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August 2, 2017

VIA ELECTRONIC FILING – www.regulations.gov

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: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments (FDA-2011-F-0172, RIN: 0910-AG57)

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,” would like to express their appreciation for the Food and Drug Administration’s (“FDA” or “the Agency”) recent delay of the final menu labeling rules¹ and the Agency’s decision to request comment on the regulatory burdens present in the final menu labeling regulations (hereinafter “Final Rule”).²

The Final Rule contains significant flaws, many of which stem from that fact that the regulations appear to have been designed for chain restaurants. In the United States, however, prepared food is sold in many different ways and formats—some stores have menus, some do not. And many retail food locations offer a wide variety of self-serve food options. In addition, many stores allow consumers to make their own foods or order “customized” foods. Certainly, all of these retail food stores – convenience stores, grocery stores, stadium vendors, etc. – look very different from one another and sell foods in unique ways. Put simply, FDA’s regulations do not provide the necessary flexibility to work for these many different formats. If the regulations

¹ Food and Drug Administration, Interim Final Rule, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments*, FDA-2011-F-0172, 82 Fed. Reg. 20825 (May 4, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-05-04/pdf/2017-09029.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), <https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf>.

are not revised, it is likely some businesses will be forced to limit some of their most innovative food offerings (fresh food offerings in particular), and consumers' access to a wide variety of affordable food options will be narrowed.

At the outset, NACS and SIGMA emphasize 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. *The Final Rule fails to achieve either of these objectives.*

One issue that stems in part from the many problems with the Final Rule is that the Agency dramatically underestimated the costs of compliance for many retailers. In its final Regulatory Impact Analysis ("RIA"), FDA estimated that there would be approximately 298,600 covered establishments, organized under 2,130 chains,³ and that the costs of compliance would amount to nearly \$1 billion over ten years.⁴ For convenience stores alone, FDA estimated that it would cost \$12.1 million on an annualized basis to comply with the regulations.⁵ These estimates, however, bear absolutely no relation to the real world costs that NACS' and SIGMA's members will incur to comply with the Final Rule. For the convenience store industry, it will cost thousands of dollars per covered store to comply, and the actual cost of compliance and enforcement for the industry will be approximately \$84.2 million dollars on an annualized basis – or seven times more than the Agency estimated for convenience stores and almost equal to the \$84.5 million that FDA estimated for all businesses covered by the rule.⁶

In fact, the actual costs of compliance for all businesses covered by the rule will exceed \$300 million per year – more than three and one-half times FDA's estimate.⁷ And, those huge costs are not even the biggest barriers to compliance for regulated businesses. Because the Final Rule makes no allowances for normal calorie and nutrition variations in foods (and resulting from food preparation), *more than 93% of foods subject to the rule are likely to be in violation of the Final Rule no matter how much time and money businesses spend attempting to comply.*⁸

³ Final Regulatory Impact Analysis, Department of Health and Human Services, Food and Drug Administration, *Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, Docket No. FDA-2011-F-0172, at 7 (Nov. 2014), available at <https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf>.

⁴ *Id.*

⁵ See Appendix A, David Zorn, *Comments on the Food and Drug Administration's Regulatory Impact Analysis and Cost Estimate for the Menu Labeling Final Rule* (Aug. 2, 2017), at 2.

⁶ *Id.*

⁷ *Id.* at 1.

⁸ *Id.* at 1.

In light of the unworkability of the Final Rule and the considerable burden it would impose on NACS' and SIGMA's members, the associations call upon FDA to withdraw and subsequently rewrite the Final Rule to ensure that regulated businesses can reasonably comply with the rule and provide their customers with usable information. Below, the associations set forth the most important concerns raised by the Final Rule along with suggestions for how those concerns could be addressed.

I. 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. Many of these small format stores – which are, on average, 2,960 square feet in size – are owned and operated by NACS' and SIGMA's members.⁹

In 2015, the convenience and fuel retailing industry employed more than 2.7 million workers and posted \$574.8 billion in total sales, representing approximately 3.2 percent of the U.S. GDP.¹⁰ 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 over 80 billion payment transactions per year. Yet, the industry is truly an industry of small businesses—approximately 63 percent of convenience store owners operate a single store, and approximately 75 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/package sandwiches, hot dispensed beverages, cold dispensed beverages, and frozen dispensed beverages) only accounted for 6.63% of total sales.¹¹

A. There is no “typical” convenience store business model.

⁹ 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.

¹⁰ All of the data points about the convenience store industry come from the NACS, *State of the Industry: Annual Report* (2015).

¹¹ *Id.*

Within the convenience store industry, there are many distinct business models.¹² One type is the typical franchise model (e.g., 7-Eleven franchisees), where a franchisee operates one or more locations pursuant to a contract that allows it to use the name of a larger franchisor. In some of those instances, the franchisor has established parameters on food offerings but in other situations it has not.

Another type of business arrangement, which is little known or understood outside the retail fuels space, is when a retail motor fuel outlet is branded with the name of a major oil company or a private brand.¹³ In some instances, under such a branding contract, a store contractually agrees to the sale of motor fuels under the brand name (e.g., Exxon, Shell, Tesoro, Chevron, etc.). That brand, however, may have nothing to do with in-store food service offerings or sales. When people talk about a branded ExxonMobil retailer, for example, the brand may have nothing to do with the food store operated next to the fuel pumps. Thus, the branded retailer model is frequently very different from the traditional restaurant franchisee model because the branded fuel retailer may operate his convenience store as an independent business without any restrictions imposed by the brand on food offerings.¹⁴ Thus, even though some may think that many of the nation's over 154,000 convenience stores are owned and operated by larger companies with 20 or more stores, over 63 percent of them are run by single-store owners and operators, many of which have complete discretion regarding the foods they offer for sale and how they offer them for sale. In that aspect of their businesses, they operate as completely independent food sellers even though they use the name of, and buy their motor fuel from, a large, recognized business.

B. The convenience store business model is different from the chain restaurant model.

Generally, at all of their respective locations, sit-down chain restaurants and quick-service restaurants sell nearly identical food offerings, prepared in the same way, and displayed on the same menu. Their primary business is the sale of prepared food. As noted above, often that is not the primary business of convenience stores (and it is typically not even the secondary business of such stores). Menu labeling for many chain restaurants is fairly straightforward: the

¹² There are at least 16 models for convenience and fuel retailing stores that involve different versions of the fuel models and in-store models described below: (1) company owned, company operated sites; (2) company owned, dealer operated sites; (3) dealer owned, dealer operated site; (4) commission agent site; (5) company merchandize and company foodservice, (6) company merchandise and franchise foodservice; (7) franchise merchandise and franchise foodservice; (8) rented out location, etc.

¹³ Under 4% of all retail fuels stations are owned or operated by the integrated oil companies.

¹⁴ In fact, many businesses still do not understand whether they are covered under the Final Rule. 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 controlled by the refiner, and the relationships centers around the sale of fuel. In most of those branded contract relationships, the fuel brand is not involved with food offerings. It is 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 has nothing to do with food sales, it is inappropriate for such establishments to be covered under the rule.

restaurant provides calorie counts next to every item on the menu or menu board. And, franchisees that operate chain restaurants can receive assistance from their franchisors on collecting and posting the necessary information because the franchisor directs the food offerings of the franchisees – and sometimes establishes the supply arrangements for those foods.

This is not the case for the convenience store industry, where stores do not have identical business plans and even stores within the same chain do not have identical product offerings. For the convenience industry, store location and geography-related market demands result in great differentiation between stores, even between stores that are part of the same chain. Thus, a store in Boston, Massachusetts will likely offer substantially different foods from one with the same name in Iowa City, Iowa or Gainesville, Florida. And, should stores within a chain sell the same items, many times, the way the stores *offer* those items differ. For instance, some store locations may have a self-serve station for customers to get a hotdog; other stores might offer “made to order” hotdogs where the store puts different toppings or condiments on a hotdog based on the customer’s selection. In addition, stores with similar food offerings might have different suppliers, so the food items themselves are not identical across stores.

