



October 12, 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**RE: Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010, 75 Fed. Reg. 52426 (August 25, 2010)**

**Docket No. FDA-2010-D-0370**

Dear Commissioner Hamburg:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act<sup>1</sup> (PPACA). FMI looks forward to working with FDA to assist the agency in its implementation of these provisions.

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

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<sup>1</sup> P.L. 111-48.

50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

Section 4205 of PPACA amended the Federal Food, Drug and Cosmetic Act<sup>2</sup> 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 FDA is soliciting comments on Draft Guidance to Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of PPACA ("Draft Guidance"). FMI believes if FDA incorporates the recommendations contained within these comments into its final guidance, it will implement § 4205 in an effective manner. Text in italics references specific text in the Draft Guidance. On September 7, 2010, FMI submitted comments separately on the docket FDA established to solicit information regarding implementation of § 4205.<sup>3</sup> These comments are attached as Exhibit A.

## Questions and Answers

### A. Covered Establishments

#### **3. What is meant by "doing business under the same name"?**

*FDA considers this phrase to refer to establishments that share the same name and are owned, controlled, or operated by a single corporate entity (including those operated as franchised outlets of a parent company).*

Many food retailers allow flexibility in the deli/bakery offerings of their various store locations, including flexibility as to types of food products at different locations and/or different times, as well as ingredient choices which may vary in order to incorporate seasonal items, local preferences, and/or new sourcing opportunities. This makes them very different from the types of monolithic chain restaurants that can identify specific calorie counts and ingredient specifications for portion-controlled, ready-to-eat meals dispensed on an immediate-purchase basis. This type of flexibility to source and offer locally sensitive, location and/or seasonally-varied products should not be deterred by regulations inducing food retailers into the box of commoditized products that must be exactly the same for each item dispensed across the chain. Therefore, the mere fact that a large number of grocery stores are under common ownership doesn't mean that the various deli/bakery locations are under the types of rigid, unchanging menu requirements conducive to the menu labeling rules proposed for chain restaurants.

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<sup>2</sup> 21 U.S.C. §§ 301 et seq.

<sup>3</sup> 75 Fed. Reg. 39026 (July 7, 2010).

In addition, many 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. Members of a cooperative remain separate corporate entities however, 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 the same banner. The degree of uniformity among retail members of co-ops varies from co-op to co-op, however co-ops are not owned, operated or controlled by a single corporate entity. The co-op does not control its members, rather it is the members that control the cooperative.<sup>4</sup> **FMI does not believe that independently-owned retail stores which are members of the same co-op should be aggregated together for purposes of determining the 20 or more location threshold of applicability for § 4205 as they collectively are not owned, controlled or operated by a single corporate entity.**

*FDA considers the term “same name” to cover names that are the same in all relevant aspects, including where slight variations exist in the name (e.g., “ABC” and “ABC Express”). FDA seeks comment on how we should apply this interpretation to contractors, such as managed food services, or other corporate entities that own, control or operate restaurants or SRFEs offering substantially the same menu items using names specific to a location.*

Retail stores of members of a cooperative may operate under completely different banners; may have different banners, but display a common logo on the sign; or may share the same banner. Separately-owned retail members of co-ops that share a common logo or part of a name should not be aggregated together for purposes of determining the threshold. For example, stores may share an aspect of name or logo within a co-op such as “Jim’s Independent Grocery Co-op” and “Pine Mountain Independent Grocery Co-op.” FMI does not believe that these names should be viewed by FDA as “slight variations.” As such they should not be considered doing business under the same name. Even where independently-owned retail outlets of cooperatives share the same banner, FMI does not believe they should be aggregate collectively for purposes of determining the applicability of § 4205.

