topped with honey mustard, your choice of cheese, and Ham.</td>
</tr>
</tbody>
</table>

**FRYZ, ONION RINGZ & CHICKEN STRIPZ**

<table>
<thead>
<tr>
<th>FRYZ &amp; ONION RINGZ</th>
<th>Bag • Cup • Bucket</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHICKEN STRIPZ</td>
<td>3 piece • 5 piece</td>
</tr>
</tbody>
</table>

**MAC & CHEESE**

<table>
<thead>
<tr>
<th>MAC &amp; CHEESE</th>
<th>MAC &amp; CHEESE</th>
<th>CHILI MAC &amp; CHEESE</th>
<th>THREE CHEESE MAC &amp; CHEESE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheetz Mac &amp; Cheese topped with chili sauce</td>
<td>Add bacon, shredded Colby Jack cheese and some Parmesan to Sheetz Mac &amp; Cheese to get this instant classic.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**GRILLED CHICKEN BREAST SANDWICH**
A toasted corn-dusted or wheat roll and grilled chicken breast topped with your choice of spreads, cheese & toppings.

**SOUTHWEST CHICKEN BREAST SANDWICH**
A toasted corn-dusted or wheat roll and grilled chicken breast topped with BBQ sauce, your choice of cheese, sliced bacon and coleslaw.

**SHMOKEHOUSE CHICKEN BREAST SANDWICH**
A toasted corn-dusted or wheat roll and grilled chicken breast topped with honey mustard, Ham and your choice of cheese.

**CORON BLEU CHICKEN BREAST SANDWICH**
A toasted corn-dusted or wheat roll and grilled chicken breast topped with honey mustard, Ham and your choice of cheese.
LIST OF ADVERTISEMENTS THAT ARE NOT “PRIMARY WRITINGS”

Below is a list of pieces that are used in the restaurant industry for the primary purpose of advertising a promotion, product or offer. This list was created from polling a number of restaurant brands. However, it is not inclusive of every single advertising piece and does not incorporate new elements that may be created in the future. The definition of advertisements should not be limited to these elements only. But these are some of the most common pieces in the industry, and we believe that specifying in the final rule that these pieces are excluded from labeling requirements would give much-needed certainty to restaurants and regulators.

**Exterior Advertisements**

- Promotional banner
- Window cling (exterior facing)
- Reader board (pole sign)
- Lawn Sign
- Roadside Banner
- Vehicle signage, including car tops, magnets or wraps
- Wobble boards team members shake outside by traffic to indicate a special offer
- Feather Banners (flags)
- Billboards

**Interior Advertisements**

- Wall graphics
- Banners
- Beverage carrier
- Customer Service Monitor Frame (used for phone suggestive selling)
- Counter Mat
- Table Tent
- Posters (including at the hostess stand area)
- Door Cling
- Window Cling (interior facing)
- Ceiling Banner or Danglers
- Server Buttons
- Register Toppers
- Placemats
- Pole Signs
- Translites (back lit advertisements featuring bundles, offers, products or promotions)

**Items sent to customer’s homes.**

*These items can also be found in storage in stores or on display in the customer area.*

- Pizza Box toppers (coupons, promotional products or deals glued to the top of pizza boxes)
- Box stickers
- Door Hangers (deals placed on customer’s door handles)
- Magnets (a magnet customers can put on their fridge that references a deal, phone number)
- Post its
- Direct mail cards
- Gift cards (often just feature the name of the restaurant or one product/promotion)
• Newspaper ads

**Digital Advertising**

• Digital banners on internet websites, often advertising a product or promotion
• Emails (sent to customers promoting a product or deal)
• Mobile ads (sent to customer’s phones)
• Text messages
• Social Media (advertising through venues like followers on Facebook)

**General Media**

• TV ads
• Radio ads

**PICTORIAL EXAMPLES**

**Table Stands.** This stand sits on top of tables at a casual dining restaurant and has pages you can flip to view featured items. That information will already be calorie labeled on the casual dining menu.

**Translites.** These are pieces that are usually housed in the bottom section of the counter at a restaurant. They display promotions or products in that space between the countertop and the floor and may be backlit with a lighting element. The menu board is usually overhead, and the translites repeat menu items offered on that menu board, often in different bundles or with different promotional price points.
**Pizza box-toppers.** These pieces are glued to the top of a pizza box. They show the featured product or promotion at a restaurant and include a few coupons, but they typically do not list the full list of menu items and prices of a restaurant.

**Door-hangers.** These are advertisements placed on customers’ door handles to promote a restaurant in their area. Door hangers usually feature a new product, promotion or coupons, but can also list general menu variety messages (like example attached showing this restaurant has chicken products and bread sides). But they typically do not list the full list of menu items and prices of a restaurant.

**Tray liners.** Some restaurants have paper liners that protect the trays they hand customers. Those tray liners can be the individual trays given to customers at the ordering counter to take their food away, or placed on large plastic catering trays sent with customers’ catering order. These tray liners are seen by the customer after they place their order, and may feature offers and promotions.