Thus, beyond offering consumers many different types of foods, convenience stores offer food to consumers in many different settings. For example, a store may have only a few or close to a dozen different food and beverage stations on the main retail sales floor (e.g., roller grill, behind-counter primary menu board, hot coffee station, iced coffee station, soda fountain, frozen carbonated beverage dispenser, pizza case, bakery case, fruit stand, grab-and-go case, salad bar, hot food bar) where the current regulations would require the retailer to post calorie signs and other mandatory disclosures (i.e., “2,000 calories a day is used for general nutrition advice, but calorie needs vary” and “Additional nutrition information available upon request”). This and other variations make menu labeling compliance under FDA’s Final Rule far more complicated than in the chain restaurant context.

With regard to food preparation, restaurant franchises generally prepare food offerings in a far more homogenous manner, as dictated by a uniform corporate policy. A grilled chicken sandwich at a national chain is prepared in a manner developed, directed, and used by a corporate headquarters at all of that company’s franchises or company operated stores. In contrast, not all food offered at convenience stores is prepared the same way. In some chains, the size and preparation of a particular portion is at the discretion of the employees of that particular store.

Convenience stores also differ from chain restaurants because many of the industry’s food offerings allow for “customization,” meaning the customer can tailor the food item according to her tastes. A store, for example, may offer a “chicken sandwich” on a menu board. The customer, however, will be able to customize that sandwich by choosing her bread, whether to grill or fry the chicken, and whether to add other ingredients like cheese, sauces, or vegetables. Moreover, the customer might make some of these customizations herself using free condiments, or request the same customizations by asking an employee or by using a kiosk ordering system.¹⁵

¹⁵ Electronic, touch-screen kiosk ordering systems are becoming more common in larger, more sophisticated chains. They are not, however, the norm across the industry.

When purchasing drinks from a fountain, customers will inevitably put different amounts of ice in their cups. They may also mix soda flavors to create their own special blend. Taken together, these human/personalized elements make the food experience at convenience stores unique to each individual offering in the same store and at different stores owned by the same entity. Catering to individual preferences is a defining trait of the industry that is difficult to regulate in a consumer-friendly fashion.

II. COMMENTS ON THE MENU LABELING REGULATIONS

FDA's final menu labeling regulations were promulgated on December 1, 2014¹⁶ – four years after Congress enacted the menu labeling provisions as part of the Patient Protection and Affordable Care Act (“ACA”).¹⁷ Unfortunately, the Final Rule largely ignored the myriad real-world complications of implementing the underlying statute. For example, FDA failed to properly consider the dissimilarity between restaurants and other retail businesses, what rules made sense for non-restaurant businesses, and whether non-restaurant small businesses with less than 20 locations should be covered by the rule at all. Several related problems under the Final Rule followed, including a lack of flexibility for different business models with respect to how and where calorie counts are displayed, uncertainty related to key definitions and elements of the Final Rule (e.g., what constitutes a “menu”), failure to take into account natural calorie variations of food products and food preparation, and harsh penalties for non-compliance—including criminal penalties—that are out of proportion to the prospective violations at issue.

Despite the many problems with the Final Rule, NACS' and SIGMA's member businesses are spending tremendous resources trying to implement the Final Rule's requirements, even though they do not have a clear picture of what is necessary to comply.

A. The Final Rule fails to differentiate between menus (which require calorie information) and marketing materials (which do not require calorie information).

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 food retailers to identify a *single* “primary” menu in the store and include nutrition information on that menu. Congress concluded that consumers would benefit if they had easy access to calorie information in one place.

¹⁶ Final Rule, Dept. of Health and Human Services, 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>.

¹⁷ Section 4205, Pub. L. 111-148, 111th Congress (Mar. 23, 2010).

In the Final Rule, however, FDA has 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.¹⁸ 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. This creates fundamental problems that are at odds with the statute. Convenience stores, for example, would need to include calorie information on virtually *any writing* in a store that is visible to the customer as he or she is deciding what food to order. In fact, as currently drafted – and based on FDA’s own inability to clarify or differentiate between menus and advertisements – marketing materials would also require calorie information.

For instance, during a July 2016 education session hosted by FDA on the Final Rule,¹⁹ NACS, SIGMA, and others requested clarity on some fundamental issues. NACS’ and SIGMA’s counsel asked FDA staff to delineate the distinction between a menu, which requires calorie information, and an advertisement or marketing piece, which does not require calorie information. FDA staff could not provide an answer. Instead, they admitted that they had not made determinations on these kinds of very basic compliance questions.

The FDA’s inability to specify what constitutes a “menu” according to the Final Rule is a fundamental bar to compliance (with attendant enforcement risks).²⁰

Under NACS’ and SIGMA’s members’ business models, marketing pieces change frequently and they are widely dispersed throughout the store (e.g., by self-service stations or kiosks, in store windows, on shelves, hanging from the ceiling, etc.) and the immediately surrounding property (e.g., on sidewalk boards and lawn signs, and pump-toppers or gas dispensers, and on radio or television). Every one of these advertisements, which showcase special food deals, regularly include names, images, and prices of standard food items. Further, they are part of broader advertising campaigns, which are planned and created over a period of months. FDA cannot tell us when a customer can (and cannot) make an order selection from an advertisement. Agency staff has indicated that signs located outside a store might allow this to happen because a customer could remember what was on the sign and then enter the store, but staff has not provided any definitive answer or any reliable way for businesses to make this determination. Because of the lack of answers from FDA as to which materials are required to have calorie counts, businesses must *guess* at how to comply.

¹⁸ *Id.*

¹⁹ FDA Public Workshop to Address Menu Labeling Final Rule, College Park, MD, July 7-8, 2016, notice available at: <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm506247.htm> (last visited June 20, 2017).

²⁰ FDA, *A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11): Guidance for Industry* (April 2016), available at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM461963.pdf> (hereinafter “final guidance”).

In addition, if the signage did require calorie information (and under the Final Rule almost every sign appears to require calorie data), the related font size rules would require such huge print that it would take away the marketing value of the sign, become overwhelming to consumers, or displace other more important signage. Significantly, posting of such calorie information may even threaten violation of zoning ordinances or other regulations, including, but not limited to, fire codes mandating line-of-sight between cash registers and gasoline dispensers, or zoning ordinances imposing dimensional limitations on storefront signage.

1. How FDA Should Fix Final Rule

It would be relatively straightforward for FDA to address the concerns laid out above. FDA should state 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 ordering kiosk) at the point of sale or a printed menu, copies of which are given to customers to peruse to make their selection.

Such changes are necessary because the Final Rule places an undue burden on businesses, which will expend substantial resources to provide duplicative nutritional information on advertisements and other materials with minimal benefit to their customers.

B. The Final Rule will overload consumers with information because it requires stores to post menus anywhere food is “on-display” or offered to consumers in a self-service format.

Under the Final Rule, NACS’ and SIGMA’s members will need to post calorie information anywhere a customer would “make a decision to purchase food.” As described in Section I.B of this letter, convenience stores offer food and beverages to consumers at multiple locations throughout a store. Thus, because the regulations not only obligate retailers to publish calorie information on menus or menu boards for standard menu items, but also on signs adjacent to self-service or “on-display” items,²¹ convenience stores will need to put up menus all over their stores. The repetition and profusion of signs will create such a busy visual field that many customers may well suffer “information overload” and block out the disclosures altogether—a phenomenon demonstrated across many studies.²² These consumers will get little to no benefit

²¹ Self-service items include items such as sodas and coffee, while food on display would be a hotdog or prepared sandwich.

