

November 2, 2015

Submitted Electronically

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods- Part II; Draft Guidance for Industry

Docket No: FDA-2011-F-0172-0577

Dear Sir or Madam,

On September 11, 2015, the U.S. Food and Drug Administration (FDA or the agency) released draft guidance, “A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods- Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11” (draft guidance). The Food Marketing Institute (FMI) appreciates the opportunity to respond to FDA’s request for comments on the draft guidance intended for covered establishments subject to the nutrition labeling requirements under the Federal Food, Drug and Cosmetic Act (FD&C Act) and the implementing regulations. These requirements include the menu labeling provisions of section 403(q)(5)(H) and the final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments published on December 1, 2014.¹ The draft guidance attempts to provide additional information on the nutrition labeling that is required for foods sold in covered establishments that are subject to FDA’s Final Menu Labeling Rule (final rule).

The Food Marketing Institute (FMI) proudly advocates on behalf of the food retail industry. FMI’s U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost \$770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

¹ 79 Fed. Reg. 0577 (September 11, 2015).

FMI appreciates the agency's recognition that additional time and guidance is needed for covered establishments subject to the final menu labeling regulation. On July 9, 2015 the agency released a statement acknowledging that clarifying guidance is needed to help facilitate efficient compliance across all covered businesses and for covered establishments to come into compliance with the final rule until at least December 1, 2016.² FMI appreciates the agency's commitment to propose draft guidance for covered establishments and urges the agency to move swiftly to finalize the draft guidance. The agency also states that "in addition to the guidance, the FDA will also provide educational and technical assistance for covered businesses and for FDA state, local, and tribal regulatory partners to support reasonable and consistent compliance nationwide. Now and following the December 1, 2016 compliance date, the FDA will work flexibly and collaboratively with individual companies making a good faith effort to comply with the law."³ FMI appreciates the opportunity to submit comments on the draft guidance and looks forward to continue working with FDA to answer many of the outstanding questions and concerns that are essential for supermarkets to move forward with implementing a rule intended for chain restaurants.

While the "draft guidance" begins to address some of the outstanding questions and concerns, FMI members are seeking clear answers. FMI appreciates the agency's extension of the December 1, 2015 compliance date and commitment to provide additional educational and technical assistance for covered establishments. However, as of November 2, 2015, the agency has yet to provide clear guidance on FDA's enforcement considerations such as training and potential partnerships with state and local jurisdiction. To that end, it would be consistent for FDA to further extend the compliance date until no earlier than one-year after final guidance has been published.

Introduction

The supermarket industry is committed to providing consumers with nutrition information, and as discussed in these comments, has been held up as a model for other segments of the food industry to follow. Health and nutrition is of the utmost importance to retailers and for years, FMI and its members have recognized the need to help consumers navigate the abundance of health, wellness and nutritional offerings within today's supermarket. This also makes good business-sense by sustainably utilizing fresh, wholesome produce and other items that would otherwise become food waste.

The supermarket industry has seen robust competition among retailers as they battle to win over consumers with innovative new ways of providing nutritional information. Retailers have created a marketplace for nutrition information in response to consumer demand and continue to strive for innovative new ways to provide nutritional

² FDA Statement on Extension of Menu Labeling Compliance Date, Mike Taylor, FDA Deputy Commissioner for Foods and Veterinary Medicine, July 9, 2015 *available at* <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm453529.htm> (last accessed November 2, 2015).

³ *Id.*

information. In fact, prepared foods are a large part of retailers' offerings for 2015; retail executives are expecting further investments in these key areas of success, especially fresh and prepared foods. The intense and varied competition, along with the ever-growing number of options in foodservice, is spurring constant in-store innovation for grocery operators. These fresh, healthy items offered in a grocery store increasingly appeal to consumers as a less expensive, much healthier alternative to standardized fast-food items. FMI members are committed to providing nutrition information to their customers and believe that FDA should provide additional flexibility to allow grocery stores to do so in a way that works in a grocery store setting. FMI strongly urges FDA to acknowledge the unintended consequences and costs associated with supermarket compliance under a law aimed at chain restaurants. The one-size fits all regulation constructed for chain restaurants does not work in a grocery store setting due to the variety of formats, range of menu items and the lack of standardization from store to store. First, the majority of these items are not listed or sold via a menu or a menu board, therefore menu labeling is a misnomer and labeling items not on a menu or menu board becomes the challenge.

