FOOD MARKETING INSTITUTE

September 7, 2010

Submitted Electronically

The Honorable Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
White Oak Building 1
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

RE: Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39026 (July 7, 2010)

Docket No. FDA-2010-N-0298

Dear Commissioner Hamburg:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments and information to assist the agency in implementation of § 4205 of the Patient Protection and Affordable Care Act[1] (PPACA). FMI looks forward to working with FDA on this important matter.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

[1] P.L. 111-48.

2345 Crystal Drive, Suite 800 • Arlington, VA 22202-4801 • T 202.452.8444 • F 202.429.4519 • fmi@fmi.org • www.fmi.org

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. The supermarket industry has seen robust competition among retailers as they battle to win over consumers with innovative new ways of providing nutritional information. These innovations are benefitting consumers by making it easier for them to identify nutritious foods. FDA should encourage such innovation, not implement regulations in a manner which will limit it. Consumers are demanding nutrition information and supermarkets are responding. No less than 89 percent of Americans say that they are either somewhat or very concerned about the nutritional content of their food intake.[2] In the most recent study on shopper trends conducted by FMI, 70 percent of shoppers surveyed rated the availability of nutrition and health information as being a somewhat or very important factor in selecting a primary grocery store, and 71 percent of consumers stated that their primary store provides nutrition and health information.[3] Sixty percent of consumers use this resource at least once a month and 21 percent use it once a week.[4] Supermarkets are responding to consumers' demands. Almost 70 percent of retailers compete on the basis of consumer wellness and family health.[5]

Section 4205 of PPACA amended the Federal Food, Drug and Cosmetic Act[6] (FDCA) to require chain restaurants and certain "similar retail food establishments" to disclose nutrient content information for standard menu items appearing on restaurant menus and menu boards among other things. FDA is soliciting comments to inform them in the implementation of § 4205. FMI believes if FDA follows the recommendations contained within these comments, it will implement § 4205 in an effective manner. Headings that are italicized reference specific requests for information posed by FDA in the notice. FMI's comments herein focus on the legislative intent and scope and application of § 4205. FMI intends to comment separately on the § 4205 draft guidance document released in August 2010.[7]

I. Legal and Regulatory Burden Analysis

Supermarkets Generally are Not "Similar Retail Food Establishments"

Section 4205 applies only to certain foods sold at restaurants and "similar retail food establishments." Unlike the Nutrition Labeling and Education Act[8] (NLEA) which applies to foods

[2] Food Marketing Institute, 2009 U.S. Grocery Shopper Trends.
[3] Id.
[4] Id.
[5] Id.
[6] 21 U.S.C. §§ 301 et seq.
[7] 75 Fed. Reg. 52426 (August 25, 2010).
[8] P.L. 101-535.

generally,[9] the application of § 4205 is dependent on the type of establishment serving the food. Congress used the term "similar retail food establishment" but did not define it. It is essential then to view the term in the context of the statute § 4205 modifies, 21 U.S.C. §343(q). Within paragraph (q) the term "food retailer" is used to describe entities that are subject to nutrition labeling of meat and fish and the term is generally understood and has been construed to apply to supermarkets. Instead of using this term, Congress chose to use "similar retail food establishment." It is always appropriate to assume that Congress knows the law.[10] "Where Congress includes particular language in one section of a statute, but omits it in another. . . it is generally assumed that Congress acts intentionally and purposefully in the disparate inclusion or exclusion."[11] FDA must assume that Congress did not intend for "similar retail food establishments" and "food retailers" to have the same meanings.