²² See e.g., Bialkova, S., Grunert, K., & Van Trijp, H. (n.d.), *Standing out in the crowd: The effect of information clutter on consumer attention for front-of-pack nutrition labels*, 41 Food Policy 65-74(2013), at 72 (finding that “the more messages appear on a food label, the more the clutter is and thus the less the attention-getting properties of any single message...We believe that attention is a major bottleneck with regard to the effect of nutrition labels on consumer food choice...”); Hilke Plassman et al., *Branding the brain: A critical review and outlook*, Journal of Consumer Psychology (2012), 2 (stating “The amount of information consumers are exposed to is enormous, yet our processing capacity is limited. Each second we are exposed to an estimated 11 million bits of information that reach

from menu labeling, but the businesses that post those menus will have to shoulder significant costs to do so.

Beyond the sheer number of menus required under the Final Rule, the requirement to maintain and update signage is (in and of itself) a gargantuan undertaking. Convenience stores constantly update signs to account for evolving product offerings—and once signs are posted, customers continually bump into and knock them over, particularly during mealtime or commuter rush hour. Thus, stores will always have to be on high alert to repost and replace signage that has been knocked over, stepped on, or otherwise damaged by consumers—or risk penalties for non-compliance.

1. How FDA Should Fix Final Rule

This problem can be remedied in the same way that the problem of the lack of clarity of the distinction between marketing materials and menus can be remedied. As noted there, FDA should revise this rule to allow retailers to offer nutritional information on **one** central menu board or menu where consumers can access nutritional information. This should include the possibility that the one menu is provided through an electronic ordering kiosk rather than on a physical menu/menu board. In the case of a store that designates its electronic kiosk as its primary menu, FDA should not require the information also be posted on a menu board.

C. The Final Rule does not account for natural calorie variation in foods or natural variation in food preparation.

The Final Rule does not recognize that even the same foods vary in calorie and nutrition content. For example, while 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. Yet, when NACS and SIGMA raised this concern with FDA staff mere weeks before the original compliance date,²³ FDA staff could not provide an answer as to how stores should comply with the law. In a similar vein, while FDA has provided for standard nutrient values for raw fruits and vegetables,²⁴ the Agency has not accounted for differences when those items are included in or on other dishes.

Of equal concern is that stores frequently may be supplied by different vendors of the same “product”—and those vendors prepare the product differently so that it has different calorie content (e.g., a smoked turkey from Boar’s Head is different from a smoked turkey from Dietz & Watson).

us through all our senses, yet humans are capable of processing only around 50 bits of that information, letting most of the input go by unnoticed”).

²³ In a call with FDA staff on October 13, 2016, NACS’s and SIGMA’s counsel specifically asked FDA staff how the associations’ members should provide calorie counts for fried chicken, given that chickens and their parts come in different sizes.

²⁴ Appendix C of 21 CFR part 101.

In addition to these natural variations, food preparation cannot be done exactly the same way every time. Despite the industry’s best efforts to standardize preparation techniques throughout the day within a store, across employees in the same store, and across stores in a chain, it is simply impossible for items to be prepared exactly the same way and result in exactly the same nutritional profile every time. One employee, for example, may include less mayonnaise on a sandwich or more lettuce in a salad in one instance and a little less in the next instance. That employee might also differ slightly on those ingredients compared to another employee. Convenience stores simply cannot override the laws of nature and businesses should not be liable for variations that they have no ability to control.

1. How FDA Should Fix Final Rule

First, the Agency should acknowledge and emphasize that foods will naturally differ or vary with respect to calorie counts and other nutrition values. In its acknowledgement of this reality, FDA should specify that such variation is present because of the naturally occurring differences in similar food items – such as different size parts of an animal – as well as the differences in preparation by individual employees that will arise despite efforts at preparation standardization. Specifically, the Agency should state that a store’s nutrient content disclosures may vary from actual nutrient content (because of variations in serving size, inadvertent human error in formulation or preparation of menu items, variations in ingredients, or other reasonable variations) as long as the disclosures comply with current standards for determining nutrient content on a reasonable basis.

Second, FDA should explicitly state that such reasonable differences will not result in violations of the regulations or a finding of noncompliance.²⁵

D. The inflexible labeling requirements often lead to unhelpful information.

Under the Final Rule, the rigid and arbitrary calorie labeling requirements often result in consumers’ receiving unhelpful and confusing information. Under the existing regulations, for example, a multi-serving cake may have calorie counts posted per slice if it is a pre-sliced cake—but not if it is a whole cake that is only sliced at the time the customer orders a slice.²⁶ Such distinctions are arbitrary.

²⁵ If the threat of criminal penalties were not enough (*see* Section II.G), under the existing law, plaintiffs’ attorneys in certain states will be able to file class action lawsuits against retail chains to penalize even inadvertent errors (including errors in preparation among other reasonable mistakes). The regulations require convenience stores to display calorie information throughout the store. In addition to the inadvertent errors that might arise due to the natural variability of foods and variability related to food preparation, undoubtedly, consumers and employees will jostle or bump into those food displays. Store employees already work constantly to keep displays clean and fully stocked—under the rules, they will also be required to make sure the signage is visible and placed appropriately. This will certainly be a challenge and there will sometimes be lapses in compliance, despite the best efforts of the store manager. Yet, such situations should not place a store at risk of private litigation. This is particularly true given the complexities of FDA’s menu labeling rules. An upsurge in private litigation in this area will provide no benefit to consumer health, but it will succeed in discouraging retailers from providing consumers with varied food options and will lead retailers to raise prices.

²⁶ 21 C.F.R. 101.11(b)(2)(i)(A).

For self-service beverages, retailers must post the calorie count for each specific flavor or type of beverage available at the machine,²⁷ in every cup size that is available. That will require posting dozens or even more than a hundred different individual calorie numbers even at relatively small soda machines.²⁸ Given the large numbers of calorie counts that must be posted in these areas, many retailers will have difficulty providing this information in the space available while ensuring that their customers can actually read and make sense of the information.

1. How FDA Should Fix Final Rule

FDA should modify the Final Rule to provide greater labeling flexibility and allow retailers, including convenience stores, to disclose calorie amounts in ways that fit the industry's ordering model so that it will be useful to customers and easier for businesses to implement. When a store offers a cold beverage, such as a Coke or Sprite, it should be allowed to simply disclose the number of calories the beverage contains per ounce rather than requiring a posting of the amount of calories present in every cup size available. And businesses should be allowed to post calorie numbers for foods on a per serving basis or on the basis of a common unit of measurement – whichever makes the most sense for their business and offering – and not simply be required to post calories for an entire multi-serving item (whether or not it is pre-sliced).

FDA should revise the Final Rule and allow retailers to provide: (1) the number of calories contained in the whole menu item; (2) the number of servings and number of calories per serving; or (3) the number of calories per common unit of measure (such as per ounce). This will permit a store to pick the method that works best for a particular item. This is the most workable regulatory scheme because different food and beverage items are sold and presented in many different ways in a single business location as well as across locations. In providing this flexibility, FDA will allow the associations' members to provide customers the nutrition information they need in a workable, efficient manner.

E. The Final Rule hurts small business suppliers.

In the convenience store industry, many stores work with local, small business food suppliers to give their offerings a local flavor and support their community.²⁹ These local suppliers often operate a single location and do not have the size and scale to send out their foods for scientific nutrition content analysis *and* comply with all of the attendant regulatory requirements (e.g., documenting calorie counts and providing the retailer with the necessary documentation and affidavits, etc.) necessary for the store to protect itself. But, small business suppliers often supply stores that are part of a chain or that share a name with numerous other

²⁷ See generally 79 Fed. Reg. 71225.

²⁸ 21 C.F.R. 101.11(b)(2)(iii)(A)(3)(ii)

²⁹ Again, if a store changes vendors, all the menus would have to change given the variation that will occur in the products.

locations. As soon as the supplier provides food to one of these stores, however, the stores must foist all of the nutrition and calorie disclosure burdens onto that supplier in order to get the right information and have confidence in its accuracy. The unfortunate result is that the menu labeling rules sweep these small business suppliers into their coverage even though the law was not intended to burden small businesses. The negative consequence of this has been significant: in the process of preparing to comply with this Final Rule, several of the associations' members began cutting off these small suppliers when those suppliers could not provide the necessary nutrition information and documentation of how it was collected. This result hurts small businesses, reduces local and fresh food offerings, and undermines the intent of the law that should protect these small businesses.