Background

FDA's Final Menu Labeling Regulation, published on December 1, 2014, is incredibly broad, impacting thousands of supermarkets across the country, and hundreds to thousands of items at each store. While FMI's member companies continue to believe that a grocery store is a very different entity from a chain restaurant, particularly since the two have been treated separately with regard to each of the past regulatory and legislative requirements under FDA's purview; however, our members are working swiftly to try to implement the final rule. Since the final rule was released in December, FMI members continue to struggle with a large number of unanswered questions as to how a regulation intended for chain restaurants can apply in a grocery store setting and specific members of a cooperative that either own and operate less than 20 stores, and those that own and operate more than 20 stores, but do not necessarily offer standard menu items in each location. Additionally, FMI members continue to seek answers from the agency as to the types of items that FDA considers to be "restaurant type" foods and the need for much needed flexibility for posting calorie information for self-service foods and foods on display. While chain restaurants have the same items offered at every location, there is an incredible amount of variation in the items a supermarket offers for sale, making compliance even more challenging. Unlike chain restaurants, supermarkets do not typically have menu or menu boards.

Former FDA Commissioner Dr. Margaret Hamburg acknowledged this complexity at an Appropriations Budget Hearing on March 4, 2015, stating that the menu labeling regulations "turned out to be one of the most complex undertakings that I've been involved in in my tenure, and so I understand why industry is concerned, and why there is anxiety about what does it mean, and how do we implement it."⁴

⁴ FDA in the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies on Wednesday, March 4, 2015.

FDA Should Provide a One-Year Implementation Date Following Publication of Final Guidance

Given the complexity of the regulation and the lack of final guidance from FDA, implementation continues to be incredibly frustrating for supermarkets. FMI members are committed to providing nutrition information that their consumers demand, but they need the flexibility to do so in a way that is feasible in a supermarket setting. Without answers to many of the outstanding questions that are essential for companies to make important business decisions, and additional flexibility for items that are not on a menu or menu board, FMI members will have obstacles in trying to move forward with implementation.

The beginning of the implementation process for supermarkets will require a significant investment in structural resources, nutritional analysis, signage design and development, employee training and enormous recordkeeping burdens, to name a few. The lack of guidance to date has also significantly increased the likelihood for errors, further corrections, and higher compliance costs further exacerbating the unintended and undesirable consequences of this regulation, such as reduced fresh, healthy offerings in the food retail environment. Covered establishments are almost one-year into the implementation period and supermarkets are still trying to figure out the scope of foods that are covered, how to conduct the nutrient analysis, how to standardize food offerings across all locations, develop signs and labels, modify store formats and hire additional employees to oversee implementation and train employees. Additionally, supermarkets face a host of labeling and food safety rules that restaurants do not and compliance departments of retailers are stretched thin. This comes at a time when the supermarket industry is also preparing for compliance with the final regulations under the Food Safety Modernization Act, the biggest change to our food safety laws in over 70 years — none of which affect restaurants.

Compliance with the final rule is a tremendous undertaking and, as one can imagine, FMI members are incredibly reluctant to invest in significant resources to comply with a regulation until clear, final guidance and answers are provided by FDA. This is important, not only to covered establishments trying to comply with the rule, but it is also imperative to ensure federal, state and local health officials and the industry have the same interpretation and proper training regarding the application of the rule. Therefore, FMI respectfully requests that FDA provide a one-year implementation time following publication of **final guidance** in accordance with FDA's Good Guidance Practices. The extended timeline would allow FDA and covered establishment's adequate time to work through the large number of questions that were not addressed in the draft guidance and will provide more adequate time for training and outreach to affected industry.

