



National Grocers Association

July 28, 2017

The Honorable Scott Gottlieb Commissioner
U.S. Food and Drug Administration White Oak Building 1
10903 New Hampshire Ave. Room 2217
Silver Spring, MD 20993

Submitted Electronically

Re: Docket No. FDA-2011-F-0172 for Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments

Dear Commissioner Gottlieb,

The National Grocers Association (NGA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA, the Administration) regarding the nutrition labeling of standard menu items in restaurants and similar retail food establishments. (Docket No. FDA-2011-F-0172).

NGA greatly appreciates the FDA's decision to reopen the comment period and reevaluate the nutritional labeling of standard menu items in restaurants and similar retail food establishments. The scope of the rule has widened considerably since its inception and now includes a far more diverse array of business models and industries than originally intended. A federal menu labeling law was originally requested by chain restaurants who were struggling to contend with conflicting state and local guidelines, but was later expanded by the FDA during the rulemaking process to include entities such as grocery and convenience stores-exceeding the original mandate set forth in the Affordable Care Act (ACA). As such, the need for increased clarity and flexibility has become abundantly clear, as many affected independent supermarket operators have struggled while trying to comply with the rule that was previously set to go into effect on May 5, 2017. NGA welcomes the opportunity to provide the FDA with input from the independent supermarket industry and looks forward to continuing a long-standing partnership with the Agency as the rulemaking process continues.

Independent grocers have been a steady partner throughout the rulemaking process and have taken every opportunity to provide the FDA with feedback on the proposed rule. NGA and our member companies have submitted comments during the appropriate comment periods, as well as submitting questions and comments through the FDA comment and help line on multiple

occasions. Additionally, NGA and the National Association of Convenience Stores (NACS) submitted a citizen's petition requesting that the FDA stay and reconsider the rule.

The menu labeling rule was borne out of the passage of the ACA in 2010 and it was not until December of 2014 that a final rule was issued. Since then, the rule's implementation has been delayed by Congress on multiple occasions (. In the intervening years, FDA has provided guidance documents, that while well intentioned, ultimately created additional confusion for covered entities. On behalf of our member companies, NGA hopes to provide the FDA with sufficient input to assist the Agency in developing a final rule that can be implemented across different business formats following an appropriate education and implementation timeline.

NGA is the national trade association representing the retail and wholesale grocers that comprise the independent channel of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating a variety of formats. Most independent operators are serviced by wholesale distributors, while others may be partially or fully self-distributing. Some independents are publicly traded, but with controlling shares held by the family and others are employee owned. Independents are the true "entrepreneurs" of the grocery industry and dedicated to their customers, associates, and communities. The independent supermarket channel is accountable for close to one percent of the nation's overall economy and is responsible for generating \$131 billion in sales, 944,000 jobs, \$30 billion in wages, and \$27 billion in taxes.

Businesses Need Predictability and Time to Comply

As we approached the May 5, 2017 implementation deadline for the final menu labeling rule, NGA companies were gripped by worry and uncertainty. Many companies had yet to receive clarity as to whether they would qualify as a covered establishment and have to comply with the rule or not, and many companies, including NGA, were unaware of the FDA's plan for enforcing the rule after May 5.

The decision whether to move forward with a compliance strategy or not is, for some companies, a multimillion dollar decision. Some larger NGA members have reported spending upwards of \$30 million on first year compliance. For independent grocers who operate on a 1-2 percent net profit margin, the decision to spend even a few thousand dollars on a compliance effort that may not be applicable to a company can be disastrous. NGA members operate under a number of different ownership formats, such as marketing alliances or as part wholesale cooperatives, that are not chains and do not require a standardized menu to be provided at each store. In some arrangements, stores are not even required to have a deli. **For companies that do not require a standardized menu to be provided at each store, NGA requests the FDA provide greater clarity and assurances for these non-chain companies as to whether they will be required to comply with the menu labeling rule.** NGA and relevant member companies have submitted formal questions and letters to the FDA on this matter on seven separate occasions. Of those inquiries, only one has received a substantive response thus far. While NGA appreciates the FDA responding to one of our member's queries, many companies continue to have significant questions regarding the implementation of the rule.

At FDA listening sessions held in Maryland, Illinois and California in 2016, FDA staff

announced that the first year following the implementation would be used to educate covered entities on the rule, and criminal penalties and fines would be forgone. Additionally, FDA staff made this same pronouncement on a webinar held with NGA members in October of 2016. However, these assurances were not made public on the FDA website and were not broadcast to businesses who were not in attendance at the three listening sessions. **With significant changes to the final rule expected to be made as a result of this comment period, NGA and our member companies implore the FDA to publicly announce its plan to make the first year after enactment an educational period without enforcement actions, and make assistance available to those companies who seek it.**

What Constitutes a Covered Establishment?