1. How FDA Should Fix Final Rule

The Agency could easily cure this problem by ensuring that such local offerings are not covered by the regulations. This would be done by applying the regulations only to food items that are offered at 20 or more locations.

F. There is considerable confusion regarding who is covered under the Final Rule.

In addition to the problems described above, many businesses still do not understand whether they are covered under the Final Rule. 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 controlled by the refiner. 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.

1. How FDA Could Fix Final Rule

FDA should amend the definition of a covered establishment to clarify that only a branded store or franchisee that 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 influence what foods are sold inside the store and how they are prepared—that store should not be covered by the Final Rule.

G. The penalties for non-compliance are unreasonable and draconian.

While it may be valuable to provide consumers with calorie information, the penalties in place for non-compliance – including errors made in good faith – are draconian and out of proportion relative to the severity of the offense. Under the Final Rule, every store location must have an employee “certify” that food is prepared at that location consistent with the way that the company determined the calorie counts for those foods.³⁰ False certifications to FDA, including if there are good faith efforts to comply, could result in criminal charges for such employees, possibly including felony charges. That is out of proportion for a violation of these regulations.

Despite the industry’s best efforts to standardize preparation techniques across stores in a chain, it is simply impossible for items to be prepared exactly the same way with exactly the same ingredients every time. For example, one employee may put less ketchup on a burger or more croutons in a salad compared to another employee. Alternatively, each drumstick in a fried chicken basket will be slightly different in size. Inevitably, both these human and naturally-occurring variations will lead to different calorie counts for a particular product. While it is valuable to provide nutritional information to consumers, it is just not appropriate for errors related to such information to result in criminal penalties.

These overly-severe penalties will discourage food retailers from continuing to offer the variety of food options that customers have come to expect. Ultimately, therefore, the menu labeling regulations will harm consumers and retailers alike.

1. How FDA Could Fix Final Rule

The Agency should remove the certification requirement, which increases the penalties for violations and makes them unreasonable. FDA also should revise its regulations to ensure that retailers are provided with an opportunity to correct any compliance errors prior to FDA beginning an enforcement action or imposing a penalty.

H. FDA has dramatically underestimated the costs of compliance for non-restaurant retailers.

FDA was required to perform a regulatory impact analysis (“RIA”)³¹ under the guidelines set out under Executive Order 12866,³² Executive Order 13563,³³ the Regulatory Flexibility

³⁰ 21 C.F.R. 101.11(c)(3)(i)(G).

³¹ See Final Regulatory Impact Analysis, *supra* note 3.

³² “Significant regulatory action” means, among other things, any regulatory action that is likely to result in a rule that may have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Exec. Order No. 12866, 58 Fed. Reg. No. 190 (Sept. 30, 1993), available at www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.

Act,³⁴ as amended by the Small Business Regulatory Enforcement Fairness Act,³⁵ and the Unfunded Mandates Reform Act of 1995.³⁶ The Final Rule was designated to be “economically significant”³⁷ as FDA found that the costs of compliance would amount to nearly \$1 billion over ten years.³⁸ These estimates, however, bear absolutely no relation to the real world costs that NACS’ and SIGMA’s members (as well as many other businesses) will incur to comply with the Final Rule. This is because the Agency did not complete a proper RIA. First, the Agency failed to analyze the rule in light of the way the U.S. convenience industry and other businesses such as grocers and package stores, which are subject to the Final Rule, operate. Second, the Agency based its analysis on data that was out-of-date. Third, FDA completely failed to account for enforcement costs.

Included with these comments as Appendix A is a report on FDA’s cost estimates for the Final Rule prepared by Mangum Economics. Key findings of the report include:

- Actual costs of compliance and enforcement of the FDA Final Rule for all covered industries are estimated to be more than 3.6 times FDA’s estimates and for the convenience store industry 7 times FDA’s estimates;
- Annual costs of compliance and enforcement of the FDA Final Rule are projected to exceed \$306 million;
- Actual costs of compliance and enforcement of the FDA Final Rule for the convenience store industry alone are almost equal to the total cost that FDA estimated for all covered industries;
- Because the Final Rule makes no allowances for normal calorie and nutrition variations in foods, more than 93% of foods subject to the rule are likely to be in violation of the Final Rule no matter how much businesses spend attempting to comply; and
- Enforcement costs (including fines, legal fees, and negative publicity) alone of the Final Rule are likely to vastly exceed FDA’s total estimate of the compliance costs of the Final Rule.

Please see Appendix A of this document for a complete analysis of the shortcomings in the Agency’s RIA.

³³ Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan.18, 2011). Executive Order 13563 demands that an agency “tailor its regulations to impose the least burden on society.”

³⁴ Pub. L. 96-354, 5 U.S.C. § 601 *et seq.*

³⁵ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. § 601 *et seq.*). In the event that a proposal is projected to impose a “significant economic impact on a substantial number of small entities,” a federal agency must assess that impact and consider regulatory alternatives that would minimize the impact to small businesses. 5 U.S.C. § 603, 605.

³⁶ Pub. L. 104-4 (Mar. 22, 1995); 2 U.S.C. § 1501 *et seq.*

³⁷ Final Regulatory Impact Analysis, *supra* note 3, at 4.

³⁸ Final Regulatory Impact Analysis, *supra* note 3, at 7.

III. NACS AND SIGMA CALL ON THE AGENCY TO WITHDRAW AND REVISE THE FINAL RULE.

FDA's Final Rule contains many problematic provisions which will make compliance onerous for NACS' and SIGMA's members. The Final Rule has so many problems that, in the past, FDA staff have not even been able to answer basic questions about how businesses can comply with it – and, in fact, it will be scientifically impossible for most businesses to comply with the Final Rule no matter how many resources they expend attempting to do so. As noted, any regulatory mandate 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 fails to achieve either of these objectives.* Therefore, FDA should withdraw the Final Rule in order to make revisions to it and then publish a new rule that meets those essential objectives.

Sincerely,

A handwritten signature in black ink, appearing to read 'Douglas S. Kantor', with a long horizontal line extending to the right.

Douglas S. Kantor
Counsel to NACS and SIGMA

APPENDIX A

Comments on the Food and Drug Administration's Regulatory Impact Analysis
and Cost Estimate for the Menu Labeling Final Rule

by
David Zorn, PhD
Mangum Economic Consulting
Prepared for the
National Association of Convenience Stores (NACS)

Comments on the Food and Drug Administration's Regulatory Impact Analysis and Cost Estimate for the Menu Labeling Final Rule

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In its Regulatory Impact Analysis¹ of the menu labeling Final Rule,² the Food and Drug Administration (FDA) underestimated the costs for regulated businesses to comply with the Final Rule. This analysis provides a more accurate estimate focused principally on the FDA's shortcomings in analyzing costs to the convenience store industry. Convenience store estimation problems serve as a reliable proxy for the estimation problems FDA's analysis has with respect to grocery and general merchandise stores.

Key Findings

- Actual costs of compliance and enforcement of the FDA Final Rule for all covered industries are estimated to be more than 3.6 times FDA's estimates and for the convenience store industry 7 times FDA's estimates;
- Annual costs of compliance and enforcement of the FDA Final Rule are estimated to exceed \$306 million;
- Actual costs of compliance and enforcement of the FDA Final Rule for the convenience store industry alone are almost equal to the total cost that FDA estimated for all covered industries;
- Because the Final Rule makes no allowances for normal calorie and nutrition variations in foods, more than 93% of foods subject to the rule are likely to be in violation of the Final Rule no matter how much businesses spend attempting to comply; and
- Enforcement costs (including fines, legal fees, and negative publicity) alone of the Final Rule are likely to vastly exceed FDA's total estimate of the compliance costs of the Final Rule.