FDA Needs to Clarify the Definition of “Restaurant-Type Foods”

In the preamble to the final rule, FDA states that the definition of restaurant type food only covers those foods described in sections 403(q)(5)(A)(i) and(ii) of the Food Drug and Cosmetic Act that are most like the food sold in restaurants and does not cover foods that are more commonly considered to be groceries. The rule defines “restaurant-type food” in a way that both focuses on the food most like the food offered for sale in restaurants and reflects the statutory context of section 4205 of the ACA. While FDA provides some examples of foods that generally would be considered restaurant type food (e.g., foods that are usually eaten on the premises, while walking away, or soon after arriving at another location), as well as examples of foods that generally would be not be considered restaurant type food (e.g., foods that are grocery type items that consumers often store for use at a later time or customarily further prepare), there is very little guidance for determining whether an item is more like a grocery item opposed to a restaurant type food. In addition to the prepared foods on a salad/ hot bar or items sold on a menu or menu board, fresh prepared items are sold in a variety of formats within a supermarket, however they are not intended for immediate consumption.

The agency states that “restaurant-type food” includes food for immediate consumption at a sit-down or quick service restaurant; food purchased at a drive-through establishment; takeout and delivery pizza; hot pizza at grocery and convenience stores that is ready to eat; pizza slice from a movie theater; hot buffet food, hot soup at a soup bar, and food from a salad bar; foods ordered from a menu/menu board at a grocery store intended for individual consumption (e.g., soups, sandwiches, and salads); and self-service foods and foods on display that are intended for individual consumption (e.g., sandwiches, wraps, and paninis at a deli counter; salads plated by the consumer at a salad bar; cookies from a mall cookie counter; bagels, donuts, rolls offered for individual sale). **Foods that are similar to grocery items that may be ready for immediate consumption but that consumers usually store for use at a later time or customarily further prepare would not be included within the meaning of “restaurant-type food.”**

FDA states that they would **not** consider the following foods to be “restaurant-type foods;” food to be eaten over several eating occasions or stored for later use (e.g., loaves of bread, bags or boxes of dinner rolls, whole cakes, and bags or boxes of candy or cookies); foods sold by weight that are not self-serve and are not intended solely for individual consumption (e.g., deli salads sold by unit of weight such as potato salad, chicken salad), either prepacked or packed upon consumer request; and foods that are usually further prepared before consuming (e.g., deli meats and cheeses).

While FDA provides some examples of items that would constitute restaurant type food, it is challenging to distinguish the difference between a grocery item and food intended for immediate consumption. This is even more puzzling because a restaurant operation does not compare to a retail supermarket. The lineal footage of display cases and menu boards for each department far exceed any restaurant operation. Restaurants typically

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identify their offered foods and pricing through a single menu board and/or menu. Grocery stores don't typically have menus or menu boards or may only have a few items listed on a menu or menu board.

In a teleconference hosted by FDA soon after the final rule was released, senior FDA policy officials emphasized that the regulations are intended to be confined to areas similar to restaurant-type settings, such as a food bar, salad bar or prepared foods area, but not to other store departments that may offer items that could be considered ready-to-eat but are otherwise part of a grocery store's operations, such as a produce area, bakery display, seafood counter or dairy case.

Supermarkets sell a large variety of items that are prepared and processed in a supermarket many of which are grocery type items stored for later use and consumed over a period of time. Unlike restaurant type foods, these fresh prepared grocery items are packaged in a clam shell or container. Outside of a salad bar, hot bar or menu board, defining a restaurant type food subject to the rule is perplexing, to say the least. Clearly Congress did not intend for foods that are not served for immediate consumption to be covered under the rule, however we are now nine months into implementation and supermarkets are still seeking basic answers to questions as to what constitutes a "restaurant-type" food. Prepared and packaged items offered for sale in a grocery store are not like items offered in a restaurant. They are packaged so customers can bring home an item and eat it later, or use as one component in a home cooked meal.