NGA cannot stress enough to FDA that there is great confusion regarding covered entities. While we appreciate FDA's attempts to clarify the criteria that determines whether a business is a covered entity, FDA's explanations have fallen short. This has led to confusion not only for companies, but for enforcement agencies as well. While the previous final rule noted that all three criteria must be met (businesses must operate at least 20 stores-doing business under the same name, and selling substantially the same menu items) in order for a business to be held under the menu labeling regulation, NGA is aware of state inspectors notifying stores that they would be captured under the rule, despite the fact that these businesses did not meet all three criteria to be considered a covered entity. This speaks to a need for greater education on the part of the FDA with businesses, explaining whether they qualify for the regulations, and for greater training to be done with state and local inspectors that will be enforcing this regulation.

NGA strongly urges FDA to develop a number of real world examples to help clarify what constitutes "similar retail establishments" under the rule. In addition, NGA requests that FDA develop specific training materials for inspectors to help them understand what determines whether a business is a covered entity and conduct regional training sessions. NGA requests FDA make these sessions open to industry as well to help industry prepare for compliance inspections. NGA members want to make sure that they are in compliance with any required regulations and want to maintain good standing with the FDA, but require greater clarity before many of them invest thousands of dollars to comply with a rule that may not apply to them.

The independent supermarket industry can be a unique industry in terms of determining whether a store is part of a chain or not. As an example, NGA represents a worldwide marketing alliance that does not have any say over the goods sold inside of participating stores. Some of these stores have sophisticated deli operations while others do not have a deli at all. The purpose of the marketing alliance is to help brand each store, primarily for the purpose of advertising efficiencies. NGA believes strongly that these individual stores are not a chain, but need further confirmation from the FDA that can provide certainty to marketing alliances, wholesale cooperatives, and some of our more unique business operations, that they are not held under the rule if they do not fully meet the criteria.

Similarly, NGA represents a number of independent supermarkets, operating under similar banners, which operate as licensing agreement in order to increase their marketing presence. However, that is where the similarities between the stores ends. These stores operate independently of one another and do not offer a standardized menu in fact, some of these stores

are not even required to have a deli. A number of these entities have reached out to the FDA in order to confirm that they are not subject to the rule, as they do not operate as a chain, nor do they offer standardized menu items. Despite not meeting all of the coverage criteria, some stores have been told by state inspectors that they would be subject to the rule. NGA represents a variety of business formats that do not fit neatly into the criteria laid out in the final rule and would be happy to provide additional examples to the FDA if requested.

The scope of the rule is limited to “a chain” of restaurants or similar retail food establishments with 20 locations or more, but does not define what qualifies as “substantially the same menu items.” Though this issue is addressed in the most recently released menu labeling guidance document, the term “substantially the same” is a subjective term that is open to interpretation and puts businesses in a precarious position. NGA has a number of members that operate 20 or more stores under the same banner, but that do not have a centrally set menu from a corporate entity the way a chain restaurant might. However, these operations do offer some similar items such a rotisserie chickens or salad bars. Grocery stores often sell similar items in a bakery section or in a deli, but many businesses do not have a standardized menu at each location and the preparation methods will often vary from store to store. NGA requests that the FDA clarify what constitutes “substantially the same” menu items.

What is a Menu? What is an Advertisement?

In the past iteration of the final rule, the FDA failed to adequately clarify where the line is drawn between a menu and advertising - a significant opportunity for potentially avoidable fines and penalties. Prior FAQ's and guidance documents disseminated by the FDA provided contradictory explanations of what constitutes a menu, defaulting to stating that a menu ‘must be within view of the purchasing area,’ while also stating that sign twirlers that advertise a product standing hundreds of feet away from a store could also count as a menu, and must therefore be labeled. With a blurry line as to what comprises a menu and what is an advertisement, NGA member companies run the risk of either overspending on signage or facing criminal penalties and lawsuits.

NGA requests the FDA make clear the definition of and menu and of an advertisement NGA strongly believes that a “menu” should not include advertisements made outside the store such as billboards, signs, fliers, or other publications used to broadcast the availability of certain items. Requiring these advertising items to be labeled will dramatically increase to cost of the regulation on businesses.

Costs to Comply are Significant for Supermarkets

The cost for the average supermarket to come into compliance with the menu labeling rule will be significant. Costs to develop or replace menu boards and other in-store equipment such hardware and software were estimated to range from at least \$2,000 to more than \$30 million for larger store groups. One of the biggest challenges for an independent retailer will be the development of nutritional and recipe standards. NGA members have estimated their costs to develop nutritional information for recipes range from \$10,000 to at least \$1.5 million on a company-wide basis. This will be an ongoing cost as stores are constantly adapting and adding to their menu offerings. It's important to understand that these estimates are just that, estimates.

Real figures, including labor costs, will likely be much higher.

The average net profit for the independent sector of the supermarket industry has long stood between 1-2 percent. Additional operational costs, when taken with rapidly rising health care costs and changing labor costs, can have a significant negative impact on independent supermarket operators. NGA strongly encourages FDA to take into consideration the initial and ongoing costs supermarkets have and will continue to bear in order to comply, in particular considering the current economic climate businesses are operating in. NGA urges FDA to take steps to minimize the cost of compliance, and provide regulatory flexibility wherever possible to minimize the impact on the industry and, in particular, on small businesses. While many would not consider a business that operates more than 20 stores to be a “small business,” more than 50% of NGA members are single store operators, many of whom operate as part of larger chains. Though the regulation targets large chain operations, the burden will be heaviest on those single store owners who operate as part of larger supermarket chains.