Regulated Establishments Must Be Similar to Restaurants

Congress could have simply used the term "retail food establishment"--which is defined by FDA to include grocery stores[12]--but instead qualified it with the word "similar."[13] This implies that being a retail food establishment alone does not bring the business under the PPACA § 4205 regime; the retail food establishment must be similar to a restaurant. As the term establishment means "a place of business,"[14] FMI believes FDA must assess a retail establishment as a whole when evaluating whether it is "similar" to a restaurant given the language that Congress has chosen. The law only provides for regulation of similar retail food ***establishments***, not individual departments or operations within establishments that are not similar to restaurants. **FMI does not believe that FDA has authority under § 4205 to regulate individual departments or operations within a retail food establishment unless that establishment as a whole is similar to a restaurant.**

---

[9] NLEA applies to ". . . food intended for human consumption and is offered for sale . . ." 21 U.S.C. §343(q)(1) whereas § 4205 applies to ". . . food that is a standard menu item that is offered for sale *in a restaurant or similar retail food establishment* that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items . . ." (emphasis added).

[10] "It is always appropriate to assume that our elected representatives, like other citizens, know the law;" *Cannon v. University of Chicago*, 441 U.S. 677 (1979).

[11] *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)); *see also Bailey v. United States*, 516 U.S. 137, 146 (1995) (distinction in one provision between "used" and "intended to be used" creates implication that related provision's reliance on "use" alone refers to actual and not intended use); *Bates v. United States*, 522 U.S. 23, 29 (1997) (inclusion of "intent to defraud" language in one provision and exclusion in a parallel provision).

[12] 21 C.F.R 1.227(b)(11).

[13] *See Platt v. Union Pacific R. Co.,* 99 U.S. 48, 58 (1879) ("[A] legislature is presumed to have used no superfluous words.").

[14] http://www.merriam-webster.com/dictionary/establishment.

As such, the agency should view the amount of restaurant-like activity (i.e., serving of food for immediate consumption on the premises) in proportion to the other operations of the establishment to determine whether such establishment is indeed similar to a restaurant.

FMI believes the best way to determine whether a supermarket establishment is similar to a restaurant is to examine the percentage of sales derived at a particular retail location from food served for immediate consumption on the premises. **If more than 25 percent of total sales at a retail location are derived from the sale of food served for immediate consumption on the premises, the retail outlet is similar to a restaurant and should fall within the scope of § 4205. If less than 25 percent of total sales are derived from the sale of food served for immediate consumption on the premises, the retail location should be completely exempt from the application of § 4205.** FDA has established a similar test for determining whether a facility is a restaurant in the regulations implementing the Bioterrorism Act.[15] States have established similar tests for distinguishing between supermarkets and other establishments.[16]

Legislative History

The primary champion of menu labeling in the Senate, Senator Tom Harkin, has repeatedly held up supermarkets as the model for providing nutrition information to consumers. As the sponsor of the bill that served as the basis for § 4205, Senator Harkin's statements are particularly probative in determining Congress's legislative intent.[17] In his floor statement introducing the MEAL Act (S. 1048), Senator Harkin stated: "Consumers say that they would like nutrition information provided when they order their food at restaurants, yet, while they have good information in supermarkets, at restaurants they can only guess."[18] Furthermore, Senator Harkin cited several laws and initiatives and municipalities in his statement **none of which regulate supermarkets**.[19] In Senator Harkin's past press releases he also praised supermarkets: "It makes no sense that American consumers can go to a grocery store and find nutrition information on just about anything, but then they are totally

[15] "A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumer for immediate consumption are more than 90 percent of its total sales." 21 C.F.R. § 1.327.
[16] If sales of prepared food is greater than 75 percent of total sales a retailer is considered to be predominantly in the business of selling prepared food by that retailer. This threshold ". . .attempts to identify those retailers who are similar in nature to a restaurant rather than a grocery store." Maine Revenue Service, Sales, Fuel & Special Tax Division, A Reference Guide to the Sales and Use Tax Law (November 2008); Streamlined Sales Tax and Use Agreement (August 17, 2010).
[17] *National Woodwork Mfgs. Assn. v. NLRB*, 386 U.S. 612, 640 (1967) ("It is the sponsors that we look to when the meaning of the statutory words is in doubt.") (quoting *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384 (1951)); *NLRB v. St. Francis Hosp. of Lynwood,* 601 F.2d 404, 415 n. 12 (9th Cir.1979) ("[W]e would look to the language of the sponsors of the bill as being more demonstrative of the congressional intent rather than the other comments made on the Senate floor.").
[18] 155 Cong. Rec. S5522 (May 14, 2009) (statement of Senator Harkin).
[19] Id.