A practical example of the complexity and challenge in interpreting the definition of a restaurant-type food is demonstrated best by applying the regulation and logic to cut fruit cups sold in a grocery store. Fresh cut fruit is often prepared and packaged in a grocery store and sold by variable weights. Mixed fruits and/or vegetables are cut into convenient sized pieces and packaged for sale. For example, a grocery store might sell a mixed berry cup with raspberries, blueberries and blackberries. The selection is based on seasonal availability and varies greatly. The various types of prepared fruit cups are sold in a number of sizes and often displayed in a cooler near the produce area of a grocery store. A large refrigerator in or near the produce department may sell an 8 ounce, 12 ounce, 20 ounce or 60 ounce variety of mixed fruit cups, none of which are intended for immediate consumption. The same fruit may also be sold in the salad bar or offered on a menu or menu board as a standard menu item. Unlike the packaged fruit cups, foods on a salad bar are intended for immediate consumption. Customers purchase all different variations and sizes of fresh cut fruit to eat over the course of the week. Fresh fruit cups provide an easy alternative for time-constrained shoppers or those who enjoy the convenience of fresh cut fruit without having to purchase and cut up an entire watermelon or pineapple.

The option to purchase the same fruit cup in a 12 ounce, 24 ounce, or 60 ounce container does not transform a grocery item into a restaurant type food. This is not only true for fruit cups that are offered, but for virtually all of the prepared items in a grocery store that are not on a menu or salad/hot bar. Questionable examples include the same cake and pie displayed whole, sliced in half, sliced in quarters, etc.; rotisserie chicken, chicken tenders, served both hot and cold; a salad displayed in the service case and pre-packed in

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containers, muffins sold in a bulk bin, 2 pack container and 4 pack container, cut fruit and/or vegetables sold in containers.

FDA should clarify that items prepared and packaged for home consumption in a grocery store like fruit cups, chopped onions, fresh squeezed fruit juice, salsa and similar items not intended for immediate consumption, regardless of the serving size are grocery type items.

As stated above, former Commissioner Hamburg has stated that foods outside of the prepared foods section, or items not offered on a menu or menu board are outside the scope of the rule. "... in the grocery stores, which I know has been a place of concern, we tried to very clearly limit it to the components of the grocery where there's sort of a mini-deli kind of setting, or a salad bar type setting, which is explicitly in the law for coverage, and in the deli where there's a menu. So if it's a ham and cheese sandwich that's prepared, and there's a menu then it would apply. If you're buying a pound of ham and a pound of cheese and a loaf of bread that would not be subject to oversight."

Under the rule and draft guidance, hundreds if not thousands of items sold in a grocery store may be a restaurant type food depending on where it is sold within the store. It is unreasonable and unduly burdensome for supermarkets to have to develop signage and evaluate the thousands of items that could potentially be sold for immediate consumption without some guidelines from the agency. Items such as cut fruit or a rotisserie chicken are packaged in a separate container and offered in various formats throughout a grocery store. FMI members need clarification that prepared packaged items, regardless of the serving size are not restaurant type foods because they are typically eaten over a period of time or stored for later use.

FDA defines restaurant-type food as "food that is usually eaten on the premises, while walking away, or soon after arriving at another location." How does FDA intend to make determinations as to whether an item constitutes a "restaurant type" food? Most items offered for sale in a supermarket are not intended for immediate consumption and are items stored for use at a later time. **This is a fundamental difference between grocery stores and restaurants.**

FDA should not apply a policy that would limit offerings such as fresh fruit. Without clear guidance, FMI members will be forced to label everything in a store that could potentially be covered, resulting in billions of dollars per year in unnecessary regulatory costs. Items such as a rotisserie chicken and cut fruit cups sold in a grocery store are portioned and packaged in a supermarket and as such are not restaurant type foods consumed on the premises, while walking away or shortly after arriving at another location.

FDA should clarify that items prepared and packaged for home consumption in a grocery store like fruit cups, chopped onions, fresh squeezed fruit juice, salsa and similar items not intended for immediate consumption, regardless of the serving size are grocery type items.