Incorporate the Common Sense Nutrition Disclosure Act

NGA and our member companies have been advocating for the passage of the Common Sense Nutrition Disclosure Act (CSNDA) over the course of the last several years in the hopes that it would provide added flexibility for businesses whose operations differ from the quick-serve restaurants and chain operations the rule was designed for. Importantly, **the CSNDA would not exempt any of the businesses currently held under the rule**, but would make judicious changes to the law that would allow it to be more workable for varying business formats.

The CSNDA would allow businesses to provide customers with nutritional information via a centralized menu board instead of being required to individually label each item available for sale. This would prevent simple mistakes like the mislabeling of items as they are changed at the salad bar or in the bakery section while still providing customers with easy access to the required information.

Importantly, the CSNDA would protect businesses from fines suffered due to inadvertent human errors. This would allow companies to correct simple mistakes that could otherwise lead to stiff penalties, such as adding too many pickles to a sandwich or too many chocolate chips in the cookie batter. These types of errors happen from time to time, but an accidental extra tomato on a sandwich should not lead to felony penalties or fines for an establishment that is trying in earnest to comply with the spirit of the law.

Similarly, the CSNDA would allow for the use of averages or ranges for variable menu items. Items such as fruit salads can have a variable range of calories depending on the fruit available that day, which should be reflected on the information given to customers. Additionally, the caloric content of an item such as a fruit salad can change significantly over time as the sugars in the item break down. In order to prevent possible infractions based on this variability, the CSNDA would allow for these items to be presented using a range or average in order to give customers the best possible information.

Lastly, unique items sold at only one location would not be covered under the rule. Many grocers partner with local bakeries or restaurants to provide local items in their stores, which

has provided significant benefits to grocers, their partners, and customers. Oftentimes grocers partner with local bakeries to provide an item that is only sold in that region or city and which helps provide a local flavor and is not sold in other stores. As the menu labeling rule seeks to address “standard menu items,” items that are sold at covered businesses but that are not standard items should not be subject to caloric labeling. If a waiver for unique items is not granted, NGA member companies have reported being wary of entering into the aforementioned agreements with local businesses, as they would be required to pursue caloric testing for the items and seek legal assurances that the provided caloric information is correct. In all likelihood, if a waiver is not granted for these unique items, local business relationships will suffer and businesses will shy away from providing local items in their stores.

NGA believes that incorporating these changes into the final rule will make the regulation more workable for businesses of all types while providing customers with clear information. Again, the goal of the Common Sense Nutrition Disclosure Act is not to exempt any covered entity from the rule, but simply to provide additional flexibility to businesses while still providing customers with the required information.

FDA Should Focus on Education and Defer Enforcement

NGA urges the FDA initially focus on educational compliance and defer enforcement for at least a year. NGA would also request that the FDA discourage states and localities from enforcing their own versions of the menu labeling rule until after a workable final rule has been issued (California tried to implement the rule early, and New York City has moved forward with its own version of the rule that diverges from the federal rule and violate federal pre-emption) and appropriate time has passed to allow covered businesses to comply. Though NGA understands that the rule has taken a substantial amount of time to be finalized and many are anxious to see it put into effect, the implementation of this rule will take considerable time, effort, and cost for businesses. Affected businesses will need to send recipes away for testing, employees must be retrained on menu preparation, packaging and display, while signage will have to be redesigned, procured and installed. For larger companies, this will be a massive undertaking. For smaller businesses with less expertise and wherewithal, it will be exponentially more difficult and will have a more pronounced proportional impact in terms of cost and effort.

It would do a disservice to the customers who come through the doors of our supermarkets for the FDA to rush the implementation and enforcement of the new rule in order to meet an arbitrary deadline set for 2018. If the goal is to provide consumers with transparent and accessible nutritional information, independent supermarkets would request a reasonable amount of preparation time in advance of the effective date in order for the FDA to provide training for inspectors, and respond to those businesses who remain unclear as to their status under the rule.

Conclusion

NGA and our members believe that the previous iteration of the menu labeling rule failed to adequately clarify key components of the rule, and left significant unanswered questions that could have allowed businesses to face unnecessary fines and penalties. Moving forward, NGA hopes that the FDA will seek to address these concerns and work with the business community in order to rectify any grey areas that may lead to accidental infractions.

Independent supermarkets request clarity, flexibility, and a reasonable amount of time and guidance to adequately implement the menu labeling rule. NGA supports the goal of providing customers with nutritional information but requests that the rule be updated to account for the vast differences between the quick-serve restaurant industry and its highly standardized menus and the independent supermarket industry

NGA appreciates the opportunity to provide comments to the FDA and looks forward to working closely with the Administration as these regulations continue to develop and are implemented. If NGA can provide any further information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in blue ink that reads "Greg Ferrara". The signature is written in a cursive style with a large, stylized initial "G".

Greg Ferrara
Senior Vice President
Government Affairs & Public Relations