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Anna K. Abram
Deputy Commissioner for Policy, Planning, Legislation, and Analysis
Office of Policy, Planning, Legislation, and Analysis,
U.S. Department of Health and Human Services
10903 New Hampshire Avenue, Room 2335
Silver Spring, MD 20993

RE: Menu Labeling: Supplemental Guidance for Industry (FDA–2011–F–0172)

Dear Deputy Commissioner Abram,

The National Association of Convenience Stores ("NACS") and the Society of Independent Gasoline Marketers of America ("SIGMA"), referred to collectively as "the associations," submit these comments in response to the Food and Drug Administration (FDA)'s draft supplemental guidance for industry ("Guidance")[1] on the final menu labeling rules ("Final Rule").[2]

At the outset, NACS and SIGMA want to reemphasize that the convenience store industry supports providing nutrition information to consumers. Indeed, many of NACS' and SIGMA's members already voluntarily provide such information in response to consumer demand for such data. Disclosing nutrition information, in fact, can be part of a company's marketing strategy. But, any regulatory mandate requiring such disclosures must accomplish two objectives: (1) the regulated parties must be able to achieve compliance in a manner which is practical for their business format, and (2) compliance must result in consumers being provided understandable and usable information. Unfortunately, many of the Final Rule's regulatory requirements do not meet these two objectives.

[1] Food and Drug Administration, *Menu Labeling: Supplemental Guidance for Industry; Availability, FDA-2011-F-0172*, 82 Fed. Reg. 216 (November 9, 2017) [hereinafter "*Guidance*"], https://www.gpo.gov/fdsys/pkg/FR-2017-11-09/pdf/2017-24246.pdf?; Draft Guidance *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM583492.pdf.

[2] Food and Drug Administration, Final Rule, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines*, 79 Fed. Reg. 71156 (Dec. 1, 2014) (hereinafter "Final Rule"), https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf.

While the associations appreciate FDA's attempt to clarify the Final Rule with this Guidance, the Guidance itself will not be enough to overcome the many problems in the Final Rule. This is in part because no matter how comprehensive or helpful the Guidance may be, it cannot resolve some of the problems that businesses will face as they implement the Final Rule—the only way to resolve those problems with the Final Rule would be for FDA to withdraw and revise the rule.

Below, the associations set forth the most important concerns that remain despite FDA's issuance of the Guidance.

I. BACKGROUND ON THE CONVENIENCE AND FUEL RETAILING INDUSTRY

The convenience store and fuel retailing industry as a whole operates over 154,000 stores across the United States. These stores provide consumers with convenient locations and extended hours, with many open 24 hours per day, seven days per week. These small format stores are, on average, 2,950 square feet in size.[3]

In 2016, the convenience and fuel retailing industry employed more than 2.3 million workers and posted $549.9 billion in total sales, representing approximately 3 percent of the U.S. GDP.[4] In light of the number of fuel and other transactions in which the industry engages, convenience and fuel retailers handle approximately one of every 30 dollars spent in the United States. These retailers serve about 160 million people per day – around half of the U.S. population – and the industry processes approximately 73 billion payment transactions per year. Yet, it is truly an industry of small businesses—approximately 63 percent of convenience store owners operate a single store, and approximately 74 percent of NACS' membership is composed of companies that operate ten stores or fewer.

Food service has become an increasingly important component of the convenience store industry. Nevertheless, unlike restaurants and businesses similar to restaurants, the sale of prepared food is far from the primary business of NACS' and SIGMA's members. In fact, the most recent industry data shows that food service (prepared foods, commissary/packaged sandwiches, hot dispensed beverages, cold dispensed beverages, and frozen dispensed beverages) accounted for approximately 7 percent of total sales.[5] For further information on the convenience and fuel retailing industry, see the associations' comments on the Interim Final Rule.[6]

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[3] NACS is an international trade association representing the convenience store industry with more than 2,100 retail and 1,600 supplier companies as members, the majority of whom are based in the United States. SIGMA represents a diverse membership of approximately 260 independent chain retailers and marketers of motor fuel.

[4] All of the data points about the convenience store industry come from the NACS, State of the Industry: Annual Report (2016).