In the preamble the agency states that “certain foods offered for sale in grocery stores that are visible to the consumer before the consumer makes a selection, such as prepared sandwiches, freshly cooked pizza, and salad and hot food bars would meet the definition of restaurant type food and do not have an ordinary expectation of further preparation by the consumer before consumption. These foods meet the definition of foods on display. Other foods commonly offered for sale by grocery stores are not within the definition of restaurant-type foods and would not be subject to the nutrition disclosure requirements of the rule (*e.g.*, foods such as dried fruit and nuts bought from bulk bins or cases; foods such as loaves of bread, bags or boxes of dinner rolls, whole cakes, bags or boxes of candy or cookies to be eaten over several eating occasions or stored for later use; foods such as deli salads sold by unit of weight that are not self-serve and are not intended solely for individual consumption, either prepacked or packed upon consumer request).

Supermarkets have a greater variety of items not only in terms of the number of different grocery items offered for sale, but also in the way those foods are sold throughout the store. Consumers primarily shop in supermarkets by visually evaluating items and virtually all foods in a supermarket are “on display” or viewable by consumers. But this in no way means they are being sold for immediate consumption. For example, in the deli, whole hams and turkey breasts are visible to consumers, but they are not on display for purposes of serving the product for immediate consumption. Foods on display could arguably include items such whole cakes and pies, large trays of mixed fruits and vegetables, whole deli hams and whole rotisserie chickens. These items would be eaten over a period of time and are not being served for immediate consumption. Another step is required—the cutting of the item into individual portions is necessary—before consumption. A large platter of mixed fruit would be eaten over the course of a few days or a week, not on the premises, while walking away or shortly after arriving at another location. As stated above, these items are often packaged and sold throughout the grocery store. For example, a rotisserie chicken served hot or cold is packaged and intended to be consumed over the course of the week and is used as one component of a meal. FMI urges FDA to also clarify that foods such as deli salads sold by unit of weight that are not self-serve either prepacked or packed upon consumer request are not restaurant type foods regardless of the serving size. A half-pound prepacked deli salad is not being sold for immediate consumption and the same is true for a quarter pound deli salad.

FDA should also clarify that bulk items that are purchased to be consumed later, such as bagels, cookies, doughnuts, and rolls, are similarly not covered. Bagels or rolls offered in bulk bins require further preparation (*e.g.*, slicing, toasting etc.) A customer could purchase one roll in the morning for dinner the following day or twelve bagels for the week-- neither of which are intended for immediate consumption. Unlike bagels offered for sale in a bulk bin or display case, a bagel offered on a menu or menu board is more like a restaurant type food. A policy that focuses on whether a particular consumer intends to eat a bagel from a bulk bin immediately or while walking away is simply unworkable.

In the draft guidance, FDA states that “in general, our aim is to cover the food most like the food offered for sale in restaurants. If the item, for example a two-piece barbecue chicken lunch or a slice of pizza, is routinely included on a menu or menu board, or offered at a hot self-service buffet, then that item would be covered and the covered establishment would be required to provide calorie and other nutrition information for such menu item. If, on the other hand, the food requires additional preparation, such as reheating before consuming and is typically eaten over several eating occasions or stored for later use, such food would generally not be covered (e.g., cold, prepared barbecue meat items offered from behind a deli counter sold by weight rather than by piece and that is generally reheated by the consumer before being eaten).”

FDA goes on to state that cold prepared foods that are (1) sold from behind a deli counter, (2) do not appear on a menu or menu board, and (3) require further preparation by the consumer before consumption would not be considered a “restaurant-type food.” FMI agrees that cold prepared meat items sold from the deli counter in a grocery store that require reheating prior to consumption are not a restaurant type food subject to the rule. However, FDA should clarify that the same logic applies to any item offered for sale in a grocery store that requires reheating-- clearly these items are not intended for immediate consumption. If a food is not served at the temperature at which it is traditionally consumed, the food is not being served for immediate consumption. Examples include cold family size lasagna prepared on site and offered in the deli area or a cold chicken breast sold by weight behind the deli case.

Flexibility for Self-Serve and Foods on Display

Section 4205 of the ACA amended the FD&C Act to require chain restaurants and certain “similar retail food establishments” to post calorie and other nutrition information for standard menu items. In the statute, Congress clearly acknowledged the distinction between those items offered for sale on a menu or menu board and self-serve and foods on display. For those items not offered on a menu or a menu board, flexibility is provided in the statute given the impracticability of requiring covered establishments to invest in signage and menu boards for self-serve and foods on display.