¹ Food and Drug Administration, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Final Regulatory Impact Analysis, November 2014, available at <https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.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), <https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf>; Final Regulatory Impact Analysis, Department of Health and Human Services, Food and Drug Administration, *Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, Docket No. FDA-2011-F-0172, at 7 (Nov. 2014), available at <https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf>.

Introduction

The convenience store industry operates in a very decentralized manner (i.e., stores tend to differ from one another even if they are part of the same chain) that does not fit well with the way that FDA's rule is written. FDA's analysis of the rule does not match the way that the modern convenience store industry operates. FDA also based its cost estimates for all of the industries covered by the Final Rule on a model that best fits restaurants. In restaurants there is one menu or one menu board and food is offered to customers at one location – the counter or the table. Unlike fast food restaurant chains with identical and limited offerings usually in only one portion size, convenience stores offer different items in different stores (even stores that are a part of the same chain) and often in three or more different portion sizes. Convenience stores also offer food to consumers at many points around a store rather than at one central location.

This analysis allows FDA to understand the impact of the rule on the convenience store industry as it operates. The way that the Final Rule is written makes it almost certain that convenience stores will face enforcement actions no matter how hard and diligently they try to comply. Yet, FDA's analysis of the rule does not include enforcement costs that will inevitably occur. This analysis accounts for the cost of enforcement actions. In addition, most of the data used for FDA's cost analysis of the rule date back to 2007. This analysis makes use of much newer and more detailed data that is available. This analysis assists FDA with updating the impact of the rule using the federal government standards of OMB Circular A-4 for economic analyses.³

FDA estimated that the costs for convenience stores to comply with the rule would be \$12.1 million⁴ on an annualized basis. **As this analysis shows in the sections that follow, the actual cost of compliance and enforcement by convenience stores is \$84.2 million on an annualized basis – or 7 times the FDA estimate for convenience stores and almost equal to the \$84.5 million that FDA estimated for all chain stores covered by the rule.**

Because of the similarity of convenience stores to grocery stores and general merchandise stores, and because FDA estimated the costs for all three of those types of stores in the same way, it is likely that the actual cost of the rule to those stores for compliance and enforcement is 7 times FDA's estimate of \$17.7 million⁵ on an annualized basis – \$123.9 million.

The analysis shows that assuming FDA estimated the compliance (non-enforcement) costs of the rule *correctly* for all restaurants; managed food service; lodging; and sports, recreation, and entertainment establishments (so that the only underestimates are for the compliance costs by grocery, convenience and general merchandise stores and the enforcement costs in all

³ Office of Management and Budget, Circular A-4, 68 Fed. Reg. 58366 (Oct. 9, 2003); *see also* Circular A-4, https://www.whitehouse.gov/omb/circulars_a004_a-4.

⁴ This is FDA's estimate when 20 years of costs are annualized at a 7% discount rate. Unless otherwise noted, all annualized estimates in this analysis are calculated on that basis.

⁵ FDA does not report its complete estimate of the cost of the rule to the various industry segments. The \$17.7 million estimate comes by multiplying the annualized cost estimate of the full rule by the 21% of the initial costs of the rule associated with grocery, convenience, and general merchandise stores.

establishments), then the actual costs of the rule are \$306 million on an annualized basis. If FDA underestimated the compliance costs to any restaurants; managed food service; lodging; or sports, recreation, and entertainment establishments, then the actual costs would be even higher than \$306 million on an annualized basis.

Enforcement Costs for Imperfect Declaration of Calorie Content⁶

The biggest shortcoming of FDA's analysis is that it ignores a serious flaw in FDA's Final Rule. The regulation provides no allowance for normal variation from one serving of food to the next in the number of calories and nutrition content. This effectively makes full compliance impossible. FDA's policy on how the rule will be enforced has several features that make enforcement costs inevitable.⁷

- 1) FDA's guidance for the rule provides only a 5-calorie deviation (for foods with over 50 calories) for unit to unit variability of the same product. For example, a slice of cheese pizza declared at 270 calories is misbranded if it contains 264 calories or less, or if it has 275 calories or more.⁸ A difference of just 2 grams (0.07 ounces) of cheese on a typical slice of pizza would make it misbranded.
- 2) The rule does not permit declared calories to be given in ranges to account for variability from one unit to the next or the same unit over time.⁹ The caloric content of some foods can change over a short amount of time. For example, the calorie content of a single sausage held on a roller grill will go down as fats drip off.
- 3) Research has repeatedly revealed that calorie declarations are never perfect.
 - a. Urban, et al., 2010¹⁰ tested the caloric content of 29 restaurant meals and 10 frozen packaged meals. None of the calorie declarations matched the tested amount exactly. Twelve of the 29 (41%) restaurant meals tested within 10% of the declared calories, and even 3 of the 10 (30%) packaged meals tested outside of 10% of the declared calories.

⁶ This analysis identifies as "enforcement costs" the costs that regulated entities incur to deal with enforcement actions. Costs include fines, legal fees and negative publicity.

⁷ The estimate of enforcement costs in this analysis is an incomplete estimate of the full enforcement costs that face covered establishments. For example, beyond imperfect calorie declarations, establishments would face enforcement costs if they are found not to have the nutrition information (beyond calorie content) that is required by the rule.

⁸ Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11), at 22.

⁹ Ranges are only allowed to account for different customer choices for combination meals of three items or more.

¹⁰ Lorien E. Urban, MS, Gerard E. Dallal, PhD, Lisa M. Robinson, RD, Lynne M. Ausman, DSc, RD, Edward Saltzman, MD, and Susan B. Roberts, PhD, "The Accuracy of Stated Energy Contents of Reduced-Energy, Commercially Prepared Foods." *J Am Diet Assoc.* 2010 January; 110(1): 116-123. doi:10.1016/j.jada.2009.10.003.

- b. Urban, et al., 2011¹¹ tested 269 restaurant food portions. Only seven percent of the portions tested within 10 calories per portion of the declared amount, and 19% of the portions tested differed from the declared amount by more than 100 calories.
 - c. Jumpertz, et al., 2013¹² tested the caloric content of 24 common packaged snack foods. Of the 24, 10 (42%) had the declared calorie content within the 95% confidence interval of the test results.
- 4) Portion and ingredient control issues pose problems in a foodservice setting that are absent in a food manufacturing setting for packaged foods where automation can more easily control for many variable factors. Therefore, it is unlikely that caloric declarations in a foodservice setting could ever reach the 42% accuracy found for manufactured packaged foods by Jumpertz, et al. After all, if a convenience store were to open packages of the snack foods tested by Jumpertz, et al. and offer them for sale with the calorie declarations from the packages, we can say, with 95% confidence, that those calorie declarations could be found to be in violation of FDA's rule 58% of the time. But it is more likely that even the 93% violation estimate in found by Urban, et al., 2011 is aspirational because that study accepts a 10-calorie variation, whereas FDA's guidelines accept only a 5-calorie variation (related to rounding).

Using this peer-reviewed research it is possible to estimate the cost of enforcement actions against convenience stores under FDA's rule. If calorie declarations for restaurant-type foods remain only as accurate as found by Urban, et al., 2011, then if 1 food item in 1% of the 47,200¹³ covered convenience stores were to be tested per year, and if 93% were found to be misbranded (as Urban, et al., 2011 implies),¹⁴ then about 439 stores would be found to be in violation annually. If fines, legal fees, and negative publicity cost covered establishments \$50,000 per occurrence, then the total cost for the convenience store industry to deal with enforcement and non-compliance would be at least \$21.9 million per year.¹⁵

¹¹ Lorien E. Urban, PhD, Megan A. McCrory, PhD, E. Dallal, PhD, Krupa Das, PhD, Edward Saltzman, MD, Judith L. Weber, PhD, RD, and Susan B. Roberts, PhD, "Accuracy of Stated Energy Contents of Restaurant Foods." *JAMA*. 2011 July 20; 306(3): 287–293. doi:10.1001/jama.2011.993.

¹² Reiner Jumpertz, Colleen A Venti, Duc Son Le, Jennifer Michaels, Shannon Parrington, Jonathan Krakoff, and Susanne Votruba, "Food Label Accuracy of Common Snack Foods." *Obesity* (Silver Spring). 2013 January; 21(1): 164–169. doi:10.1002/oby.20185.