in the dark when they go to a restaurant for dinner."[20] ". . . information is lacking is in our restaurants. Even though consumers have ready access to nutritional information at grocery stores, they are left to guess and estimate when they go out to eat."[21] **Nowhere in the legislative history is there an indication that Congress contemplated regulating supermarkets under § 4205.**

Regulatory Burden

There is no reference to supermarkets in the text or legislative history of § 4205 and it is clear grocers were not the focus of this legislation. Unfortunately, if the law is construed by FDA to apply broadly to supermarkets, they will bear the biggest share of its regulatory burden.

Unlike chain restaurants which tend to have a regimented supply chain for the foods they serve, supermarkets have a supply chain for ingredients that is much more variable. Sources for ingredients frequently change and supermarkets offer a much wider range of items than the typical fast food or chain restaurant targeted by this legislation. Supermarket prepared food offerings are not nearly as uniform as those found in restaurants chains and are changed much more frequently. Supermarkets are making more efforts to source products and ingredients from local sources, and a broad application of § 4205 would make it much harder to utilize local sources in prepared foods. It also could lead to less variety in supermarket food offerings and make it more difficult to offer new nutritious prepared food items.

Indeed, many of the challenges faced by small restaurant operators are shared by supermarket retailers of all sizes. Congress recognized these challenges and exempted smaller restaurants and similar retail food establishments. **If § 4205 is applied broadly to the supermarket industry, initial and ongoing compliance costs for the industry are likely to exceed $100 million.** FDA must consider these significant economic impacts in conducting a cost-benefit analysis of the regulation. It is important to note that a very small proportion of consumers utilize supermarkets like restaurants, namely eating the foods they purchase with the store. **Yet it is supermarkets that stand to bear the largest share of the regulatory burden if § 4205 is implemented in a broad manner.** Furthermore, applying § 4205 to the supermarket industry will be vastly more complex for FDA than applying it to restaurants, the primary focus of the legislation. It will consume a great amount of FDA staff time and resources while resulting in very little regulatory "bang for the buck."

[20] Press Release, Senator Tom Harkin, "Harkin Introduces Restaurant Labeling Initiative" (June 8, 2006) http://harkin.senate.gov/press/release.cfm?i=256693.
[21] Press Release, Senator Tom Harkin, "Statement of Senator Tom Harkin on Ruby Tuesday's Decision to Provide Nutrition Information" (April 27, 2004) http://harkin.senate.gov/press/release.cfm?i=256693.

II. Scope and Application of § 4205

FMI believes that FDA authority under § 4205 extends only to foods served for immediate consumption at retail food establishments that are similar to restaurants. FMI believes FDA should evaluate the following factors in determining whether a retail food establishment exceeds the threshold proposed in these comments of 25 percent of total sales derived from the sale of food served for immediate consumption on the premises.

Facilities for Immediate Consumption

In the context of a supermarket, FMI believes a separate seating area with tables, chairs or benches, utensils and condiments provided adjacent to where foods are being sold for immediate consumption constitutes a facility for immediate consumption.

Many stores provide benches or picnic tables outside the front of the store—FMI does not believe FDA should consider these seating areas facilities for immediate consumption. Stores similarly may have seating areas inside the store adjacent to the entrances or exits of the premises. These seating areas are often provided as a place for employees or consumers to rest or wait to be picked up. Consumers may use them when waiting for family members or friends to conduct their shopping. Consumers may also utilize such seating areas to wait with grocery purchases while a friend or family member pulls a vehicle up to the store for loading. These seating areas should not be considered facilities for immediate consumption. Many stores with pharmacies will have seating areas for customers to wait to pick up a prescription. None of these seating areas should be considered facilities for immediate consumption. **Only seating areas adjacent to where food is being served for immediate consumption and which provide tables and condiments should be considered facilities for immediate consumption.**