In the preamble to the final rule, FDA states that the rule is intended to provide flexibility, for covered establishments to choose among several options for declaring calorie information for standard menu items, including self-service foods or foods on display in cafeteria and buffet-type settings. While we believe FDA intended to provide the necessary flexibility for declaring calorie information for self-serve and foods on display, we are concerned that without further clarification, FMI members will not be able to do what is critical to provide clear, accurate information for the hundreds of items offered on a salad or hot bar. Due to the number of stores FMI members operate, and the product offerings that vary significantly from store to store, as well as by hour to hour depending on current inventory levels, it is virtually impossible to execute the rule for self-serve foods at a salad or hot bar. In the preamble, the agency recognizes the unique

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challenges associated with declaring calories on a buffet or salad bar where items are constantly changing. To provide additional flexibility for these items, FDA states that a sign may be placed on the wall behind the station, on a sign at the beginning or end of the station, or at another location so long as the consumer can read the name, calorie declaration, and serving or unit of a particular menu item while selecting the menu item, however the agency stops short of recognizing more feasible alternatives for posting calorie information.

On a supermarket salad bar, items are constantly being added and deleted based on the needs and wants of the customer and the availability of offerings sourced within the store. One salad bar or hot bar may have hundreds of items offered for sale throughout the day. For example, a hot bar may have a breakfast offering, a lunch offering and a dinner offering. In addition to changing out items depending on the time of day, items are typically changed every four hours for food safety reasons or replenished as needed. Retailers make items based on product availability in the store from a wide variety of items. Labeling and determining calorie information for these items will be profoundly difficult. Additionally, each store has multiple formats and departments involving numerous associates in food preparation across a broad spectrum of hours from early morning to late evening.

The layout and sheer number of items offered on a salad bar make it virtually impossible to display nutrition information on a single sign that will be visible from every bin while a customer is making a selection without cluttering space or obstructing a customers view. Additionally, there is no sign or placard large enough to provide the calorie information for hundreds of items on the salad bar that are constantly changing. Even if the required information was updated hundreds of times per day, the likelihood for errors is substantial. Without additional flexibility for posting calorie information, supermarkets will be forced to rely on an in-store associate to update a sign or calorie information on the sneeze guard hundreds of times per day—this is simply impracticable. In the preamble to the final rule, FDA acknowledges the likelihood that customers will inadvertently move signs for self-service foods, and therefore, states that a better alternative might be to provide the calorie declaration on a counter or display case. The agency also notes that more flexibility is needed for foods that are constantly being replenished or changed, such as a supermarket salad bar. However, FMI members believe additional guidance is needed to allow grocery stores the flexibility to post a single sign, booklet, pamphlet, or use other reasonable means for calorie information at the end of a salad bar. This would allow retailers to consolidate all of the nutrition information for the hundreds, if not thousands of items that are potentially offered for sale on a salad or hot bar. FDA already provides similar flexibility for voluntary nutrition information under the voluntary labeling program for fruits and vegetables recognizing that retailer operations are complex.

Non-Standardized Unique Items

As stated above, consumer demand and supermarkets are constantly striving for innovative new ways to meet various lifestyles, but our customers also rely on quality, convenience and price. FMI is concerned that this innovation will be eliminated as an unintended consequence of the final rule. Unlike a chain restaurant with prescribed recipes and ingredients, many retailers give individual stores flexibility to create healthy, local and innovative offerings at individual stores. The complexity of the assortment and product offering makes standardization very difficult.

In some cases, a supermarket chain will offer a number of items that are standardized across all locations. They do so to ensure that customers have access to their favorite prepared foods regardless of the location where they decide to shop. Supermarkets want to ensure these items are consistently prepared with the same ingredients at every location. Consumers rely on this consistency and appreciate the predictability for their favorite items. For those standard items offered at every location, covered establishments are able to complete the nutrition analysis and develop strategies for implementation and signage in each individual store.