¹³ This estimate of the number of convenience stores covered by the rule will be explained later. There are good reasons to believe that the actual number of stores covered by the rule is much higher.

¹⁴ Note that the Urban, et al., 2011 interpretation of compliance (accepting 10-calorie variance) is more lenient than FDA's guidance permits (5-calorie variation related to rounding). Therefore, more than 93% of tested foods are likely to be found to be misbranded.

¹⁵ Note that the regulation allows for enforcement of many other issues than the one issue (accuracy of the declaration of calorie content) identified and quantified here. Moreover, the FDA will not be the only institution that may enforce the rule. Therefore, the estimates made here are almost certainly a conservative underestimate of the actual costs.

This enforcement jeopardy is not unique to convenience stores. If the same probabilities of misbranding are extended to all of the roughly 309,600 establishments covered by the rule (47,200 convenience stores + 262,400 other establishments), then the annual cost of fines, legal fees, and negative publicity associated with enforcement of the rule would be about \$144 million. **In other words, the enforcement cost of the rule alone likely exceeds by 70% the annualized costs of nutrition analysis, signage and training as estimated by FDA.**¹⁶

How Convenience Stores Differ Dramatically from Restaurants

FDA modeled the cost of convenience stores to comply with the rule in the same way that it modeled the cost of quick service restaurants to comply – with one or two new menu boards being sufficient to meet the requirements of the rule. However, convenience stores are almost nothing like quick service restaurants.

The convenience store industry is primarily the retail sector of the motor fuel industry. What most people call “gas stations” are usually convenience stores that sell gasoline. Convenience stores sell 80% of the motor fuel sold in the United States.¹⁷ For the convenience store industry as a whole, 75% of stores sell fuel.¹⁸ For chains with 26-500 stores, 98% of stores sell fuel, and for chains with over 500 stores, 80% sell fuel.¹⁹ On average, from 2006 to 2015, fuel pump revenue accounted for 69% of total convenience store industry sales.²⁰ That percentage can fluctuate significantly from year to year as fuel prices fluctuate. As fuel prices become more volatile, convenience stores increasingly depend on revenue from the sale of merchandise and from food service to provide a stable source of income.

Although the most identifiable product that a convenience store sells is gasoline and/or diesel fuel (half of the all of the stores that sell fuel, sell fuel from one of the major refiners²¹), almost none of the stores are owned by the major refiners. The 5 largest oil companies only own less than one-half of 1% of the convenience stores that sell fuel.²² So, although many convenience stores may do business under the name of one of the major fuel refiners and the refiners exercise some contractual control over the fuel-related aspects of the stores, the refiners have nothing to do with the nonfuel items sold in the convenience store.

¹⁶ Similar problems were present in the packaged food space and addressed by FDA in the regulations. *See* 21 C.F.R. §101.9(g)(4), (5).

¹⁷ [NACS 2015 Retail Fuels Report](#), at 30.

¹⁸ [NACS State of the Industry Annual Report 2015 Data](#), at 7.

¹⁹ [NACS State of the Industry Annual Report 2015 Data](#), at 7.

²⁰ Calculations based on data from [NACS State of the Industry Annual Report 2015 Data](#), at 12.

²¹ [NACS 2015 Retail Fuels Report](#), at 30.

²² [NACS 2015 Retail Fuels Report](#), at 29.

For the most part, there are two types of convenience store “chains.”²³

- 1) The 20 largest chains that are unrelated to the major fuel refiners and sell gasoline under their own brands (if the stores sell gasoline at all). These chains operate nationally or regionally. These 20 chains account for a total of about 29,000 stores.²⁴
- 2) The smaller chains that sell branded or unbranded motor fuel and operate over smaller geographical areas than the largest chains. These chains have between 2 and 500 stores each and account for about 56,800 stores in total.²⁵ There are between 1,400 and 2,400 such chains. About 380 (possibly as few as 239 and as many as 521) of these smaller chains are chains operating 20 or more stores (about 18,200 stores belong to smaller chains with 20 or more locations).²⁶

This estimate of the number of convenience stores covered by the rule is almost certainly a large underestimate of the number of stores covered by the rule. It is based on the best data available from TDLinx. However, the definition of chain that is commonly used within the industry and recorded by TDLinx differs from the definition of chain used by FDA in the Final Rule. FDA considers an establishment to be part of a chain if the establishment is visibly branded to customers with a common name. For example, if an independent convenience store (whose owner owns and operates only a single store) sells ExxonMobil gasoline and prominently displays the Exxon sign at the store, FDA considers that store to be part of a chain, which (given the scale of ExxonMobil) would have over 20 establishments. However, within the convenience store industry, that independent convenience store owner would never consider herself to be part of the ExxonMobil Corporation or its chain of establishments. Therefore, to the extent that this analysis underestimates the number of convenience stores covered by the rule, the cost estimates made here are lower than the actual cost of the rule.

Foodservice in Convenience Stores

More convenience stores sell food or beverages covered by FDA’s rule than sell motor fuel. Seventy-five percent of convenience stores sell gasoline. But 99% sell hot dispensed beverages, 98% sell cold dispensed beverages, 95% sell food prepared at an off-site commissary, 83% sell food prepared on site, and 75% sell frozen dispensed beverages.²⁷ Due to the nature of the business, stores in larger chains are more likely than single-store, independent operations to offer

²³ Data on the number of convenience stores were collected by TDLinx, a service of Nielsen. TDLinx is the industry-accepted standard channel database of retail locations providing universal coverage for every store in retail trade channels and for every outlet in on-premise trade channels. Data on products offered come from the CSX database. CSX provides business intelligence and benchmarking tools for reporting and financial analysis in the petroleum marketing and convenience store industry. See [NACS State of the Industry Annual Report 2015 Data](#), at 4.

²⁴ [NACS State of the Industry Annual Report 2015 Data](#), at 140.

²⁵ [NACS State of the Industry Annual Report 2015 Data](#), at 7.

²⁶ Calculations based on data from [NACS State of the Industry Annual Report 2015 Data](#), at 7.

²⁷ [NACS State of the Industry Annual Report 2015 Data](#), at 50.

restaurant type foods. Therefore, FDA's rule will apply to all stores in all chains operating 20 or more stores, not 60% of stores as estimated by FDA.

Within each of these broad categories of products (hot dispensed beverages, cold dispensed beverages, food prepared at an off-site commissary, food prepared on site, and frozen dispensed beverages) convenience stores commonly sell a wide variety of products placed throughout the store. For example, coffee islands are in one area, cappuccino and hot chocolate machines are in a different area, cold fountain sodas are in another area, pastries are in a separate area, and hot lunch and breakfast foods each have their own areas. Separate signs will be needed in each location to comply with the rule (contrary to FDA's estimates, 2 menu boards per store will not be sufficient).

Additionally, convenience stores offer customers a much wider range of food service choices than do many other food service retailers. For example, a typical convenience store will offer at least 8 varieties of cold fountain drinks in 4 different sizes. Each variety-size combination is likely to contain a different number of calories. Providing calorie content for each variety in each size will require an enormous sign just for cold fountain drinks. The same is true for the range of frozen beverages offered in a separate location from the cold beverages, thereby requiring a separate sign. Convenience stores also employ a wide range of promotional displays for food in places like the fuel pumps, the windows and doors, and hanging from the ceiling. All those promotional displays will need to be redesigned and replaced under the rule if FDA or other enforcers of the regulation interpret promotional displays as menus (an issue which FDA has not yet definitively addressed).