[5] *Id.*

[6] *See* NACS and SIGMA Letter, *Comments on Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments* (August 2, 2017) [hereinafter "*Interim Final Rule Comments*", *available at* https://www.regulations.gov/document?D=FDA-2011-F-0172-2677]

II. COMMENTS ON FDA'S DRAFT SUPPLEMENTAL GUIDANCE DOCUMENT

The associations appreciate FDA's attempt to bring more clarity to the menu labeling regime via the release of the Guidance. Despite FDA's efforts, however, many regulatory requirements remain unclear while others remain more burdensome than they should be. These problems include the following:

A. The Guidance does not provide a definition of marketing materials *inside* a store

Under the menu labeling provisions originally passed by Congress, covered establishments must include calorie information on the "primary writing" from which a consumer selects food. Reading that language, it is evident lawmakers intended for there to be a *single* "primary" menu in the store and for that single menu to include nutrition information. In the Final Rule, however, FDA interpreted the term "primary" in a way that is inconsistent with the statute. The regulation creates a series of factors for determining whether a writing is a "primary writing" including, *inter alia*: whether it lists the name of a standard menu item or an image of a standard menu item; whether it gives the price of that item; and whether it can be used by a customer to make an order selection at the time the customer views the writing.[7] Under this standard, businesses may have any number of different writings that qualify as the "primary" writing. Nothing about these factors requires that a writing be the most prominent one in a business location – or that a writing, to qualify as a menu, be distinguished from other writings in any way. In fact, many advertisements and marketing materials that are not intended to be menus at all may qualify as "menus" under the Final Rule. This creates serious compliance hurdles for business because it is unclear what does and does not require nutrition information and it may dramatically increase the cost associated with complying with the Final Rule.

The Guidance helpfully clarified that marketing materials *outside* a business that are designed to entice someone to enter the business are not menus.[8] However, the Guidance failed to clarify how to distinguish between menus and marketing displays *inside* a business. For this reason, NACS and SIGMA urge FDA to rework this section of the Guidance to clarify what material *inside* the store is considered a menu and what is not. As the associations told FDA in their August 2, 2017 comment letter,[9] FDA could address this concern in a straightforward manner by stating that the term "menu" or "menu board" refers to a *single* listing of items, which the retail food establishment, reasonably believes to be – and has designated – as the primary listing from which customers choose/select their food that they then order. In other words, there should be *one* menu per store—and this one menu could be a board (including an electronic

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7 Section 4205, Pub. L. 111-148, 111th Congress (Mar. 23, 2010).

8 *See* Guidance, *supra* note 1, Section 4.1.

9 *See* Interim Final Rule Comments, *supra* note 6, page 8.

ordering kiosk) at the point of sale or a printed menu, copies of which are given to customers to peruse to make their selection.

Unless that change is made, confusion between marketing material and menus inside a store will continue. This will present particular problems for small format stores because marketing material within those stores can often be viewed from many different places within a store. Simply because a customer might be able to see marketing material when they order their food should not turn that marketing material into a menu. Retailers in this channel of trade typically have one menu board over their point(s) of sale. A growing number are also turning to having menus at electronic kiosks – either on their own or in conjunction with menu boards. There is no reason for marketing materials that are not intended to be menus to create confusion and additional regulatory burdens.

B. The Guidance does not clarify which businesses are subject to the regulation

Many businesses still do not understand whether they are covered under the Final Rule—and the Guidance did not alleviate any of this confusion. FDA's 20-plus location determination for covered businesses is effectively a "same name" test, which has led to some confusion. This is particularly true in the retail fuels space, where many retailers have a "brand" relationship with a fuel supplier. Under such contracts, the trade mark or the brand name (e.g., Exxon, Chevron, Tesoro, etc.) that is on the retailer's fuel canopy or store front is owned by the refiner and the retailer is given the rights to use the name. The centerpiece of those business relationships is an agreement to purchase motor fuel from that supplier. In most of those branded contract relationships, the fuel brand is not involved with food offerings. It is sometimes unclear, based on the Final Rule's "same name" test, whether such retailers would be covered by the rule. Given the fact that the "name" that triggers the 20 or more store threshold often has nothing to do with food sales, it is inappropriate for such establishments to be covered under the rule.