In addition to the standard menu items that are offered across a chain, FMI member companies often provide discretion to individual stores to provide non-standardized, unique products offerings. For example, an individual store within a supermarket chain may be contractually obligated to offer 75% of the standardized items each day, but 25% of the items offered are within the store's discretion. Many times, a supermarket provides a specific recipe to employees preparing the standard menu item at store level and has policies in place to ensure the associate does not deviate from the recipe.

However, for unique non-standardized items, many retailers give individual stores the flexibility to adapt recipes to the local regional taste profiles or to utilize offerings from the store and reduce food waste. Unlike restaurants, stores often serve as their own suppliers for prepared foods. The meat department supplies the meat for items, the produce department supplies fresh fruits and vegetables and packaged foods may also be used in creating prepared items. These unique, non-standardized items, typically sourced from the store, however are often sold or may be sold for more than 60 days per year if they are popular with customers.

Consumers rely on these unique items and grocery stores are able to cater to their loyal customers and local tastes. FMI strongly urges FDA to clarify that for these unique, non-standardized items that are offered for sale in only a few locations within a chain of 20 or more locations are not standard menu items subject to the final rule. Limiting the rule to only those items that are standardized across a supermarket chain would save billions of dollars each year for the supermarket industry and would allow these items to continue to be offered. An unintended consequence of FDA's current guidance, will be to force supermarkets to centralize processes and standardize foods to avoid liability concerns, which is also contrary to many government and other initiatives FMI is involved in to promote local items and reduce food waste.

FMI members want to promote local, healthy items and are increasingly relying on in-store chefs to develop recipes and prepared items their customer demand. We do not believe applying the rule to these unique offerings is the intent of Congress or the FDA. Without guidance related to these unique items, FMI members companies will have to resort to standardization of all items sold across a supermarket chain because is simply not feasible for supermarkets to conduct the necessary nutrition analysis and rely on in-store employees for compliance under the rule for each of those unique non-standard offerings. To do so, supermarkets would have to hire regulatory experts and dietitians at each location to oversee the nutrition analysis and signage imposing astronomical costs on an industry operating on a 1% profit margin.

Further, FDA has grossly underestimated the number of items covered if the rule applies to non-standardized unique product items. According to an FMI audit, the average supermarket has over 200 items that, as we currently understand the rule, would constitute restaurant type foods. However, due to the variability in the items offered from store-to-store, the number of covered items is in the billions. This is a far cry from a chain restaurant who offers the same standard menu items on a menu board at every location. **Consumers benefit from regional items and FDA should not implement a policy which could reduce consumer choice and limit innovation leading to more formulaic items.**

It would be much less burdensome and impractical for establishments to evaluate all of the menu items offered by a corporate chain to determine which items are offered corporate-wide to evaluate whether a given menu item is a standard menu item subject to requirements of this rule.

In the draft guidance, FDA states that they do not expect new menu items to be introduced frequently so they would evaluate requests on a case-by-case basis when standard menu items change. This may be true for chain restaurants who sell the same standard menu items across the country, but this is fundamentally not the case in the supermarket industry. Supermarkets sell new items every day. If one supermarket within a large chain decides to offer a quinoa salad at one location due to local preferences and customer demand, does a store associate need to contact FDA if it ends up being sold 61 days per year? Would that associate then need to do an intensive nutrition analysis and develop signage in accordance with the rule? It's hard to believe that was the intent when Congress passed a menu labeling law aimed at chain restaurants designed to help reduce obesity rates. FDA should clarify that unique offerings sold at only a few locations are not standard menu items under the rule.

In addition to the costs and impracticability noted above, supermarkets will no longer be able to source ingredients from within the store resulting in significant amounts of food waste and increased costs.

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Conclusion

FMI appreciates the opportunity to comment on the draft guidance and urges the FDA to consider the unique challenges supermarkets face with compliance under a rule written for chain restaurants. FMI will continue to share additional questions with the agency moving forward and appreciates FDA's willingness to work with supermarkets to provide necessary flexibility and answers that are crucial for supermarkets subject to the final menu labeling rule.

Please contact Stephanie Barnes at sbarnes@fmi.org or (202) 220-0614 with any questions.

Sincerely,

Stephanie K. Barnes