It is important to note though that while some supermarkets provide these facilities, they are infrequently used. The vast majority of grocery consumers take all foods purchased home for future consumption. According to FMI's most recent consumer study, of all of the features offered by supermarkets, consumers are least likely to use sit-down eating areas.[22] Fewer than one in ten consumers use such facilities.[23] Moreover, only seven percent are very interested in having these facilities within a store.[24]

[22] FMI U.S. Grocery Shopper Trends 2009.
[23] Id.
[24] Id.

Serving Food For Immediate Consumption—Considerations:

Temperature

If a food is not served at the temperature at which it is traditionally consumed, the food is not being served for immediate consumption. In such instances, the consumer must take another step before the food is ready-to-eat. For example, cold prepared food traditionally eaten warm—such as a cold chicken breast, salmon fillet, soups or mashed potatoes—is not being served for immediate consumption and should not be subject to § 4205. U.S. Department of Agriculture regulations make a distinction between hot and cold foods in determining the foods eligible for purchase under the Supplemental Nutrition Assistance Program (SNAP). Foods sold hot at the point-of-sale are generally not eligible for purchase with SNAP benefits.[25] The temperature at which a food is served is also relevant to the applicability of sales taxes in 23 states.[26] **If food is not served at the temperature at which it is traditionally consumed it is not being served for immediate consumption and thus should not be subject to § 4205.**

Containers and Plates

Whether a food is served on a plate, in a closed container or in a wrapped and sealed package is relevant to determining whether a food is sold for immediate consumption. Packaging such as rigid locking or otherwise sealed clamshells, containers with snap-on or otherwise sealed tops and boxes taped or sealed shut with a label is intended for consumers to use to transporting foods off the premises for future consumption. State laws contemplate that packaging does not constitute the plating of food for immediate consumption.[27] **If a food is sold in a container that snaps shut or in a box that is taped or sealed shut with a label, it is not being served for immediate consumption and should be exempt from § 4205.**

Utensils

If utensils are not given to the consumer when the food is sold, the food is not being served for immediate consumption. Utensils include knives, forks, spoons, glasses, cups, napkins or straws as contemplated by state tax laws in much of the nation.[28] While supermarkets may make utensils

[25] "*Eligible foods* means: (1) Any food or food product . . . except . . . hot foods and hot food products prepared for immediate consumption." 7 C.F.R. 271.2.
[26] See Streamlined Sales Tax and Use Agreement p. 132 (August 17, 2010). Twenty three states are members of this agreement http://www.streamlinedsalestax.org/uploads/downloads/Archive/SSUTA/SSUTA%20As%20Amended%208-17-10.pdf.
[27] "A plate does not include a container or packaging used to transport the food." Id.
[28] " "Prepared food" " means: . . . Food sold with eating utensils provided by the seller, including plates, knives, forks, spoons, glasses, cups, napkins or straws." Id.

available to consumers in some parts of the store, this is done for the convenience of consumers and not necessarily to permit customers to consume foods on the premises. Merely making utensils available to consumers is not the same as selling a product with utensils. States acknowledge this for purposes of determining whether foods are served for immediate consumption.[29] [30] Customers may take disposable utensils home with them to consume a meal at a future time. **Only when utensils are physically given to the consumer should FDA consider them to be a factor in evaluating whether a food is being served for immediate consumption.** States contemplate this distinction.[31]

Multiple Servings

Foods sold in multiple servings such as a whole rotisserie chicken, full rack of ribs, pie or cake are not being served for immediate consumption. Another step is required by the customer — the cutting of the item into individual portions is necessary—before consumption. None of these foods should be regulated under § 4205. Under state sales tax laws, prepared foods sold in multiple servings are treated differently than foods sold in individual servings.[32]