The Guidance says that a motor fuel outlet branded with the name of a major oil company is not subject to the regulations if its store has a different name that is not shared by 19 other stores.[10] The Guidance also says that if a store shares a name with 19 other businesses but those businesses do not have substantially the same menu items, then it is not subject to the regulations.[11] But, many motor fuel outlets that operate under the name of a refiner's brand do have substantially the same menu items. It is not uncommon, for example, for those stores to all carry soft drinks, coffee, hot dogs, breakfast sandwiches, deli sandwiches and more common items. Whether they do or do not have substantially the same menu items is often very difficult to determine. Outlets using the same brand can be spread throughout the United States and retailers do not have access to a central listing of the menu items that such stores carry. With hundreds or thousands of retail stores sharing the same brand names, how can a retailer assure itself that there aren't 19 of them that carry the same menu items it carries?

The guidance does not provide a good answer to this question. That is why NACS and SIGMA urge FDA to address this problem and clarify that only a branded store or franchisee that

[10] *See* Guidance, *supra* note 1, Section 8.2.

[11] *See* Guidance, *supra* note 1, Section 8.1 & 8.2.

is part of a chain where the brand or franchisor actually exerts substantial control over the food service operations will be considered to be part of a chain for the purposes of these regulations. In other words, when an oil company's name is present on a fuel canopy or retail outlet where fuel is sold, but the brand does not control what foods are sold inside the store and how they are prepared—that store should not be covered by the Final Rule (unless that individual store owner has 20 or more locations).

C. The Guidance does not resolve compliance burdens for self-serve and "on-display" items

In comments submitted to FDA, the associations asked the agency to streamline the requirements for self-serve or "on-display" food items which, as currently defined in the Final Rule, will require businesses to post calorie signs in many different places throughout their stores.[12] Doing so will be at a significant cost to the retailer with little to no benefit to the consumer who will be inundated with information.[13]

Problematically, the Guidance does not resolve this concern and under the regulations, businesses will need to post individual labels or menus everywhere self-serve items can be found in a store rather than allowing businesses to put all the information on one, centrally located menu board.[14]

These costs and logistical problems can be avoided in the same way that the confusion between menus and marketing materials can be avoided – by making clear that nutrition information can be posted on one menu rather than by requiring separate displays along with every self-serve and on-display food in a store.

D. The Guidance does not address concerns about hot food and salad bars

Many members of the associations maintain hot food and/or salad bars at which customers can select their own meals in the proportions they would like. The regulations and guidance, however, do not provide the flexibility that is needed for these types of displays.[15] Having the nutrition information for all of the potential foods available at a hot food or salad bar on one menu would allow for these food options to be available as they are today. This is true because foods offered in those setting change multiple times per day (both at different meal times and within meal times based on availability of different items). And, the offerings in these settings can also change from day to day. It is not workable for stores to place individual calorie

[12] *See* supra note 6, page 8.

[13] Beyond the sheer number of disclosures required under the Final Rule, the requirement to maintain and update signage is (in and of itself) a difficult and expensive undertaking. Convenience stores regularly update signs to account for evolving product offerings—and once signs are posted, they get significant wear-and-tear from contact with customers, particularly during mealtime or commuter rush hour. This will make the requirements of multiple disclosures throughout a store very challenging and more expensive than estimated by FDA.

[14] *See* supra note 1, Section 3.1

[15] *See* Guidance, *supra* note 1, Section 3.

disclosures next to each and every item in a hot food or salad bar. Because those items can change places during the day and be removed entirely during certain hours (in favor of alternatives), individual calorie disclosures would require large expenditures of employee time and would frequently result in misplacement of those disclosures. For example, during the lunch rush, an item such as cranberry raisins might be substituted for raisins but the old label might accidentally be left next to that bin. With multiple items changing multiple times during busy hours of the day, such mistakes will be commonplace. That is why having all the items compiled in one place for customers to view is a more workable solution.

The requirement in the regulations that customers be able to view the calorie information of an item at the point they are standing when putting that item into their container means that a central disclosure will not be allowed in many retail settings. The physical layout of stores means that some food bars are against walls while some may be in an open space. Others might be crowded into limited space near other food displays. These different layouts make it impossible for many stores to design a central menu with calories that can be viewed from each and every point at a food bar (especially when the ends of such bars are often used for customers to select salad dressings, soups and the like. The inflexibility of the regulations in requiring calorie numbers to be viewed from each and every point at a salad or food bar where an item is selected makes these provisions unworkable and that requirement should be removed.