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<sup>4</sup> “The most definitive set of principles was developed in 1987 by USDA. Modern principles are: . . . 2. The User-Control Principle: Those who control the principle are those who use the cooperative.” Baarda, James, Current Issues in Cooperative Finance and Governance, U.S.D.A. Coop. Programs, Rural Development (April 2006) citing Dunn, John, *et al.*, Positioning Farmer Cooperatives for the Future: A Report to the Senate Agricultural Appropriations Subcommittee, U.S.D.A., Agric. Coop. Service (October, 1987), p. 14. The International Cooperative Alliance has established seven principles that define co-ops as part of the Statement on Cooperative Identity. . . . 2<sup>nd</sup> Principle: Democratic Member Control “Cooperatives are democratic organizations controlled by their members, who actively participate in setting their policies and making decisions. Men and women serving as elected representatives are accountable to the membership.” <http://www.ica.coop/coop/principles.html>.

**5. What are some examples of establishments that would be covered because they are part of a chain with 20 or more locations, “doing business under the same name,” and “offering for sale substantially the same menu items”?**

*Many grocery stores have cafes, food courts, or otherwise sell food that is for immediate consumption directly to consumers. These establishments would be considered restaurants or SRFEs. If they are part of a chain that meets other relevant characteristics (i.e., 20 or more locations, “doing business under the same name,” and “offering for sale substantially the same menu items”) they would be covered.*

A number of retail supermarkets have fast food or quick service restaurants operating on the premises under a banner distinct of that of the supermarket. These restaurants may be operated by independent franchisees, operated by the parent company of the restaurant or operated by a supermarket retailer pursuant to a licensing or franchise agreement. Examples of such restaurants operating within supermarkets include: McDonald’s®, Pizza Hut®, SUBWAY®, Starbucks®, Jamba Juice®, Dunkin’ Donuts® and DQ®. These operations generally have all of the following characteristics:

1. They are in an area set apart from the rest of the supermarket by a wall, half-wall, railings, gates, barriers, distinct counter or a distinct floor (e.g. different tile color or design).
2. Utensils and condiments are provided to customers within the area.
3. They operate under a banner distinct of that of the supermarket and such banner is separately trademarked.
4. Food and beverages are sold in a purchase transaction inside the area for immediate consumption on the premises.
5. Portions of food and beverages are controlled and dictated by the parent company of the restaurant. Suppliers and ingredients are dictated by the parent company as well.
6. More than 75 percent of the total sales within the area are from foods served for immediate consumption.
7. Customers are required to purchase food items served within the area.

These restaurants are effectively separate establishments from the overall retail store since they are subject to the control of the restaurants’ parent company. As such FMI believes they fall within the

scope of the regulatory authority conferred to FDA by § 4205. FMI agrees with FDA that they should comply with § 4205. They are indeed “restaurants or similar retail food establishments” unlike a supermarket which is generally not.

*FDA intends to ensure that establishments that offer comparable food items for immediate consumption are treated comparably. Some grocery stores, whether or not they have cafes, food courts, or in-store restaurants, have facilities that offer foods that could be consumed immediately or could be purchased as traditional grocery items for future consumption, such as in-store bakeries, salad bars, pizza bars, or delicatessens. In this context FDA is seeking comments on what facilities in grocery stores, beyond the cafes, food courts, and in-store restaurants, should also be covered by section 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. Only if an establishment is similar to a restaurant, can FDA require it to comply with §4205. Unlike the Nutrition Labeling and Education Act<sup>5</sup> (NLEA) which applies to foods generally,<sup>6</sup> the application of § 4205 is dependent on the type of establishment serving the food. As the term establishment means “a place of business,”<sup>7</sup> 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, facilities or operations within establishments that are not similar to restaurants. FDA in this very guidance document makes such a distinction.<sup>8</sup>

Congress used the term “similar retail food establishment” but did not define it. Supermarkets generally are not “similar retail food establishments.” Please see the comments submitted by FMI on September 7, 2010 (Attachment A) for a more detailed legal analysis. **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.** 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.

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<sup>5</sup> P.L. 101-535.

<sup>6</sup> 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).

<sup>7</sup> <http://www.merriam-webster.com/dictionary/establishment>.