Foods Sold By Weight

Foods sold by weight should not be subject to § 4205. Enormous logistical challenges exist in providing consumers with nutrition information —particularly when they are mixing and matching items in one container, as is the case at a self-service bar. Consumers may have difficulty utilizing such information as well. An accurate calorie total will be impossible to achieve for self-service bars with a wide variety of items. If items are labeled individually, consumers may have challenges ascertaining serving sizes. Deli items sold by weight are not foods being sold for immediate consumption. A 2 lb container of coleslaw being packed for a consumer or a 1 lb package of deli meat sliced at the request of the consumer is not being sold for immediate consumption. State laws

---

[29] ". . . merely making utensils available for the customer to take at the customer's discretion does not constitute "sold with eating utensils." For example, bakery items are not "sold with eating utensils" when the seller has merely placed a napkin dispenser on the counter or has set up a utensil "island" for customers in the store. Similarly, when a grocery store sets out a stack of small plates in its bakery section, it is not considered to be selling the bakery items with eating utensils." Washington State Department of Revenue Special Notice, Sales of Bakery Items (April 7, 2004). http://dor.wa.gov/Docs/Pubs/SpecialNotices/2004/sn_04_SalesOfBakeryItems.pdf.

[30] Streamlined Sales Tax and Use Agreement p. 154 (August 17, 2010).

[31] "Sale of food item is taxable . . . if the seller's practice is to physically give eating utensils to the customer . . . Sale of the food item . . . is not taxable when eating utensils are just made available to the customer." Minnesota Dept. of Revenue, Prepared Food Fact Sheet, 102D (May 2010) http://taxes.state.mn.us/sales/Documents/publications_fact_sheets_by_name_content_BAT_1100127.pdf.

[32] Streamlined Sales Tax and Use Agreement p. 154. See Maine Revenue Service, Sales, Fuel & Special Tax Division, A Reference Guide to the Sales and Use Tax Law p. 52 http://www.maine.gov/revenue/salesuse/RefGuideNov2008%20%282%29.pdf.

do not consider foods sold by weight to be served in a ready-to-eat manner.[33] **Food sold by weight should not be viewed as food sold for immediate consumption and should thus be exempt from § 4205.**

Bakery Items

Bakery items such as bagels, bread, donuts, cakes, pies and pastries, regardless of whether they are sold individually or packaged in multiple servings,[34] should be exempt from § 4205. Many state sales tax laws treat these items differently from foods served at a restaurant. [35] Additionally, bakery items hot from the oven should not be considered a food sold hot for immediate consumption.[36] **Supermarket bakery items should be exempt from § 4205.**

Foods on Display

Consumers primarily shop in supermarkets by visually evaluating items and virtually all foods in a supermarket are 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 products for immediate consumption.

Deli Meats

The act of slicing a deli meat does not constitute the serving of food for immediate consumption. States laws acknowledge this.[37] **Deli meats should be excluded from regulation under § 4205.**

---

[33] "The following items may be taxed differently that "prepared food". . . Food sold in an unheated state by weight or volume as a single item." Streamlined Sales Tax and Use Agreement p. 132 (August 17, 2010).

[34] ". . . bakery items are exempt from retail sales tax . . .The quantity of goods sold . . . (has) no bearing on the exception." Washington State Department of Revenue Special Notice "Prepared Food" Tax Changes, (May 29, 2007) http://dor.wa.gov/Docs/Pubs/SpecialNotices/2007/sn_07_PreparedFoodChgs.pdf.

[35] "The following items may be taxed differently that "prepared food". . . Bakery items, including bread, rolls, buns, biscuits, bagels, croissants, pastries, donuts, Danish, cakes, tortes, pies, tarts, muffins, bars, cookies, tortillas." Streamlined Sales Tax and Use Agreement p. 132 (August 17, 2010).

[36] ". . . bakery items are exempt from retail sales tax . . .the fact that goods may be sold "hot from the oven," . . . (has) no bearing on the exception." Washington State Department of Revenue Special Notice "Prepared Food" Tax Changes, (May 29, 2007).