These problems are made clear by the examples that FDA provided in the Guidance. Figure 1 in section 3 of the Guidance, for example, shows a flat display of the calories for multiple items above the food bar. While that display is visible while standing in front of it, many food bars of that kind have salad dressings, soups or other items at the ends of the food bar. If the customer in the picture happened to be standing at the end of the food bar, facing lengthwise down the food bar, the flat display would not be visible and would not be compliance with FDA's requirement that calories be visible from every position where a consumer might select a food. So, Figure 1 in section 3 does not comply with the regulations if it were used by many retailers.

Figure 3 in section 3 of the Guidance presents different problems. The calorie displays above each item in the figure are attached to the glass fixture above the food items. But, as noted above, in many establishments the food item at each of those positions will be completely different at different meal times. For example, the spinach and romaine depicted might be scrambled eggs and bacon at breakfast and might be roasted chicken and potatoes at dinner. Similarly, the romaine might be changed to iceberg lettuce in the middle of the lunch rush based on availability. The calorie disclosures depicted could not be removed and replaced as those items are changed through the course of the day. Using calorie disclosures of the kind depicted in Figure 3 would likely lead to non-compliance. Figure 5 uses calorie displays with the same problems. Those disclosures cannot be changed and moved as the offerings change.

Figure 4 combines the challenges presented by Figure 1 with those presented by Figures 3 and 5. If a customer can scoop a selection from the end of the food bar on the far right of the picture in Figure 4 (which is the layout of many food bars), then the flat calorie display will not be visible at the moment that item is being selected and it will not be in compliance. The display is also affixed to the sneeze guard and therefore cannot be changed as the items in that portion of

the food bar are changed throughout the day. That means Figure 4 will not work because of the frequency of changing offerings at many food bars.

Again, all of these problems can be addressed simply by removing the requirement that the calorie disclosure be visible from each and every position at a food bar where food can be selected by a customer. The associations urge FDA to make this needed change.

E. The Guidance does not address concerns about the natural variations in calorie counts.

Under the Final Rule, a business is required to determine the nutritional content of standard menu items by a "reasonable basis."[16] This "reasonable basis" approach, however, applies only to the collection of calorie information for a specific item rather than the actual calorie content of a particular item in the store. In other words, the Final Rule fails to recognize that even the same foods vary in calorie and nutrition content. Even though a store can test a standard chicken breast that goes on a grilled chicken sandwich for its nutrition content, not all chickens (and their various parts) grow to be exactly the same size with exactly the same nutritional profile. Thus, no matter whether a business based its nutritional content determination on a methodology that qualified as a "reasonable basis," the calorie count of an actual food product offered for sale to a consumer may differ from the sample food that the business tested or used to find its calorie determinations. In essence, the regulations do not provide a margin of error or other recognition that even the same foods naturally vary in calorie counts from one to the next.

Food preparation results in variations as well. Even if food is prepared in the same way, variations in the amounts of different ingredients (such as the amount of cheese or lettuce on a sandwich) cannot be removed. Small variations in cooking times can also change calorie and other nutrition amounts significantly. For example, many of the associations' members sell hot dogs that are heated on roller grills. The number of calories in each hot dog can vary based upon how long it is heated on the grill prior to sale. These variations cannot be avoided.

The Guidance alludes to these problems with respect to calculating calorie amounts.[17] But, the "reasonable basis" language relied upon by the Guidance does not address the problem of food natural variations in foods and food preparation. Those variations lead to real world discrepancies that are inconsistent with FDA's requirement that store-level personnel certify as to their method of preparing foods. Those certifications will create potential non-compliance issues on a regular basis. As noted in the attachment to the Interim Final Rule Comments that NACS and SIGMA filed, 93 percent of all prepared foods will fall outside of the parameters of calorie numbers that FDA set in its rule. That reality, combined with the store-level certification requirement in the rule will lead to an explosion of enforcement and noncompliance disputes.

[16] 21 C.F.R. §101.11(c).

[17] *See* supra note 1, Section 7.1 & 7.2.

FDA needs to include in the rule some allowances for natural food and food preparation variations by removing the store-level certification requirement and making explicit that variations in actual calorie counts do not violate the regulations. This may be done with the use of margins of error or otherwise, but the current flexibility in how calorie counts are gathered does not provide assurance that inspectors (or private litigants) won't allege regulatory violations based on unavoidable variations in actual calorie counts.