<sup>8</sup> “FDA considers the term “facility” as it is used in section 4205 to refer to a self-service fixture in a restaurant or SRFE, not to an entire retail food establishment.”

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 25 percent or more of total sales at a retail location is 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 is 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.<sup>9</sup> States have established similar tests for distinguishing between supermarkets and other establishments.<sup>10</sup>

While FMI believes that supermarkets are generally not “similar retail food establishments” and thus not subject to § 4205, in the limited circumstances where they may be, we offer the following comments:

### **In-store Bakery Items**

**In-store bakeries should not be subject to § 4205.** Supermarket bakeries may sell cookies, cakes, pies, pastries, bagels, breads and donuts among other items. These items are virtually always sold in a sales transaction at the front-of-store checkout register for future consumption off of the premises. Many state sales tax laws contemplate this fact and treat these items differently from foods served at a restaurant.<sup>11</sup> Bakery items may be sold individually, as in a single muffin or cookie, or may be sold in multiple servings, such as whole cakes, pies, and loaves of bread or a container of a dozen cookies. Under state sales tax laws, prepared foods sold in multiple servings are treated differently than foods sold in individual servings.<sup>12</sup> **Bakery items regardless of whether they are sold individually or packaged in multiple servings,<sup>13</sup> should be exempt from**

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<sup>9</sup> “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.

<sup>10</sup> 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).

<sup>11</sup> “The following items may be taxed differently than “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).

<sup>12</sup> See 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>.

<sup>13</sup> “. . . 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](http://dor.wa.gov/Docs/Pubs/SpecialNotices/2007/sn_07_PreparedFoodChgs.pdf).



§ 4205. Items sold in multiple serving packages (e.g. a four pack of muffins) are being sold for future consumption, not immediate consumption. Similarly, whole cakes, pies and loaves of bread are not being sold for immediate consumption. Another step is required by the customer — the dividing of the item into individual portions is necessary—before consumption. Individual bakery items are essentially always sold for future consumption as well. They are generally sold in boxes, bags and plastic clamshell containers to allow the consumer to transport the item away from the store for future consumption. Bakery items hot from the oven should not be considered a food sold hot for immediate consumption.<sup>14</sup>

### Self-Service Bars

Many supermarkets have self-service food facilities including salad bars, hot food bars and olive bars, among other things. The vast majority of these products are sold by weight. Foods sold by weight in general 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, which also may change by season, supplier, and locale. If items are labeled individually, consumers may have challenges ascertaining serving sizes. State laws do not consider foods sold by weight to be served in a ready-to-eat manner.<sup>15</sup> **Food sold by weight should not be viewed as food sold for immediate consumption and should thus be exempt from § 4205.** In some circumstances, hot foods may be sold by item, rather than by weight. The variety of foods sold typically change regularly, if not daily at hot food bars, and there is not a “standard menu” as in chain restaurants. **Salad bars, hot food bars and other self-service facilities in supermarkets should not be subject to §4205.**

### Deli Items

Many supermarkets have delis offering cold-cuts, cheese, deli-salads (e.g. coleslaw, chicken salad, egg salad) and cold prepared foods. Most of these items are sold by weight and as contemplated by state sales tax laws,<sup>16</sup> should not be considered as 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. The act of slicing a deli meat

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<sup>14</sup> “. . . 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).

<sup>15</sup> “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).

<sup>16</sup> Id.

does not constitute the serving of food for immediate consumption. States laws acknowledge this.<sup>17</sup> Many prepared food items in the deli case, such as cooked chicken breasts or salmon fillets are not sold at the temperature of consumption. Foods not sold at the temperature of consumption are 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.<sup>18</sup> The temperature at which a food is served is also relevant to the applicability of sales taxes in 23 states.<sup>19</sup> **Deli items should generally be exempt from § 4205.**