[37] "Prepared food **does not** include: Food that is only sliced . . . by the seller . . . such as luncheon meats, cheeses, meat and cheese trays . . . Food sold in an unheated state by weight or volume as a single item . . ." Nebraska Department of Revenue, Nebraska Sales and Use Tax Guide for Prepared Food (March 2007) http://www.revenue.state.ne.us/info/6-432.pdf.

Self-Service Bars

Many supermarkets have self-service food facilities including salad bars, hot food bars and olive bars, among other things. In most circumstances the containers provided to consumers at these facilities include some sort of lid or locking top, as in a rigid clamshell. Even if the food is being sold at the temperature of consumption—as in the case with a salad bar—that does not necessarily mean it is being sold for immediate consumption. The vast majority of consumers using salad and olive bars do not consume the salads or olives within the store. Salads can be taken away from a retail location and eaten hours later. Olives can be eaten days later. **Supermarket salad and olive bars should generally be exempt from § 4205.**

Pizza Facilities

A number of supermarkets contain facilities for preparing freshly cooked pizza on the premises. Generally, consumers can order a whole pizza or individual slices. In most cases the pizza is placed in a box to allow the consumer to transport the food home for future consumption. As such, FMI believes pizza facilities should be exempt from § 4205.

Doing Business Under the Same Name

A number of food retailers are members of cooperatives. The cooperative structure allows independent retailers to take advantage of economies of scale for supply chain and joint marketing, among other things. However, members of the co-op remain separate corporate entities that operate more or less independently and have their own recipes and prepared food offerings. While a co-op may be comprised of 100 stores operating under the same banners, it may actually be a grouping of 50 separate owners that operate two stores each. Store owners enjoy—and exercise—vastly more independence than owners of franchise restaurants. Stores in co-ops may operate under completely different banners, may have different banners but display a common logo, or may share all aspects of the same banner. FMI believes stores that belong to a co-op but are independently owned, separate corporate entities should not be aggregated by FDA for purposes of determining the applicability of § 4205.

III. Responses to Specific Questions in ANPRM

Current Practices Within the Restaurant or Similar Retail Food Establishment Industry with Respect to the Use of Menus and Menu Boards

FMI believes supermarkets are generally not similar retail food establishments under § 4205. Supermarkets generally do not have traditional menus, as in a list of items appearing on a single

sheet of paper. Some stores may have menu boards to list sub sandwiches or hot prepared combination meals. Outside the sub sandwich and hot prepared food sections of the store, prepared food items are generally identified with tags, placards and small signs. Unlike restaurants, which generally communicate item information to consumers only on traditional menus or menu boards, supermarkets utilize a wide range of methods. **It is essential that FDA clarify to the supermarket industry that which constitutes a menu or menu board.**

Considerations in the disclosure of calorie information for food sold at a salad bar

Although FMI believes salad bars should generally be exempt from § 4205 because they contain items sold in packaging intended to transport the food, in circumstances where they fall within § 4205, the calorie information should be required to be no larger than necessary to be visible to consumers and not obstruct the visibility of items or compromise the functioning of cold storage compartments. Information should be permitted to be placed on top of or below the sneezeguard, or alternatively provided on a tent card at the end or on top of the salad bar. FDA must consider the sanitary issues associated with the proximity of signs to foods as well. In many respects, a salad bar merely provides ingredients to consumers to allow them to prepare their own custom salads. It is essentially impossible to provide consumers with an accurate total calorie count for the salads they create. Furthermore, consumers are likely to have difficulty discerning what constitutes a serving size for a salad ingredient. FMI seeks clarification whether raw commodities in the salad bar will require labeling.