With hundreds of different chains covered by the rule, it is no surprise that there are different ways that convenience store chains operate. Some chains may establish a uniform set of foodservice items across all stores, while other chains (for example, those that are primarily focused on motor fuel brand and sales) may have no established standards for what foodservice items are offered. So, some chains may only offer specific brands and sizes of cold fountain sodas and hot coffee throughout the entire chain of stores, while other chains may have stores that offer different brands and sizes of cold fountain sodas and hot coffee across the chain. Also, some chains may have established standards for some foodservice items offered but not for others. This leads to a situation where all stores in the chain must offer a specific brand and sizes of cold fountain sodas and hot coffee, but may choose to offer different pastries, snacks, hot dogs, breakfast sandwiches, and other meal items.

At the same time, some chains may have a single supplier for every foodservice item sold in the chain, while other chains may have multiple suppliers of many of the foodservice items sold in the chain. An example of the latter case would be where a chain has multiple suppliers of items like sausage, pastries and self-serve ice cream. Therefore, although two different suppliers may offer the same "product" by name (e.g., "hot dog"), the caloric content of those products with the same name are unlikely to be identical.²⁸

²⁸ Even products for which FDA has established standards of identity will have variations in calorie content.

For over a decade the trend in foodservice has been toward increasing customization and localization.²⁹ Chain stores increasingly customize their offerings in different stores to appeal to local tastes, to offer items sourced locally or nearby, and to coincide with seasonal trends. It would be very unusual today for most of the foodservice offerings in a chain store in the upper Midwest to be identical to most of the foodservice offerings of another store in the same chain in the Southwest. Likewise, summer offerings will differ from winter offerings. And offerings will change over time as new products are brought in to replace existing products.

All of these operational factors reveal why the costs of the rule cannot be modeled (as FDA did) primarily on a per product and per chain basis. Large chains are more likely to have different stores offering different products from multiple suppliers of the same product. A two-tiered cost model will be closer to reality than FDA’s one-size-fits-all cost model (although even this two-tiered model is an extreme oversimplification). The following tables provide a detailed explanation of the basis for the cost estimates in this analysis.

Table 1 details the cost model for the rule (based on food offerings in typical convenience store chains of different sizes) versus FDA’s cost model for nutrition analysis.³⁰

Table 1. Convenience Store Costs for Nutrition Analysis

	20 Largest Chains	380 Smaller Chains	FDA’s Estimate for All 450 Chains³¹
Stores in Chains with 20+ Stores Needing Signage	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
Stores with Food for Immediate Consumption	100%	100%	60%
Distinct Products Sold Over Course of Year Common Throughout Chain	122 ³²	34 ³³	40
Distinct Products That Need Analysis Over Course of Year Common Throughout Chain	0 ³⁴	0 ³⁵	40
Suppliers per Product for Products Common Throughout Chain	1	1	1
Distinct Products Sold Over Course of Year Not	88 ³⁶	52 ³⁷	5

²⁹ Howard Riell, “[Revitalized Roller Grill Sales](#),” Convenience Store Decisions, August 24, 2011.

³⁰ Estimates are rounded to the nearest \$1,000.

³¹ For its estimate of the number of chains, FDA uses data from the 2007 Economic Census. This analysis uses data from the NACS State of the Industry Report 2015. The NACS report mentions on page 19 that “consolidation among chains remained an ongoing strategy.” This likely explains why FDA’s estimate of the number of chains is larger than the estimate made in this analysis.

³² 16 varieties of cold fountain drinks @ 4 sizes of cups + 16 varieties of frozen beverages @ 3 sizes of cups + 6 varieties of flavoring syrup for coffee + 2 varieties of chicken nuggets + 2 varieties of frankfurters. Some fountain drinks, frozen beverages and flavoring syrups for coffee change seasonally.

³³ 8 varieties of cold fountain drinks @ 3 sizes of cups + 4 varieties of frozen beverages @ 2 sizes of cups + 2 varieties of frankfurters.

³⁴ All products have known caloric content per serving and will be provided by the suppliers.

³⁵ All products have known caloric content per serving and will be provided by the suppliers.

Common Chainwide	20 Largest Chains	380 Smaller Chains	FDA's Estimate for All 450 Chains ³⁸
Distinct Products That Need Analysis Over Course of Year Not Common Chainwide	64 ³⁹	44 ⁴⁰	5
Suppliers per Product for Products Not Common Chainwide	2.5	1.25	1
Distinct Products from All Suppliers That Need Analysis Over Course of Year Not Common Chainwide	160	55	5
Price to Analyze Each Product	\$800 ⁴¹	\$800	\$660
Cost per Chain for Analysis	\$128,000	\$44,000	\$26,400
First Year Cost for Nutrition Analysis per Size Category of Convenience Store Chain	\$2,560,000	\$16,720,000	\$11,880,000
Distinct New Products from All Suppliers Introduced Annually that Need Analysis ⁴²	32	11	12
Recurring Annual Cost for Nutrition Analysis per Size Category of Convenience Store Chain	\$512,000	\$3,344,000	\$3,564,000

³⁶ 32 varieties of pastries + 8 varieties of sausage + 16 varieties of savory snacks + 8 varieties of self-serve ice cream @ 2 sizes of bowls + 8 varieties of pizza + 4 varieties of sweetened hot beverages @ 2 sizes of cups.

³⁷ 32 varieties of pastries + 4 varieties of sausage + 4 varieties of savory snacks + 2 varieties of self-serve ice cream @ 2 sizes of bowls + 4 varieties of pizza + 2 varieties of sweetened hot beverages @ 2 sizes of cups.

³⁸ For its estimate of the number of chains, FDA uses data from the 2007 Economic Census. This analysis uses data from the NACS State of the Industry Report 2015. The NACS report mentions on page 19 that “consolidation among chains remained an ongoing strategy.” This likely explains why FDA’s estimate of the number of chains is larger than the estimate made in this analysis.

³⁹ 32 varieties of pastries + 8 varieties of sausage + 16 varieties of savory snacks + 8 varieties of pizza.

⁴⁰ 32 varieties of pastries + 4 varieties of sausage + 4 varieties of savory snacks + 4 varieties of pizza.

⁴¹ A June 2016 internet search of prices for the nutrition analysis needed for menu labeling revealed a median cost of about \$800.

⁴² Estimated annual introduction of new products (including changes in suppliers of existing products) of 20% of products that are not common to all stores in the chain.

Table 2 details the cost model for providing nutrition information (based on food offerings in typical convenience store chains of different sizes) versus FDA’s cost model.⁴³

Table 2. Costs for Convenience Store Signage and Pamphlets

	20 Largest Chains	380 Smaller Chains	FDA’s Estimate for All 450 Chains
Stores in Chains with 20+ Stores	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
Number of Signs Positioned with Products and Promotional Displays per Store for Compliance per Year	15 ⁴⁴	11 ⁴⁵	2
Price for Design of Each Sign and Promotional Display	\$3,700	\$3,700	\$3,700
Cost for Design of Signs and Promotional Displays per Chain	\$55,500	\$40,700	\$7,400
Initial Cost for Design of Signs and Promotional Displays per Size Category of Convenience Store Chain	\$1,110,000	\$15,466,000	\$3,330,000
Cost of Point of Sale Signs ⁴⁶ and Labor to Place New Signs	\$591	\$591	\$591
Number of Signs per Store	1	1	2
Initial Cost of New Point of Sale Signs per Size Category of Convenience Store Chain	\$17,139,000	\$10,756,000	\$42,552,000
Cost of Signs and Labor to Order Appropriate Signs and Place New Food Display Signs ⁴⁷	\$20	\$20	0
Number of Signs per Store	8	6	0
Initial Cost of New Food Display Signs per Size Category of Convenience Store Chain	\$4,640,000	\$2,184,000	0
Hours of Verifying, Maintaining and Replacing Food Display Signs per Store per Year	26	26	0
Average Hourly Wage ⁴⁸	\$15	\$15	
Annual Labor Cost of Verifying, Maintaining and Replacing Food Display Signs per Size Category of	\$11,310,000	\$7,098,000	0

⁴³ Estimates are rounded to the nearest \$1,000.