F. The Guidance does not protect small business providers of locally made/locally sourced foods

The rules do not provide any flexibility to preserve locally made and locally sourced foods. These foods are often sold by small local businesses. But, if those small businesses sell to a single covered establishment, then those businesses must provide the covered establishment with the full range of compliance information for that food. This includes not only full nutrition information on the food, but also certification as to the method of arriving at those figures, methods of preparation and other information necessary to ensure the covered establishment that it will not suffer liability for carrying the food. The result in the associations' industry is that many covered establishments have had to end relationships with small local businesses that reported they could not provide the necessary information and assurances on the foods they make. Flexibility should be included in the rule to exempt small food suppliers that provide foods to fewer than twenty establishments.

G. The Guidance does not provide needed flexibility for delivery restaurants.

Delivery businesses like pizza restaurants want to be able to comply by displaying calorie information where their customers will see them – on their websites. But, the regulations require these businesses to include calorie information on any menu boards that exist on their premises. The Guidance attempted to address this by saying that calories could be disclosed on electronic devices in stores – but it did not address the problem that physical menu boards would still need to have duplicative information even if electronic devices were used.[18] So, these businesses will be presented with a bad choice – providing duplicative information on physical menu boards that will be expensive to provide and will not be seen by many consumers or removing menu boards from their stores. The second option will be an expensive way to provide consumers with less information. Surely, compliance in a store through electronic means should be adequate without maintaining a duplicative physical posting requirement on menu boards. The Guidance could and should allow this basic flexibility.

Again, this problem could be resolved by changing the rule so that stores are required to have a single menu. Then, delivery restaurants could provide electronic access to the information in their stores and not be faced with a duplicative physical posting requirement.

[18] *See* supra note 1, Section 5.2.

H. The Guidance does not provide flexibility for family style/multi-person dishes.

Businesses that serve items intended for multiple people (such as family style restaurants) want flexibility to display the calories that are in each serving of the item and the number of servings rather than displaying the total number of calories in the entire item. This would be more helpful to customers sharing those orders. The regulations do not allow restaurants to comply by displaying the calories per serving and number of servings – that can only be given as additional information so it would not relieve any compliance burden.[19]

III. LIABILITY CONCERNS EXACERBATE THESE PROBLEMS

The potential liability that businesses face from the provisions of the Final Rule exacerbates the issues that remain opening following guidance. In particular, a variety of state laws – some of them that generally prohibit unfair and deceptive acts and practices and others that specifically implement state menu labeling rules – create the potential for private lawsuits and even class action litigation against businesses that have minor compliance issues with the rules. The associations, in their prior comments on the Final Rule,[20] provided FDA with an economist's report which found that because there was no mechanism in the Final Rule providing for the fluctuations in calories that occur naturally in foods and inevitably in food preparation, ninety-three percent of all prepared foods would be out of compliance with the posted calorie requirements no matter how much businesses spent attempting to comply. This reality, along with the confusion and unanswered questioned detailed above, creates an unacceptably large potential liability for food businesses.

And, penalties that regulators could seek for noncompliance of any kind include criminal penalties under the Food, Drug and Cosmetic Act. That too is unacceptable – especially for store level employees who will be put at risk simply for doing things like putting the wrong amount of cheese on a sandwich. No one should face that type of potential liability.

These outsized potential liabilities and penalties make it essential that the rules are clear, reasonable, and can be followed. Unfortunately, the Final Rule is not yet there. That is why, in addition to the items noted above, businesses should be given a period of time in which they can correct violations after being notified of those violations by any state or federal entity. That will at least provide them a chance at compliance.

IV. NACS AND SIGMA CALL ON THE AGENCY TO REVISE THE GUIDANCE AND FINAL RULE

FDA's Guidance does not relieve the burdens of or clarify many of the problematic provisions included in the Final Rule which will make compliance onerous for NACS' and SIGMA's members as well as small business suppliers. As noted, any regulatory mandate

[19] *See* supra note 1, Section 5.7.

[20] Interim Final Rule comments, supra note 6.

requiring the disclosure of nutrition information must accomplish two objectives: (1) the regulated parties must be able to achieve compliance in a manner which is practical for their business format, and (2) compliance must result in consumers being provided understandable and usable information. The Final Rule and Guidance, taken together, do not achieve either of these objectives. Therefore, FDA should make revisions to the Final Rule before letting it go into effect.

Sincerely,

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