Methods related to presentation of nutrient content for standard menu items that come in different flavors, varieties or combinations

For products like subs, there is great variability related to toppings and condiments and type of bread. Many stores do not simply offer a description of the sandwich on the sign above the sub operations. Stores may display a list of meats, cheeses, vegetables, breads and condiments from which the consumer can create his or her own custom sub. The combinations of sandwiches a consumer can order are virtually limitless. Calculating nutrition information for such items will be extremely difficult and very costly. **FMI believes these types of sandwiches should fall under the custom order exception. Only if a sandwich is listed as a discrete item (e.g., "Turkey Sub") should nutrition information be required.** Calorie information posted should be based on a sandwich as it is described on the board. For example, a made-to-order sandwich listed as a "turkey sub" should have calorie information based on a sub with meat and bread. It should not include calorie information for cheese, condiments or vegetables as it is not advertised as having these additional ingredients. There is high variation among the use of condiments. Unless the sandwich is described as having such condiments, they should not be included in the calorie calculation. If a sandwich is advertised as having such condiments or cheese in its description (e.g.

"Cuban Sandwich—ham, roasted pork, swiss cheese, mustard and pickles on Cuban bread"), only then is it appropriate to include all the listed toppings and condiments in the calorie calculation.

Factors to consider with respect to availability and use of space on menu boards

Space on menus and menu boards is at a premium. The size of the text of the calorie disclosure should be no larger than necessary to be visible to consumers. In no cases should it be larger than the price display or the description of the item. It should not be more prominent than either of these two components. Supermarkets frequently have multiple signs for the same item. FMI seeks clarification if multiple signs for the same item all must be labeled with calorie information across locations of the store or if merely one sign closest to the where the consumer makes their order is sufficient. The agency's implementation of menu labeling requirements should not limit the ability of an establishment to describe and market items to consumers.

Information on Variations of Ingredients

Unlike restaurants, supermarkets source ingredients from a vast range of suppliers, creating greater logistic challenges in calculating nutrition information for the products in which they are utilized. Ingredient variation in the supermarket environment is much higher than in the chain restaurant industry. More frequently, supermarkets obtain ingredients from nearby family farms and other local sources. FMI fears that broad application of § 4205 to the supermarket industry would threaten the utilization of local ingredients. As a result, FMI believes FDA should implement a policy that allows these relationships to continue to flourish, rather than rigidly apply regulations under § 4205 that could threaten the use of local sources.

In addition, many stores offer items on a regional basis. FMI seeks clarification regarding application of § 4205 to these items. If such products are only offered in 10 stores of a 100 store chain are they subject to § 4205? If FDA applies § 4205 in a broad manner to the supermarket industry, grocers will face tens of millions of dollars in compliance costs to examine variations of ingredients and products. Overall costs of compliance with § 4205 are likely to exceed $100 million.

Implementation and Enforcement

Implementation of § 4205 will be very costly and complex for the supermarket industry. It will pose enormous logistical and operational challenges and will require intensive and time consuming training of staff. If FDA determines that any aspect of the statute is applicable in supermarket environments, FMI believes the agency should use its enforcement discretion and give the supermarket industry at least 18 months to comply with § 4205 following publication of the final rule implementing the provisions.

IV. Conclusion

FMI believes that supermarkets are generally not similar retail establishments and FDA does not have authority under § 4205 to regulate individual departments or operations within a retail food establishment unless that establishment as a whole is similar to a restaurant. In determining whether a retail location is similar to a restaurant FDA should examine the percentage of sales derived at a particular retail location from food sold for immediate consumption on the premises. If less than 25 percent of total sales are derived from the sale of food served for immediate consumption on the premises, the retail location should be completely exempt from the application of § 4205. In assessing whether a retail food establishment exceeds the threshold, FDA should consider factors outlined in section II of these comments. There is no reference to supermarkets in the text or legislative history of § 4205 and it is clear the industry was not the focus of this legislation. Unfortunately, if the law is construed by FDA to apply broadly to supermarkets, they will bear the brunt of its regulatory burden. If § 4205 is applied broadly to the supermarket industry, initial and ongoing compliance costs are likely to exceed $100 million.

FMI appreciates the opportunity to comment on this important matter and looks forward to assisting FDA in its implementation of § 4205.

Sincerely,

Erik R. Lieberman
Regulatory Counsel