⁴⁴ 8 food display signs + 6 promotional displays + 1 point of sale sign

⁴⁵ 6 food display signs + 4 promotional displays + 1 point of sale sign

⁴⁶ The regulation requires calorie content declarations wherever covered food and beverage items are listed for sale and also wherever the foods are displayed. Point of sale signs are those menu-board-type signs located near the checkout registers.

⁴⁷ The regulation requires calorie content declarations wherever covered food and beverage items are listed for sale and wherever the foods are displayed. Food display signs are small relatively inexpensive signs placed very near every place in the store where covered food and beverage items are displayed. Because of their proximity to food and customers, they are likely to have to be replaced frequently due to loss and damage. Modeling this cost on a per store basis is a serious oversimplification that ignores the cost of handling, storing and transporting the signs throughout the company’s distribution chain. So even the estimates in this analysis underestimate the true cost of the Final Rule.

⁴⁸ [NACS State of the Industry Annual Report 2015 Data](#), at 144.

Convenience Store Chain			
Annual Cost of Replacing Food Display Signs on a Quarterly Basis due to Damage, Loss or Out of Date	\$18,560,000	\$8,736,000	0
Cost per Store for Nutrition Pamphlets per Year ⁴⁹	\$22	\$22	\$22
Annual Cost per Category of Nutrition Pamphlets per Size Category of Convenience Store Chain	\$638,000	\$400,000	\$792,000

Table 3 details the cost model for training employees to maintain compliance versus FDA’s cost model for training.

Table 3. Cost for Convenience Stores of Training Employees to Maintain Compliance⁵⁰

Average Employees per Store Needing Training ⁵¹	18	18	
Average Hourly Wage	\$15	\$15	
Hours of Training per Employee per Year	0.5	0.5	
Cost of Employee Compliance Training per Store per Year	\$135	\$135	\$103
Annual Cost of Employee Compliance Training per Size Category of Convenience Store Chain	\$3,915,000	\$2,457,000	\$3,708,000

⁴⁹ Modeling this cost on a per pamphlet/per chain basis is a serious oversimplification that ignores the cost of updating, handling, storing and transporting the pamphlets throughout a company’s distribution chain.

⁵⁰ Estimates are rounded to the nearest \$1,000.

⁵¹ [NACS State of the Industry Annual Report 2015 Data](#), at 144.

Summary of Compliance and Enforcement Costs for Convenience Stores

Table 4 summarizes the first-year costs of compliance and enforcement versus FDA’s estimate of first-year costs.

Table 4. Summary of Convenience Store First Year Costs of Compliance and Enforcement

	20 Largest Chains	380 Smaller Chains	FDA’s Estimate for All 450 Chains
Stores in Chains with 20+ Stores	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
First Year Cost for Nutrition Analysis per Size Category of Convenience Store Chain	\$2,560,000	\$16,720,000	\$11,880,000
Initial Cost for Design of Signs and Promotional Displays per Size Category of Convenience Store Chain	\$1,110,000	\$15,466,000	\$3,330,000
Initial Cost of New Point of Sale Signs per Size Category of Convenience Store Chain	\$17,139,000	\$10,756,000	\$42,552,000
Initial Cost of New Food Display Signs per Size Category of Convenience Store Chain	\$4,640,000	\$2,184,000	0
Annual Labor Cost of Verifying, Maintaining and Replacing Food Display Signs per Size Category of Convenience Store Chain	\$11,310,000	\$7,098,000	\$0
Cost of Replacing Signs Quarterly in the 2 nd , 3 rd and 4 th Quarters of the First Year due to Damage, Loss or Out of Date (75% of the annual cost)	\$13,920,000	\$6,552,000	\$0
Annual Cost per Category of Nutrition Pamphlets per Size Category of Convenience Store Chain	\$638,000	\$400,000	\$792,000
Annual Cost of Employee Compliance Training per Size Category of Convenience Store Chain	\$3,915,000	\$2,457,000	\$3,708,000
Total Cost of Compliance in First Year for All Convenience Store Chains		\$116,865,000	\$62,262,000
Total Annual Cost of Enforcement for All Convenience Store Chains		\$21,900,000	\$0
Total Cost of Compliance and Enforcement in First Year for All Convenience Store Chains		\$138,765,000	\$62,262,000

Table 5 summarizes the recurring costs of compliance and enforcement versus FDA’s estimate of recurring costs.

Table 5. Recurring Convenience Store Costs of Compliance and Enforcement

	20 Largest Chains	380 Smaller Chains	FDA’s Estimate for All 450 Chains
Stores in Chains with 20+ Stores	29,000 (avg 1,450 per chain)	18,200 (avg 50 per chain)	36,200 (avg 80 per chain)
Recurring Annual Cost for Nutrition Analysis per Size Category of Convenience Store Chain	\$512,000	\$3,344,000	\$3,564,000
Annual Labor Cost of Verifying, Maintaining and Replacing Food Display Signs per Size Category of Convenience Store Chain	\$11,310,000	\$7,098,000	\$0
Annual Cost of Replacing Food Display Signs on a Quarterly Basis due to Damage, Loss or Out of Date	\$18,560,000	\$8,736,000	\$0
Annual Cost per Category of Nutrition Pamphlets per Size Category of Convenience Store Chain	\$638,000	\$400,000	\$792,000
Annual Cost of Employee Compliance Training per Size Category of Convenience Store Chain	\$3,915,000	\$2,457,000	\$3,708,000
Total Annual Recurring Cost of Compliance for All Convenience Store Chains		\$56,970,000	\$7,272,000
Total Annual Cost of Enforcement for All Convenience Store Chains		\$21,900,000	\$0
Total Recurring Cost of Compliance and Enforcement for All Convenience Store Chains		\$78,870,000	\$7,272,000

Table 6 summarizes the annualized cost of compliance and enforcement versus FDA’s estimate of annualized cost.

Table 6. Annualized Convenience Store Costs of Compliance and Enforcement

	400 Chains	FDA’s Estimate for All 450 Chains
Total Cost of Compliance and Enforcement in First Year for All Convenience Store Chains	\$138,765,000	\$62,262,000
Total Recurring Cost of Compliance and Enforcement for All Convenience Store Chains	\$78,870,000	\$7,272,000
Annualized Cost of Compliance and Enforcement over 20 Years at 7% for All Convenience Store Chains	\$84,154,000	\$12,123,000
Annualized Cost of Compliance and Enforcement over 20 Years at 3% for All Convenience Store Chains	\$82,779,000	\$10,861,000

Conclusion

FDA estimated that the costs for convenience stores to comply with the rule would be \$12.1 million on an annualized basis. **As this analysis showed, the actual cost of compliance and enforcement by convenience stores is \$84.2 million on an annualized basis – or 7 times the FDA estimate for convenience stores and almost equal to the \$84.5 million that FDA estimated to be the cost for the universe of chains covered by the Final Rule.** Due to the similarity of convenience stores to grocery stores and general merchandise stores, and because FDA estimated the costs for all 3 of those types of stores in the same way, it is likely that the actual cost of the rule for those stores is, similarly, 7 times FDA's estimate of \$17.7 million⁵² on an annualized basis – \$123.9 million.

FDA estimated that the total cost of compliance with the rule for all covered establishments was \$84.5 million (\$17.7 million for grocery, convenience, and general merchandise stores plus \$66.8 million for all other 248,000 covered establishments). Adding \$115.3 million for enforcement costs for the 248,000 establishments that are not grocery, convenience, or general merchandise stores to the compliance cost of \$66.8 million estimated by FDA for those 248,000 establishments yields an estimate of \$182.1 million for the cost of the rule for stores that are not grocery, convenience or general merchandise stores. Therefore, the total cost of the rule is \$306 million (\$182.1 million + \$123.9 million), assuming that FDA correctly estimated the costs of the rule to all of the establishments beyond those that are in the grocery, convenience, or general merchandise industries.

⁵² FDA does not report its complete estimate of the cost of the rule to the various industry segments. The \$17.7 million estimate comes by multiplying the annualized cost estimate of the full rule by the 21% of the initial costs of the rule associated with grocery, convenience, and general merchandise stores.