FOOD MARKETING INSTITUTE

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Submitted Electronically

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Restaurant Menu and Vending Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act[1]

Docket No. FDA-2010-N-0567

On November 5, 2010, the Food and Drug Administration (FDA) published in the Federal Register for comment a proposed collection of information for Restaurant Menu and Vending Machine Labeling: Recordkeeping and Mandatory Third Party Disclosure Under Section 4205 of the Patient Protection and Affordable Care Act of 2010 (PPACA) (the "Proposed Collection").

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the FDA's request for comments and information to assist the agency in assessing the burden of the recordkeeping and mandatory third party disclosure provisions of Section 4205 of PPACA.

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.

These comments will address the accuracy of FDA's estimate of the Proposed Collection as well as ways to minimize the burden of the collection of information on respondents

[1] 75 Fed. Reg. 68361 (November 5, 2010).

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I. The Accuracy of FDA's Burden Estimate

A. Burden for Calorie Analysis and Recording

1. Hourly Burden

FDA has estimated the hourly burden of calorie analysis for chain retail food establishments to be 4 hours per menu item. It is important for FDA to consider that for standard menu items, a thorough nutrition analysis is required, rather than just an analysis for calorie content. FMI believes the estimate of 4 hours is accurate for a calorie or nutrition analysis on simple items in which the formula and nutrition information is readily available. Gathering unavailable formula information for calorie and nutrition analysis may make the analysis process take 10-12 hours. Locating formula and nutrition information for food service items can be particularly difficult for retailers if it is not readily available from a supplier. It can take many hours to find formula information before an analysis can be conducted. If outside firms are used to conduct the analysis, it may take 5-20 days or more for the retailer to receive the results. Formulas are not static in foodservice items. Any change could potentially require that a reanalysis be conducted. It is conceivable that a particular item could change formulas or ingredients several times over the course of a year. If retailers are required to conduct multiple tests for the same menu item in a slightly different formula, the burden of compliance will be very large. FDA is required by Section 4205 to consider this in promulgating regulations.[2]

2. Cost Burden

FDA has estimated that the average cost of a full nutrition analysis is $269 per item. FMI believes this is significantly underestimating the cost to the grocery industry. While a handful of retailers may have existing staff who can handle this responsibility, many retailers will be required to hire additional staff at a large cost. Adding or reallocating a single full-time employee for this task has been estimated to cost $70,000-$120,000. Retailers may be required to hire several new employees to comply with this new regulatory requirement.

Many retailers will need to enlist the help of outside labs and labeling firms to comply with the requirement. These firms generally charge $500-$1,000 per item. A lab analysis of an item will far exceed the $269 estimate. It will likely cost $750-$1,000 per item. Only for items with simple ingredients where there is comprehensive supplier-provided information available to the lab or labeling firm, will the cost of conducting an analysis by an outside firm be near the $269 estimate.

[2] § 4205(x)(II)(aa).

It is also important to consider the costs of training associates in-store on the requirements for complying with the regulations. Depending on how broadly FDA applies § 4205 to supermarkets, for smaller chains this may be in the tens of thousands of dollars, mid-size chains may face training costs of $100,000 or more and large chains may face costs of many hundreds of thousands of dollars or more.

3. Number of Items

Section 4205 applies only to certain foods sold at restaurants and "similar retail food establishments" (SRFEs). FMI believes that supermarkets are generally not SRFEs for the reasons outlined in our previous comments which are included as Attachment A. As such, we do 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. Based on the text of the law and its legislative history, we believe that supermarkets are generally not subject to § 4205. Only if a supermarket exceeds a threshold whereby 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 do we believe it is similar to a restaurant and thus covered under the law. Supermarkets are not restaurants and their operations are vastly different. If a supermarket does exceed such a threshold, we believe that only foods sold for immediate consumption should be covered by the regulations.

In the absence of a proposed rule, it is difficult to ascertain how many items in a store will be required to have labeling. If FDA decides to regulate items such as subs and deli sandwiches, pizza, hot food bars and hot prepared foods beyond items offered in in-store restaurants operating under a separate banner, then the number of items subject to § 4205 will far exceed 40. An average is likely more around 125 items, with many retailers dealing with the burden of labeling 200 or 300 items, and perhaps more depending on how broadly the regulations are applied.

B. Burden for Third Party Disclosures

1. Hourly Burden

FDA has estimated that 2 hours of time will be needed to change each menu board and that grocery and convenience stores average 1 menu board per establishment. FMI believes both figures are too low. Redesigning menu boards can be a complex task, especially when significantly more text must be placed on a limited space. Many retailers will have to do major redesigns of their menu boards. FMI estimates that for most retailers it will take 8-15 hours to redesign each menu board to accommodate the information required by § 4205. Furthermore, the average supermarket is likely to have 5 menu boards, with some having as many as 15. The number of these boards that will require redesigns will depend on how broadly FDA applies § 4205 to supermarkets.

2. Cost Burden

FDA has estimated the average cost of a menu board to be $550. While this will be accurate for some retailers, particularly those who have already installed boards which permit flexibility to accommodate changing offerings, for many other retailers the costs are likely to be greater—approximately $1,000 to $1,500 or more per menu board.

II. Ways to Minimize the Burden of the Collection of Information on Respondents

As FMI has expressed in prior comments, we believe that supermarkets are generally not SRFEs under § 4205 and the law only provides for regulation of similar retail food ***establishments***, not individual departments or operations within establishments that are not similar to restaurants. We believe § 4205 does not give FDA authority to regulate individual departments or operations within a retail food establishment unless that establishment as a whole is similar to a restaurant. FMI proposed in its prior comments that if more than 25 percent of total sales at a retail location are derived from the sale of food sold for immediate consumption on the premises, then a retail supermarket is similar to a restaurant and should fall within the scope of § 4205. Otherwise it should not.

FDA must consider the legislative history of § 4205. In his floor statement introducing the bill that served as the basis for § 4205, Senator Harkin, the primary champion of menu labeling in the Senate, cited several state and municipal laws and initiatives, **none of which regulate supermarkets**.[3] **Nowhere in the legislative history is there an indication Congress contemplated regulating supermarkets under § 4205.**

The text of § 4205 in light of the legislative history can easily be read to not encompass supermarkets at all and FDA could clearly justify doing so. Excluding supermarkets from the scope of § 4205 is the best way to minimize the information collection burden on our industry.

Based on the Proposed Collection however, FDA intends to apply § 4205 in some manner to the supermarket industry. If FDA limits the applicability of § 4205 only to supermarkets that are similar to restaurants—retail outlets where more than 25 percent of total sales are derived from food sold for immediate consumption on the premises—then the burden of this collection of information will be minimized. FMI believes this is reflective of Congressional intent and the proper manner in which to implement the law. Limiting the scope of applicability to items in the store only clearly sold for immediate consumption—as described in our previous comments (Attachment A)—is

[3] 155 Cong. Rec. S5522 (May 14, 2009) (statement of Senator Harkin).

another key way FDA can minimize burdens. FDA can also limit burdens by not requiring retailers to reanalyze a particular item unless a very significant formula change has occurred.

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