### **Rotisserie Meats**

Many supermarkets sell rotisserie chickens and racks of ribs. These items may be sold hot or cold, whole or cut and packaged into multiple servings. Rotisserie chickens, racks of ribs and other multiple serving meat items even if sold hot are not being sold for immediate consumption. Supermarkets sell them in sales transactions together with all other items purchased by the customer, at the front-of-store checkout register for removal from the premises and future consumption. A consumer must cut apart whole chickens or slice up rack ribs into individual portions before consuming. Packages containing whole chickens cut into pieces, packages of cooked chicken breasts, wings and thighs and sliced ribs are sold in multiple servings. Under state sales tax laws, prepared foods sold in multiple servings are treated differently than foods sold in individual servings.<sup>20</sup> Products, recipes and ingredients often vary by season, supplier and locale, posing enormous challenges in calculating calorie totals. **Rotisserie chicken, racks of ribs and other similar hot items sold by supermarkets should be exempt from § 4205.**

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<sup>17</sup> “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>.

<sup>18</sup> “*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.

<sup>19</sup> 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>.

<sup>20</sup> 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>.



## **Pizza Bars**

A number of supermarkets sell hot pizza at pizza bars. Pizzas may be sold whole or by the slice. In most circumstances these items are given to consumers in a box intended for the convenience of consumers so they may transport the item off of the premises. Pizza served in a box intended for transporting the item off the premises should not be considered sold for immediate consumption. State laws contemplate that packaging does not constitute the plating of food for immediate consumption.<sup>21</sup> The vast majority of consumers purchasing pizza, whether in individual slices or entire pies are not consuming them within the store. Variations by customer choices, season and locale also exist. **Pizza sold by supermarkets should generally be exempt from § 4205.**

## **B. Covered Food**

### ***5. What is food on display?***

*FDA recognizes that certain foods on display provide multiple servings, for example a whole cake or loaf of bread, and is soliciting comments on whether and how these foods are covered by the requirements of section 4205.*

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. Foods on display providing multiple servings such as a whole cakes and pies, whole deli hams and whole rotisserie chickens are not being served for immediate consumption. Another step is required—the cutting of the item into individual portions is necessary—before consumption. The act of slicing a deli meat does not constitute the serving of food for immediate consumption. States laws contemplate this.<sup>22</sup> **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.<sup>23</sup>

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<sup>21</sup> “A plate does not include a container or packaging used to transport the food.” Id.

<sup>22</sup> “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>.

<sup>23</sup> 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>.

## **7. What are “custom orders”?**

*FDA considers a “custom order” to be an order that is prepared in a specific manner for an individual consumer, which requires the restaurant or SRFE to deviate from its usual preparation of a menu item.*

Some supermarkets offer custom made deli sandwiches and submarine sandwiches to consumers. Rather than having individual sandwiches listed on a menu or menu board, the consumer is presented with a list of breads, meats, cheeses, toppings and condiments from which to choose from—resulting in nearly endless combinations. Salads may similarly be ordered from a list of vegetables, proteins, fruits and dressings. The consumer is in essence ordering their own custom sandwich or salad. FMI believes when sandwiches or salads are not listed as an item on a menu or menu board, just as separate ingredients from which the consumer builds their own sandwich or salad, this should be considered by FDA as a custom order and thus exempt for §4205. These foods are not “standard menu items.” The logistical challenges in determining nutrition information in this manner are much greater than that for pizza and ice cream which FDA has listed as variable menu items.

### **D. Timing of Compliance**

#### **1. Does FDA intend to begin taking enforcement action against chain retail food establishments and chain vending machine operators that are not in compliance with the provisions of section 4205 that became requirements immediately upon enactment of the law?**

*No. FDA is aware that industry may need additional guidance from FDA and time to comply with the provisions of section 4205 that became requirements immediately upon enactment of the law. Accordingly, FDA expects to refrain from initiating enforcement action until after a time period established in the final guidance. FDA is interested in comments on the appropriate time period for enforcement after the issuance of final guidance. FDA anticipates issuing final guidance in December 2010.*

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.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Erik R. Lieberman". The signature is fluid and cursive, with the first name "Erik" being the most prominent.

Erik R. Lieberman  
Regulatory Counsel